**BACKGROUND FOR USING THIS GUIDE**

We have attempted to create one guide that researchers doing both behavioral (we use this term to include behavioral, social, education throughout) and biomedical research can use in providing answers to the items in the IRB protocol template. It is our intention to add to and modify this document over time so you may want to grab a fresh copy from the website whenever you start a new protocol. You may find that we have added just what you need.

While some may wish to only look at sections of this guide that they are stuck on, it would be a good idea to also read through other sections that may be relevant because, in order to handle submittals as efficiently as possible, the BRO, CRO, staff cannot and will not provide specific modification requests when the particular topic is already covered in this document. Rather, you will be referred to this document.

While we have tried to include relevant examples and wording for both types of research, a guide that would cover every situation would need to be infinitely long and complex because all research is different. It is therefore our intention to include information and examples that will fit for many different projects and not include things that are only applicable to few. When the sample wording does not perfectly fit your situation, read the discussion sections and the other examples as they will give you an idea of what to write. Even an example that may not seem relevant (for instance a biomedical example when a project is clearly in the area of education) may be precisely what you need to help you to better understand the concept behind the question.

Occasionally we have omitted directions, discussion or examples because either we thought that there would be little need for assistance with a particular item or because the variety of responses needed would have been so great that this document would have become more unwieldy than it already is. These sections are also usually the ones that as an investigator you will already know how to answer.

Note that the discussion sections are usually paired with each question in the IRB application, but occasionally we have deviated from this format to put the discussion at the start of a protocol section.

Finally, please read through the “**Things to Consider First**” section before you start. It covers a few key concepts that, if you have them in mind as you write your protocol, could save you significantly later.

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# Things to Consider First

Think about your protocol as being the directions for your research. It should be written such that another person could carry it out from start to finish and yield the same result as if you had carried it out. If something is in your head, it needs to get on paper as a part of your protocol.

## **Filling in the Specifics**

Even when one of the examples we have given fits your study and you can copy/paste it into your protocol, you must add the specifics as they pertain to your study. Often we have left a couple of nonsense letters like NNN or “…” to indicate where details need to be given but there is no substitute for reading what you are submitting (you can’t blame us if you don’t read what you submit carefully) and editing it to fit your particulars.

## **Lay Language and Abbreviations**

A protocol should be written in lay language so that a person without your degree of scientific knowledge could carry it out. Abbreviations must be defined (does CAS stand for the College of Arts and Sciences, Chemical Abstracts Services or Cost Accounting Standards) or better yet, don’t use them at all.

## **Information that Appears to be Obvious**

There are some items in the protocol template that are requested not because they are provide direct information about study procedures but rather because the IRB needs to be able to document particular information in order to meet the requirements of the federal regulations. In these cases, even though a response may seem obvious, the response still needs to be written out. Think of these responses from you as pointing things out to the IRB and assisting them in making a valid and justifiable argument.

## **Redundant Items**

Some of the questions in the protocol template may appear to be redundant. Yes, in some cases they may be, but in other cases it is not the question that is redundant but actually just your response. For example, in section 9 Recruitment Methods, a researcher might have written a screening procedure into the responses but then upon reading section 8 Screening, he would think the questions to be redundant. In fact it is only his response that is redundant because section 9 does not ask for screening procedures.

There are two ways to deal with this.

* Write what you think you need in the earlier section and then do a little bit of cutting/copying/pasting into the later sections when necessary.
* Try and anticipate all of the later questions as you answer the earlier ones.

With a lot of experience, the later choice will be possible but we suggest using the former.

## **What if you can’t Specify Something Distinctly?**

The protocol needs to be specific but you can leave yourself options where it makes sense to do so. For example, in a biomedical situation, research may have to be conducted at a defined medical facility for the safety of the participants, but an interview protocol dealing with a topic that does not require a great deal of confidentiality, could be conducted in an office, an empty classroom or even in a semi-public setting (like a coffee shop) if the participant is comfortable with that location. When there is no need to lock yourself in to a particular situation write your protocol to describe the likely options but try to give the IRB sufficient information (in terms of description) so that they can understand and approve your plan.

## **Participant Groups**

A participant group consists of people who will all experience the same procedures. Many studies only have one participant group. The rules of thumb for determining if another participant group is as follows. If when filling out in you cannot provide an answer in a given participant group section that will cover all participants you intend to be in a group, you probably should add another participant group. If after completing two separate participant groups, you find that all answers are nearly the same (and could be the same if you phrased them the same), you probably only need one participant group.   Consider the following examples when determining if additional participant groups are needed.

1. A study in which intends to compare words spoken by native English speakers and people who speak English as a second language, but all procedures for data collection, consent and recruitment are identical for both groups. This would probably be one participant group even though the data collected would be analyzed as a part of two subsets of speakers.
2. A study performing a records review of 500 students in a school in order to invite only students who are failing history but getting A's in math to take part in an interview would be 2 participant groups (one for the interviews of an estimated 10 students and another for the 500 records reviewed to determine eligibility).
3. A study in which a teacher agrees to be observed delivering a lesson to students and then interviewed about that lesson would consist of two participant groups: 1) the teacher who is both observed and interviewed and 2) the students who are observed. If the researcher wanted to also interview some of the students, a third participant group of students to be interviewed would exist as well.
4. A study in which there are two different groups of first responders to be surveyed (fire and police) using two different sets of interview questions could probably be one participant group that references the two different instruments because the procedures would be identical for both groups. Even if one group did the survey on paper and another on the web, this might still be one participant group.

One very common error that researchers make is to forget about one or more sections of the protocol for one of their participant groups. Consider number 2 above. The researcher’s real interest is in the interview data and therefor it would not be hard to imagine that the entire protocol would be compete for the interview group but that a consent waiver might be forgotten to be included for the records review portion of the study.

Once you have identified your participant groups, you should focus on each of them one at a time, completing the protocol for that group and then move to the next participant group and do the same.

**Template Instructions as given in HRP-503**

***Sections that do not apply:***

* In several sections, the addition of checkboxes for **Not Applicable** have been added to the template as responses.
  + If an N/A checkbox is present, select the appropriate justification from the list.
  + If an N/A checkbox is not present, or if none of the existing checkboxes apply to your study, you must write in your own justification.
* In addition:
  + For research where the only study procedures are records/chart review: Sections 19, 20, 22, 23, 24, 25, 31, and 32 do not apply.
  + For exempt research: Sections 31 and 32 do not apply.

**Studies with multiple participant groups:**

* If this study involves multiple participant groups (e.g. parents and children), provide information in applicable sections for each participant group. Clearly label responses when they differ. For example:

Response:

Intervention Group:

Control Group:

**Formatting:**

* Do not remove template instructions or section headings when they do not apply to your study.

If you are pasting information from other documents using the “Merge Formatting” Paste option will maintain the formatting of the response boxes.

**Amendments:**

* When making modifications or revisions to this and other documents, use the **Track Changes** function in Microsoft Word.
* Update the version date or number **on Page 3.**

# PROTOCOL TITLE:

|  |
| --- |
| Include the full protocol title. |
| **Discussion- Title.**  The title MUST be identical on both the protocol and the consent documents. This title does NOT need to match the title any intended publications or thesis titles. It also does not need to match the title of any grant application unless required by the sponsor. |

**PRINCIPAL INVESTIGATOR:**

Name

Department

Telephone Number

Email Address

# VERSION:

*Include the version date or number.*

# GRANT APPLICABILITY:

|  |  |  |
| --- | --- | --- |
| Indicate whether this protocol is funded by a grant and if so, which portions of the grant this study covers. For example, for an(e.g. NIH or, foundation grant). For a grant with multiple aims, indicate which aims are covered by this research proposal.  NOTE: This question does not apply to studies funded by a sponsor contract. NOTE:  http://www.clipartbest.com/cliparts/acq/eAx/acqeAxyRi.pngInclude a copy of the grant proposal with your submission. | | |
| **Discussion- Grant Applicability**  The reason that this is being requested is that the IRB needs to be able to verify that all phases of a grant that require human subjects approval will be reviewed and there is not always a 1:1 correspondence between IRB protocols and funding applications. There may be some large grants that fund a number of separate projects as well as some situations where funding from more than one source is used to cover all aspects of a human research protocol. | | |
| **B** | | **Grant Applicability** | |
| 1 | **Unfunded.** This is an unfunded study. |
| 2 | **Funded**. This study is funded by the following Grants or Contracts:  The following aspects of this grant are coved by this IRB submittal (either indicate the grant in its entirety or the specific portion of the grant covered by this IRB protocol). |

# RESEARCH REPOSITORY:

|  |  |
| --- | --- |
| Indicate where the research files will be kept, including when the study has been closed. The repository should include, at minimum, copies of IRB correspondence (approval, determination letters) as well as signed consent documents. This documentation should be maintained for 3 years after the study has been closed. | |
| **Discussion- Repository.**  In some cases, such as research sponsored by certain federal agencies or drug and device trial information used in support of a marketing application, the retention requirements are longer than 3 years and may include additional information. If you fall into one of these cases, contact the Rib to find out the specific requirements.  However, for most studies, the repository requirement deals with **only human subjects documentation, not data storage** which is covered in the confidentiality section of the protocol. All study approval documentation is stored electronically by the IRB. Official correspondence is also stored by the Click IRB system. Therefore, in most cases, the only additional records that one would expect need to be retained by the investigator are **copies of signed consent documents**. If your study will **not be obtaining signed documentation of consent, no separate repository** location will be needed in most cases.  When a repository is needed, it must be a professional office location that can be made accessible to the IRB or federal auditors upon request. Private residences are not acceptable. Students should consult with their faculty sponsor for a permanent repository location.  **From OHRP Guidance:**  The HHS protection of human subjects regulations require institutions to retain records of IRB activities and certain other records frequently held by investigators for at least three years after completion of the research (45 CFR 46.115(b)). In addition, other regulations may apply and require retention of these records for a longer period of time. Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducted research that are typically held by investigators and must be retained for at least three years after completion of the research, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent (45 CFR 46.117).  If investigators have been designated to retain certain records (e.g., informed consent documents signed by subjects) on behalf of the institution as required by the HHS regulations at 45 CFR 46.115(b), they must retain the records in some form. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (45 CFR 46.115(b)). Retention of multiple copies of each record is not required. Investigators should follow the institution’s policies and procedures for retaining records. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated, for the period of time required under HHS regulations at 45 CFR 46.115(b). | |
| **A** | | **NA Type Response:** All study approval documents and correspondence is stored in the Click System and no part of the study requires signed documentation of consent. Therefore a repository for this study is not necessary. |
| **B** | | All study approval documents and correspondence that is not stored in the Click System will be retained in the office of Dr. ‎William Tweed, Department of Political Machinery, Room 505 Tammany Hall, Main Street Campus, University at Buffalo. |

# Objectives

|  |  |  |
| --- | --- | --- |
| Describe the purpose , specific aims, or objectives of this research. State the hypotheses to be tested , if applicable. A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives, above. | | |
| **Discussion- Purpose and Hypothesis.**  A project without a specific goal or objective to be proven or contribute to knowledge about a topic is not ethical to conduct because, even if there is no risk, the risk:benefit ratio is unfavorable.  Even in qualitative behavioral research there are usually hypotheses so don’t mark this question with an NA unless you have thought long and hard about it. IF you do put NA in this blank, be sure to give the reason why the particular methodology has no hypothesis. | | |
| **B** | | **Purpose and Hypothesis.** | |
| 1 | As the purpose of every project is different, it is all but impossible to provide guidance on how to answer these two items. If you are having trouble, try completing the sentence, “The purpose of this study is to…” with what you are trying to discover. |
| 2 | **Biomedical Example.**  The hypotheses to be tested are:   1. The test product is significantly more effective than the negative control for improvement of symptoms of ………in ……..patients. 2. The test product has a safety profile comparable to that of the negative control. |

# Scientific Endpoints

|  |  |  |
| --- | --- | --- |
| Describe the scientific endpoint(s) , the main result or occurrence under study.  NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should not be a date. | | |
| **Discussion- Scientific Endpoints.**  **Clinical Studies**. As there are often significant risks to clinical trials, therefore primary endpoints should generally not be a measure of something that is not important to the patient (exception: validated surrogate endpoint). In clinical investigations, study endpoints should therefore usually be one of the following:   * Improved survival (e.g. a cancer drug that puts the cancer into remission so that the person lives longer) * A benefit that was detectable by the patient (improvement in symptoms, improvement in functional capacity) * Decreased the chances of developing a condition or disease complication that is itself apparent to the patient and is undesirable (e.g. stroke)   **Behavioral Studies** can often define study endpoints that are similar to these that are important to the subject such as:   * Improved learning (educational research to determine better teaching strategies) * Positive change in behavior (helping participants to quit smoking or improve interpersonal skills)   When a study endpoint can be directly stated in terms of the detectable benefit or knowledge gained toward understanding how to achieve that benefit, do so.  When a behavioral study cannot state the specific aim in terms of an item that would be directly relevant/important to the subject, they should be stated in terms of the addition to knowledge on the topic being studied. | | |
| **B** | | **Study Endpoints:** | |
| 1 | **Clinical Endpoint.** The primary endpoint for this trial is a safety endpoint: The incidence of major bleeding events during the ….procedure….  The secondary endpoints for this trial are the incidence of the  following efficacy and safety endpoints:   * Stroke/Systemic Embolism (SE)/TIA events during the procedure…. * Minor bleeding events during the procedure… * A composite of major bleeding events and thromboembolic events (Stroke, SE and TIA) during the procedure…. |
| 2 | **Validation of a Surrogate Endpoint.** The study will determine if… can be used as a surrogate as a measurement of…in cases where… |
| 3 | **Knowledge Addition.** The study will add to the body of knowledge on the topic of…specifically by… |
| 4 | **Education Endpoint.** The primary endpoint for this study is determining whether or not the new computer interface can improve the learning process for children having difficulty with multiplication. |
| 3 | **Change in Behavior.** The primary endpoint for this study is determining whether or not the behavioral therapy support program reduces factors such as agitation in persons who have just quit smoking. |

# Background

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| Provide the scientific or scholarly background , rationale, and significance of the research based on the existing literature and how it will contribute to existing knowledge. Describe any gaps in current knowledge. Include relevant preliminary findings or prior resear5ch by the investigator. Include complete citations or references. |
| **Discussion- Scientific Rationale and References.**  A study based on poor science cannot possibly achieve its objectives. Therefore the rationale, or reasons for conducting this particular study must be provided. Be sure to point out how the study will fill a gap in existing knowledge and back up your rationale with experience and preliminary data where available.  **References**. Be judicious in your reference selection so as to provide only those references necessary for supporting the scientific rationale or methods in the study. Do not provide extraneous references. In other words, providing too much information in this case is as bad as too little.  A specific format (e.g. MLA, APA, etc.) for references is not specified, use whatever your field of study uses but make sure that you provide a complete citation so that a person who wanted to consult the reference could do so. |

# Study Design

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| Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, , observational). |
| **Discussion- Study Design.**  This is a section that we find it difficult to provide examples for because all research differs. Be sure to describe and explain the study design so that an outside person can understand it and could replicate the design. Relate why your study design is appropriate for achieving the objectives, proving the hypothesis and reaching the endpoints. |

# Local Number of Subjects

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| **Discussion- Local Number of Subjects.**  **“Locally.”** The term “locally” means under the local protocol, not necessarily in WNY so if you are doing a study where you are going to travel to another part of the country or world to gather your data from participants, and the data will be gathered by you or a member of the research team from UB, those are “local” subjects.  **Record Reviews.** Also consider that subject accrual in a record review study, every chart that you will look at containing identifiable information is an accrued subject, whether or not they have the particular condition of interest/meet your inclusion criteria because you have obtained identifiable information about the subject.  You will also want to indicate different participant groups here when applicable. |

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| Indicate the total number of subjects that will be enrolled or records that will be reviewed locally. | | |
| **B** | **Number** | |
| 1 | **Simple Answer.** The total number of subjects to be accrued under the local protocol will be between 15 and 20 depending on whether or not participants meeting inclusion criteria decide to enroll. |
| 2 | **Records Review.** It is expected that between 75 and 100 records will need to be reviewed for this study. |

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| If applicable, indicate how many subjects you expect to screen to reach your target sample (i.e. your screen failure rate). | | | |
| **B** | **Screening Rates** | |
| 1 | **Simple Answer.** It is anticipated thatapproximately 80 % of respondents to the advertisement will meet inclusion criteria and enroll in the study. As the local study intends to enroll between 15 and 20 participants, it is expected that between 18 and 25 people will need to be screened. |
| 1 | **Records Review.** It is expected that between 1200 and 1500 records will need to be reviewed in order to find the 100 cases meeting inclusion criteria needed for the study. |

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| Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? | | | |
| **B** | **Feasibility of Recruitment** | |
| 1 | **Biomedical Examples.** Patients will be recruited from individual practice plans or when they are seen by the PI during a scheduled clinic office visit. Based on our UBMD clinic population of approximately…..patients, there are a sufficient number of potential participants to meet local participant target of …. in adherence to the protocol.  OR  Based on our standard feasibility review by the CRO, there are a sufficient number of potential participants among the sites identified of about…..patients to meet local participant target of….. in adherence to the protocol. We anticipate that ….will be screened to possibly enroll ….patients. |
| 2 | **Behavioral Example.** There are 30,000 undergraduate college students on the UB campus. Of this number, roughly 4% (approximately 1200) are veterans or current military and will meet the inclusion criteria. As only 10 participants are needed for the qualitative portion of the study, less than a 1% response rate is needed in order to obtain sufficient participation. |

# Inclusion and Exclusion Criteria

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| **Discussion- Inclusion and Exclusion Criteria.** Think about your inclusion and exclusion criteria together. Use your inclusion criteria to narrow down the focus from everybody in the world, to the population of interest and then narrow down further for any practical reasons. Then use the exclusion criteria to exclude particular situations that do not fit. One way to approach this is to start by stating any particular conditions required to participate and then narrowing down further using any other inclusion criteria needed for practical reasons (like geography).  Consider a treatment study (either behavioral and biomedical), one of the inclusion criteria is obviously that the individual have disorder, illness, injury or other circumstance to be treated and then maybe an additional condition is that they either present with the condition at a particular facility  In an educational study, one of the inclusion criteria would obviously be that the participants have the condition (e.g. they are 5th grade math students or college students in a certain program) and then the other inclusion criterion might be that they are in a particular school where you will be working or in a Western NY College or University.  **Patients are not the only Participants.** The definition of a participant is a living individual “about whom” a research learns information through intervention or interaction or access to identifiable private information. While in FDA trials, the patients and subjects are often synonymous, in other studies, the participants might not be the patients at all but could be the doctors. You must ask yourself the question, “who are we learning about?”  For example, while a records review study of treatment records to see if a training session on the use of a newly approved medication was being prescribed for the correct conditions would have to look at patient records (and would therefore be HIPAA applicable), the actual subjects of the study on the effectiveness of the training session are the prescription writers (MDs, PAs and NPs) who we are looking at to find out if they are prescribing the medication appropriately.  **Interventions vs Inclusion Criteria.** Keep in mind that there is a distinction between an intervention for research purpose and inclusion criterion. Inclusion criteria are things that happen outside of the research context whereas an intervention only occurs because of the research. Depending on the study design, an activity could be either.  For example, attendance at a workshop taught on how to sing harmony could be an inclusion criterion if the only persons who may attend and take a follow up survey are those that are enrolled in a music education research project. On the other hand, if the harmony singing lessons are open to everybody but in order to participate in a follow on survey a participant obviously had to attend the workshop, then the workshop is an inclusion criterion. |

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| Describe the criteria that define who will be included in your final study sample. This may be done in bullet point fashion. Describe the criteria that define who will be excluded from your final study sample. This may be done in bullet point fashion. | | |
| **A** | | **NA Type Responses:** Unless every man woman and child in the world will be included, NA is probably not a valid response. | |
| **B** | | **Inclusion Criteria:** | |
| 1 | Examples of **Conditions of Interest.**   * Adults between the ages of 45 and 65 with hypertension… * Adults and children with a specific type of cancer who have not responded to a prior treatment regimen… * Parent and child dyads where the parent’s native language is English, English is the primary language spoken in the household and the child is learning how to read English at a first grade level... * Any adult participant… |
| 2 | Examples of **practical conditions** that narrow down the population.   * …who present at Buffalo General Hospital in a particular clinic. * …who have been referred to the researcher by their primary physician and are able to travel to BGH for further treatment. * …at East End Elementary School. |
| 3 | Examples of **Exclusion Criteria** that might further narrow down the population.   * Participants may not be diabetic. * Participants may not be on the following medications. * College students may not be under the age of 18. * Children may not have been home schooled at any point in their education. * Participants may not be pregnant. * Participants may not be children. |

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| Indicate specifically whether you will include any of the following special populations in your study.  NOTE: Members of special populations may not be targeted for enrollment in your study unless you indicate this in your inclusion criteria.   * Adults unable to consent * Individuals who are not yet adults (infants, children, teenagers) * Pregnant women * Prisoners | | |
| **Discussion- Special Populations.**  Keep in mind that any time **even one person** from the above groups is to be included in the research, the project will need to meet all regulatory requirements for that group. For instance, if you are going to include even one adult who is unable to consent, you will need to specify alternative consent processes for legally authorized representative permission and potentially assent of the individual later in this protocol.  For each of the above populations you need to consider whether or not the population is a target of the research and/or if you would want to include them if they happen to meet inclusion/exclusion criteria. For example, one might have a protocol designed for conditions of pregnancy (e.g. a study of a new drug to treat gestational diabetes or a behavioral study to assist pregnant women to avoid drugs and alcohol). Pregnancy would be an inclusion criteria. Alternatively you might have a study where most people in the study are not pregnant but if a woman happened to be pregnant you would still include her (e.g. most behavioral research would not adversely affect the pregnancy so there would be no reason for excluding pregnant women). In either case pregnant women need to be indicted here.  If on the other hand you are excluding pregnant women from the study because of possible scientific (e.g. women at times have changes in hearing during pregnancy so a study involving hearing tests might exclude them) and/or safety reasons (e.g. the obvious drug trial or study involving strenuous exercise) be sure to have a method in the screening section to exclude pregnant women.  **Inclusion of prisoners** is a situation where a number of regulatory issues must be addressed and many protocols cannot possibly be designed to meet these requirements so in general they will fall under the excluded. | | |
| **B** | | **Special Populations:** Each group should be listed under one of the three categories so cut and paste to the right place. | |
| 1 | * The following Groups will be specifically targeted for this study because they are the population of interest:   + Individuals who are not yet adults (infants, children, teenagers) * The following groups will be allowed as participants if they meet other inclusion criteria but are not specifically targeted as the population of interest:   + Pregnant women * The following groups are exclude from participation:   + Prisoners   + Adults unable to consent |

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| Indicate whether you will include non-English speaking individuals in your study. **Provide justification if you will exclude non-English speaking individuals.** In order to meet one of the primary ethical principles of equitable selection of subjects, non-English speaking individuals may **not** be routinely excluded from research as a matter of convenience. In cases where the **research is of therapeutic intent** or is designed to investigate areas that would necessarily require certain populations who may not speak English, the researcher is required to make efforts to recruit and include non-English speaking individuals. **However, there are studies in which it would be reasonable to limit subjects to those who speak English.** Some examples include pilot studies, small unfunded studies with validated instruments not available in other languages, studies with numerous questionnaires, and some non-therapeutic studies which offer no direct benefit. | | |
| **Discussion- Including non-English speaking individuals.**  The intention of this question is to allow the IRB to determine two things, first if subject selection is equitable and secondly, it gives the reviewers a heads up that they need to look for procedures and documents to be used with non-English speaking individuals later in the protocol.  Before you answer, consider that a person who is fluent in both English and another language is not non-English speaking (or without the double negative, they are English speaking). This person would be able to consent to a research process in English. It would only be a situation where a person to be enrolled did not speak English with reasonable proficiency to be able to consent that non-English speaking individuals are actually going to be enrolled.  **So, what is “reasonable proficiency” in English?** It is actually protocol dependent and related to the ability of a person to be informed before obtaining their consent to participate. For example, for most behavioral studies with little to no risk, it could be assumed that the ability of anyone who can read the invitation and answer the researchers questions (which are in English) would have a reasonable ability to be informed sufficiently before consenting. College students who are studying at an institution where the primary language of instruction is English would certainly be capable of consent for these types of studies. However this level of understanding may not be sufficient comprehension for a clinical trial where there are significant risks and procedures may be very involved or complex.  **Justification for not enrolling non-English speaking participants** can be in terms of scientific reasons or practical reasons. One obvious scientific example would be a linguistic study where English is the language of interest. An example of a practical reason for not including non-English speakers might be that it is a survey being done to collect opinions about resources on a website that is published in English. Conducting the survey in English only would be reasonable because the website would be used by primarily English speakers.  Finally, sometimes enrollment of non-English speaking persons in a study will have no effect on the rest of the protocol. For example, a records review study may include people who speak a number of different languages but speak no English but there would be no need for any special procedures in the protocol for non-English speakers in this case because consent is waived. | | |
| **B** | | **People who don’t Speak English:** | |
| 1 | **Non-English Speakers Included.** Persons who do not speak English will not be excluded from participation in this research. |
| 2 | **Non-English speakers Excluded.** Persons who do not speak English are excluded from this research based on…   * this is a pilot studies that if successful will be used to support a future study in which persons who do not speak English will be included. * this is a small unfunded studies with validated instruments not available in other languages * this is a study with numerous questionnaires that have no valid non-English versions. * this is a non-therapeutic study which offers no direct benefit and low risk… * the study must be conducted in English for the following scientific reason… |

# Vulnerable Populations

If the research involves special populations that are considered vulnerable, **describe the safeguards included to protect their rights and welfare.**

NOTE: You should refer to the appropriate checklists, referenced below, to ensure you have provided adequate detail regarding safeguards and protections. You do not, however, need to provide these checklists to the IRB.

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| For research that involves pregnant women , safeguards include:  See “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information.  N/A: This research does not involve pregnant women. | | |
| **Discussion- Pregnant Women** are considered a vulnerable population mainly because research procedures can have adverse effects on their pregnancy. Pregnant women should not however be excluded from research where there is no scientific or safety reason to justify doing so. In other words, most research should consider the inclusion of pregnant women so that results are generalizable to a population that includes them.  In order to meet the additional requirements for inclusion of Pregnant Women in research, one set of the criteria below must be met. The Criteria must be met regardless of whether pregnant women are the target population or they are **encountered as a part of a larger population** that includes women who are not pregnant and men.  “Pregnancy” encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.  “Fetus” means the product of conception from implantation until delivery | | |
| **A** | | **NA type responses:** | |
| 1 | **Pregnant Women Excluded.** The screening procedures for this research adequately exclude pregnant women from this research. |
| **B** | | **Pregnant Women.** This is a set of directions to provide information to the IRB and make the argument that this study meets the regulations for involving pregnant women. Keep in mind that if you cannot meet the requirements of the questions in one of the categories below, there is a good chance that pregnant women may not be allowed to be involved in this research. Only one of the categories should apply to any given research project (start at the top, if the first one fits, then go no further).  For the category you choose, restate the category (the first sentence in each section) and then provide the information requested by the follow on bullets for that category. | |
| 1 | **Non-Federally Regulated Minimal Risk Research.** Where the research meets the following criteria, simply state (copy and paste) the information below into your protocol.  This Non-Federally Regulated Minimal Risk Research will include pregnant women because:   * The research is NOT conducted, funded, or otherwise subject to regulation by DHHS, or the Environmental Protection Agency (EPA). * The research involves no more than Minimal Risk to pregnant women and fetuses. * The research is not funded by Department of Defense, or does not involve interventions/invasive procedures to the woman or fetus and does not involve fetuses or neonates as subjects. |
| 2 | **Research Involving Pregnant Women under 45 CFR §46.204.**   * Where scientifically appropriate, describe preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. * Describe why one of the following is true:   + The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.   + There is no prospect of benefit to the fetus, the risk to the fetus is NOT greater than Minimal Risk, and the purpose of the research is the development of important biomedical knowledge (For Department of Defense (DOD) research and behavioral research where there is no foreseeable risk to the fetus, the phrase “biomedical knowledge” can be replaced with “generalizable knowledge.”) which cannot be obtained by any other means * Describe why any risk is the least possible for achieving the objectives of the research. * Describe process in place to ensure that individuals engaged in the research   + will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy   + will have no part in determining the viability of a neonate.   + will not offer inducements, monetary or otherwise, to terminate a pregnancy. * Choose One and provide the required information   + Consent of the mother is required because...     - Explain how the research meets one of the following criteria:     - The research holds out the prospect of direct benefit to the pregnant woman,     - The research holds out the prospect of a direct benefit both to the pregnant woman and the fetus     - There is no prospect of benefit for the woman nor the fetus when risk to the fetus is NOT greater than Minimal Risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.   + Consent of the pregnant woman and the father is required, except that the father’s consent need NOT be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest because…     - Explain how the research holds out the prospect of direct benefit solely to the fetus, * Describe how each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. * Choose One and provide the required information   + If children who are pregnant are to be excluded from participation in this research, state how the exclusion will be carried out (i.e. how do you screen them out).   + If children who are pregnant are to be included in this research describe the parental permission and assent processes making certain that they meet the requirements for involvement of children as described in HRP-416-Checkist-Children. |
| 3 | The research does NOT meet the requirements of 45 CFR §46.204.   * State which requirement of the above cannot be met and why it cannot be met in terms of the scientific design of the research. * Describe why the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.   \*\*note that in this circumstance a determination from the DHHS may be required before the IRB can approve the project. |

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| For the research involves neonates of uncertain viability or non-viable neonates, Safeguards include:  See “CHECKLIST: Neonates (HRP-413)” or “HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provided sufficient information.  **N/A:** This research does not involve neonates of uncertain viability or non-viable neonates. | | |
| **Discussion- Neonates.**  Special protections are afforded neonates of uncertain viability and non-viable neonates. Viable neonates are children and are treated as such with no additional protections required. Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.  **Consent for Neonates.** Depending upon whether neonates are viable, non-viable or of uncertain viability, there are differing consent requirements with respect to the need for the mother’s, father’s or both parents’ consent. Research that will utilize all 3 types of neonates will need a procedure to ensure that all three consent requirements are met. | | |
| **A** | | **NA type responses:** | |
| 1 | **Neonates not Involved.** This research does not involve neonates of uncertain viability or non-viable neonates. |
| **B** | | **Neonates.** This is a set of directions to provide information to the IRB and make the argument that this study meets the regulations for involving Neonates. **Viable neonates are treated as children** so if you are also working with viable neonates (or neonates of uncertain viability that must be tracked after they are have become viable) you should also complete the section for children. Keep in mind that if you cannot meet the requirements of the questions in one of the categories below, there is a good chance that non-viable and uncertain viability neonates will not be allowed to be involved in this research. It is possible that more than one of the categories below will apply.  For the category you choose, restate the category (the heading sentence in each section) and then provide the information requested by the follow on bullets for that category. | |
| 1 | **Non-Viable Neonates under 45 CFR §46.205.**   * Where scientifically appropriate, describe preclinical and clinical studies that have been conducted and provide data for assessing potential risks to neonates. * Explain why the purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means. * Explain why there will be no added risk to the neonate resulting from the research. * Describe the processes in place to ensure that:   + Individuals engaged in the research will have no part in determining the viability of a neonate.   + Vital functions of the neonate will not be artificially maintained.   + The research will not terminate the heartbeat or respiration of the neonate. * Describe how the legally effective informed consent of both parents of the neonate (legally authorized representatives of either or both of the parents of a nonviable neonate cannot be used in place of parental consent) is obtained, unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity and the consent of the father need not be obtained if the pregnancy resulted from rape or incest. * Describe how each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. |
| 2 | **Neonates of Uncertain Viability under 45 CFR §46.205.**   * Where scientifically appropriate, describe preclinical and clinical studies that have been conducted and provide data for assessing potential risks to neonates. * Explain why one of the following is true:   + The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective.   + The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research. * Describe the processes in place to ensure that:   + Individuals engaged in the research will have no part in determining the viability of a neonate. * Describe how the legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accord with the regulations, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest. (“N/A” if the consent process is waived) * Describe how each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. (“N/A” if the consent process is waived) |
| 3 | The research does NOT meet the requirements of 45 CFR §46.205.   * State which requirement of the above cannot be met and why it cannot be met in terms of the scientific design of the research. * Describe why the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.   \*\*note that in this circumstance a determination from the DHHS may be required before the IRB can approve the project. |

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| For research that involves prisoners , safeguards include:  See “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information.  **N/A:** This research does not involve prisoners. | | |
| **Discussion- Prisoners.**  Most research at UB affiliated institutions does not use prisoners as subjects so in most cases the NA box above is correct. However, if you think you might be dealing with persons who are “detained” or “confined” you should consult the BRO or CRO ahead of time to discuss.  **“Prisoner”** means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass:   Individuals sentenced to such an institution under a criminal or civil statute;   Individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; or   Individuals detained pending arraignment, trial, or sentencing.  **NOTE: Probation and parole are usually NOT considered as incarceration.**  ***Definition: “Minimal Risk”*** *under Subpart C (for Prisoners) of the Federal Regulations is: “the probability and magnitude of physical and psychological harm that is normally encountered in daily lives, or in the routine medical, dental, or psychological examination of healthy persons.*  Prisoners are considered vulnerable to coercion because of their regimented lifestyle and the controls associated with prison living. In order to prevent future abuses, the prisoner regulations are very restrictive. | | |
| **A** | | **NA type responses:** | |
| 1 | **No Prisoners.** This research does not involve prisoners. |
| **B** | | **Prisoners.** | |
| 1 | **Prisoners**. This is a set of directions to provide information to the IRB and make the argument that this study meets the regulations for involving prisoners in research embodies in CHECKLIST: Prisoners (HRP-415). It is based on the regulations that the IRB needs to find to meet certain criteria for approval for prisoners. Keep in mind that if you cannot meet the requirements of the questions below, there is a good chance that prisoners may not be allowed to be involved in this research.   * First, identify and state which of the following 4 categories the study fits into (start with the first two if they fit as they are easier to approve):   + The research is a study of the possible causes, effects, and processes of incarceration, and/or of criminal behavior (46.306(a)(2)(i)).     - Explain why the research is no greater than minimal risk (as defined for prisoners), and represents no more than inconvenience to the subjects.   + The research is a study of prisons as institutional structures or of prisoners as incarcerated persons (46.306(a)(2)(ii)).     - Explain why the research is no greater than minimal risk (as defined for prisoners), and represents no more than inconvenience to the subjects.   + The study represents research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults). (46.306(a)(2)(iii)). \*Note that research in this category may require a determination from DHHS before the IRB can approve the study.     - Explain the condition(s) that will be studied and provide the rationale as to why the condition particularly affects prisoners.   + The study represents research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. (46.306(a)(2)(iv)). \*Note that research in this category may require a determination from DHHS before the IRB can approve the study.     - Explain the research practices used in this study and how they are intended to improve the health and well-being of the subjects * Then state the reason why you believe that the study falls into the category you have selected and answer the follow on bullet for that question. For example, if you were doing a study of the reasons for burglaries, a response might be words to the following affect:   This study investigates the causes of incarceration for the crime of burglary. As the study is conducted via an interview process where all data is recorded anonymously, the risk would be considered to be minimal for a non-prisoner subject.   * Now answer each of the following with about a paragraph or more where necessary (of course a “none” answer will be a 1 sentence paragraph):   + Explain the possible advantages that can be expected for prisoner subjects (if none, state so) and explain why any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are NOT of such a magnitude that it impairs his or her ability to weigh the risks of the research against the value of such advantages in the limited environment of the prisoner?   + Explain the possible risks (if none, state so) that can be reasonably expected for prisoner subjects and explain why the risks in the research are commensurate with the risks that would be accepted by non-prisoner volunteers.   + Describe the procedures for selection of subjects within the prison and explain how these procedures are immune from arbitrary intervention by prison authorities and/or other prisoners.   + State whether or not persons considered prisoners will be randomized into a control group and, if so, how the control group will also potentially benefit from the research.   + Describe how you will ensure that information presented will be in language that is understandable to the prison subject population.   + Describe how adequate assurance exists that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole.   + Describe how each prisoner will be clearly informed in advance that participation in the research will have no effect on his/her parole.   + Will there be any need for follow-up exam or care of participants after the end of their participation.   + Taking into account the varying lengths of individual prisoners' sentences describe any provisions for follow-up exam or care of participants after the end of their participation (if none is necessary, state so) and how you will communicate this to the prisoner-subject. |

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| For research that involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), safeguards include:  See “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information.  **N/A:** This research does not involve persons who have not attained the legal age for consent to treatments or procedures (“children”). | | |
| **Discussion- Children.**  Children require additional protection because, even in the case of a defiant adolescent, they generally are not completely free of undue influence when an adult asks them to do something. Most of the requirements surrounding children are therefore related to the consent process. However, research with children is restricted to certain categories by the federal regulations that are embodied in CHECKLIST: Children (HRP-416). This section will assist you in ensuring that you have provided sufficient information for the IRB to make the required determinations.  The definition of who is considered a child is based on local law or custom. As most UB affiliated research occurs within NY State, a child is considered to be a person **under the age of 18** for purpose of enrollment in research. If you will be working outside of NY and a **different local/state/national law or custom applies** to the determination of whether or not an individual is a child, this should be covered in section 12.2 Site-specific regulations or customs affecting the research.  **Consent, Assent and Parental Permission** requirements for inclusion of children are covered in sections 26 and 27 of this protocol document so additional information on consent is not usually needed here.  Addition information for the inclusion of **wards of state or any other agency, institution, or entity** in the research are only required in specific circumstances. See below.  **Viable neonates** are considered children under the regulations. | | |
| **A** | | **NA type responses:** | |
| 1 | **No Children.** This research does not involve children. |
| **B** | | **Children.** This is a set of directions to provide information to the IRB and make the argument that this study meets the regulations for involving children. Keep in mind that if you cannot meet the requirements of the questions in one of the categories below, there is a good chance that children may not be allowed to be involved in this research. Only one of the categories should apply to any given research project (start at the top, if the first one fits, then go no further). If you are not sure which to apply, you may use more than one but be careful in doing so as sometimes a response provided in a second category can make the other category invalid.   * For the category you choose, restate the category (the first sentence in each section) and then provide the information requested by the follow on bullets for that category. | |
| 2 | The research presents no greater than **minimal risk**. Most behavioral, education, social and records review research fits here.   * Explain why the research is no greater than minimal risk. A good way of doing so is to make a comparison between the risk of an activity used in your research that people encounter all the time in life or is similar to routine physical or psychological treatment. For example, if the research activity involved discussing their feelings with a trained counselor, this could be equated to routine psychological treatment. Another example is if the research activity involved completion of an activity that is similar to schoolwork encountered by children every day, then the risk of the activity is identical to the risk of everyday life activities. |
| 3 | The research is **greater than minimal risk** but presents **direct benefit(s)** to the subjects or the risk to children is presented by a monitoring procedure that is likely to contribute to the subject’s well-being.   * Restate the direct benefits to the subjects (you probably already have this in the benefits section of this document) or tell how the monitoring procedure contributes to the child’s well-being. * State any available alternative procedures that could achieve the same direct benefit, if none, say so. * Briefly explain why the risk is justified in terms of the anticipated benefits. * Briefly explain why the relationship of anticipated benefit to risk is at least as favorable as that presented by available alternative approaches. |
| 4 | The research is **greater than minimal risk** and presents **NO direct benefit(s)** to the subjects but the study is **likely to yield generalizable knowledge about the subject's disorder or condition**.   * State why the risk represents only a minor increase over minimal risk. * Briefly explain how the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition: * Briefly explain why the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.   \*\*note that in this circumstance permission of BOTH parents will likely be required for a child to participate in this project.) |
| 5 | The research is **greater than minimal risk** and presents **NO direct benefit(s)** to the subjects is **NOT** **likely to yield generalizable knowledge about the subject's disorder or condition** but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.   * Briefly discuss how the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children:   \*\*note that in this circumstance permission of BOTH parents will likely be required for a child to participate AND a determination from the DHHS may be required before the IRB can approve the project.) |
| **C** | | **Wards.** DO NOT include the following information unless the research falls into category 4 or 5 above and you plan on involving wards of the state or any other agency, institution, or entity in the research. | |
| 1 | State that **wards a will be included in this research** then provide the requested information for the bullets below.   * Describe how the research is related to their status as wards or the research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. * Describe the process to appoint an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. * Describe how you will determine that the advocate(s) will have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child’s participation in the research. * Describe how you will ensure that the advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization. |

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| For research that involves cognitively impaired adults , safeguards include:  See “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information.  **N/A:** This research does not involve cognitively impaired adults. | | |
| **Discussion- Cognitively Impaired Adults.**  While the subject of this section is cognitively impaired adults, many of the same principles should be used in the design of a study for cognitively impaired children where, when a required protection for children is greater than or equal to the requirements for cognitively impaired adult, the requirements for research involving children may be substituted.  **Consent, Assent and Parental Permission** requirements for inclusion of Cognitively Impaired persons as well as those for children are covered in sections 26 and 27 of this protocol document. | | |
| **A** | | **NA type responses:** | |
| 1 | **No Cognitively Impaired Adults.** This research does not involve Cognitively Impaired Adults. |
| **B** | | **Cognitively Impaired Adults.** This is a set of directions to provide information to the IRB and make the argument that this study meets the regulations for involving cognitively impaired adults in research. Keep in mind that if you cannot meet the requirements of the questions in one of the categories below, there is a good chance that cognitively impaired persons may not be allowed to be involved in this research. Only one of the categories should apply to any given research project (start at the top, if the first one fits, then go no further). If you are not sure which to apply, you may use more than one but be careful in doing so as sometimes a response provided in a second category can make the other category invalid.   * For the category you choose, restate the category (the first/heading sentence in each section) and then provide the information requested by the follow on bullets for that category. | |
| 1 | **Research Involving cognitively impaired adults with anticipated direct benefit to the subject**.   * Explain why one of the following is true:   + Subjects have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual subject that is unavailable outside the research context.   + The objectives of the trial cannot be met by means of study of subjects who can give consent personally. * Explain why risks to subjects are reasonable in relation to anticipated benefits to subjects. * Explain why the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. * Describe how you have verified that the trial is not prohibited by law. * Describe the processes in place to ensure that:   + Subjects will be particularly closely monitored.   + Subjects will be withdrawn if they appear to be unduly distressed. * State that the plan for the assessment of the capacity to consent, providing information to and obtaining assent from the subject to the extent compatible with the subject’s understanding and documentation of LAR permission and assent are covered in sections 26.8-26.12. |
| 2 | **Research involving cognitively impaired adults with NO anticipated direct benefit to the subject.**   * State the disease or condition for which the procedures involved in the research are intended. * Explain why the objectives of the trial cannot be met by means of study of subjects who can give consent personally. * Describe why the foreseeable risks to the subjects are low. * Describe why it is anticipated that the negative impact on the subject’s well-being is minimized and low. * Describe how you have verified that the trial is not prohibited by law. * Describe the processes in place to ensure that:   + Subjects will be particularly closely monitored.   + Subjects will be withdrawn if they appear to be unduly distressed. * State that the plan for the assessment of the capacity to consent, providing information to and obtaining assent from the subject to the extent compatible with the subject’s understanding and documentation of LAR permission and assent are covered in sections 26.8-26.12. |

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| Consider if other specifically targeted populations such as students, employees of a specific firm or educationally/economically disadvantaged persons are vulnerable. Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence. | | |
| **Discussion- Other Specifically Targeted Populations.**  While not specifically named in the federal regulations, other populations can be subject to coercion or undue influence due to their relationship to the person conducting the trial or by virtue of their state in life. This can leave the person in a position where they cannot or do not objectively evaluate the risks and benefits of a research study before making their choice to become a subject. For example, students may be interested in impressing a professor, so they might choose to sign up for his research study or a person who cannot read due to an educational disadvantage might not be able to adequately consider a consent document. These groups sometimes require additional protections.  **Specifically Targeted**. Added protections for these populations are usually limited to situations where the population is specifically targeted for a study because, except in rare cases, it would be unnecessary to add protections for a person just because for instance, they happen to be employed (as most of the population of the US is employed somewhere). Furthermore, the potential subject is not responding to the study advertisement because she is employed, but rather because she probably is a part of the population meeting the inclusion criteria.  Consider the examples in the chart below, along with the added protections that might be used.   |  |  | | --- | --- | | Study and Population | Possible Added Protections | | In a study of illiteracy, the scientifically necessary population would be educationally disadvantaged persons. | Verbal consent process, Additional time to consider enrolling, Family member or friend present for consent to assist the individual. | | A study of an innovative educational technique would obviously require students. | Mechanism to blind the classroom teacher to participation such as completely anonymous surveys, Explicit Statement in the consent process to notify participants that the research is not a part of their grades | | Study of business practices in a particular industry would probably need people who were employees of that industry. | Permission from management to conduct the study. Process to ensure that management has no ability to know who chose to participate and who did not. |   There are two general categories of vulnerable populations being specifically targeted.  **Targeting Because of Inclusion Criteria.** Sometimes, especially in behavioral research, a population is specifically targeted because of the topic of study. In these cases the scientific process requires the population and there can be some flexibility with respect to the level of undue influence that may be allowed.  **Targeting for Convenience.** Very few peoplewould choose to recruit a population from Los Angeles when a viable population exists right here in Buffalo but when a subset of the population meeting inclusion criteria exists that is very easy for a researcher to gain access to, if that population could be vulnerable to undue influence, additional protections will be necessary to reduce the risk of coercion to the level that would occur if recruitment did not use the convenience sample. For example, in a study of general cognition, college students would represent a sample of adults in the general population but the reason that the students are being targeted is not because it is scientifically necessary to utilize students, but rather because they are conveniently on campus. In these cases, the IRB will typically require that the potential for undue influence be virtually eliminated.  **Both Types of Targeting.** Sometimes researchers make the mistake of thinking that a population is being chosen solely for inclusion criteria when in actuality the population is being chosen for both inclusion criteria and convenience. For example, a music teacher may want to use a class he teaches who have been studying a specific type of music as a part of a research study and make the argument that they are being chosen based on inclusion criteria. In actuality, there are probably a number of music classes in western NY that could meet the inclusion criteria (and instruction could be delivered to as the teacher already has done in his class) so the class is being chosen for convenience. | | |
| **A** | | **NA type responses:** | |
| 1 | **No.** This research does not specifically target other vulnerable populations. |
| **B** | | **Specifically Targeted Populations.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Students**. Where students are a convenience sample, procedures such as those employed in the research participation groups should be used. Blinding of the instructor to participation should also be considered. When students are the scientifically required population, consider first if there is not another population (i.e. another class in another school) available where undue influence will not be present at all. |
| 2 | **Research Participation Group Students.** The IRB approved procedures for the (PSY, COM, OHR) RPG have procedures in place such as alternative assignments, multiple research opportunities, and a centralized grading process for assigning RPG Credit to minimize the potential for coercion and undue influence while providing students with a valuable learning experience about the research process. |
| 3 | **Employees**. When a specific firm(s)/Company(s) is/are the target, permission from management and their agreement that raw data will not be shared with them should be obtained. Anonymous participation is best as, even if a piece of data were to be accidentally disclosed, it could not result in negative job repercussions. Disclosure in the consent process that while permission from management has been obtained to conduct the study, the research is not required as a part of their job duties. Recommendation to participants that any electronic surveys not be done on company computers. |
| 4 | **Educationally and/or Economically Disadvantage People.** Consider an enhanced consent process with additional time, a family member or friend present and maybe an audio/visual presentation. Also consider that compensation that would otherwise not be coercive, could be so in this case. |

# Eligibility Screening

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| Describe screening procedures for determining subjects’ eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.  http://www.clipartbest.com/cliparts/acq/eAx/acqeAxyRi.png Include all relevant documents with your submission (e.g. screening protocol, script, questionnaire). | | |
| **Discussion- Screening Procedures**  Screening procedures achieve two main goals:  They ensure that you have the correct population to obtain scientifically sound results.  They protect participants from risks that would not be present in the population of interest but could be present in an excluded population.  Consider a study investigating the academic choices of college students. Screening might occur in one of two ways. One way is to restrict recruitment to the particular population so that only college students would be able to participate, for example by sending the invitation out through an e-mail list of college student, the researcher would be reasonably certain that the only people replying would be college students (yes there might be one lying brother who hacks his sibling’s e-mail but some degree of dishonesty can’t be avoided and, if the sample is well designed, this should not significantly affect the results). A second way would be to ask the person directly if they are a college student (again, we can’t completely avoid a liar) either through some process when they reply to recruitment materials (such as a brief set of questions when they call to set up an appointment) or when they actually consent and participate in the study.  When considering screening procedures, it is important to note that when the federally designated vulnerable populations of prisoners, children and pregnant women are not to be included, there must be a “reasonable” effort to ensure that they are actually excluded.  **Prisoners.** Most studies exclude prisoners even though this exclusion criterion need not be specifically listed on recruitment materials because when a potential subject shows up for a research procedure appointment and is not in handcuffs being escorted by two police officers, one can reasonably assume that they are not a prisoner. However, when there is a reasonable potential for encountering a prisoner in the recruitment population (e.g. doesn’t ECMC handle some number of inmates when holding center health facilities are insufficient for their healthcare) and prisoners are one of the exclusion criterion does a specific procedure need to be spelled out here. On the flip side of this coin, if you are actually doing research where prisoners are the population of interest, it is usually pretty easy to spell out how you will know that you are actually working with a prisoner (the front gate to the facility is usually a pretty good indicator).  **Children.** The inclusion or exclusion of children is usually only little more problematic than for prisoners. This can usually be achieved through a combination of targeted recruitment and/or a simple question or two just prior to participation. In some cases it may be necessary to check documentation (such as a photo id or medical records) in order to verify when person is a child or an adult but this is not needed in every case. Of course if your research is interviewing octogenarians there is no reasonable chance that a child would be participating and your eyes can do the screening but if you are working with college students, many freshmen are under 18 years of age and there are some accelerated students who might be very young and one’s outward appearance does not change much just because they have had their 18th birthday.  **Pregnant Women.** Pregnant women should not be excluded unless there is a scientific or safety reason for such exclusion. A survey or interview procedure would not typically require exclusion of pregnant women but consider a study recruiting both men and women between the ages of 20 and 40 that needs to exclude pregnant women because of a potential adverse effect on the pregnancy. There would usually not be a good way to restrict the recruitment to non-pregnant women in this population (although the recruitment materials would probably state pregnancy in the exclusion criteria) so only an interactive screening method will be useful. Some options might be to cover pregnancy during a response to recruitment materials (a screening question), or asking the women when they show up for their appointment or in some cases, administration of a pregnancy test may even be necessary.  The choice of which methods of pregnancy screening are sufficient depends upon the risk of the research to a possible pregnancy. For example, because hearing can be affected by pregnancy, a study that includes a standard hearing screening could exclude pregnant women by simply asking the woman if she is pregnant. A study where alcohol is being administered or of a drug that may have significant deleterious side effects on pregnancy might however require that a pregnancy test be performed before participation.  **Consent For Screening**. Keep in mind that screening information generally cannot be used as data and should not be retained more than momentarily unless consent from the individual is obtained or the IRB grants a waiver of consent to collect it and retain it in the research record. If for scientific purposes it is important to track screen failure information beyond the number of passes and number of failures, then the screening process represents a situation where the researcher is obtaining information about an individual through interaction and the individuals who are screened are research participants even though they are not necessarily the “desired” research participants.  Additionally, even when data is not being retained in a screening procedure, if a procedure asks questions which would generally be considered private information a consent process should take place before the screening procedures. The nature of what is private may be study specific. For example, asking a group of public figures who are already members of a public LGBT group their sexual preference during screening might not be considered private or sensitive enough to warrant the need for consent but asking the same question of a group of clergy might.  While there are cases where screening consent and later research procedure consent could be combined into one process (e.g. an online survey where the first few questions are for screening) consent for screening should not automatically use the same consent process or document as for the later research procedures. Rather the consent for screening should focus only on the procedures to be encountered in the screening process. | | |
| **A** | | **NA Type Responses:** Caution, before you select an NA choice, make sure that the screening process does not require an appropriate procedure to ensure that any excluded populations indicated in section 6 are screened out if they might present for the research. | |
| 1 | **NA Records**- Subjects will not need to be screened in any way in the record review (part of the) study where no intervention or interaction will take place because every record that is accessed will meet inclusion criteria. |
| 2 | **NA Observation Only**- Subjects will not need to be screened in any way in the observation phase of the study where no intervention or interaction will take place. |
| **B** | | **Screening Procedures** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Records Review.** Not all records present in the initial data set will meet inclusion criteria so records are screened first for applicable inclusion/exclusion criteria by the research team and only those that meet this criteria will be included in the final data set for analysis. The total number of records screened will be recorded but no identifiable information from the failures will be recorded. |
| 2 | **Mailed Targeted Recruitment.** Screening is achieved through a targeted recruitment process where materials are sent to people who are…The mailing list was provided/obtained by… It is expected that all respondents will therefore meet eligibility criteria and no further screening will be required in order to ensure that participants qualify. |
| 3 | **Phone Screening without Consent.** While recruitment materials state general eligibility criteria, it is possible that some respondents to advertisements will not meet criteria for participation. In order to minimize loss of time for participants and research team members, when participants call for further information, a set of screening questions will be asked of them (attachment Nn- Screening Script). No data will be recorded for the screening process. If a participant’s responses to the screening indicate that they are not eligible, they will be thanked for their interest. A record of the number of screen failures will be kept but no direct data about participants. |
| 4 | **Phone Screening with Consent.**  While recruitment materials state general eligibility criteria, it is possible that some respondents to advertisements will not meet criteria for participation. In order to minimize loss of time for participants and research team members, when participants call for further information, a set of screening questions will be asked of them (attachment Nn- Screening Script). A verbal script included with the screening questions will be used for consent to screening over the telephone prior to administering the screening questions. Data will be recorded for the screening process because there is a research interest in the reasons that participants who respond to the advertisement do not meet inclusion criteria. If a participant’s responses to the screening indicate that they are not eligible, they will be thanked for their interest. |
| 5 | **Web Survey.**  Participants will become aware of the access the web based interaction because they have visited the website at… It is expected that the major inclusion criterion of having visited the website will be met. After web based consent (attachment Nn- Web Consent Information Sheet) is administered, participants will begin the survey. The first 10 questions of the survey cover the screening for additional inclusion/exclusion criteria and a response that results in a participant no longer meeting criteria will result in the survey being stopped after question 10 and the thank you message being displayed. Data will be recorded for the screening process because the web based interface requires this information in order to calculate whether or not a person meets criteria, but like all data it is anonymous. |
| 6 | **In Person Targeted Recruitment.** Screening is achieved through a targeted recruitment process where the people who are invited to participate are present at…It is expected that all respondents will therefore meet eligibility criteria and no further screening will be required in order to ensure that participants qualify. |
| 7 | **In Person Screening with Consent.**  While recruitment materials state general eligibility criteria, it is possible that some respondents to advertisements will not meet criteria for participation. When participants call for further information, they will be informed that their first appointment will include the screening process and that based on the screening they may or may not qualify for further participation. Signed Consent will be administered prior to any screening (attachment Nn- Screening consent). The screening process will follow the procedures listed in section 8 and data will be recorded for the screening process because there is a research interest in the reasons that participants who respond to the advertisement do not meet inclusion criteria. Participants will be contacted approximately 5 days after screening to either inform them that they are not eligible or schedule their next appointment. |
| 8 | **Department RPG Auto Screening.** The department administers a mass testing process as a part of the RPG. Answers provided by participants in the mass testing are used by the computerized system to determine eligibility for this study. If a participant is not eligible, they will not be able to access participation information for this study. No further screening is required. The RPG procedures also ensure that no persons under the age of 18 participate in any studies. |
| 9 | **Screening out Children where direct interaction occurs.** In order to help ensure that children do not participate in this study, all participants are asked their age at the beginning of the screening process. All persons under the age of 18 will be excluded from participation. |
| 10 | **Screening out Children by Checking IDs.** In order to help ensure that children do not participate in this study, all participants are asked to present photo ID at the beginning of the screening process. All persons under the age of 18 will be excluded from participation. |
| 11 | **Screening out Children for Distance Procedures.** There is no in person contact between the researcher and respondents to this web survey but it is unlikely that children would be interested in participation or contacted in the recruitment process. In order to further help ensure that children do not participate in this study, the consent information sheet indicates that persons under the age of 18 should not participate. |

# Recruitment Methods

**N/A:** This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections

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| Describe when, where, and how potential subjects will be recruited. NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. Include specific methods you will use (e.g. searching charts for specific ICD code numbers, Research Participant Groups, posted advertisements, etc.). Describe how you will protect the privacy interests of prospective subjects during the recruitment process. NOTE: Privacy refers to an individual’s right to control access to him or herself. | | |
| **Discussion- Recruitment Methods**  Recruitment covers the identification of potential participants, any advertising, any preconsent discussions and some sort of response from the participants to the recruitment. Privacy issues related to recruitment processes should also be addressed in this section.  Just about every study has some sort of recruitment procedure. The only general exceptions to this would be records review studies and a few observational studies where there is no interaction between the research team and the subjects.  When we hear the term recruitment, we often think in terms of recruiting someone to join the military or a civic or religious organization. In those cases, recruitment is often a formal process but at its base, recruitment is merely inviting or asking someone to take part in something. So, what this section is asking you to do is to state the details of the procedures that you will use to ask a person to be in your research.  Research recruitment is the beginning of the informed consent process. Often participants need to be located by means of some form of screening to target them or an advertisement but, even when participants are known to a researcher and may be predisposed toward participation in a project; there must be some method of asking them to do so.  Most research participant groups only have one recruitment process even though multiple modes of recruitment (e.g. flyers to be passed out may be used along with an announcement script, as well as newspaper advertisements) may be used. In some cases, different groups of participants need to be recruited in different ways (e.g. teachers may be asked to participate verbally using an announcement at a faculty meeting while parents may have a letter sent home in order to secure their participation). When recruitment procedures need to be described separately because there are significant differences, be sure to do so and label each group appropriately and clearly.  Some examples/options for recruitment responses are given below. Except in the cases where recruitment is clearly not applicable, you should probably be using at least one of the choices from each group but you may decide that you want to use more than one from each group. If one of these is not directly applicable, please try and use the ones that are closest to your plan and edit as necessary to reflect your intended recruitment processes.  One last item. Where you can be more specific, you should do so. For example, the general statement, “Participants will be contacted by research staff…” should be modified to state specific research staff, not necessarily by name but rather by position. If the Principal investigator is going to do this procedure then the statement should read “Participants will be contacted by the PI…” | | |
| **A** | | **NA type responses:** | |
| 1 | NA- Subjects will not need to be recruited or asked to participate in any way in the **record review** (part of the) study where no intervention or interaction will take place. |
| 2 | NA- Subjects will not need to be recruited or asked to participate in any way in the **observation** phase of the study where no intervention or interaction will take place. |
| **B** | | **Identification of Subjects:** | |
| 1 | **No information** will be accessed/obtained in order to target recruitment. Participants who respond to the advertisement will come from…(the general public at large responds to the TV ad, anyone who clicks on the link on the website at [www.nnn.buffalo.edu](http://www.nnn.buffalo.edu) , persons who are read the in class recruitment announcement, etc.) |
| 2 | **Only publically available** information will be accessed/obtained in order to target recruitment. The information obtained will come from…(the public website at [www.nnnnn.com](http://www.nnnnn.com), the phone book, etc.) |
| 3 | Participants have **previously given permission** to put their information into a database to be used for eligibility determination and recruitment for future studies. The researcher will use the database parameters to screen for eligibility and generate post cards (attachment Nn- Recruitment post card) to be sent to eligible participants. |
| 4 | No information other than **basic directory/contact information** will be accessed/obtained in order to target recruitment to the desired population. The information obtained will come from…(a membership list provided by…). |
| 5 | **Records information** containing more than just directory/contact information will be accessed in order to better target recruitment to the intended population. The information will come from a search of…(medical records at…for people meeting the inclusion criteria, educational records from the East End Elementary school provided by…) Access to the records has been granted to the research team by…(Hospital Administrator, School Principal, etc.). The principal investigator has continuing access to these records because (she works in the hospital from which the records are derived, they are records of work done by students he has taught over the past few years, etc.). |
| 6 | Information will be obtained through an **interactive screening process** that includes more than just directory/contact information. When potential participants respond to advertisements by calling the number provided, they will be read Attachment A, Script for consent to screening and then if they respond affirmatively they will be asked to respond to the questions in Attachment B, Screening Questions. If after answering these questions it is determined that they meet eligibility criteria, they will be invited to participate using the script in Attachment C, Invitation to Eligible Participants Script. |
| **C** | | **Methods of Communicating Recruitment Information:** | |
| 1 | The **Flyers/signs/posters/bills** in attachment A will be placed on bulletin boards and hallways…(on the UB campus, at the East End Community Center, in teacher’s mailboxes at East End Elementary School, etc.) |
| 2 | A group of **print advertisements** (attachment N, Print advertisements) will be run in the classified section of (The Buffalo News, Artvoice, the Spectrum). Specific ads will be selected from the approved advertisements and run depending upon recruitment goals (e.g. we will start with the first ad for general recruitment but if the study has recruited sufficient females and still needs to recruit males, the ad targeting males will be run). |
| 3 | A group of **radio/TV advertisements** (attachment N, advertisements) will be broadcast on local radio/TV stations. The text of these advertisements has been provided for approval. After recording the final audio/video form of the ads, will be provided to the IRB as a study amendment for approval before they are run by the radio/TV station. |
| 4 | A **verbal announcement** of the research opportunity will be made…(in the Chem 101 classes, at the public meeting of the east end PTA, to all attending the lecture/training sessions) by (the PI, specific research team members). The announcement will be read from the script in attachment N, Recruitment announcement. |
| 5 | A **letter/e-mail** (attachment N, recruitment letter) will be sent out by (the PI, research staff, the community organization, etc.) inviting people to participate in the project. |
| 6 | A page on the **website** (be sure to tell what website) will invite people to participate in the project. The text of the webpage has been provided for approval (Attachment N, webpage). After the final webpage has been completed but prior to public publication of the webpage, a pdf of the page along with the web address to be used will be provided to the IRB as a study amendment for approval before the page is made live. |
| 7 | The (Indicate Department- PSY, COM or OHR) **Research Participation Group** procedures previously approved by the IRB are being utilized for recruitment through the departments RPG web interface. Students are screened based on their responses during mass testing procedures and only those students who meet eligibility criteria are able to sign up for this particular protocol. The study description presented to the participants for this particular protocol as a part of the RPG interface is given in Attachment Nn- RPG sign up announcement. |
| 8 | **Research Match** procedures previously approved by the IRB are utilized for recruitment procedures. Participants will receive the study description presented in Attachment Nn- Research Match Posting. |
| 9 | Participants will be contacted by research staff via **telephone using the script** in attachment Nn- Recruitment Phone Script. |
| 10 | An **in person one on one procedure** will be used for recruitment - don’t forget to specify the WHO and WHERE for this. |
| **D** | | **Possible methods of response to recruitment information:** | |
| 1 | Participants **will respond** to recruitment information by (calling the phone number, replying to the e-mail) presented in the recruitment materials. |
| 2 | Participants **use a link/button** to an internet site to access further information, sign up, and/or participate in the study. |
| 3 | Participants respond by **using study materials** that are available to choose to participate (e.g. they fill out and turn in a survey that was passed out or mailed to them with the recruitment and consent materials). |
| 4 | Participants **reply verbally** to one on one communication after being provided with the information in the recruitment script and having any questions answered by the study staff present. If participants reply affirmatively, the consent process will follow. |
| **E** | | **Addressing Privacy During Recruitment:** | |
| 1 | Privacy of potential subjects is protected because the participant controls his/her own response to **recruitment materials that are presented publicly**. |
| 2 | No invasion of privacy occurs during the initial mailing because **all information comes from publicly available** phone records. |
| 3 | While **private records must be accessed** in order to target recruitment to the appropriate population, accessing these records represents a minimal invasion of privacy because…(the research team already has access to these records in the course of their other duties, there is an institutional gatekeeper for these records who is not affiliated with the research project and has given permission to access them, etc.). |
| 4 | **The face to face recruitment procedure** does not cause an unreasonable invasion of the person’s privacy because the condition for which the study is designed is already known to the potential subject and the recruitment procedures are conducted in a private setting with only the research team and those authorized by the subject present. |
| 5 | No invasion of privacy occurs during the recruitment procedures because the potential subject has **previously given permission** for his/her records to be placed in a specific research database and to be contacted for future studies based on this information. |

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| Identify any materials that will be used to recruit subjects. Note: Examples include scripts for telephone calls, in person announcements / presentations, email invitations.  http://www.clipartbest.com/cliparts/acq/eAx/acqeAxyRi.pngFor advertisements, include the final copy of printed advertisements with your submission. When advertisements are taped for broadcast, attach the final audio/video tape. NOTE: You may submit the wording of the advertisement prior to taping to ensure there will be no IRB required revisions, provided the IRB also reviews and approves the final version. | | |
| **Discussion- Recruitment Materials**  Depending on how well you addressed 7.1, some of this may just be a repeat of the things you said there with a slight change in sentence structure. A bulleted list summarizing items like the example below should suffice if the use of the recruitment items were all appropriately covered above. Make sure to name items in this protocol exactly as you name the uploaded files so that reviewers have an easier time. | | |
| **A** | | **NA Type responses:** | |
| 1 | NA- Subjects will not need to be recruited or asked to participate in any way in the **record review** (part of the) study where no intervention or interaction will take place. |
| 2 | NA- Subjects will not need to be recruited or asked to participate in any way in the **observation** phase of the study where no intervention or interaction will take place. |
| **B** | | **Example Bullets for Recruitment Materials** | |
| 1 | Appendices A-E- **Flyers/signs/posters/bills** to be placed on bulletin boards and hallways…(on the UB campus, at the East End Community Center, in teacher’s mailboxes at East End Elementary School, etc.) |
| 2 | Attachment F- **print advertisements** to be run in the classified section of (The Buffalo News, Artvoice, the Spectrum). |
| 3 | Attachment G- Text for **radio/TV advertisements** to be broadcast on local radio/TV stations. After recording, the final audio/video form of the ads, will be provided to the IRB as a study amendment for approval before they are run by the radio/TV station. |
| 4 | Attachment H- **Verbal Recruitment Announcement Script** to be read to…(the Chem 101 classes, the public meeting of the east end PTA, all attending the lecture/training sessions) by (the PI, specific research team members). |
| 5 | Attachment I- **Letter/e-mail** to be sent out by (the PI, research staff, the community organization, etc.) inviting people to participate in the project. |
| 6 | Attachment J- **Text for Webpage** on (be sure to tell what website) to invite people to participate in the project. After the final webpage has been completed but prior to public publication of the webpage, a pdf of the page along with the web address to be used will be provided to the IRB as a study amendment for approval before the page is made live. |
| 7 | Attachment K- The **RPG Sign up announcement** presented to departmental RPG students inviting them to participate in this particular protocol through the RPG interface. |
| 8 | Attachment L- **Research Match study description**. |
| 9 | Attachment M- **Telephone Script** procedures to be used when contacting potential participants. |
| 10 | Attachment N- Script to be used for in person one on one recruitment. |

# Procedures Involved

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| Provide a description of all research procedures or activities being performed and when they are performed once a subject is screened and determined to be eligible. Provide as much detail as possible. NOTE: This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research. For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in your response. | | |
| **Discussion- Research Procedures**  Research Procedures include the things that the research team has to do to gather data as well and what the participants have to do in order to provide data. This can include both interventions and providing materials/data.  **Procedures added to Mitigate Risks, Address Harms or Monitor for Safety** should be covered in Section 21 Risks.  **Interventions** depend on study design and can include data collection but often they do not. Some examples of interventions that might not result in data collection points (except maybe for a note that they did actually occur) are, taking a medication, participating in counseling sessions, playing a computer game designed for the study, watching a video presentation, or listening to mood setting music.  **Interventions vs Inclusion Criteria.** Keep in mind that there is a distinction between an intervention for research purpose and inclusion criterion. Inclusion criteria are things that happen outside of the research context whereas an intervention only occurs because of the research and depending on the study design, an activity could be either. For example, attendance at a workshop taught on how to sing harmony could be an inclusion criterion if the only persons who may attend and take a follow up survey are those that are enrolled in a music education research project. On the other hand, if the harmony singing lessons are open to everybody but in order to participate in a follow on survey a participant obviously had to attend the workshop, then the workshop is an inclusion criterion.  **Providing Materials/Data.** The collection of data is usually a two way process where the researcher asks for something to be provided and the participant provides it. Examples of things that can be provided are blood samples, answers to survey or interview questions, artifacts of previous school work, readings on medical devices (e.g. blood pressure, x-ray, MRI). Even though the researcher in some cases may run the machine, keep in mind that it is a two part way process where (using the blood pressure example) the researcher asks the participant to put his/her arm in the cuff and then pushes the button to take the subject/patient’s reading.  It is very difficult for an outsider to provide a description of the research procedures you will use because the research procedures vary so much from biomedical to experimental behavioral to qualitative to records review based research. Additionally, you as the researcher probably have a pretty good idea of what you intend to do so our template words would have little applicability. We have therefore provided a few examples for simple research procedures which are often used at UB and if your study is similar to one of these, we recommend using one of them as a starting point. For investigator initiated biomedical research (clinical trials) or behavioral treatment research that does not fit one of these cases, if you are struggling to do this, we suggest finding a colleague with a sponsor initiated clinical trial to use for development of the research procedures section of your protocol.  Interventions and Data Collections. Keep in mind that research procedures include two basic items  **Multi-Site Situations.** Keep in mind as you write this section that the local IRB and scientific review process is mainly focused on what takes place under our local approval. Therefore, while it may be necessary to mention that part of the data will be provided by another site or that analysis of de-identified materials will be provided by a colleague at another university, where there is another IRB taking responsibility for those parts of the study, this local protocol does not need to provide the explicit details of those procedures in most cases. Where an exception to this rule of thumb occurs, we may have to add to this protocol but, unless you are sure that you need to do so, hold off on the outside procedures to both save yourself some potential work and save the possibility of confusion. When the CRO or BRO think you need to specify those procedures in greater detail, we will let you know and the IRB will do so if we miss them. | | |
| **A** | | **NA Type Responses:** (For obvious reasons, NA responses to this question are generally not acceptable) | |
| **B** | | **Research Procedures** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Records Review.** After screening all records provided by…for inclusion criteria, the remaining records will be used. The researcher will extract from each qualifying record and create an entry in a spreadsheet for the record containing the information specified in attachment Nn- Recorded Raw data. All records obtained from… will then be either returned to the provider or deleted/destroyed by shredding. The procedures for analysis in 16.0 Data Management and Analysis will then be followed. |
| 2 | **One Time Survey Procedure.** After consenting, participants will be asked to complete the study instruments indicated in 9.2 below. Participants will submit these by…(mailing them in the postage paid envelope included, clicking the submit button on the final page of the survey, dropping them in the envelope on their way out of the room, etc.). Then tell how the data is gathered by the researcher and/or tabulated or otherwise organized for analysis. The procedures for analysis in 16.0 Data Management and Analysis will then be followed. |
| 3 | **Multi-Interview Procedure with Intervention Between Sessions.** If the participant has agreed to be taped, the researcher will record responses using a digital audio recorder. Data will later be transcribed by the researcher and the original recordings erased. Otherwise, taping will not occur and data will be recorded with hand written notes only.  After consenting for the first interview, participants will be asked the questions in attachment Nn- Interview Questions specified for the first interview. At the end of the first interview the participant will be instructed in the Yoga relaxation techniques attachment Nn- Yoga Techniques. The participant will be asked to practice the techniques for 15-30 minute per day until the next interview session.  Interview sessions 2-4 will be held at one week intervals. After reminding the person that their continued participation is voluntary, the participant will be asked the question in attachment Nn- Interview Questions specified for interviews 2-4. After completion of the interview, the Yoga techniques in attachment Nn- Yoga Techniques, will be reviewed. The participant will be asked to practice the techniques for 15-30 minute per day until the next interview session.  Interview session 5 will be held one week after session 4. After reminding the person that their continued participation is voluntary, the participant will be asked the question in attachment Nn- Interview Questions specified for interview 5. After completion of the interview, the participant will be thanked for their participation and offered literature on non-research Yoga programs in the area that they may wish to take advantage of.  The procedures for analysis in 16.0 Data Management and Analysis will then be followed. |
| 4 | **Observation Procedure with follow up Interview.** When the research team member arrives at the school and is greeted by the classroom teacher who has agreed to be observed and interviewed, the team member will obtain the signed consent form that was provided and discussed previously. The researcher will then be provided with a seat in the back of the classroom by the teacher where observations of the lesson will be recorded from. The teacher will inform the students that, just like when the principal comes a couple of times a year to evaluate him/her, he/she is being observed and video recorded by researchers from UB for today’s lesson but that the students will not be recorded on video. The lesson of approximately 30-40 minutes will then be video recorded by the researcher.  The researcher will take the video back to the lab and analyze it using the procedures in 16.0 Data Management and Analysis to generate a series of cuts from the video that will be played back for the teacher as a part of the interview session.  The follow up interview session will take place within one week of the video creation. During the interview session, the participating teacher will view cuts of their own video-recorded teaching and will be asked the question included in attachment Nn- interview schedule. Most of these questions focus on what the teacher’s intentions and goals were during particular parts of the lesson. At the completion of the interview, the teacher will be asked if they would be willing to be contacted at a later date to get their permission for specific video clips to be made public as a part of the publication of the data and/or for further information or clarification on any of the video or interview data. The participant will again provide contact information if they are willing to do so.  Data from the interviews along with the video analysis will be analyzed using the procedures in 16.0 Data Management and Analysis. |

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| Describe what data will be collected? Note: For studies with multiple data collection or long term follow up, consider the addition of a schedule or table in your response. List any instruments or measurement tools used to collect data (e.g. questionnaire, interview guide, validated instrument, data collection form).  http://www.clipartbest.com/cliparts/acq/eAx/acqeAxyRi.pngInclude copies of these documents with your submission. | | |
| **Discussion- Data Collection.**  See discussion under 9.1 above. This item should present a list of items that will be used to collect data, i.e. specific questionnaires developed for the study, standardized data collection instruments (e.g. the Beck Depression inventory, the Peabody Picture Vocabulary Test, etc.), data collection sheet/forms for use in extracting relevant information from records, data collection rubric or checklists to be used in observations. When some items will be used either at different points in time or with different participant groups, a chart here should make it clear to the reviewers which instruments are being used and when and with whom. | | |
| **A** | | **NA Type Responses:** (For obvious reasons, NA responses to this question are generally not acceptable) | |
| **B** | | **Research Procedures** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Records Review.** The researcher will extract from each qualifying record and create an entry in a spreadsheet for the record containing the information specified in attachment Nnn- Recorded Raw data. |
| 2 | **One Time Survey Procedure.** The only data collected will be that indicated by participant responses to the items in the following study instruments which have been included as attachments:  Study demographics  Standardized Questionnaires (specified by name)  Study Specific Questionnaires (specified by name) |
| 3 | **Multi-Interview Procedure with Intervention Between Sessions.** If the participant has agreed to be taped, the researcher will record responses using a digital audio recorder. Data will later be transcribed by the researcher and the original recordings erased. Otherwise, taping will not occur and data will be recorded with hand written notes only.  After consenting for the first interview, participants will be asked the questions in attachment Nnn- Interview Questions specified for the first interview. At the end of the first interview the participant will be instructed in the Yoga relaxation techniques attachment Nnn- Yoga Techniques. The participant will be asked to practice the techniques for 15-30 minute per day until the next interview session.  Interview sessions 2-4 will be held at one week intervals. After reminding the person that their continued participation is voluntary, the participant will be asked the question in attachment Nnn- Interview Questions specified for interviews 2-4. After completion of the interview, the Yoga techniques in attachment Nn- Yoga Techniques, will be reviewed. The participant will be asked to practice the techniques for 15-30 minute per day until the next interview session.  Interview session 5 will be held one week after session 4. After reminding the person that their continued participation is voluntary, the participant will be asked the question in attachment Nnn- Interview Questions specified for interview 5. After completion of the interview, the participant will be thanked for their participation and offered literature on non-research Yoga programs in the area that they may wish to take advantage of.  The procedures for analysis in 16.0 Data Management and Analysis will then be followed. |
| 4 | **Observation Procedure with follow up Interview.** When the research team member arrives at the school and is greeted by the classroom teacher who has agreed to be observed and interviewed, the team member will obtain the signed consent form that was provided and discussed previously. The researcher will then be provided with a seat in the back of the classroom by the teacher where observations of the lesson will be recorded from. The teacher will inform the students that, just like when the principal comes a couple of times a year to evaluate him/her, he/she is being observed and video recorded by researchers from UB for today’s lesson but that the students will not be recorded on video. The lesson of approximately 30-40 minutes will then be video recorded by the researcher.  The researcher will take the video back to the lab and analyze it using the procedures in 16.0 Data Management and Analysis to generate a series of cuts from the video that will be played back for the teacher as a part of the interview session.  The follow up interview session will take place within one week of the video creation. During the interview session, the participating teacher will view cuts of their own video-recorded teaching and will be asked the question included in attachment Nn- interview schedule. Most of these questions focus on what the teacher’s intentions and goals were during particular parts of the lesson. At the completion of the interview, the teacher will be asked if they would be willing to be contacted at a later date to get their permission for specific video clips to be made public as a part of the publication of the data and/or for further information or clarification on any of the video or interview data. The participant will again provide contact information if they are willing to do so.  Data from the interviews along with the video analysis will be analyzed using the procedures in 16.0 Data Management and Analysis. |

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| Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records.). | | |
| **Discussion and Directions- Source Records.**  One way to think about this is, “Where does the data about subjects come from?”   * If it is only provided directly by the participant as a part of questions they answer in the form of a survey or interview, then the NA response will be appropriate. * If it comes from records- list which records you access to collect the data and provide a data collection form or spreadsheet as an attachment in your submittal to show the information you will collect from the records. | | |
| **A** | | **NA Type Response** | |
| 1 | All information is provided directly by the participants so no source records will be accessed. |
| **B** | | **Source Records.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Biomedical.**  Individual results from the patient records at ECMC will be accessed in order to extract the data needed for the study. The data extracted will include the information in attachment Nnn- record data collection instrument. |
| 1 | **Education.**  Parents will grant permission for access of their child/student’s academic records by the research team as a part of the consent process. The researcher will then obtain the records from the school in order to extract the data needed for the study. The data extracted will include the information in attachment Nnn- record data collection instrument. |

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| Indicate whether or not individual subject results , such as results of investigational diagnostic tests, genetic tests, or incidental findings, will be shared with subjects or others (e.g., the subject’s primary care physician) and if so, describe how these will be shared. Indicate whether or not study results will be shared with subjects or others, and if so, describe how these will be shared. | | |
| **Discussion- Providing Results to Others.**  Results do not necessarily need to be shared with subjects or others in most cases. There is an important difference between sharing study results and sharing individual results. Sharing of study results (such as a report of findings or statistical data) usually would not result in a disclosure of confidential or private information but individual results might.  **Individual Results.** Situations where individual results could be shared are most common when there is an important need to inform a participant or his/her physician about results of tests or incidental findings. In some of these cases, it may be necessary to do so in order to minimize risks or provide for the subject’s well-being.  By extension, behavioral situations where individual results might be shared could include educational or psychological testing but they may also extend to situations such as providing an individual with an audio or video recording of their own participation in an interview.  **Study Results.** Usually study results are provided to others only through publication but occasionally a researcher, as a demonstration of good will, may decide to share study results with either individual subjects or an organization that worked with the researcher to provide access to subjects (such as a school that gave a researcher access to students). While there is usually not a problem with doing so because there is no individually identifiable information, it may be best to allow for the option of doing so in the protocol and not state that you will provide study results to others.  **Other Important Considerations**. Provision of results to a participant or others is not a study benefit or form of compensation. Provision of individual results to a person other than directly to the individual or a child’s parent is a HIPAA disclosure when health information is involved. | | |
| **A** | | **NA Type Response** | |
| 1 | Neither individual nor study results will be provided to persons outside of the research team. |
| **B** | | **Providing Results to Others.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Individual/Biomedical.**  Individual test results from the following tests… will be provided to the subjects to be shared with their physician if they wish.  -Or-  Individual test results from the following tests… will be provided to the subject’s physician if the patient desires upon providing the contact information and signing a separate HIPAA authorization (attachment NNn- HIPAA release form) to allow the release. |
| 2 | **Sharing of Study Results.** Final study results in the form of a draft of the thesis will be provided to the school principals that allowed the researcher access to the subject population as well as to the individual teachers who participated and indicated that they would like the results either via e-mail or when asked at the end of their interview. |

# Study Timelines

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| **Discussion- Study Timelines**  Even records reviews have estimated time lines so while some questions in this section may be NA, not all will be.  Provide your best estimate of the time frames that you anticipate. We recommend that you be a little bit pessimistic in your prediction (in other words overestimate the time frame by a little bit but not unreasonably so). For example, if you think it will take 4 months to enroll all subjects, give yourself 6 months. Don’t forget to cover all participant groups separately along with the entire study time line (see examples below). |

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| Describe the anticipated duration needed to enroll all study subjects. | | |
| **A** | | **NA Type Responses:** NA responses to this question are generally not acceptable | |
| **B** | | **Enrollment Times** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Records**- Subjects will not need to be enrolled in any way in the record review (part of the) study where no intervention or interaction will take place. It is expected that all records will be in possession of the research team for screening and analysis within 2 weeks after study approval. |
| 2 | **Observation Only**- Subjects will not need to be enrolled in any way in the observation phase of the study where no intervention or interaction will take place. It is expected that all observations will take place within 6 months of approval depending upon scheduling and availability of the community partners. |
| 3 | **General Response with multiple parts**- The following times for enrollment are anticipated:  Records review screening procedures- It is expected that all records will be in possession of the research team for screening and analysis within 2 weeks after study approval.  Enrollment of primary focus research participants- the enrollment period will last from 6 months to a year depending on response rate.  Enrollment of secondary participant family members for the quality of life follow up- This will commence after 6 months of participation by primary focus participants and will last for approximately 1-2 months beyond that point.  Total study- the cumulative study enrollment period will last between 9 and 24 months. |

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| Describe the duration of an individual subject’s participation in the study. Include length of study visits, and overall study follow-up time. | | |
| **A** | **NA Type Responses:** | |
| 1 | **NA Records**- There will be no intervention or interaction in this record review (part of the) study. |
| **B** | **Duration of Participation** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Observation Only**- While no active participation will take place by participants in the observation phase of this study, each observation period will last for approximately the length of a class period (50-135 minutes) and a total of 5 visits to each of 3 classes will be made over the course of the semester (3 months). |
| 2 | **General Response with Multiple Parts**- The following times for participation are anticipated:   * Records review screening procedures- No participation for the records review will occur. * Primary focus research participants- the primary focus participants will be involved with the following visit schedule: * Initial Visit- 1 hour * Visits 2,3,4,5- 30 minutes each conducted at approximately 1 month intervals * Visit 6- 1 hour conducted approximately 1 month after visit 6 * Primary focus research participants will also be required to spend approximately 15 minutes each day for the 6 month period in completion of an electronic log entry.   Overall time commitment- 4 hours for study visits and approximately 45 hours of individual log entry completion.  Secondary participant family members for the quality of life follow up- No visits will be required. Secondary participants’ research involvement will be for a one time survey that will take approximately 30-45 minutes to complete. |

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| Describe the duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed). | | |
| **A** | **NA Type Responses:** NA responses to this question are generally not acceptable | |
| **B** | **Completion Times** (Keep in mind that you may need a combination of these for your particular study)  **= Time for Enrollment (10.1) + Participation (10.2) + Data Analysis** | |
| 1 | **Records**- It is expected that this records review and analysis will take approximately 6 months to complete. |
| 2 | **Observation Only**- Subjects will not need to be enrolled in any way in the observation phase of the study where no intervention or interaction will take place. It is expected that all observations will take place within 6 months of approval depending upon scheduling and availability of the community partners. |
| 3 | **General Response with multiple parts**- The following times for enrollment are anticipated:  The cumulative study enrollment period will last between 9 and 24 months because primary participants will have to complete participation before secondary participants are enrolled. It is expected that the secondary participation will only take 2 months to complete and final data analysis another 3 months after that. Total time for the study will be between 14 and 29 months (note how this time is reflective of the answer in 10.1). |

# Setting

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| **Discussion- Setting**  Be sure to cover ALL research settings. Even records reviews should specify facilities where records will be worked with to analyze data.  The IRB uses this section to evaluate both the safety of the facility and the privacy of the facility/situation for the given study. Keep in mind that for some research a very narrow range of facilities will be allowable for safety (e.g. no one would consider submitting a study involving major surgery to be done outside of a hospital) or privacy (e.g. when an interview response might cost a participant their job, it should not be done at the local coffee shop) reasons while other research may be allowable in a more open setting (such as a classroom or even in a public venue). Propose what you think is needed for the setting(s) and let the CRO/BRO/IRB recommend if it is not sufficient. In most cases you will be fine as proposed because you are also focused on protecting participants’ safety and privacy.  When there are physical safety concerns, you should specify any equipment/facilities immediately available for use in emergency circumstances unless the setting by its nature is understood to be comprised of certain equipment/facilities (e.g. it is safe to assume that certain equipment is available in an accredited hospital emergency room). When in doubt, stating the equipment/facilities available for foreseen complications is not a bad idea even if you think they would be understood.  **Privacy.** When there are no physical safety concerns, privacy will be the most important factor considered in this section. Privacy refers to how a people control access to themselves. While a participant may be granting you as a researcher access to them, the location where research procedures take place should be chosen with the following in mind:  Some research procedures should be conducted in a setting that is completely private (i.e. only the research team and the participants are present).  Most procedures should be conducted in a setting where similar non-research procedures would be conducted.  Sometimes it is fine to allow the participant to select their own level of privacy for research procedures. In these cases, while a less private location of their choosing may be fine, you should be offer a completely private setting for them to select where appropriate. It may even be the case that the research location cannot at all be controlled the researcher (consider a mailed or internet survey- the participant alone controls where he/she fills it out). In cases like these it may be appropriate to recommend that a participant complete the procedure in a private location but, of course, it cannot be specified. |

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| Describe all facilities/sites where you will be conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.  Note: Examples, of acceptable responses may be: “A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software,” “The angiogram suite at Buffalo General Medical Center, a fully accredited tertiary care institution within New York State with badge access,” or, “Community Center meeting hall” | | |
| **A** | | **NA Type responses:** NA responses to this question are generally not acceptable | |
| **B** | | **Setting** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Records Only**- All records will be initially accessed in the records department of Buffalo General Hospital through their EMR software package with permission of…Data for the cases of interest will be transferred to a password protected USB drive that will be stored in a locked drawer in room 414 Ewe Hall. Data analysis will be carried out in room 414 Ewe Haul, the private office of the PI. |
| 2 | **Observation Procedure with Follow Up Interview.** The research observations will take place in the high school classrooms of the participant teachers with only the teacher, students and research team members.  The follow up interview session will take place at a location of the teacher’s choosing. These locations may include the teacher’s classroom, the researcher’s private UB laboratory (415 Tammany Hall) or a semi-public location like a local restaurant or library. If the classroom or laboratory are chosen by the participant, only the research team members and persons authorized by the participant will be present during the interview.  Data storage and analysis will take place in either the private laboratory or the home of the PI. In either case, only members of the research team will be present in the room when analysis is taking place. |
| 3 | **Low Risk Clinical Procedure.** The outpatient treatment process will take place in the clinical office of the PI’s private practice located at... The office contains three private examination rooms where the participant and research team members will be able to complete research procedures as well as the consent process in privacy. Should procedures require further medical attention, the office is equipped with…  Data storage and analysis will take place in either the private office of the PI. Only members of the research team will be present in the room when analysis is taking place. |
| 4 | **High Risk Clinical Procedures.** The University at Buffalo is an academic institution with affiliations with Kaleida Health, ECMC, and Practice Plans. ECMC and Kaleida Health, BGMC are fully accredited tertiary care facilities in the Buffalo area.  The …..procedure will be done in the Interventional Radiology Suite at Buffalo General Medical Center, which is fully equipped with ……to handle…. |
| 5 | **Distance Procedure (phone, mail or internet).** The research procedures setting is controlled completely by the individual participants in that they can access the web survey form any computer or even via apps on their phones. Participants are encouraged to log in from a private location using a home (not office) computer and to close their browser after completion.  Some interviews will take place via telephone or skype. In either case the setting is controlled by the individual participants in that they can choose where they participate from. Participants are encouraged to schedule the interview at a time when they can be in a private location.  Data storage and analysis will take place in either the private laboratory or the home of the PI. In either case, only members of the research team will be present in the room when analysis is taking place. |
| 5 | **Biomedical Laboratory Facility Procedures.** The samples are processed in Dr. ….. laboratory within CTRC. It is a fully equipped laboratory which has a centrifuge, -80 freezer, vials, storage boxes, tubes, gloves, vials, PBS, Ficoll, western blot, and ELISA facilities. |

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| For research conducted outside of UB and its affiliates , describe:   * Site-specific regulations or customs affecting the research * Local scientific and ethical review structure   NOTE: This question is referring to UB affiliated research taking place outside UB i.e. research conducted in the community, school-based research, international research, etc. It is not referring to multi-site research. UB affiliated institutions include Kaleida Health, ECMC, and Roswell Park Cancer Institute.  ☐ N/A: This study is not conducted outside of UB or its affiliates. | | |
| **Discussion- Research Conducted Outside the Organization.**  Research conducted in UB facilities or at a Kaleida or ECMC facility is considered to be conducted within the “organization.” Any other research locations should provide an answer to this based upon the locations where the research will be conducted.  Please keep in mind that while the cultural examples below have all been actually encountered by the authors of this document, they have been generalized for purpose of these examples and are not necessarily extendable to every case. So, when we say “Native American Lands” we are saying that this is where we have encountered this practice in the past, not that this practice would apply in all studies with Native American participants or that it only applies in Native American cases. It is the responsibility of the researcher to identify these issues for areas they will be working in and obtain appropriate approvals before the research is conducted.  The actual approval is covered in section 15 Other Approvals.  **Research outside of NY State.**  A researcher is considered to be working outside of NY state when either:   * The research team puts “boots on the ground” by physically going to another state or country. * The research team specifically targets participants by using information from an organization within another state or country (e.g. recruitment of students at an out of state university by using the university’s student data base) where only a limited number of states are involved.   Under this definition a national survey of university presidents from a large number of states would not be considered research outside of NY as the research data is actually being collected in Buffalo even though contact information may have come from websites housed in every state of the Union. | | |
| **A** | | **NA Type Responses:** | |
| 1 | There are no site specific regulations or customs and no scientific or ethical review requirements beyond what is required by the organization. |
| **B** | | **Local context** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Schools in Eastern Rim Countries.** The research will be conducted in Schools in... While there are no site specific regulations and no scientific or ethical review requirements beyond what is required by the organization there is a local custom that affects the research. In these schools, the parents implicitly give the headmaster significant authority over their children. For activities taking place in the school, if the headmaster says they are allowed, then parents are not consulted to obtain permission for their children to participate. It is actually considered inappropriate in this culture to ask parental permission for minor students to participate in an educational research project taking place in the schools. The reason that the researcher is aware of this is because she is from… and attended school there for grades 1-12. |
| 2 | **Native American Lands.** In many Native American cultures, it is both customary and a legal requirement to obtain approval from the local council government before a research study is conducted on nation territory. The local council government appoints a team to conduct both an ethical review as well as providing a determination as to whether or not the research is sufficiently in the interest of the people to allow it to be conducted. |
| 3 | **Some African and Eastern European Countries.** All research conducted by foreigners in the country of… must have the approval of the Ministry of… before it is conducted. The minister conducts the equivalent of a local ethics review. When the researcher is from the US, the minister will sometimes require a copy of the IRB letter and materials. |
| 4 | **Businesses.** The research will be conducted with employees of businesses in NY City. While there are no laws preventing a researcher from doing a study within a specific business, a researcher would not typically be able to gain access to employees without approval of management. |
| 5 | **Other Colleges and Universities.** The research will be conducted on the campuses of other colleges and universities in the US. There are no members of the research team from these campuses, therefore they are not engaged in the research. However, permission will be obtained from the director of the office of… in order to conduct the study on their campus.  There are no site specific regulations or customs and no additional scientific or ethical review required for the organizations to be utilized. |
| 6 | **Distance Procedures- Phone, mail, internet, Skype.** The research will be conducted over the internet. The target population of the study is in the US, so there are no site specific regulations or customs and no scientific or ethical review requirements beyond what is required by the organization. |
| 7 | **Studies at VA Hospitals.** We are not going to try and provide an example but rather just let you know that THERE WILL BE requirements imposed by the VA that are above and beyond those required by the organization. You can list them here after you contact the VA that you will be working with. |

# Community-Based Participatory Research

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| Describe involvement of the community in the design and conduct of the research. NOTE: Community-Based Participatory Research (CBPR) is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.  **N/A:** This study does not utilize CBPR. Describe the composition and involvement of any community advisory board.  ☐ N/A: This study does not have a community advisory board. | | |
| **Discussion- CBPR**  Even when research is conducted outside of UB facilities and involves a community group (e.g. school children or personnel, outside medical facilities, a community organization or business allowing research to be conducted at its facilities, etc.), the research is NOT usually Community-Based Participatory Research (CBPR). CBPR only occurs when the community is involved with the design and conduct of the research.  Determining whether or not a community is involved in the design or conduct is not always simple. Consider the following cases:   * A researcher designs his project to be conducted with a local church. He is given permission by the pastor to conduct the project during the coffee hour after services. The pastor includes an announcement about the research at the end of the service and the researcher conducts the study. * A researcher designs his project to be conducted with a local church. He is given permission by the pastor to conduct the project during the coffee hour after services. Members of the parish have been lined up by the pastor to pass out and collect materials during the coffee hour. The pastor includes an announcement about the research at the end of the service and the researcher conducts the study with the assistance of the church members. * A researcher works with a local parish council to design and administer a study to be conducted during the coffee hour after services. The pastor includes an announcement about the research at the end of the service and the researcher and parish council members conduct the study.   It can easily be seen that as you read the later cases, there is a greater and greater involvement of the community organization with the research. The first bullet is most probably not CBPR because the researcher administers the whole thing himself (the pastor’s announcement does not cause this project to “belong to” the church any more than a recruitment advertisement in the Buffalo News classified ads causes a project to “belong to” the paper. The third case is most probably CBPR as the goals of the project are dictated by both the researcher and the church. Whether or not the second case is CBPR probably depends upon what exactly the parishioners do. If they are only acting like a “mailman” by passing out and collecting information that is in sealed envelopes, they are probably not causing the project to “belong to” the church but if they are handling identifiable private information, that may cause them to become engaged in the research.  While the strength of CBPR lies in its equitable involvement of the community, CBPR poses a few unique challenges to the human subjects ethics of a project:   * There can sometimes tension between the goals of the researcher and the goals of the community. * The community may not be well attuned to or may be frustrated by the research ethics requirements when, if they weren’t working with this person from UB, they would otherwise have the right to do things within their organization as they please (they may even try to start a project before you have your IRB approval in hand so be sure to make it completely clear why this cannot happen). * Sometimes it is difficult to discern when a member of the community is a researcher and when they are a participant and they may be BOTH. In the third example above, there would be no reason why the parish council members who are members of the research team could not also be participants by filling out a survey themselves (they would probably meet the inclusion criteria). * Community researchers may be in a position that can complicate ethical requirements. For example, because the parish council member would probably have friends within the church who they have known for years, it might make for possible breaches in confidentiality because responses might be identifiable to them, where they would not be so to an outsider. This might even pose a risk of straining relationships.   If you are conducting CBPR, you should keep the above items in mind as you craft your other protocol sections. | | |
| **A** | | **NA Type Responses:** | |
| 1 | NA- The study does not involve CBPR. |
| **B** | | **CBPR** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | We apologize but we have not reviewed sufficient projects involving CBPR to be able to create template examples at this time. Most of the researchers who frequently engage in CBPR will have no problem with these answers and we would welcome if they would provide a couple of examples that we can build into future versions of this document. |

# Resources and Qualifications

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| Describe the qualifications (e.g., education, training, experience, expertise, or certifications) of **the Principal Investigator and staff** to perform the research. When applicable describe their knowledge of the local study sites, culture, and society. **Provide enough information to convince the IRB that you have qualified staff for the proposed research.** NOTE: If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify a person by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not usually require prior approval by the IRB, provided that the person meets the qualifications described to fulfill their roles. | | |
| **Discussion- Qualifications of the Team.**  A good way to approach this question is to consider what you intend to have done by each type of person on the research team and then create a list of procedure types along with the “reasonable” qualifications you would consider adequate for performing those procedures. The “reasonable” qualifications should usually not be the exact qualifications of your staff unless you believe that these are truly the minimums needed to perform the duty. If this is the case then be careful or else you may run into a problem later should a staff member leave his/her position and need to be replaced by a slightly less qualified individual. | | |
| **B** | | **Qualifications of the Team.**  (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | For a **biomedical example** (pleases excuse the author’s imperfect knowledge of actual qualifications) a study that includes a surgical procedure, blood pressure monitoring, two complete follow up physicals, a few of blood tests, and a stress test. One could group the study procedures like this (but it is not the only way).   * The Surgical Procedure- will be performed only by the PI or Co-PI who ae board certified surgeons with at least 10 years of experience in surgical techniques of…(only give the relevant techniques even though they may have more). * Stress test and follow up physicals will be performed by the certified cardiologists on the study staff. * Blood pressure monitoring and blood draws procedures may be performed by either the certified surgeons, the certified cardiologists, one of the registered nurses on the team or one of the medical technicians being overseen by the RN. |
| 2 | **Behavioral research** usually does not have (as many) distinct categories that would require separate qualifications to be listed but can in some cases. For example a research project that administers a depression inventory might require the following breakdown:  All questionnaires may be administered by the PI, graduate research assistants or undergraduate research assistants supervised by the graduate research assistants.   * Undergraduate research assistants will be at least second year psychology students. * The graduate research assistants will be clinical psychology students who have been trained in the identification of the endorsement of suicide related questions on the depression inventory. * The PI is a licenses clinical psychologist in NY State and will be responsible for immediate follow up if responses to suicide related questions in the depression inventory trigger the need for intervention- see data safety and monitoring section. |

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| Describe the time and effort that the Principal Investigator and research staff will devote to conducting and completing the research.  NOTE: Examples include the percentage of Full Time Equivalents (FTE), hours per week. The question will elicit whether there are appropriate resources to conduct the research. | | |
| **Discussion-Time and Effort.**  This question is trying to get information to determine if there are enough human resources available to meet the requirements for the study. It is understood that sometimes there are factors that cause more time to be needed than anticipated but a reasonable estimate should be provided. | | |
| **B** | | **Time and Effort.** | |
| 1 | While time per week will vary depending upon number of qualifying subjects presenting per week, it is expected that on average about 5 hours of staff time will be devoted to this study per week out of 65 total staff hours available. |

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| Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable.  NOTE: One example includes: on-call availability of a counselor or psychologist for a study that screens subjects for depression. | | |
| **Discussion- Medical or Psychological resources.**  When there are physical or psychological risks, should the harm occur, the research team should have any resources needed readily available to mitigate the harm. | | |
| **A** | | **NA Type Responses:** | |
| 1 | NA- There are no reasonably anticipated physical or psychological risks that would require medical or psychological resources. |
| **B** | | **Medical or Psychological resources.**  (Keep in mind that you may need a combination of these for your particular study and there could be other ways to do this that would be acceptable) | |
| 1 | The study is being conducted in a fully accredited **tertiary care institution**. Arrangements have already been made to **provide the following treatments** if necessary… |
| 2 | Students who participate in the study are provided with **a referral sheet** that directs them to the student psychological services center if they are… |
| 3 | While the study is being conducted on the North Campus, arrangements have been made with Dr. XXX who is trained in YYY **should participants need to be treated for**… |

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| Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions. | | |
| **Training the Team.**  The PI (and faculty sponsor for student projects) is ultimately responsible for ensuring that personnel are adequately informed about duties and functions. As such, when the protocol is not followed, the lapse it is on the PI whether s/he is directly responsible or not.  This training deals directly with the specific protocol procedures, not general human subjects or scientific training. . | | |
| **A** | | **NA type responses:** | |
| 1 | NA- There are no persons assisting with this study. Only the PI (and faculty sponsor) will be conducting research procedures. |
| **B** | | **Training the Team.**  (Keep in mind that you may need a combination of these for your particular study and there could be other ways to do this that would be acceptable) | |
| 1 | The **study sponsor** conducts extensive training with the research tea. This training consists(ed) of… |
| 2 | The **PI uses hands on training** of all research personnel in their duties by…Describe a hands on training method with and oversight process like running two participants with the staff member observing and then asking the staff member to run the third and fourth participant with the PI assisting and the fifth participant with the PI observing. |
| 3 | All study team members are provided with **explicit written directions** for their portion of the protocol. They are also asked to read the entire protocol and meet with the PI to discuss any ambiguity, questions they may have before they begin their duties. |

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# Other Approvals

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| Describe any approvals that will be obtained prior to commencing the research (e.g., school, external site, funding agency, laboratory, radiation safety, or biosafety).  ☐ N/A: This study does not require any other approvals. | | |
| **Discussion- Prior Approvals**  You should list here approvals that have been obtained along with those that will be obtained. When an approval will not be necessary to start the research in this protocol but will be required before a later stage of the research, indicate so.  There is no need to list here UB scientific approval or approval from Thesis or Dissertation Committees or the signing of the Clinical Trial Agreement (CTA).  Funded research usually has approvals related to grants and contracts that are handled by Sponsored Programs Services. Unfunded research will often have no additional approvals.  Be sure to cover any approvals that you identified in section 12.2 under local regulations and customs. | | |
| **A** | | **NA Type Responses:** | |
| 1 | NA- The study does not require any other approvals. |
| **B** | | **Other Approvals** | |
| 2 | The following approvals have been or will be obtained prior to commencing the research:   * UB Biosafety Committee * Approval from NIH for funding * SPS approval of contract * Community organization acceptance- note that this will not be required until stage 4 of the project where materials are distributed to the community. * Due to the local custom described above in section 12.2, the Headmaster, Tribal Council, Minister of Research, Management of the businesses, etc. will be presented with the study materials and approval will be obtained before the study is conducted. * etc. |

# Provisions to Protect the Privacy Interests of Subjects

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| Describe how you will protect subjects’ privacy interests during the course of this research.  NOTE: Privacy refers to an individual’s right to control access to him or herself. Privacy applies to the person. Confidentiality refers to how private information provided by individuals will be protected by the researcher from release. Confidentiality applies to the data.  Examples of appropriate responses include: “participant only meets with a study coordinator in a classroom setting where no one can overhear,” or “the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering.” | | |
| **Discussion- Privacy.**  Privacy refers to an individual’s right to control access to him or herself. An obvious loss of privacy would occur if a person were to be interviewed in a crowd, but for some people this may acceptable in that they are willing to allow this type of access to themselves. Consider as an example of this the vast number of people who are willing to grant access to very personal information on internet face pages. However, some people may even have a difficult time with granting access to their personal information when the setting is completely confidential. Consider as an example a person who won’t tell his doctor about a bad health habit because he is embarrassed by it. So privacy protection does not apply to the disclosure of information only to outsiders, but also to the research team.  Some privacy issues are covered in the sections for recruitment, for the research procedure setting and the consent process but in some cases additional privacy protections may be needed. Additional privacy protections should be considered when:   * Providing a responses to questions cause emotional discomfort in the particular population. * Participation in a project might result in embarrassment or other negative social context. | | |
| **B** | | **Privacy** | |
| 1 | Privacy issues are covered in sections 9.2 for recruitment, 12.1 for the research procedure setting and 26.2 for the consent process. Additional privacy protections to allow participants to control access to themselves include:   * Participants are informed during the consent process and reminded periodically that they may skip any items they wish and stop the research at any time. * Participants are given the option of providing contact information for a reminder call for their future appointments. If they decide not to do so, they will not receive reminder calls. Any message left for their reminder will only state words to the effect of the following. “This is a reminder that you have an appointment this week, please call us at XXX-XXXX for specific time and location.” The specific purpose of the appointment will not be disclosed on the answering device. |

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| Indicate how the research team is permitted to access any sources of information about the subjects.  NOTE: Examples of appropriate responses include: school permission for review of records, consent of the subject, HIPAA waiver. This question does apply to records reviews. | | |
| **Discussion- Permission to Access Information.**  Tell how individuals control access to themselves. Indicate here how participants controlled the disclosure or how you otherwise were permitted to access the information for the research purpose. | | |
| **B** | | **Permission to Access Information**. (You may need only some of these bullets and for other types of information you may need to create one yourself) | |
| 1 | * **Interview/Survey.** After the consent process, the participant controls the research team’s access to the following information because it was directly provide by the participant through an interview/survey procedure:   + List the study instruments from the procedures section that this applies to. * **Clinical Tests.** The participant controls the research team’s access to the following clinical testing information by providing their signed consent and HIPAA authorization to the researcher:   + List the study instruments/materials from the procedures that this applies to. * **Records after consent.**  The participant controls the research team’s access to the following information by providing their signed consent and HIPAA authorization for the researcher to access it:   + List the study instruments/materials from the procedures that this applies to. * **Records without consent.**  The researcher is authorized to access protected health information without consent for the records review portion of the study by virtue of the HIPAA waiver and consent waiver granted for this protocol which are verified by the hospital records staff before providing the information. |

# Data Management and Analysis

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| Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis. |
| **Discussion- Data Management and Analysis.**  Even qualitative projects need a data analysis plan.  This is another section where it is difficult to provide examples because all research is somewhat different. As usual, provide sufficient information so that another person could carry out the analysis based on your directions here. Avoid terms and statements like, “We will perform an analysis using the XXX technique.” Rather describe the analysis plan in a stepwise manner. |

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| If applicable, provide a power analysis. NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion. | | |
| **Power Analyses** are generally not needed for qualitative research, pilot studies or observational studies. They are generally required for clinical studies in order to show that sufficient participants will be studies to either prove or disprove the hypothesis because a study without sufficient power to do so would not have a favorable risk:benefit ratio. | | |
| **A** | | **NA Type Responses:** | |
| 1 | NA- The study is a…and therefore a power analysis is unnecessary. |
| **B** | | **Power Analysis** | |
| 1 | Provide the results of the power analysis. |

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| Describe any procedures that will be used for quality control of collected data. | | |
| This is another section where it is difficult to provide examples because all research is somewhat different. As usual, provide sufficient information so that another person could carry out the procedures based on your directions here.  Many studies do not need procedures for quality control verification of collected data but they can be used in both behavioral and biomedical research. | | |
| **A** | | **NA Type Responses:** | |
| 1 | NA- There are no procedures that will be used for quality control of collected data. |
| **B** | | **Quality Control** | |
| 1 | The procedures that will be used for quality control of collected data are as follows:   * List of procedures. |

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# Confidentiality

## Confidentiality of Study Data

*Describe the local procedures for maintenance of confidentiality* *of study data and any records that will be reviewed for data collection .*

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| **Discussion- Confidentiality**  **Consider all forms of Data from start to finish.** When considering confidentiality of records collected for research purpose you must consider all forms of data from the start to the finish of the study and also after study completion. For example, if an interview is to be audio recorded and later transcribed, confidentiality procedures for both the audio files and the transcription need to be described from the date of creation of the first audio recording through the date that the audio files and transcribed words are deleted, destroyed or put in a permanent storage location (like an archive).  The adequacy of confidentiality procedures will often be based on the type of data and the degree to which it will be identifiable. Data that is completely unidentifiable or is completely innocuous will typically require lower levels of confidentiality protection while identifiable data that if disclosed could result in harm to a participant will require a greater degree of security.  Keep in mind that a **breach of confidentiality is a risk** that should be minimized within the context of the research design. Therefore data should only be recorded in an identifiable manner when necessary to achieve the scientific goal of the study. For example, while an interview may require audio recording that is to be transcribed at a later date in order to obtain accurate data, unless there were inaudible responses (like body language) were built into the data analysis scheme, video recording should not be used in the study because it is more identifiable than an audio recording. Consider also that a test, retest methodology would potentially require identifiable data for a short period of time so that answers from the pretest could be directly compared with answers in the post test for the same participant, a single point test would not require identifiable information to be associated with the data in most cases.  **Final disposition of data.** As scientists we hate to see data destroyed so when possible, de-identify it rather than destroy it. Only in the riskiest of data (e.g. opinions of workers about their boss, HIV status) will de-identification not be sufficient. |

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| Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, and separation of identifiers and data, as applicable. Include physical (e.g. paper) and electronic files. | | |
|  | | **Data Storage.** For each piece of data that will be handled differently, you will need to:   * Describe the data * Tell its degree of identifiability * Tell how and where it is stored * If one form of data is used to create another form (e.g. transcription of audio data), describe the process (and then you have another piece of data to describe). * Tell the data’s final disposition | |
| **B** | | **Describe the Data.** (Be sure to add any specifics to these general categories) | |
| 1 | Notes written/entered in a data file (paper or electronic) by a member of the research team |
| 2 | Paper document(s) completed and submitted by the participant |
| 3 | Electronic document submitted/created by the participant actions (possibly from the web) |
| 4 | Audio or Video recordings of… |
| 5 | Transcriptions of Audio or video recordings of… |
| 6 | Paper or electronic access to records not created directly for the research |
| 7 | Specimens from… |
| 8 | Artifacts provided by the participant (e.g. writing samples) |
| 9 | A spreadsheet or other form of software that data has been recorded in for analysis |
| **B** | | **Degree of Identifiability.** | |
| 1 | Anonymous data. This data is completely anonymous. It would be impossible of any member of the research team to associate this data with identity. |
| 2 | Audio or video data that is by definition identifiable. |
| 3 | Coded data where identity is separate but linked in some way. While identity will not be directly recorded with data, the study records will contain a link to identity or other information that could make the data reasonably identifiable (master list). |
| 4 | Specimens with links to identifiers that are recorded in a specimen tracking sheet. |
| 5 | Data with identity recorded on it (e.g. a record that contains a medical record number or name at the top of the page.) |
| **B** | | **Storage.**  The examples are how, you need to add WHERE. | |
| 1 | will be stored in password protected electronic files on a (laptop, usb drive, network drive, etc.)… |
| 2 | will be stored in a locked cabinet in… |
| 3 | will be made accessible to the public by posting to the web or otherwise used in publications or presentations. Participants have given permission to do this as a part of the consent process. |
| 4 | will be coded such that if it were accidentally accessed by unauthorized persons it would be difficult or impossible for them to associate data with identity. The master list containing the linking information will be stored separate from the data. |
| 5 | will be stored in a locked laboratory in… |
| **B** | | **Conversion.** (Keep in mind that every time you convert a piece of data to another format, you will need to cover the confidentiality procedures for both the old and the new format). | |
| 1 | Video and audio data will be transcribed. After transcriptions have been verified/reviewed for accuracy any information that makes the transcript identifiable will be replaced with information to make it unidentifiable. |
| 2 | Data from paper instruments will be entered into the following software program for analysis… |
| 3 | Data from excel files will be used to create an SPSS file for analysis. |
| 4 | A file of names and contact information is created from the intake data so that participants can be contacted to schedule follow up appointments. |
| **B** | | **Final Disposition.**  The examples are how, in some cases you may need to add WHERE. | |
| 1 | data will then be deleted or erased, shredded otherwise destroyed. |
| 2 | Identifiable data will be de-identified by the removal of any information that makes the records identifiable (or complete destruction). This will occur either by deletion of the identifiable portion of the record, destruction of the links in the master list containing the linking information, or replacement of identifiable information with information to make it unidentifiable. Nothing will then remain that could be used to link back to the identity for de-identified records. The de-identified data will then be retained in… |
| 3 | data will be retained in an identifiable form under the security procedures defined above until destroyed/deleted. |
| 4 | Video and audio data will de-identified by digital alteration so as to mask participants' identities. |
| 5 | Video and/or audio and/or other identifiable data will be retained in an identifiable format and then put into a “permanent” repository. This will occur only when participants provided consent to do so. |
| 6 | Video and/or audio and/or other identifiable data will be made accessible to the public by posting or otherwise used in publications or presentations. This will occur only when participants provided consent to do so. |

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| How long will the data be stored? | | |
| **B** | **How Long will data and specimens be stored?** | |
| 1 | Be sure to cover the timeline for every data form that you have listed in 17.1 above. For example, for an audio recording that will be transcribed   * Each audio recordings will be retained for approximately 3 weeks from the data of creation to the date of erasing. * De-identified transcriptions created from audio recordings will be retained for 6 years. |

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| Who will have access to the data? | | |
| **B** | **Access to Data.** Data access should be based on need of the project. When there will be differing procedures for different forms of data, be sure to point out differences.Don’t use names of people here, rather designate by position or duties. | |
| 1 | Data access will be limited to the following classes of people:   * Identifiable information will be only accessible to authorized study personnel and/or others that the participant has granted permission for access. * De-Identified materials will also be given to the statistician for analysis. * Video data will be posted to a website and accessible to the public when the participant has given permission to do so. |

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| Who is responsible for receipt or transmission of the data? | | |
| **B** | **Receipt and Transmission.**  **Receipt.** Whether the data comes directly from the participant or from a record, there will always be someone receiving data. These people are then responsible for receipt and putting the data in the location specified by the confidentiality procedures.  **Transmission.** Sometimes there is no intent for transmission of the data to others. If this is the case say so. When there is going to be transmission to other persons not directly identified as part of the study team in this protocol like the sponsor, a coinvestigator at another institution or the participant’s physician, state who must authorize transmission to them and also who will be responsible for the physical communication. | |
| 1 | **Receipt.** The following study team members will be responsible for receipt of data:   * The Principal Investigator * The study Coordinator * Graduate or undergraduate research assistants * Etc. |
| 2 | **Transmission.**  There is no intent for transmission of the data to persons not directly identified as part of the study team in this protocol.  -OR-  The Principal Investigator or Study Coordinator are responsible for authorization of transmission of any data to persons outside of the research team. Physical communication of the information will be handled by either the study coordinator or one of the two senior research assistants. |

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| How will the data be transported? | | |
| **Discussion- Transportation of Data and Specimens**  Often there is no need to transport data or specimens because the information is collected in the same place that it will be stored. However, when data will be collected in one location and stored in another the procedures for this transportation need to be specified so that the IRB can determine whether or not the following are adequate.  **Confidentiality protections during transportation.** Consider that data could be collected on a laptop recording device at an off campus location (maybe in Syracuse). It was placed in a locked trunk of a car to be driven back to campus. Due to the distance that had to be driven, the research assistant decided to stop for lunch at a thruway service area and while eating his car was stolen with the laptop in the trunk. Situations just like this have occurred so the IRB needs to be able to verify that any confidentiality procedures are reasonable during transportation.  The best thing to do is to not transport sensitive data in an identifiable format. Separate the data from identifiers at the earliest possible time. When this is not possible, encrypt electronic files right away and/or retain personal physical possession and control of the data until it can be put into the secured location specified in the protocol..  **Physical preservation procedures for Specimens.** This one is pretty obvious, if a specimen will spoil or could become contaminated the transportation process should spell out how this will be prevented (i.e. in dry ice, taken to the refrigeration unit within 20 minutes of collection, etc.). | | |
| **A** | | **NA type response** | |
| 1 | NA- there is no need to transport data or specimens because the information is collected in the same place that it will be stored. |
| **B** | | **Receipt and Transmission.** | |
| 1 | After completing the interview, the audio file will be encrypted and saved on the recording device for transport to the laboratory where it will be downloaded to the server. |
| 2 | Materials collected at the community center will remain in the physical possession of the research assistant collecting the data until they can be placed in the locked file cabinet in her office. |

## Confidentiality of Study Specimens

*Describe the local procedures for maintenance of confidentiality of* ***study specimens****.*

**N/A:** No specimens will be collected or analyzed in this research.   
(Skip to Section 19.0)

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| Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable. How long will the specimens be stored?Who will have access to the specimens?Who is responsible for receipt or transmission of the specimens?How will the data be transported? |
| **Discussion- Specimens**  Keep in mind that not all specimens are biological. Some specimens could include physical items like examples of student work, an artifact collected from someone’s home or a water sample to be tested for lead.  See corresponding sections Confidentiality of Data. |

# Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A: This study is not enrolling subjects., or is limited to records review procedures only. This section does not apply.

NOTE: Minimal risk studies may be required to monitor subject safety if the research procedures include procedures that present unique risks to subjects that require monitoring. Some examples include: exercising to exertion, or instruments that elicit suicidality or substance abuse behavior. In such cases, N/A is not an acceptable response.

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| Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe. Describe what data are reviewed , including safety data, untoward events, and efficacy data. Describe any safety endpoints. **Discussion- Safety Endpoints.**  *Safety endpoints usually only apply in all treatment studies/clinical trials. They usually do not apply in non-treatment situations such as a medical records review, education research, basic psychology or social research. A safety endpoint is one where a protocol will be stopped completely because of a concern for the safety of participants. It is* ***not a situation where participation for a single participant will be stopped*** *because the individual is experiencing an adverse event or they are not capable of continuing in the study due to deterioration in their condition.* Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants). Describe the frequency of safety data collection.Describe who will review the safety data.Describe the frequency or periodicity of review of cumulative safety data.Describe the statistical tests for analyzing the safety data to determine whether harm is occurring. Describe any conditions that trigger an immediate suspension of the research. | | |
| **Discussion- Data Safety and Monitoring**  The degree of Safety Monitoring for Data necessary is related to the types and degree of risk. For studies in which there are no risks except possibly those related to a breach of confidentiality or those that take place in a single interaction where data could not possibly be gathered, analyzed and a change in the procedures put into place, usually data safety and monitoring for individual participant safety will not be necessary. For clinical trials, a data safety monitoring plan is a must.  Unfortunately this is another section of the protocol that it is difficult to provide examples because the monitoring needed will be dependent on the procedures, data gathered and timeframes for those procedures. | | |
| **A** | | **NA type response** (this could be applicable to all questions in this section for some studies) | |
| 1 | NA- data safety and monitoring for individual participant safety will not be necessary because the only risk to participants would be related to confidentiality. |

# Withdrawal of Subjects

**N/A:** This study is not enrolling subjects. This section does not apply.

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| Describe anticipated circumstances under which subjects will be withdrawn from the research without their consent. | | |
| **Discussion- Withdrawal Without Consent.**  Occasionally there will be times that a participant must be withdrawn from a research study without regard for the participant’s wishes. This can happen for a number of reasons including:   * A participant is not compliant with protocol procedures. * A participant is reacting unfavorably to the treatment regimen or their condition is deteriorating more rapidly than anticipated. * Participant become unavailable, does not respond to contact requests.   In cases like these it is appropriate to withdraw participants from the research study without their consent. | | |
| **A** | | **NA type responses** | |
| 1 | **Participants will not be withdrawn without their consent.** This is appropriate in many cases, especially studies that occur over a short time period (e.g. 1 visit) |
| **B** | | **Withdrawal Without Consent.** | |
| 1 | State the reasons that participants may be withdrawn without their consent. Be sure to cover these in sufficient detail so that the justification for withdrawing a particular individual is will be obvious to an auditor looking at your study. |

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| Describe any procedures for orderly termination. | | |
| **Discussion- Orderly Termination.**  When either a participant withdraws from a research study or a participant is withdrawn by the researcher, there are often procedures that must be followed that the participants need to be aware of. These procedures can often be related to:   * Notification of the research team by a participant of the desire to withdraw. * Participant Safety, i.e. if one stops a regimen before its conclusion, will there be adverse health effects. * Notifications to another physician. * Return of Equipment- when special equipment has been provided for use in a research study and the materials need to be returned by the participant. * Payments of any accrued compensation due. | | |
| **A** | | **NA type responses** | |
| 1 | **NA.** There will be no need for termination procedures. |
| **B** | | **Orderly Termination.** | |
| 1 | Describe any termination procedures. Keep in mind that you will probably want any termination procedures that participants need to be aware of in the consent document as well. Make sure the two documents are consistent. |

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| Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection. | | |
| **Discussion- Procedures when a participant withdraws.**  In most cases when a participant withdraws, there is no additional effect other than to cease data collection. However, in some cases there may be:  **Procedures for continued data collection after a participant withdraws.** Often a participant will have the option of stopping a treatment, but continuing to provide follow up data. This is sometimes the case in clinical trials where records collected for non-research purposes can be used for continued evaluation of the treatment provided but it can also apply to behavioral studies where group participation occurs (e.g. a spousal program for substance abuse- if the wife decided to withdraw, the husband might continue and would provide data that is about the both him and his wife).  **Procedures for dealing with data about the participant that has already been collected** (such as erasing/destroying any data). This can occur in some behavioral research where identifiable data is destroyed but de-identified information is retained. In FDA research, destruction of data already collected is not allowed. | | |
| **A** | | **NA type responses** | |
| 1 | **NA.** There will be no need for withdrawal procedures. |
| **B** | | **Procedures for Withdrawal.** Describe any procedures that are triggered by a withdrawal from the research for either continued participation or dealing with data of participants that withdraw. | |
| 1 | **Continued Data Collection Example.** For some participants, it may be determined by either the research team or themselves that continuing to take the drug regimen is not in their best interest. In these cases the participant will be asked to remain in the study for follow up data collection. If they decide to do so, they will be presented with attachment NNN- follow up consent for withdrawals and asked to provide signed documentation of consent according to HRP-090 and HRP-091 procedures. |
| 2 | **Withdrawal of Data Example.** Any participant who withdraws from the research will be asked if the researcher may retain their data. If the participant agrees, s/he will be asked to sign attachment NNn, the agreement for data retention form. When a participant does not agree or otherwise does not complete the study (withdrawal by action), all identifiable data about the individual will be destroyed. Any de-identified data may be retained and analyzed. |

# Risks to Subjects

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| List the reasonably foreseeable risks, discomforts , hazards, or inconveniences to the subjects related to their participation in the research. Include a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.  NOTE: Breach of confidentiality is always a risk for identifiable subject data. | | |
| **Discussion- Risks**  **Risks vs Discomforts.** Discomforts, while unpleasant, are usually things that are short lived and do not result in significant pain or stress. Risks can cause permanent damage or require intervention to control or reverse.  There can be both risks and discomforts related to any procedure. For example, two physical risk of getting a vaccination via injection are allergic reaction to the vaccination and the potential for infection at the injection site. Physical discomforts related to the vaccinations would be the slight pain associated with the injection needle and some itching or swelling at the site for an hour or two.  Another example is that of trying a new food. There could be a discomfort in that a person might not like the taste, but there also could be the risk of a food allergy. In a study using a procedure involving a procedure like this, the consent process would mention the potential discomfort as well as the risk, but specific procedures like screening participants for food allergies before starting and having a procedure to get immediate medical attention should an unknown allergy cause a severe reaction would also be incorporated into the protocol.  Psychological/mental risks and discomforts are also possible. A study could cause people some discomfort by asking questions that cause them to become emotional, even to the point of crying. Questions could also pose risks like clinical depression, suicide or a relapse into drug or alcohol use for a person who has been sober for some time.  Usually discomforts are minimized to the extent possible and need to be disclosed to participants as a part of the consent process but no extraordinary procedures are necessary to prepare for them.  On the other hand, risks usually require a stated procedure and mechanisms to minimize their probability as well as their magnitude.  **Consider all potential types of Risk.** While the primary risks in biomedical research are often physical, the most prevalent risks of social, behavioral or education research are usually those related to a potential breach of confidentiality. Be sure to consider all potential types of risk including physical, psychological, emotional, legal, social, and employment in both social/behavioral and biomedical research.  **Reasonably Foreseeable and Related to the Research.** One key concept is that the risk must be “reasonably” related. By reasonable, we must use what the legal profession calls the reasonable person concept. That is, we must ask the question, “would a reasonable person describe this as a risk or discomfort?” The reasonableness of an occurrence is sometimes circumstance dependent. For example, dying in a building fire would not be a reasonable risk of employment as an office worked at UB because, while it is possible, it is highly unlikely and not something that we would foresee as probable. However, this same risk would be described as a reasonable occupational risk for a Buffalo firefighter even though it occurs infrequently.  **Be diligent but don’t go looking for trouble where it doesn’t exist.** Some research has very little risk especially when there is not reasonable expectation of harm. For instance, records reviews, surveys or interviews that are recorded in such a way that the participant cannot be identified might be described as having no known risk because a breach of confidentiality is all but impossible and the questions asked would not potentially result in the participant being harmed (even if a few might be a bit personal and cause some discomfort). | | |
| **A** | | **NA Type Responses:** | |
| 1 | There are no reasonably foreseeable risks or discomforts to participation in this project. |
| 2 | **Behavioral.** There are no reasonably foreseeable risks to participation in this research. There is a possibility that participants might be uncomfortable in answering some of the questions about…but they are informed of these types of questions, and the fact that they may skip anything that they wish as a part of the consent process. |
| 3 | **Biomedical.** There are no reasonably foreseeable risks to participation in this research. Participants might experience some discomfort from the compression cuff as their blood pressure is taken. This discomfort is disclosed as a part of the consent process and should be expected by participants as most will have had their blood pressure taken in the past. |
| **B** | | **List of Risks** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Biomedical Example.** …has been given to a small number of patients. The most common adverse events reported have been noted below. …appears to be well tolerated.   * Local reaction at the site of drug administration: During the previous study, no local reactions were observed. * Complications of infusions: complications of infusion have been observed (i.e. poor vein access), but no increase due to the investigational medicinal product. * Possible development of anti-drug antibodies.   Blood Draw Risks  Drawing blood from a vein may cause pain at the site of the blood draw, bruising, feeling lightheaded, fainting, and very rarely, infection at the site of the blood draw.  Liver Biopsy Risks   * Pain and discomfort located at or near the puncture site and radiating upwards toward the right shoulder region * Bleeding at the biopsy site * Possible internal bleeding for up to a few hours after the procedure * Infections at the biopsy site or internal organs * Puncture of internal organs (gall bladder, lung, intestine or kidney) * Allergic reaction to the anaesthetic * 1 in 10,000 risk of death from a complication resulting from a liver biopsy |
| 2 | **Clinical Behavioral Example.** Participants may experience some discomfort in talking about…  One possible risk is that a participant may relapse into the use of alcohol because of their participation in the therapy groups. While unlikely, the research team will provide assistant to any such participant in the form of… |
| 3 | **Confidentiality Risk Only.** The pre and posttests initially require that names be on the top of the sheets so that data for each individual can be correlated to see if the program was successful. As such the data is identifiable for a period of time and presents a risk should a breach of confidentiality occur. There are no expected discomforts. |
| 4 | **Audio/Video Recording Confidentiality Risk.** Audio/Video Recordings of interviews are identifiable and present a risk should a breach of confidentiality occur. There are no expected discomforts. |

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| Describe procedures performed to lessen the probability or magnitude of risks, including procedures being performed to monitor subjects for safety. | | |
| **Discussion- Risk Mitigation.** Procedures being done for scientific purposes or routinely as a part of good practice are given in section 10. This section should describe any additional procedures for mitigation of risks that are not already given in other sections. Be sure to include any procedures for treatments to be given for injuries resulting from the research including how a participant would notify the researcher of such occurrences. | | |
| **A** | | **NA Type Responses:** | |
| 1 | There are no reasonably foreseeable risks or discomforts to participation in this project and therefore no additional risk mitigation procedures are necessary. |
| **B** | | **Risk Mitigation** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Biomedical Example.** All the investigators are experienced at conducting ……. protocols. Dr. ……. will provide instructions on ..….use and will remain in the clinic during each protocol visit. The subjects will be closely monitored and attended by at least two study personnel at all times. Stopping criteria for elevated vitals have been established and will be discussed and posted in the clinic. |
| 2 | **Clinical Behavioral Example.** As discussed above, responses to the depression inventory will be reviewed immediately after the participants complete the measure. Any participant endorsing more than 2 items on the depression inventory will be asked to remain to speak with the licensed counselor about their responses and… |
| 3 | **Confidentiality Risk Only.** The risk of a breach is reduced by the use of a sealed envelope by each participant to turn in the pre and post tests and further by a procedure whereby, once the research team is in possession of both the pre and post tests for an individual, the two data sheets are stapled together and the name of the individual is cut off of the top of the sheet. This process takes place within…of receipt of the two data instruments. |
| 4 | **Audio/Video Recording Confidentiality Risk.** Video and audio data will be transcribed. After transcriptions have been verified/reviewed for accuracy, any information that makes the transcript identifiable will be replaced with information to make it unidentifiable. Video or audio data will then be deleted or erased. This process will take place within…of obtaining data from each individual. -OR- Video and audio data will de-identified by digital alteration so as to mask participants' identities. This process will take place within…of obtaining data from each individual. -OR- Video and/or audio data will be retained in an identifiable form under the security procedures defined in the confidentiality section until destroyed/deleted. This process will take place within… |

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| If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable. | | |
| **Discussion- Unforeseeable Risks.**  Some procedures are so new that the risks associated with them are not known at the time of starting the research. A description of these procedures should be given here. Again, use the reasonable person approach. For example, while there might be some potential that walking into the building on a cold day in Buffalo might result in injury (the unforeseeable accident), no one would expect this to be described as a risk of the study. On the other hand, there may be unforeseeable side effects in a treatment study. | | |
| **A** | | **NA type responses:** | |
| 1 | There are no procedures in this research that have risks to subjects that are unforeseeable. |
| **B** | | **List of Risks** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | Create a list of procedures that could have unforeseen risks. |

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| If applicable, indicate which research procedures may have risks to an embryo or fetus should the subject be or become pregnant. | | |
| **A** | **NA type responses:** | |
| 1 | There are no procedures in this research that may have risks to an embryo or fetus should the subject be or become pregnant. |
| **B** | **List of Risks** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | Create a list of procedures along with the adverse effect on the pregnancy (i.e. miscarriage, birth defects, etc.). Include the probability of any issues and potentially break down by whether or not there are important differences/distinctions early vs late in pregnancy. |

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| If applicable, describe risks to others who are not subjects. | | |
| **Discussion- Risks to Others.** Most research does not pose a reasonable risk to non-participants. As with all risks, don’t create something that is not reasonable just to fill in the section.  “Others” to consider might include:   * A research staff member might be exposed to a disease. * A researcher collecting data on spousal abuse might become a target of the abusive spouse. * Family members of persons who are undergoing genetic testing might find out that they have a genetic marker for a condition. They might also be put in the stressful situation of finding out that they are not actually related. | | |
| **A** | | **NA type responses:** | |
| 1 | There are no procedures in this research that may have risks to others who are not subjects. |
| **B** | | **Risks to Others.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | Create a list of any “others” and the potential risks and describe any procedures to help mitigate these risks. |

# Potential Benefits to Subjects

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| Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit.  NOTE: Compensation cannot be stated as a benefit. | | |
| **Discussion- Benefits**  This section deals with only direct benefits to subjects not indirect benefits of learning about the topic of study.  In biomedical and clinical behavioral research these can often be directly related to the potential for achieving study endpoints of:   * improved survival (e.g. a cancer drug that puts the cancer into remission so that the person lives longer) * a benefit that was detectable by the patient (improvement in symptoms, improvement in functional capacity), * a benefit that decreased the chances of developing a condition or disease complication that is itself apparent to the patient and is undesirable (e.g. stroke)   In other behavioral research, sometimes these can also be related to the potential for achieving study endpoints, but often there is no potential for direct benefit to the individual subject. This is not a problem in and of itself so don’t go scrounging for benefits that are not really there.  Note also that compensation (whether monetary, course credit, gifts, or being allowed to keep a piece of equipment purchased by the research grant) is by definition NOT a benefit of the research.  Results about the individual obtained in the course study are not typically a benefit even if it they are provided back to the individual or his/her physician.  Be sure to address the probability, magnitude, and duration (if applicable) of the potential benefits. Where numerical data can be provided, do so but when it cannot, provide your best estimate. You may want to use a chart or matrix to indicate combinations of these items. | | |
| **A** | | **NA Type Responses:** | |
| 1 | NA- There are no direct benefits expected in this study. |
| **B** | | **Benefits** (Keep in mind that you may need a combination of these for your particular study) | |
| 2 | **Biomedical Example.** Subjects assigned to Arm A of the study will benefit from participating in this research by being able to receive a new heart valve without having open-heart surgery. This will reduce the length their hospital stay and…….  Subjects may benefit if …is effective in treating…  Subject may receive no benefit from their participation in this study but the study may benefit subjects with this disease in the future by contributing to the general knowledge about this disease. |
| 3 | **Clinical Behavioral Example.** Subjects may benefit by participation in a program that may assist them to cope with symptoms of PTSD. |
| 4 | **Educational Benefit.** Subject may benefit by learning how to solve algebraic expressions in a manner that is conducive to their learning style. |
| 5 | **Participation itself is a benefit**. As first year college students studying Psychology, students will benefit by participation in the experiment by learning about the psychology research process. This benefit is enhanced by providing additional educational materials including references for study methods to the students as a part of the consent process and/or after participation. |

# Compensation for Research-Related Injury

N/A: This The research procedures for this study is not enrolling subjects. This do not present risk of research related injury (e.g. survey studies, records review studies). This section does not apply.

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| If the research procedures carry a risk of research related injury , describe the available compensation to subjects in the event that such injury should occur. | | |
| **Discussion- Injury Compensation.**  This section should state the compensation availability (i.e. who will pay for what). Procedures for informing the researcher of injury so that it can be appropriately treated belong in the risk mitigation section of the protocol. The information here should be appropriately presented in the consent document. | | |
| **A** | | **NA type responses:** | |
| 1 | **Injury not Anticipated.** Research related injury is not anticipated and therefore there is no plan to compensate for injury. |
| **B** | | **Injury Compensation.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | Describe what will and what will not be paid for by the study in the case of research related injury. |

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| Provide a copy of contract language , if any, relevant to compensation for research-related injury.  NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with different language [regarding research-related injury], you must modify your response here and submit an amendment to the IRB for review and approval. | | |
| **Discussion- Contract Language.**  The IRB uses this to determine if the description of potential costs and reimbursements to the subject listed above and in the consent document are adequate. We know that the entire contract is provided with the submittal but, as contracts can sometimes be lengthy, this gives the IRB a quick reference to the appropriate materials. | | |
| **A** | | **NA type responses:** | |
| 1 | **Unfunded.** This is unfunded research and there is therefore no contract. |
| 2 | **Injury not Anticipated in the Contract.** Research related injury is not anticipated and therefor there is no language in the contract related to compensation for said occurrence. |
| **B** | | **Contract Language.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | Be sure to cut and paste the appropriate section from the contract. You should provide the reasonable context for this (in other words, include the whole paragraph or three but don’t overdo it and provide endless pages). |

# Economic Burden to Subjects

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| Describe any costs that subjects may be responsible for because of participation in the research.  NOTE: Some examples include transportation or parking.  ☐ N/A: This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply. | | |
| **Discussion- Costs to Subjects.**  The highest costs of participation are usually related to situations where the participant has to pay for medical procedures/equipment needed for the research, or injury sustained as a result of participation, that are not covered by either the sponsor or insurance. Therefore this section should reflect any costs that may reasonably be expected to be paid by the subject/patient or their insurance (including copays).  **Behavioral Research and other Indirect Costs.** There can often be costs associated with participation like the cost of travel to the site for participation, or the cost of “data rates” for use of a cell phone to take part in an online activity. When these would reasonably be expected to be incurred by participants, they must be stated. As usual, the reasonable person approach should be used. One would not list as a cost to a participant the ink needed to fill out a survey with their own pen or transportation costs to come to the North Campus for students who are generally traveling to campus for classes but one might list a transportation/parking cost for students who needed to travel to the Downtown/Medical Campus to participate.  **Time Costs need not be listed.** The time spent in participation is an obvious cost but need not be covered here. | | |
| **A** | | **NA type responses:** | |
| 1 | **No Costs.** There are no reasonably anticipated costs to subjects. |
| **B** | | **Costs to Subjects.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Medical Costs.** There will be no monetary costs to the patient for participating in this study. The patient will not be charged for the study drug(s) or any of the tests and procedures performed solely for research purposes.  Taking part in this research study may lead to added costs to you. You may be responsible for the following costs: (provide list)…  The patient’s private or public health insurance company (for example Medicare) will be billed for the procedure and the patient will be responsible for paying for any co-payment, co-insurance or deductible. The patient will not be charged for the cost of collecting the data for this study and other clinic visits and diagnostic tests done solely for the purposes of this study. |
| 2 | **Travel Costs.** Subjects are responsible for the cost of transportation to / parking at the research site. |
| 3 | **Incidental Costs.** The research procedures require that a participant makes a daily log entry into the web based electronic database. The participant is responsible for the cost of data access (i.e. their own computer internet access or cell phone data rates) to make these entries. |

# Compensation for Participation

**N/A:** This study is not enrolling subjects. This section does not apply.

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| Describe the amount and timing of any reimbursement payments to subjects including monetary, course credit, or gift card compensation.  ☐ N/A: This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply. | | |
| **Discussion- Compensation to Subjects.**  Compensation can take many forms including money, gift cards, entry into a drawing, and course credit. Compensation methods often present some of the most difficult issues for researchers because what may be perfectly acceptable outside of the research context may present an ethical dilemma where compensation for research is concerned. While many of the concepts discussed here are in terms of monetary payment, they are equally applicable to other forms of payment.  **The Idea of Payment for Data**. One argument that has been made is that payments are made for an item of value, and if a person does not participate fully, there is little value to the data a researcher receives so it is not of sufficient value to compensate a participant. While in an economic sense this may be the case and is a reasonable assumption when purchasing something, it conflicts with the ethical requirement that a person be free of coercion or undue influence in making their choice to consent to be a participant in a research project. Rather, payment is for the time and trouble of participants or reimbursement for costs incurred and not for the data. As such participants should be compensated in a reasonable manner in proportion to their participation in a project.  Consider the following. A person who was told that their parking fees would be reimbursed in addition to other payments for time and trouble if they participated in a project. When they showed up to participate for the first time, it is discovered that they do not meet inclusion criteria. Although they would not receive other payments related to prolonged participation, it would be unjust to not reimburse the parking cost associated with the first visit.  **Outside Payment Requirements.** Keep in mind that you may be restricted in the type of compensation you are offering by things outside of your control and sometimes they conflict with what is ethical in terms of the research itself. For example, when payments are fairly small (e.g. <$50), and tax documents are not going to be provided, the collection of information such as a Social Security Number would present an unnecessary increase in confidentiality risk to subjects. This would mean that while a departmental requirement to collect SS# for a payment may be acceptable in other circumstances, within the research context it may be unethical to do so.  **Practical Considerations and the Regs**. While you may want to compensate participants through a drawing to win an I-pod, it may not be practical for some situation. Consider that in order to hand out the prize, you would have to get contact information from participants. If the justification for your written documentation of consent waiver in the protocol used the reason that the consent form would be the only record linking the participant with the research and the principle risk is related to a breach of confidentiality, your collection of contact information would potentially invalidate the consent waiver.  **Do I have to Prorate Payments?** While studies that take place over a longer time period should have a proration schedule related to the time and effort of participation, payments for short term participation (e.g. a 10 minute survey, a 1 hour interview) may but do not need to be prorated. However, in these cases a point at which a person has put forth a reasonable effort to participate should be determined and full compensation made to the individual for participation at or near that point. For example, if a person consented to participation in a 1 hour interview and was to be compensated with a $20 gift card but after answering 3-4 questions over the course of the first 20 minutes they decided that they were uncomfortable with the procedures and wanted to stop, one should probably give them the $20 but if the person after reading the consent form decided to not participate, it might be reasonable to not compensate them except in the case of an expense incurred (like the $3.25 they paid to park in the North Campus visitor parking lot).  Finally, we do understand that there are people out there who like to scam the system. By careful design of the payment process, you should be able to avoid this.  **Differing payments for Different types of participants.** There can be differing payment schedules for different groups and in some cases it would be unethical to not do so. For example, it might be perfectly appropriate to pay $10 per hour to participants in the US but that same compensation rate in a developing country may be the equivalent of a week’s wages and therefore represents a coercive amount.  **Payment for Performance**. There are some fairly rare situations where an item that might be used typically as compensation is actually a part of the research manipulation. This might be the case where points are earned in a game that would translate to a prize at the end of the session. Another example might be in providing a reward for behavior modification (maybe a $10 gift certificate to a book store for every 5 pounds in a weight loss study). In these cases the prize is a part of the research manipulation and not compensation. Be sure to make this distinction.  **Class (extra) credit and Research Participation Groups (RPGs).** One inexpensive way to compensate participants is to offer research participation opportunities to students and compensate them with course or “extra” credit. A researcher reasons that, as the instructor, it is within his/her academic freedom to offer the credit and therefore not an IRB issue. Unfortunately, unless some specific rules are obeyed, this poses an ethical problem in that some participants may not necessarily free to choose to participate in the project.  Consider the following from the student’s perspective. I am failing the course right now. If I fail this course, my father is going to stop paying my tuition and I will have to drop out of college and work at the local Grocery Mart for the rest of my life. So, I have to take this extra credit opportunity and participate in the research.  This does not mean that students cannot be research participants for course or extra credit, but rather that in order to do so some added procedures are needed like providing an alternative way to earn the extra credit that in the eyes of the student is actually easier than participation (and provides a similar leaning experience), blinding the instructor to how the extra credit was earned, offering multiple options for research participation and not penalizing non-participation. These types of procedures have already been incorporated into the Departmental Research Participation Group (RPG) procedures used by the departments of Psychology, Communication and Organization and Human Resources for meeting student research components of certain courses.  **Completion payments**. While the majority of payments should be prorated, it is still possible to have a reasonable “completion” payment for completing the research. This can be ethically justified in terms of the effort needed to take place in a long term study with multiple visits. The IRB will have the final say on how much is too much to put into the completion payment but a good rule of thumb is that it should not be more than 10-15% of the total compensation.  **Timing of Payments**. . Participants have expenses that they need to take care of relate to their participation so when a study is over a long period of time, don’t “hold the money in escrow” until the end of the study. Make payments at reasonable intervals if they cannot be done immediately.  **Children and Parents.** Depending upon the age of the children involved in research, compensation payments may be made to the child (or adolescent), the parents or both. Keep in mind that parents often bear the burden of any outside costs (copays, transportation, etc.) and that to a very young child, $50 is more money than they have had in their life and may therefore be coercive to the child but not the parent who is spending close to this in gas and tolls to bring their child from Jamestown up to Buffalo. | | |
| **A** | | **NA type responses:** | |
| 1 | **No Compensation.** There is no compensation or payments to subjects for this research. |
| **B** | | **Compensation to Subjects.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Drawing for Prize.**  Describe the procedures used for entering participants in the drawing, contacting winners and the prizes to be awarded. Never use the term “lottery”, use the term drawing. |
| 2 | **Proration based on time.** Participants are compensated based on time spent in participation (e.g. they get $20/hour for every hour or fraction thereof that they spend in participating). They will receive payment by check from a university account monthly. |
| 3 | **Proration Based on Study Visits.** Use of a chart or table along with a couple of sentences describing how participants will receive their payments (cash, check, mailed to their home, from the research team member at the end of their visit, etc.). The same table may be usable in the consent document. |
| 4 | **One Time Payment with Gift Card.** Participants will receive a $50 gift card at the end of the interview. As the interview is expected to take 1.5-2 hours, any participant who spends > 30 minutes being interviewed will receive $25 and any participant who spends > 1 hour will receive payment in full. Because this is a distance interview over the phone or Skype , the gift card will be mailed to participants. |
| 5 | **Culturally Appropriate Gifts.** In the culture where the research interviews will take place, monetary compensation is not typically used for this sort of activity. However, a gift is expected to be presented to the interviewee of some type of useful or consumable item (such as 5 lbs. of sugar, or a cast iron pan). While it will not be possible to specify exactly what will be purchased for the interviewee, (it is customary to ask them if they need anything and take their suggestion), the gift will be valued at between $5 and $30 in the US and would typically equate to about 1 days wages at minimum wage in the country where the research will take place. Participants will receive this gift within 2 weeks of the interview (as it will have to be purchased by the PI while on weekly trips to the city and given upon return to the rural township). |
| 6 | **Research Participation Group.** Participants awarded credit for participation under the (PSY, COM, OHR) Procedures approved by the IRB. Participants are expected to earn 2 credits because the study is estimated to take 1.5 to 2 hours. Students who decide to withdraw will be credited with ½ credit for each fraction of a half hour they participate. Credit earned is conveyed to the departmental tracking system via (the student receiving a receipt to present to a designated person responsible for assigning credit, a research team member providing info to the person assigning credit either in writing or via electronic system, an electronic system that automatically credits the student for online participation). |
| 7 | **Course Extra Credit.** Extra credit will be offered for participation in this research project.   * State what classes/courses the credit applies to (e.g. 2 sections of Dr. Jones Archaeology 204). * For each class/course provide a brief description of the amount of credit and relative value of this credit to the student's overall grade. * Describe how students in the class are notified of this credit opportunity in a manner that lets them know about the research option, the alternatives and any procedures for obtaining the credit. * Indicate amount of credit that a person gets for “full” participation. * Describe how you will deal with participants who only partially participate (i.e. what will you do for compensation if a person quits after completing only part of the sessions/instruments). * Describe the amount of time and effort that participation in the study is anticipated to take. * Describe the alternative assignments or tasks that students can also use to obtain the credit. * Explain why you believe that participation in the study and the alternative assignments are equivalent in terms of both learning experience and effort required by the students. * Indicate how a student gets his/her credit   + Student receives a receipt to present to a designated person responsible for assigning credit   + Electronic system automatically credits the student   + Research team member provides info to person assigning credit either in writing or via electronic system. * Describe procedures that minimize any undue influence to participate in the research option as opposed to the alternatives such as blinding of the instructor to how the student received the credit (either research or alternative). |

# Consent Process

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| Indicate whether you will be obtaining consent. NOTE: This does not refer to consent documentation, but rather whether you will be obtaining permission from subjects to participate in a research study.  Consent documentation is addressed in Section 28.0.  **Yes** (If yes, Provide responses to each question in this Section)  **No** (If no, Skip to Section 27.0) |
| **Discussion- Consent.**  There are only 3 possibilities allowed under the regulations for consent for a research process.   * Consent will be obtained and documented using a signed consent form. * Consent will be obtained using a verbal process. * Consent will not be obtained (it will be waived or altered to not include required elements).   Keep in mind though that obtaining informed consent is a process. The parts to this process are:   * Conveyance of information to the participant. * Allowing sufficient time for the participant to consider the information, ask any questions and have them answered by a knowledgeable person. * An affirmative decision and response from the participant to the question, “Do you still want to participate now that you have this information?” * Documentation of consent as stated in the protocol.   **Signed Consent.** Whether you use the long form or the short form procedures, signed consent is exactly what it says it is. After information is exchanged and a person agrees to participate, this is documented by signing the consent documents. In most cases this is a pen and paper process.  **Electronic signatures** are possible but they must meet the definition of a “signature” in that there must be a verifiable process that can be tracked back to the individual. In most cases typing one’s name in a form or pasting a copy of one’s signature in a document is not the equivalent of a signature and is actually a form of verbal consent. One common example of an electronic signature that is a valid “signature” is the one we provide to the IRS when we e-file out taxes. In this example, in order for the signature to be valid, we must provide verification (like providing the previous year’s adjusted gross income figure that the IRS already has on file).  **Verbal Consent**. A verb is an action word. In the case of consent, while that action is usually speaking the word “yes” in some manner, it can also be another type of action. Most examples of this are electronic such as clicking the “I agree” button on a website, sending an e-mail, typing your name on a line, downloading software but returning a paper survey in a postage paid envelope would also qualify as a form of verbal consent. Verbal consent is usually restricted to (and actually encouraged for) low risk studies but can in a few situations be used in non-FDA regulated higher risk research when signing a consent document presents the principle risk of the study.  **Completely Waiving or Altering Consent.** If you are actually communicating with participants, in most cases you are obtaining verbal consent, not waiving it completely. Completely waiving, or altering consent by omitting required elements, requires that the research meet specific regulatory criteria. The situations in which consent is completely waived or altered are pretty well delineated. Consent can **sometimes** be waived in the following cases:   * Records/Chart Reviews * Observational studies with no intervention or interaction (rare at UB) * Planned Emergency Research (rare at UB) * Government Demonstration Projects (rare at UB) * Behavioral research where disclosing information about the study would make it impossible to obtain valid responses from participants. * Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens (rare at UB) * Certain research with children can waive parental permission and or assent of the child |

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| Describe where the consent process will take place. Include steps to maximize subjects’ privacy. | | |
| **Discussion- Consent Location.**  The location of the consent process needs to be adequately private for the type of research you are conducting. Usually the location where the research will take place is a good starting point for determining where consent will take place but sometimes another location would be better (for privacy or practical reasons). For example, while research procedures such as a blood draw may take place in a semi-open location where many people are having blood drawn for many different reasons (think about how some of the places you have given blood at are set up) the consent process may require someplace more private if the purpose of the study is to develop a blood screening for a venereal disease the participant may have. | | |
| **A** | | **NA type responses** | |
| 1 | **Consent will not be Obtained.** Consent will not be obtained. |
| **B** | | **Consent.** Give a description of the locations that will be used for the consent process. Pay attention to describe the privacy of the location. (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Exam Rooms.** The Consent process will take place in the same examination rooms used for the study. These are private examination rooms within the practice office. |
| 2 | **Office**. The Consent process will take place in the office of the PI used for the study. This is a private office rooms within the department of… |
| 3 | **Semi-public location.** The Consent process will take place in at the location that the participant selects to meet for the interview (i.e. the library, office, classroom, local restaurant). |
| 4 | **Distance Procedure**. Consent will be obtained (over the phone, via the internet, via mail). The research team will have no control over where participants complete this process but will encourage them to do so from a private location such as a home or office. |
| 5 | **Lab with multiple experiments**. The Consent process will take place in the lab of the PI (Park Hall room XXX). The lab is only used for all of Dr. Jones studies and there may be other study personnel and participants for many studies present but each experiment takes place in a separate area of the lab partitioned by ¾ height walls for purposes of privacy and keeping distractions minimal. |
| 6 | **Public Meeting/Classroom**. The Consent process will take place prior to passing out the survey instrument at the public location in a classroom of the East End Elementary School. Multiple participants will be present in the room. |

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| Describe how you will ensure that subjects are provided with a sufficient period of time to consider taking part in the research study.  NOTE: It is always a requirement that a prospective subject is given sufficient time to have their questions answered and consider their participation. See “SOP: Informed Consent Process for Research (HRP-090)” Sections 5.5 and 5.6. | | |
| **Discussion- Sufficient Time.**  No participant should feel like they are being given a hard sell to participate in a study.The amount of time sufficient for participants to consider whether or not to enroll in a study is dependent upon may factors including the complexity of the study, the risks, the time commitment required for participation, the potential vulnerability of the participants. These factors should increase the time given for a participant to consider enrolling. It is understood that sometimes extended consideration time needs to be balanced against the need to perform either a research procedure or an alternative clinical procedure in a timely manner in order to treat some medical conditions. When this is the case, provide this information to the IRB. | | |
| **A** | | **NA type responses** | |
| 1 | **Consent will not be Obtained.** Consent will not be obtained. |
| **B** | | **Sufficient Time for Consideration.** | |
| 1 | **Typical Biomedical.** The patient will have as much time as needed to review the consent. If the patient is interested in participating, they will call the office to set up an appointment.  The patient is given the consent form ahead of time and provided at least a week to review and speak with family about the study. The consent is then reviewed again when the patient comes to the office. The study is discussed and all questions are answered before the consent is signed. |
| 2 | **Survey**. The Consent process allows the participant to control how much time they need because, consent information is provided to the participant and then the participant can choose to (click the button on the website to take the survey, mail in the survey) at their own pace. |
| 3 | **General process where information is provided at screening for a later in person appointment.** The Consent form is sent to the potential participant via e-mail after screening. Appointments are scheduled approximately 2 weeks from the date of screening. When the participant arrives for their appointment, the research assistant will give the participant the consent form, ask them if they have had a chance to review it, review it with the participant, ask them if they have any questions, answer questions and ask them if they would like any additional time to consider whether or not to enroll. If the participant indicates that they need more time, it will be given, even if this means scheduling an additional appointment. If not, they will be asked to sin the consent form as documentation of their affirmative choice to be in the study. |
| 4 | **Distance Procedure**. Consent will be obtained (over the phone, via the internet, via mail). The participants are provided with the consent information sheet ahead of time and are asked if they have had sufficient time to review it and decide whether or not they want to participate before the interview begins. |
| 5 | **Public Meeting/Classroom Survey**. After the consent information sheet and attached survey is passed out, participants will be instructed to tear off the info sheet, read through it, ask any questions, take any additional time they need to consider participation and only then, if they choose, fill out and hand in the survey. |

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| Describe any process to ensure ongoing consent, defined as a subject’s willingness to continue participation for the duration of the research study. | | |
| **Discussion- Ongoing Consent.**  Ongoing consent is an issue in about half of all studies. Studies that have straight forward procedures that only require a small number of research interactions over a short period of time usually don’t have to provide a strict ongoing consent process. A more formal ongoing consent should be considered in the following cases:  When interactions take place over an extended period of time an ongoing consent process to remind the participant about his/her rights and in some cases review again the consent document (but not necessarily re-sign another document).  When research procedures and/or risks are determined to have significantly change.  When procedures involve significant discomforts or risks.  When a participant’s ability to provide consent may change over time (one obvious example would be a participant who cannot provide consent due to a mental incapacity who later recovers this capacity). | | |
| **A** | | **NA type responses** | |
| 1 | **Consent will not be Obtained.** Consent will not be obtained. |
| 2 | **Ongoing Consent will not be Needed.** A formal ongoing consent process is not necessary because participants complete their research interaction within two hours of the initial consent process and there are no significant discomforts to the research. |
| **B** | | **Ongoing Consent.** | |
| 1 | **Typical Biomedical.** Informal reiteration of the voluntary nature of the study and consent aspects are discussed with all patients on a regular basis throughout the study.  An amended consent form will be created if new information is obtained that may affect the patient’s willingness to participate in the study. Patients will be asked for new written consent when they are actively engaged in the study. |
| 2 | **Informal in Person**. Each time that a participant returns for a scheduled research interaction, they will be presented with a copy of the current (unsigned) consent form reminded that although they signed the form in the past, their consent is voluntary and they are free to withdraw from the research. |
| 3 | **Online.** Each time that a parson returns to the website to participate, the first screen they will be presented with it the online consent information sheet. The participant will need to formally consent by clicking the “I agree” button in order to provide the subsequent research data. |
| 4 | **Formal in Person**. Due to the significant time frame between appointments, the formal consent process will be re-conducted at the beginning of each appointment exactly as it is for initially obtaining consent. A separate consent document for each appointment will be retained in the participant’s file. |

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| Describe whether you will be following “SOP: Informed Consent Process for Research (HRP-090).” If not, or if there are any exceptions or additional details to what is covered in the SOP, describe:   * The role of the individuals listed in the application who are involved in the consent process. * The time that will be devoted to the consent discussion. * Steps that will be taken to minimize the possibility of coercion or undue influence. * Steps that will be taken to ensure the subjects’ understanding.   We have reviewed and will be following “SOP: Informed Consent Process for Research (HRP-090).” | | |
| **Discussion- HRP-090.**  Most treatment research that obtains consent from participants should follow HRP-090. Behavioral research often does not because the risks and complexity of procedures are usually sufficiently low that some steps may be omitted.  Be sure to read through this procedure document. It serves two major purposes:   * It serves as a prescription and starting point for how an adequate consent process should take place in many situations. * It saves researchers time in writing out the entire consent procedure in every protocol.   If your process will deviate from HRP-090, then the best way to provide the consent process description is to tell what parts of the consent process will follow HRP-090 and what parts will differ and why. Remember that the IRB will be approving this procedure based on what you write here so you must follow it. If you do not, you open yourself up to future noncompliance problems. | | |
| **A** | | **NA type responses** | |
| 1 | **Consent will not be Obtained.** Consent will not be obtained. |
| **B** | | **HRP-090.** | |
| 1 | **Follow HRP-090.** This research will follow SOP: Informed Consent Process for Research (HRP-090). (just check the box) |
| 2 | **Differ from HRP-090.** State how the process will follow HRP-090 but then tell how the process will differ from HRP-090. **Note that the example bullets below would probably not all apply to the same study**.  This research will follow SOP: Informed Consent Process for Research (HRP-090) with the following exceptions:   * The following will not be adhered to: “3.3 If the subject/representative understands more than one language, whenever possible, conduct the consent process in the preferred language of the subject/representative.” The reason is that the population for the study is college students at a university where the language of instruction is English. It is expected that a number of students might probably prefer to use their native language but there will be so much variation in languages that having available research staff to speak these languages would be impractical. Additionally, as instruction is delivered in English, it can be assumed that all students have sufficient command of this language to be able to understand the consent process. * The following will not be adhered to: “*3.7* Conduct all discussions in a private and quiet setting.” As this survey research is being presented to participants in a group setting, it will not be private. * The following will not be adhered to:   + “5.3.5 Read the script (or have an interpreter translated the script) with the subject/representative. Explain the details in such a way that the subject/representative understands what it would be like to take part in the research study.”   + “5.7 Ask the subject/representative questions to determine whether all of the following are true, and if not, either continue the explanation or determine that the subject/representative is incapable of consent:”   The reason is that the study is conducted over a website so there is no direct interaction where a person could read the script to the individual. The information sheet is however presented on the website and the participant is asked to confirm that they consent to participate in the research by clicking a button to enter the survey.   * The following will not be adhered to: “5.6 Invite and encourage the subject/representative to take the written information home to consider the information and discuss the decision with family members and others before making a decision.” The reason for this is that the research is very low risk and should not require the added consultation time in order to determine whether or not they wish to enroll in the study. Furthermore, the research is a one-time participation where participants do not returning to the site for research procedures in the future. |

**Non-English Speaking Subjects**

**N/A:** This study will not enroll Non-English speaking subjects.   
(Skip to Section 26.8)

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| Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.  NOTE: The response to this section should correspond with your response to section 6.4 of this protocol. | | |
| **Discussion- Non-English Speaking Subjects.**  Be sure to look at section 6.4 of your protocol to ensure consistency between the two sections. | | |
| **A** | | **NA type responses** | |
| 1 | **English Only.** All prospective subjects are expected to be able to speak English sufficiently so that English will be the only language used for consent and research procedures. |
| **B** | | **Non-English Speaking Subjects.** Address this in two statements usually. First state any other languages you expect to encounter, and then state whether or not the people who speak these languages also speak sufficient English to be able to consent and participate in the study in English. | |
| 1 | **Consent only in other than English.** While some participants may speak second languages, their primary language will be Mandarin Chinese. Therefore the language that consent and research procedures are conducted in will be Mandarin Chinese. |
| 2 | **Consent only in English.** While some participants may speak second languages and for some participants their primary language will not be English, it is expected that all participants speak sufficient English to be able to consent and participate in the research procedures in English because… |
| 3 | **Consent in English and Spanish.** While some participants may speak second languages and for some participants their primary language will not be English, it is expected that primary language for the majority of persons who do not speak sufficient English to be able to consent to participation in English is Spanish because… |

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| If subjects who do not speak English will be enrolled , describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.  NOTE: Guidance is provided on “SOP: Informed Consent Process for Research (HRP-090).” | | |
| **Discussion- Procedures for Non-English Speaking Subjects.**  Be sure to look at section 6.4 and 26.6 of your protocol to ensure consistency between the sections. | | |
| **A** | | **NA type responses** | |
| 1 | **English Only.** All prospective subjects are expected to be able to speak English sufficiently so that English will be the only language used for consent and research procedures. |
| **B** | | **Procedures for Non-English Speaking Subjects.** | |
| 1 | **Procedures for Non-English Speaking Subjects.**  For each language other than English that will be used to conduct the consent and research process, state the following:   * State the language that will be used for consent. * State how written information has been/will be translated into the written language of the participant. * State how verbal information will be exchanged with the participant in their language (keep in mind that in order to answer a participant’s questions, you must be able to understand the question). * State the reason that the IRB should accept that translations are adequate for example:   + State why a member of the research team would be capable of performing the translation function (for instance it is the PI’s native language)   + Name the professional translation service to be used to translate both the written and verbal processes.   + Describe another means used for the translation function and state why this would be sufficient. |

**Cognitively Impaired Adults**

**N/A**: This study will not enroll cognitively impaired adults.   
*(Skip to Section 26.9)*

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| Describe the process to determine whether an individual is capable of consent. | | |
| **Discussion- Cognitively Impaired Adults.**  While it is possible that a cognitively impaired person might attempt to enroll in any study, should one present to enroll where the protocol is not constructed for such an enrollment, an amendment will need to be approved by the IRB before the enrollment can occur. Therefore, in many cases the NA type response is appropriate. However, should your protocol be designed for a population persons where there is a high probability that a person might have a cognitive impairment, you should specify a process to be used. The degree of rigor required in making this determination will vary depending on the study but it could be a formal test of some type, a review of records, or an informal conversation whereby you ask the person a few questions about the consent information that you just went over with them.  Keep in mind that in some populations with cognitive impairments capability to consent or assent may change (for the worse or the better) over time. | | |
| **A** | | **NA type responses** | |
| 1 | **NA**. It is not anticipated that persons with cognitive impairments will be enrolled in this study. |
| **B** | | **Cognitively Impaired Adults.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Cognitively Impaired Adults.** Describe your process for determining whether or not a person is capable of consent. Be sure to be specific enough so that if another person were to need to recheck the individual you tested, the result would be reproducible. |

**Adults Unable to Consent**

**N/A**: This study will not enroll adults unable to consent. (*Skip to Section 26.13)*

When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent (Sections 26.9 and 26.10) **and, where possible, assent of the individual should also be solicited** (Sections 26.11 and 26.12).

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| Describe how you will identify a Legally Authorized Representative (LAR). Indicate that you have reviewed the “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” for research in New York State.  NOTE: Examples of acceptable response includes: verifying the electronic medical record to determine if an LAR is recorded.  ☐ We have reviewed and will be following “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).” | | |
| **Discussion- LARs in NY.**  When a person is not capable of consent due to cognitive impairment, a legally authorized representative should be used to provide consent and, where possible, assent of the individual should also be solicited.  While the list in the consent form (and below) is what is defined by NY as acceptable, it may be that for the legal or ethical concerns associated with a particular study, a researcher may want to be more restrictive. | | |
| **A** | | **NA type responses** | |
| 1 | **NA**. It is not anticipated that persons with cognitive impairments will be enrolled in this study. |
| **B** | | **Cognitively Impaired Adults.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **LAR in NY.** The use of LARs will be restricted to the following in order of priority.   * A health care agent properly designated on a health care proxy form * A court-appointed guardian or committee under the New York Surrogates Court Procedure Act Article 17-A * The spouse * An adult son or daughter * A parent * An adult brother or sister * A close friend |

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| For research conducted outside of New York State, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of “legally authorized representative” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).” | | |
| **Discussion- Criteria for determining LAR outside of NY.**  The laws regarding Legally Authorized Representative (LAR) for research purposes vary from state to state. Therefore, when conducting research outside of NY, it is important to define at what constitutes the LAR for purpose of the particular protocol and inform the IRB of how you came by this information. | | |
| **A** | | **NA type responses** | |
| 1 | **NA**. It is not anticipated that persons with cognitive impairments will be enrolled in this study. |
| 2 | **NA, Only in NY**. This study will only take place in NY State. |
| **B** | | **LAR for Cognitive Impairments** | |
| 1 | Where multiple states or countries are involved, you may need to do this for each state or country.  State what the LAR priorities are and how they will be applied.  State the process you used to make this determination. |

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| Describe the process for assent of adults. Indicate whether:   * Assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not. * If assent will not be obtained from some or all subjects, provide an explanation of why not.  Describe whether assent of the adult subjects will be documented and the process to document assent. NOTE: The IRB allows the person obtaining assent to document assent on the consent document using the HRP-503: “Template Consent Document” Signature Block for Assent of Adults who are Legally Unable to Consent. | | |
| **Discussion- Assent of Cognitively Impaired Adults.**  While, in this case we are dealing with adults, the responses in this section will often be similar to those for assent of children so please refer to section 26.14 and 26.15 for examples that can be modified as necessary. | | |
| **A** | | **NA type responses** | |
| 1 | **NA**. It is not anticipated that persons with cognitive impairments will be enrolled in this study. |
| **B** | | **Assent of Cognitively Impaired Adults.** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Assent of Cognitively Impaired Adults.** Please refer to sections 26.17 and 26.18 for examples and modify as needed. |

**Subjects who are not yet adults (infants, children, teenagers)**

**N/A**: This study will not enroll subjects who are not yet adults.   
*(Skip to Section 27.0)*

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| Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent **to treatments or procedures involved in the research** under the applicable law of the jurisdiction in which the research will be conducted **(e.g., individuals under the age of 18 years)**. For research conducted in NY state, review “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)” to be aware of which individuals in the state meet the definition of “children.”  NOTE: Examples of acceptable responses include: verification via electronic medical record, driver’s license or state-issued ID, screening questionnaire. | | |
| **Discussion- Criteria for determining who is “old enough”.**  This is important for **EVERY** project with intervention or interaction. To put the question simply, how do you make sure that a child is not participating in a study not approved for children, Just as important how do you make sure that you are not asking for parental permission for a competent adult who can consent for himself to participate in the study.  This applies to all persons who present, not just in cases where there may be persons who are underage. You must state how you reasonably determine that a person is old enough to consent for themselves. This does not always require a check of ID's. Rather you could infer their age based on population characteristics (e.g. if all were graduate students due to the inclusion criteria, their age for consent could be reasonably expected) or by virtue of their being able to complete the process of consent participation (e.g. by reading online consent information that asks for only persons who are over 18 to participate and clicking the I agree button participants indicate their age).  See Section12.2 for guidance on whether or not research is considered to be occurring outside of NY State. | | |
| **A** | | **NA type responses** | |
| 1 | **NA Record Review**. This study is a records review that waives consent. |
| **B** | | **Who is “Old Enough”** | |
| 1 | **ID Check.** All participants will be asked to present a photo ID with date of birth to be screened before they may participate. |
| 2 | **Record Check.** All participants’ medical records will be checked after consent is given in order to verify their age meets inclusion criteria. |
| 3 | **RPG.** The departmental RPG verifies age of participants and does not allow them to sign up for studies until they are 18 years of age. |
| 4 | **Inferred by population.** As all members of the (class being asked to participate are graduate students, group recruited are employed in a full time management position at the company, group being mailed the survey are members of AARP, etc.) it can be reasonably inferred that they are all at least 18 years of age. |
| 5 | **Combination visual and ID Check.** All participants who appear to be under the age of 30 will be asked to present a photo ID with date of birth to be screened before they may participate. |
| 6 | **Electronic Screening Question.** The first question of the survey asks the participant their age. If they answer < 18, the survey will immediately stop and they will be thanked for their time but informed that the study is not currently enrolling persons under the age of 18. |
| 7 | **Consent Process Check.** The consent information sheet states that participants must be 18 or older to participate. If you are not 18 or older, please do not participate in this study. |

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| For research conducted outside of New York State , provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in “SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013).” | | |
| **Discussion- Criteria for determining what “old enough” is outside of NY.**  The laws regarding what is the age when a person is no longer a child for research purposes vary from state to state. Therefore, when conducting research outside of NY, it is important to define at what age or conditions a person is no longer a child for purpose of the particular protocol procedures and inform the IRB of how you came by this information. | | |
| **A** | | **NA type responses** | |
| 1 | **NA Record Review**. This study is a records review that waives consent. |
| 2 | **NA Only in NY**. This study will only take place in NY State. |
| **B** | | **What age is “Old Enough”** | |
| 1 | Where multiple states or countries are involved, you may need to do this for each state or country.  State what the age or other criteria is for legally consenting to the procedures of this research protocol.  State the process you used to make this determination. |

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| Describe whether parental permission will be obtained from: ☐ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.  ☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.  ☐ Parent permission will not be obtained. A waiver of parent permission is being requested.  *NOTE: The requirement for parent permission is a protocol-specific determination made by the IRB based on the risk level of the research. For guidance, review the “CHECKLIST: Children (HRP-416).”* | | |
| **Discussion- One, Both or No Parents.**  Usually permission from one parent is sufficient when the research falls into one of the following two categories:   * The research presents no greater than **minimal risk**. Most behavioral, education, social and records review research fits here. * The research is **greater than minimal risk** but presents **direct benefit(s)** to the subjects or the risk to children is presented by a monitoring procedure that is likely to contribute to the subject’s well-being.   Permission from both parents will be required when the research falls into these categories:   * The research is **greater than minimal risk** and presents **NO direct benefit(s)** to the subjects but the study is **likely to yield generalizable knowledge about the subject's disorder or condition**. * The research is **greater than minimal risk** and presents **NO direct benefit(s)** to the subjects is **NOT** **likely to yield generalizable knowledge about the subject's disorder or condition** but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.   When parental permission is to be completely waived or altered, you must provide the justification in terms of the regulatory requirements for doing so. | | |
| **A** | | **NA type responses** | |
| 1 | **NA No Children**. This study does not involve children. |
| **B** | | **One, Both or No Parental Permission** | |
| 1 | **One Parent.** Permission will be obtained from only one parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. |
| 2 | **Both Parents.** Permission will be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. |
| 3 | **No Parental Permission under Standard Waiver of Consent Applicability**. This study does involve children but will not be obtaining parental permission. A waiver of parental permission is requested (see guidance under section 27 for additional information to provide in making this waiver justification) |
| 4 | **No Parental Permission**. This study does involve children but will not be obtaining parental permission because parental or guardian permission is not a reasonable requirement to protect the subjects. The research neither is FDA regulated nor involves non-viable neonates.   * Explain why the research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. * Describe an appropriate substitute mechanism for protecting the children who will participate as subjects in the research. * Provide evidence that the waiver is not inconsistent with Federal, State, or local law where the study will be conducted. |

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| Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe your procedure for determining an individual’s authority to consent to the child’s general medical care. | | |
| **Discussion- Permission from Other than Parents.**  Generally parents a must provide permission but there are times when parents are not available and another adult may be able to provide the same protection that would be provided through a parental permission process. You are cautioned that parental permission is usually the preferred mechanism and making the argument for another mechanism is often difficult. | | |
| **A** | | **NA type responses** | |
| 1 | **NA- No Children**. This study does not involve children. |
| 2 | **NA- No Parental Permission**. This study does involve children but will not be obtaining parental permission. |
| 3 | **NA- Only Parental Permission**. This study will only be obtaining parental permission. Permission from others will not be allowed. |
| **B** | | **Permission from other than Parents** | |
| 1 | Permission will be generally obtained from parents but when parents are not available, permission may be sought from…In order to determine that these individuals have the legal authority to provide consent for the child, the following procedure will be utilized… |

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| Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. | | |
| **Discussion- Assent from Children.**  For those who are confused by the term assent, just think of it as the consent process for child participants. Generally assent of the child should be obtained in some form when possible. However, the regulations give significant flexibility to the IRB because children range from age 1 day old to just less than 18 years old in most cases. Obviously assent of a baby would not be at all possible to obtain whereas assent of the 17 year old should be very similar to an adult consent process. Children somewhere between these extremes should be presented with an assent process that is appropriate given their maturity and the nature of the research. This may mean that, for a study that enrolls a wide range of ages, different assent processes, documents and information sheets may be need to be developed.  Where assent is not to be obtained, justification for not doing so must be given. See examples below. | | |
| **A** | | **NA type responses** | |
| 1 | **NA No Children**. This study does not involve children. |
| **B** | | **Assent** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **All Children Assent.** Assent of all children will be obtained before they participate in the research. |
| 2 | **Babies and Very Young Children.** Assent of children will not be obtained. All participating children are infants and therefore the capability of these children is so limited that they cannot reasonably be consulted. |
| 3 | **Some Children Assent.** Children under the age of 7 will not be asked to assent because the capability of these children is so limited that they cannot reasonably be consulted for the procedures involved. Children from 7-10 year of age will need to provide assent before they participate. |
| 4 | **No Assent under Standard Waiver of Consent Applicability**. This study does involve children and although the children are capable of assent, the study will not be obtaining assent. A waiver of assent is requested (see guidance under section 27 for additional information to provide in making this waiver justification) |
| 5 | **No Assent, Waiver for health or well-being of the child**. This study does involve children and although the children are capable of assent, the study will not be obtaining assent. A waiver of assent is requested because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research. |

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| When assent of children is obtained describe how it will be documented. | | |
| **Discussion- Documentation of Assent.**  For those who are confused by the term assent, just think of it as the consent process for child participants. Generally assent of the child should be obtained in some form when possible. However, the regulations give significant flexibility to the IRB because children range from age 1 day old to just less than 18 years old in most cases. Obviously assent of a baby would not be at all possible to obtain whereas assent of the 17 year old should be very similar to an adult consent process. Children somewhere between these extremes should be presented with an assent process that is appropriate given their maturity and the nature of the research. This may mean that, for a study that enrolls a wide range of ages, different assent processes, documents and information sheets may be need to be developed. | | |
| **A** | | **NA type responses** | |
| 1 | **NA No Children**. This study does not involve children. |
| 2 | **NA No Assent**. This study does involve children but assent of all children is to be waived. |
| **B** | | **Assent** (Keep in mind that you may need a combination of these for your particular study) | |
| 1 | **Verbal Assent.** Children between the ages of 7 and 10 will be asked to assent using attachment NN- verbal assent script. Their assent response will be noted by the research team member obtaining assent in an assent log sheet where the name of the child, date of assent, and initials of the team member obtaining assent are documented. |
| 2 | **Signed Assent- multiple documents.** Children between the ages of 7 and 10 will be asked to document assent using attachment NN- assent document 7-10 by either signing or printing their name and date on the signature line. Children from 11-14 will be asked to document assent using attachment NM- assent document 11-14 by signing their name and date on the signature line. |
| 3 | **Same Document for all Teens (both adults and children).** The population consists of 17-19 year olds. The same document (Attachment NN- Consent/Assent Document) will be used for assent of the minor participants as for consent of the adult participants because all participants will be present in the same room to participate in the focus group and there would be no reasonable reason why there would need to be simplified language for the minor participants. |

# Waiver or Alteration of Consent Process

**Consent will not be obtained, required information will not be disclosed, or the research involves deception.**

**N/A:** A waiver or alteration of consent is not being requested.

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| If the research involves a waiver or alteration of the consent process, please review the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” to ensure that you have provided sufficient information for the IRB to make the determination that a waiver or alteration can be granted.  NOTE: **For studies involving records review,** the first set of criteria on the “CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)” applies. | | |
| **Discussion- Waivers or Alteration of Consent.**  If you are actually communicating with participants, in most cases you are obtaining verbal consent, not waiving it completely. Completely waiving, or altering consent by omitting required elements, requires that the research meet specific regulatory criteria. The situations in which consent is completely waived or altered are pretty well delineated. Consent can **sometimes** be waived in the following cases:   * Records/Chart Reviews * Observational studies with no intervention or interaction (rare at UB) * Behavioral research where disclosing information about the study or obtaining an affirmative response would make it impossible to obtain valid information from participants (i.e. Deception or Incomplete Disclosure). * Government Demonstration Projects (rare at UB) * Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens (rare at UB) * Planned Emergency Research (rare at UB- covered in section 27.2) * Research meeting specific additional criteria for children can waive parental permission and/or assent of the child when these criteria are met (covered below in sections 25.12-25.14).   Most studies involving consent waivers from the first 3 bullets fall under the first set of waiver requirements in HRP-410, the Non-FDA Regulated Minimal Risk Waiver. The next 2 bullets respectively use the second and third sets of criteria in HRP-410 to justify the waiver of consent. While it is the IRB’s duty to approve and document that the waiver criteria have been met, the goal of this section is to provide the information so that the IRB has at its finger tips the justifications they will need. | | |
| **A** | | **NA type responses** | |
| 1 | **No Waiver Needed.**  A waiver of consent is not required for this research project. |
| **B** | | **Non-FDA Regulated Minimal Risk Waiver.** The regulations require that the IRB determine and document with protocol specific information that the following criteria are met.   * The research is NOT FDA-regulated. * The research does NOT involve non-viable neonates. * The research involves no more than Minimal Risk to the subjects. * The waiver or alteration will NOT adversely affect the rights and welfare of the subjects. * The research could NOT practicably be carried out without the waiver or alteration * Whenever appropriate, the subjects will be provided with additional pertinent information after participation.   We recommend the following process to provide your justification to the IRB.   * State what is being waived or altered. * While the answer to the first two items may seem obvious, restate them here. * State why the study is minimal risk or lower. * State why there is no adverse effect on the rights of subjects * State why there is no adverse effect on the welfare of subjects * State why the research could not practicably be carried out * State whether or not you will provide additional pertinent information after participation and why this is the appropriate choice. | |
| 1 | **Records Review.** Consent is being completely waived for this records review study that neither is FDA regulated nor involves non-viable neonates.   * The records review is no greater than minimal risk because (choose the one that fits the study or write your own)   + **While identifiers are seen by the research team, no identifiers are recorded in the research records.** The only risk related to the records review portion of the study is a potential breach of confidentiality. This risk is also inherent in the original data from which the research records are derived and therefore is a risk ordinarily encountered in everyday life. As no data obtained for research will contain identifiers, the risk of a breach of confidentiality for the research data set is actually less than that of the original data set from which it will be derived.   + **Identifiers are obtained by the research team but without any links to sensitive data** (Used primarily for obtaining contact information to recruit participants)**.** The only risk related to the records review portion of the study is a potential breach of confidentiality. This risk is also inherent in the original data from which the research records are derived and therefore is a risk ordinarily encountered in everyday life. Data extracted will include identifiable information but there will be no link at all in the researchers' datasets between identifiable information and personal or sensitive information. Therefore the risk of a breach of confidentiality for the research data set will be less than that of the original data set from which it will be derived.   + **Identifiers are obtained by the researcher with coded links to sensitive data.** The only risk related to the records review portion of the study is a potential breach of confidentiality. This risk is also inherent in the original data from which the research records are derived and therefore is a risk ordinarily encountered in everyday life. Data extracted includes identifiable information and while there is a link between identity and personal or sensitive information, in order to connect these two pieces of information, a person not affiliated with the research team would have to obtain two or more separate files. Therefore the risk of a breach of confidentiality for the research data set is actually less than that of the original data set from which it will be derived.   + **Identifiable data are initially obtained from records by the researchers, but identifiers are removed or coded within a very short time frame so that research records will revert to being unidentifiable.** The only risk related to this part of the study is a potential for a breach of confidentiality. This risk is also inherent in the original data from which the research records are derived and therefore is a risk ordinarily encountered in everyday life. Data obtained is identifiable but will be either de-identified or coded within EnterNumberOfDays days of obtaining the data. Due to the short time period for retention of the data in an identifiable format the risk of a breach of confidentiality for the research data set is actually less than that of the original data set from which it will be derived.   + **Identifiable data are obtained from records by the research team for the purpose of this study but, even if identifiable data were to be disclosed to someone outside of the research team, the information would pose NO reasonable risk to participants** because… * The waiver for purpose of this records review will not adversely affect the rights of participants because (choose the one that fits the study or write your own)   + **Only members of the research team that already have access** to the records from which research data are obtained will be given access to identifiable information.   + **The records belong to an institution or agency** (e.g. hospital, school, government program) and the research team is being granted access to these records by a person at the institution or agency who is authorized to do so.   + **Permission from participants was previously obtained by…**(indicate how they gave this permission)to use the records for this purpose**.** * The waiver for purpose of this records review will not adversely affect the welfare of participants because (We think that this is true in all records review cases but feel free to write your own if it does not fit)   + No intervention/interaction with the participants occurs unless consent is subsequently obtained. The research data is not going to be used to make determinations about individuals outside of the research context (i.e. research data can be used to determine eligibility in research but not for other decisions about individuals).Individually identifiable research data obtained under the waiver will not be shared with persons outside of the research team. * The records review could not practicably be carried out without this waiver because (choose the one that fits the study or write your own)   + It would be impractical to attempt to contact all of the persons to whom the records pertain because of the number of records to be viewed and/or the fact that contact information may not be sufficient to do so.   + Contact information for eligible participants is the information sought. * Participants will be provided with additional pertinent information (i.e. debriefed or otherwise contacted to provide information) after records are obtained and/or analyzed because (choose the one that fits the study or write your own)   + The records review is being used to obtain contact information for eligible individuals who will be invited to participate in a subsequent part of the study * Participants will NOT be provided with additional pertinent information (i.e. debriefed or otherwise contacted to provide information) after records are obtained and/or analyzed because (choose the one that fits the study or write your own)   + It is highly unlikely that the records review portion of this study will result in information that is pertinent to individuals.   + It would be impractical to attempt to contact all of the persons to whom the records pertain because of the number of records to be viewed and/or the fact that contact information may not be sufficient to do so. |
| 2 | **Observational study with no intervention or interaction**. Consent is being completely waived for this observational study that neither is FDA regulated nor involves non-viable neonates.   * The observation is not greater than minimal risk because (choose the one that fits the study or write your own)   + **Observation and/or recording will be occurring in the context of everyday life.** The observation is occurring in a public setting where people would expect that observations or recording would be taking place. As observation or recording in the situations being observed or recorded does routinely occur in everyday life, the risk is identical to that of everyday life.   + **Observation is occurring in a public setting where people would expect that recording is taking place (such as at a public festival, a newsworthy demonstration or a public meeting).** As a reasonable person present would expect recording of the events to take place, they would not perform actions that they would not desire to have observed or recorded. Therefore the risk of the research is equivalent to that of everyday life.   + **Observation is occurring in a setting where people are informed of the observation and/or recording occurring.** A reasonable person who knows that they are being observed/recorded would not perform actions that they would not desire to have observed or recorded. Therefore the risk of the research is equivalent to that of everyday life.   + **Observations are being made without recording of identifiable information (including not video/or audio recording).** The principal risk related to the observation is a potential breach of confidentiality but in this case, the risk is virtually eliminated by the confidentiality procedures which record data anonymously. * The waiver for purpose of this observation will not adversely affect the rights of participants because (choose the one that fits the study or write your own)   + **Participants know that the observations and/or recordings are taking place at the site** so they have the ability to “opt out” by not offering information through their words or actions.   + Participants' actions are taking place in a location where there would be **no expectation of privacy** for the information gathered.   + **Permission from participants was previously or will be given** (indicate how they gave this permission)for observation and/or recording outside of the research context and the data is not personal or otherwise sensitive so the research use of the same data does not violate participants' rights. * The waiver for purpose of this observation will not adversely affect the welfare of participants because (We think that this is true in all observation cases but feel free to write your own if it does not fit)   + No intervention/interaction with the participants occurs unless consent is subsequently obtained. The research data is not going to be used to make determinations about individuals outside of the research context (i.e. research data can be used to determine eligibility in research but not for other decisions about individuals). Individually identifiable research data obtained under the waiver will not be shared with persons outside of the research team. * The observation could not practicably be carried out without this waiver because (choose the one that fits the study or write your own)   + It is necessary to capture data on persons in **naturally occurring situations** in their environment and therefore, if consent were obtained, they might act differently than they would when consent is not obtained   + The **number of people being observed or time period** being observed is so large that it would be impractical for the researcher to obtain consent. * Participants will be provided with additional pertinent information (i.e. debriefed or otherwise contacted to provide information) after observation occurs because (choose the one that fits the study or write your own)   + The observation is being used to obtain contact information for eligible individuals who will be invited to participate in a subsequent part of the study * Participants will NOT be provided with additional pertinent information (i.e. debriefed or otherwise contacted to provide information) the observation occurs because (choose the one that fits the study or write your own)   + It is highly unlikely that the observation portion of this study will result in information that is pertinent to individuals.   + It would be impractical to attempt to contact all of the persons who were observed because of the number or timing of people observed and/or the fact that contact information may not be sufficient to do so. |
| 3 | **Behavioral research where disclosing information about the study or obtaining an affirmative response would make it impossible to obtain valid information from participants (i.e. Deception or Incomplete Disclosure).** Consent is being altered to omit required elements for this study that neither is FDA regulated nor involves non-viable neonates.   * When children are involved, state whether it is the child, their parent, or both that require the omission of relevant elements. * Identify the elements of consent that are to be omitted or altered. Consult HRP- 314 for a complete listing of the elements. Usually the only elements that are omitted/altered are one or more of the following:   + An explanation of the purposes of the research (or an incomplete explanation must be given).   + A description of the procedures to be followed (or an incomplete description must be given), and identification of any procedures which are experimental.   + Complete information **WILL** be disclosed to participants but they **WILL NOT** be required to provide an affirmative response either verbally or in writing before participation begins. Rather, they will only not participate if they actively decline to do so. * The study is not greater than minimal risk because…(sorry this is related to the procedures of the study and, as every study is different, it is impossible to write an example for this one)…Explain why the research is no greater than minimal risk. A good way of doing so is to make a comparison between the risk of the activities used in your research that people encounter all the time in life or are similar to routine physical or psychological treatment. For example, if the research activity involved discussing their feelings with a trained counselor, this could be equated to routine psychological treatment. Another example is if the research activity involved completion of an activity that is similar to schoolwork encountered by children every day, then the risk of the activity is identical to the risk of everyday life activities. * The waiver for purpose of this study will not adversely affect the rights of participants because (choose the one that fits the study or write your own)   + **Participant/Parent debriefing procedures are used to resolve omissions in the consent process.** The elements of consent that are omitted from the consent process before participation are provided to participants after participation as a part of the debriefing procedures. After learning of the deception or incomplete disclosure the participants are then given the opportunity to withdraw their data and have it deleted/destroyed if they wish. Withdrawal of data does not result in any reduction in compensation or involve any penalty or loss of benefits to which the participant is otherwise entitled.   + **Participants/Parents would not consider omissions to be relevant.** It is highly unlikely that any reasonable participant would find that the undisclosed information in the consent process would have been material to their decision to participate and therefore the deception or incomplete disclosure does not affect participants' rights.   + **Procedures used for consent are typical in the context from which participants are recruited.** This research is taking place with members of a group (school, business or other organization) who would accept the consent procedures used for participation in the interventions of this project as typical of or analogous to procedures that would be used for consent to similar data collections taking place outside of the research context. * The waiver for purpose of this study will not adversely affect the welfare of participants because (We think that this is true in all deception/incomplete disclosure cases but feel free to write your own if it does not fit)   + There can be no adverse effect on the welfare of participants because **all of the following are true**: Procedures are sufficient such that a reasonable person would not be significantly upset or distressed upon learning of the deception or incomplete disclosure. Privacy and Confidentiality are sufficiently protected because individually identifiable research data obtained under the waiver will not be shared with persons outside of the research team without the use of a complete informed consent procedure to do so. Sufficient information is provided on the reasonable other (physical, psychological, etc.) risks of participation so that no harm to any participant can occur as a result of the omitted elements of consent.  The research data is not going to be used to make determinations about individuals outside of the research context (i.e. the research data can be used to determine eligibility in research but not for other decisions about individuals). * The study could not practicably be carried out without this waiver because (choose the one that fits the study or write your own)   + **Accurate data could not be obtained**. The information disclosed or process of obtaining a fully informed consent would cause participants to act or answer study questions differently than they would in circumstances outside of the research context.   + If a fully informed consent process were utilized, **participation rate would be so significantly depressed** for some portion or all of the population of interest that obtaining a fully informed consent would result in the inability to generalize from the data. * Participants will be provided with additional pertinent information (i.e. debriefed or otherwise contacted to provide information) after study.   + Tell how this occurs along with the timing of the debriefing relative to participation in the experimental procedures. * Participants will NOT be provided with additional pertinent information (i.e. debriefed or otherwise contacted to provide information) the observation occurs because (choose the one that fits the study or write your own)   + It is highly unlikely that the undisclosed information would be pertinent to the individuals.   + It would be impractical to attempt to contact all of the persons involved and/or the fact that contact information may not be sufficient to do so. |
| **C** | | **Government Demonstration Project Waiver.** The regulations require that the IRB determine and document with protocol specific information that the following criteria are met.   * The research is NOT FDA-regulated. * The research does NOT involve non-viable neonates. * The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. * The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following:   + Public benefit or service programs.   + Procedures for obtaining benefits or services under those programs.   + Possible changes in or alternatives to those programs or procedures.   + Possible changes in methods or levels of payment for benefits or services under those programs. * The research could NOT practicably be carried out without the waiver or alteration.   We recommend the following process to provide your justification to the IRB.   * State what is being waived or altered. * While the answer to the first two items may seem obvious, restate them here. * State what State or Local Government Official has approved the project (be prepared to submit proof of this approval with your protocol). * Give a few specifics (like the name of the program, agency and benefit being evaluated) and indicate which of the following is being evaluated:   + Public benefit or service programs.   + Procedures for obtaining benefits or services under those programs.   + Possible changes in or alternatives to those programs or procedures.   + Possible changes in methods or levels of payment for benefits or services under those programs. * State why the research could not practicably be carried out without the waiver or alteration of consent * State whether or not you will provide additional pertinent information after participation and why this is the appropriate choice. | |
| 1 | **Government Demonstration Project Waiver.** We are not providing specifics here because this is so infrequent an occurrence and, when it does occur, it is pretty obvious because the funding is being provided by a local or state agency. Additionally, it is impossible to know what is being waived and why without knowing the actual scope of the study but we think that the words you will use to satisfy this requirement will probably be similar to the words that are suggested under the more common minimal risk waiver sections above. |
| **D** | | **Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens.** The regulations require that the IRB determine and document that the following criteria are met.   * The research does not involve Human Subjects as Defined by DHHS. * The study involves an in vitro diagnostic device investigation. * The testing is noninvasive. * The testing does not require an invasive sampling procedure that presents significant risk. * The testing does not by design or intention introduce energy into a subject. * The device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure. * For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: “For Research Use Only. Not for use in diagnostic procedures.” * For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: “For Investigational Use Only. The performance characteristics of this product have not been established.” * The study uses one of more of the following:   + Specimens collected for routine clinical care or analysis that would have been discarded.   + Specimens obtained from specimen repositories.   + Leftover specimens that were previously collected for other research purposes. * The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including the sponsor meaning neither the investigator nor any other individuals associated with the investigation, including the sponsor can readily ascertain the identity of the subject. * One of the following is true:   + Specimens are not coded where “Coded” means that 1) a number, letter, symbol, or combination thereof (i.e., the code) has replaced identifying information (such as name or social security number) that would enable the investigator or any other individuals associated with the investigation, including the sponsor to readily ascertain the identity of the individual to whom the specimen pertains; and 2) a key to decipher the code exists, enabling linkage of the identifying information to the specimen.   + Neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems. * One of the following is true: (Check all boxes that are true. One must be checked)   + The specimens are not accompanied by clinical information.   + Clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor. * The individuals caring for the patients are different from those conducting the investigation and do not share information about the patient with those conducting the investigation. * The individuals caring for the patients do not share information about the patient with those conducting the investigation. * The specimens are provided to the investigator(s) without identifiers. * The supplier of the specimens has established policies and procedures to prevent the release of personal information. | |
| 1 | **Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens. There is little experience with this particular category at UB and therefore we advise that,** while many of the issues above are covered in other sections of the protocol, it would be a good idea to point out in a list format how every one of the above criteria are met so that the IRB does not have to go digging through your whole study to find what is needed. It is a shame to have a study deferred for a few weeks because of something that the IRB just couldn’t find but was actually present in the protocol when it would probably take just a few minutes for the researcher to make the justifications and list them in this section. |

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| If the research involves a waiver of the consent process for planned emergency research , please review the “CHECKLIST: Waiver of Consent for Emergency Research (HRP-419)” to ensure you have provided sufficient information for the IRB to make these determinations. Provide any additional information necessary here. | | |
| **Discussion- Planned Emergency Research.**  This is such a rare occurrence that we are not providing guidance here HRP-419 should be consulted and you should contact the Clinical Research Office for further assistance. Some of the guidance above for the other waivers of consent may be helpful for some of the issues in planned emergency research. | | |
| **A** | | **NA type responses** | |
| 1 | NA. This study does not involve planned emergency research. |
| **B** | | **Planned Emergency Research** | |
| 1 | **Waiver of the Consent Process for Planned Emergency Research.** Point out in a list format how every one of the criteria of HRP-419 are met even if they are already in other sections of your protocol. |

# Process to Document Consent

**N/A:** A Waiver of Consent is being requested.   
(Skip to Section 29.0)

NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as ‘verbal consent.’

If you will document consent in writing, attach a consent document. If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. a script or Information Sheet). Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information.

You may use “TEMPLATE CONSENT DOCUMENT (HRP-502)”to create the consent document or script. **Include relevant consent documents with your submission.**

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| Describe whether you will be following “SOP: Written Documentation of Consent (HRP-091).” If not or if there are any exceptions, describe whether and how consent of the subject will be obtained including whether or not it will be documented in writing.  NOTE: If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent. This is sometimes referred to as ‘verbal consent.’ Review “CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)” to ensure that you have provided sufficient information.  http://www.clipartbest.com/cliparts/acq/eAx/acqeAxyRi.pngIf you will document consent in writing, attach a consent document with your submission. You may use “TEMPLATE CONSENT DOCUMENT (HRP-502)”. If you will obtain consent, but not document consent in writing, attach the script of the information to be provided orally or in writing (i.e. Consent script or Information Sheet).  ☐ We will be following “SOP: Written Documentation of Consent ”(HRP-091) | | |
| **Discussion- Process to Document Consent.** Most treatment research that obtains consent from participants should follow HRP-091. Behavioral research often does not because the risks and complexity of procedures are usually sufficiently low that some steps may be omitted or verbal consent may be justified.  Be sure to read through this procedure document. It serves two major purposes:   * It serves as a prescription and starting point for how an adequate consent process should take place in many situations. * It saves researchers time in writing out the entire consent procedure in every protocol.   If your process will deviate from HRP-091, then the best way to provide the consent process description is to tell what parts of the consent process will follow HRP-091 and what parts will differ and why. Remember that the IRB will be approving this procedure based on what you write here so you must follow it. If you do not, you open yourself up to future noncompliance problems. | | |
| **A** | | **NA type responses** | |
| 1 | **Consent will not be Obtained.** Consent will not be obtained because a complete waiver or alteration of consent applies to this project.   * If this is an alteration and you will be getting verbal consent, describe the process to present information to participants and obtain their affirmative response and document where applicable. |
| **B** | | **HRP-091.** | |
| 1 | **Follow HRP-091.** This research will follow SOP: Informed Consent Process for Research (HRP-091). |
| 2 | **Differ from HRP-091 without a waiver of Signed Documentation.** State how the process will follow HRP-091 but then tell how the process will differ from HRP-091. **Note that the example bullets below would probably not all apply to the same study**.  This research will follow SOP: Informed Consent Process for Research (HRP-091) with the following exceptions:   * The following will not be adhered to: “5.4 Place the signed and dated documents in the subject’s binder.” All data is collected electronically so participants do not have an individual binder. The consent documents will be placed alphabetically in one binder. * The following will not be adhered to: “5.1.3.1 Subject/Representative will not sign the document” if physically unable to do so. Many of the participants will have arthritis that would make holding a pen to sign and date the document all but impossible. They will be asked to make a mark on the page and then both the researcher and a witness will sign and date the attestation next to the mark that it was obtained from the subject whose name is printed on the page. |
| **C** | | **HRP-091. Verbal Consent/Waiver of Written Documentation.**  Use the first criteria for minimal risk studies if applicable. Only when these criteria do not work should the Principle Risk to Confidentiality set of criteria be used as the second criteria are much more difficult to meet and require additional procedures.  In this case you should do the following:   * State that you will not be following HRP-091 but you will be obtaining verbal consent. * Justify the waiver in terms of the regulatory criteria presented in HRP-411. * Describe the process to be used for obtaining consent and if/how it will be documented. | |
| 1 | **Minimal Risk Studies.** HRP-091 will not be followed. Verbal Consent is obtained after communication of all required and appropriate additional elements of consent disclosure.   * The study is not greater than minimal risk because…(sorry this is related to the procedures of the study and, as every study is different, it is impossible to write an example for this one)…Explain why the research is no greater than minimal risk. A good way of doing so is to make a comparison between the risk of the activities used in your research that people encounter all the time in life or are similar to routine physical or psychological treatment. For example, if the research activity involved discussing their feelings with a trained counselor, this could be equated to routine psychological treatment. Another example is if the research activity involved completion of an activity that is similar to schoolwork encountered by children every day, then the risk of the activity is identical to the risk of everyday life activities. * Outside of the research context the procedures would not require written consent. Give an example of a common situation where the procedures would not require written consent. * Describe how information is conveyed to subjects and how they affirmatively respond (consent) to the invitation to participate. * Either state that consent will not be documented in any way or state how the researchers will document the verbal response. |
| 2 | **Principle Risk to Confidentiality.** HRP-091 will not be followed. Verbal Consent is obtained after communication of all required and appropriate additional elements of consent disclosure. The research is not FDA-regulated.   * State that the only record linking the subject and the research would be the consent document (and make sure this is the case- for example if you are paying compensation by check, or audio recording an interview this is not true). * Explain why the principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality. * Describe how information is conveyed to subjects and how they affirmatively respond (consent) to the invitation to participate.   + Be sure to include in this description a mechanism by which Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern. |

# Multi-Site Research (Multisite/Multicenter Only)

**N/A:** This study is not an investigator-initiated multi-site study. This section does not apply.

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| **Discussion- What is Meant By Multi-Site?**  While many research projects occur at multiple sites (e.g. observations in 5 different classrooms, interviews at 10 different locations around the city), these projects do not necessarily fall into the regulatory category of multi-site research. In this context, multi-site refers to studies in which there are multiple institutions (like UB and 4 other universities, or the typical situation of a drug trial being conducted at 20 different hospitals around the country under the direction of 20 local researchers). In these cases there needs to be a plan to exchange information between the different sites about any serious problems or adverse events so that a negative event occurring at one site can be avoided at other sites. This helps to minimize risks. While most multi-site SBS research is low risk so the probability of having to use these procedures is small and often there are only a small number of sites, it is still important to have procedures in place. |

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| If this is a multi-site study where you are the lead investigator , describe the processes to ensure communication among sites, such as:   * All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization. * All required approvals have been obtained at each site (including approval by the site’s IRB of record). * All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented. * All engaged participating sites will safeguard data as required by local information security policies. * All local site investigators conduct the study appropriately. * All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy. | | |
| **A** | | **NA type responses** | |
| 1 | **NA.** We are not the lead investigator. The lead investigative site is… |
| **B** | | **Multi-Site Procedures for compliance assurance.** This section deals with communication of the big issues (i.e. things that happen once or twice) between the lead and subordinate sites. The communication from the lead site to the individual sites of ongoing information is covered in the next question. | |
| 1 | Be sure to address each of the bullets.  These first three bullets can usually be achieved by a procedure whereby materials are to be sent from the lead site to the subordinate sites and the subordinate sites provide back to the lead site the approval documentation.   * All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization. * All required approvals have been obtained at each site (including approval by the site’s IRB of record). * All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.   The later 3 bullets are best achieved by an audit procedure to evaluate compliance with the requirements.   * All engaged participating sites will safeguard data as required by local information security policies. * All local site investigators conduct the study appropriately. * All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.   While these items are not costless, they are part of the responsibilities that are taken on by the sponsor when designing an industry sponsored clinical trial and should have been budgeted for in the process of the trial design. |

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| Describe the method for communicating to engaged participating sites :   * Problems. * Interim results. * Study closure. | | |
| **B** | **Communication among sites.** | |
| 1 | Describe the communication method for how information flows from a subordinate site to the lead site and then how that information is going to be transmitted to all sites. That is, when a problem occurs at one site, how does the information about the problem get distributed to all sites so that the problem can be avoided in the future? This must be described for both cases where UB is the lead site and where it is the subordinate site. |

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| Indicate the total number of subjects that will be enrolled or records that will be reviewed across all sites. | | |
| **B** | **Total Number of Subjects for all sites.** | |
| 1 | Sorry- no additional guidance on this one. |

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| If this is a multicenter study for which UB will serve as the IRB of record, and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) describe those methods. | | |
| **A** | **NA type responses** | |
| 1 | **NA.** All recruitment methods for the local site are under the local site’s control. |
| **B** | **National Recruitment methods.** | |
| 1 | Describe any national recruitment methods that the local site does not control. You may want to include an attachment with a script of any advertisements or the words to be said by call centers. |

# Banking Data and Specimens for Future Use

**N/A:** This study is not banking data or specimens for future use or research outside the scope of the present protocol. This section does not apply.

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| **Discussion- Banking Data or Specimens**.  The key issue is to make sure that the **consent of participants** is obtained for what you intend to do with the information they provide.  When subjects provide their consent, they are agreeing to particular stated uses of their data or specimens. Therefore, if there is a possibility that the data or leftover specimens may be saved or used for another purpose, participants should be aware of this at the time of providing their consent.  When saving or storing data or specimens, in most cases, the materials should be completely de-identified (with no possible link back to the individual identity) in order to minimize any potential for a breach of confidentiality. This has the added benefit that future uses will not usually meet the regulatory definition of human subjects research and therefore IRB approval for the subsequent use can possibly be avoided.  There are cases where storing of identifiable information and even making identifiable information public (such as on a website) can be accepted because it poses no reasonable risk to the participants and they are informed of the intent to do so ahead of time. Examples of this would typically only occur in the behavioral realm such as linguistic elicitation where voice recordings of an individual are made and research projects where historically significant data is obtained. |

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| If data or specimens will be banked (stored) for **future use, that is, use or research outside of the scope of the present protocol**, describe where the data/specimens will be stored, how long they will be stored, how the data/specimens will be accessed, and who will have access to the data/specimens.  NOTE: Your response here must be consistent with your response at the “What happens if I say yes, I want to be in this research?” section of the Template Consent Document (HRP-502). | | |
| **A** | **NA type responses** | |
| 1 | **NA.** There will be no data or specimen banking related to this protocol. |
| **B** | **Storage Procedures.** A bulleted list answering the questions is the way to cover this section. Make sure that the process is describe in sufficient detail that an outside auditor could look at the materials and determine that they meet the written procedures. | |
| 1 | **Storage of De-Identified Data and Specimens.**   * Data and leftover specimens will be stored in room 415 Tammany Hall in a locked cabinet. Specimens will be preserved by… * The materials will be retained for a period of ten years after completion of the initial protocol. * Materials will be accessible only to the PI or designated staff member. |
| 2 | **Public Posting Identifiable Data.**   * Data collected consist of identifiable video recordings of interview about…The videos, along with credits to the speakers will be donated to the Buffalo and Erie County Historical Society for posting to a website. * The materials will be retained indefinitely for historical purposes. * Materials will be accessible by the public through the website and thereafter through the archive library at the Historical Society. |

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| List the data to be stored or associated with each specimen. | | |
| **A** | **NA type responses** | |
| 1 | **NA.** There will be no data or specimen banking related to this protocol. |
| **B** | **Information Stored.** Cover both data and specimens/materials. State directly whether or not there will be any links to identifiers. | |
| 1 | **Storage of De-Identified Data and Specimens.**   * Leftover specimens will be retained along with a code linking to the following data kept in a spreadsheet.   + Give a list of the fields for the data * There will be no identifiers retained in the data or otherwise associated with the data. While the participants’ zip code is a part of the data set, because all zips codes are from the Western NY area, it is highly a zip code could be used to identify a participant. |
| 2 | **Public Posting Identifiable Data.**   * There will be no biological specimens collected as a part of this project. Data collected consist of identifiable video recordings of interview about…The videos, along with the identity and age of the participant at the time of collection will be retained. * The materials are identifiable. |

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| Describe the procedures to release banked data or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens. | | |
| **A** | **NA type responses** | |
| 1 | **NA.** There will be no data or specimen banking related to this protocol. |
| **B** | **Release Procedures.** Cover both data and specimens/materials. State directly whether or not there will be any links to identifiers. | |
| 1 | **Storage of De-Identified Data.**   * Other researchers can be granted access/use of the data and specimens by contacting the PI and requesting so in writing. * No additional approvals would be required for a release of only data but approval of Environmental Health and Safety will be required if shipment of specimens off campus needed to be undertaken. * Data provided to other researchers will include all archival information stored in the spreadsheet as indicated by the field list above. There will be no identifiers retained in the data or otherwise associated with the data. While the participants’ zip code is a part of the data set, because all zips codes are from the Western NY area, it is highly a zip code could be used to identify a participant. |
| 2 | **Public Posting Identifiable Data.**   * Materials will be accessible by the public through the website and thereafter through the archive library at the Historical Society. * The materials will be accessible to all in an identifiable format. |

# Drugs or Devices

**N/A:** This study does not involve drugs or devices. This section does not apply.

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| If the research involves drugs or devices, list and describe all drugs and devices used in the research ,the purpose of their use, and their regulatory approval status. | | |
| **Discussion- List of Drugs and Devices.** The list must cover ALL drugs and devices used as a part of the study procedures along with their approval status, not just the experimental drug or device being tested in this study. | | |
| **A** | | **NA type responses** | |
| 1 | **NA.** There will be no drugs or medical devices used in this study. |
| **B** | | **List of Drugs and Devices.** A bulleted list of the drugs and devices used in this study must be given along with their approval status. | |
| 1 | Possible Approval Status for Drugs:   * The drug is being used under an IND. * The drug is Exempt from IND requirements under…(cite the exemption from HRP-306). * The drug is being used as indicated/directed under FDA approval. |
| 2 | Possible Approval Status for Devices:   * The device is being used under an IDE. * The device is being used under an abbreviated IDE. * The device is Exempt from IDE requirements under…(cite the exemption from HRP-307). * The device is Exempt from IDE requirements under…(cite the exemption from HRP-307). * The device is being used under an HDE. * The device is being used as indicated under FDA approval. |

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| Describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators. | | |
| **Discussion- Plan for Handling of Drugs and Devices.**  This section is basically the security procedures for the investigational drugs and devices. It should include a description of sufficient detail so that another person can verify that procedures have been adhered to in an audit situation. | | |
| **A** | | **NA type responses** | |
| 1 | **NA.** There will be no drugs or medical devices used in this study. |
| **B** | | **Plan for Handling of Drugs and Devices.** Describe procedures to be used. | |
| 1 | **Device study.** The Investigational devices sent to the site for the use in the surgical procedure will be sent to the attention of the responsible research coordinator. Investigational devices will be stored in a locked office of the Coordinator in the Clinical Research Center. The coordinator will deliver the devices to the operating room at the time of the surgery, complete device accountability and remove unused devices from the OR for return to the sponsor. |
| 1 | **Drug study.** The study drug will be handled, mixed, labeled, and administered per the protocol’s instructions. The site will ensure through the involvement of dedicated ……. pharmacy staff in all dealings with the study drug. The study drug will be stored, handled, and administered in a separate area from all other medications in a way that supports the parameters of the study’s protocol. |

**If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:**

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| Identify the holder of the IND/IDE/Abbreviated IDE. | | |
| **A** | | **NA type responses** | |
| 1 | **NA.** There will be no drugs or medical devices used in this study. |
| 2 | **NA.** There will be no drugs requiring INDs or medical devices requiring IDEs or abbreviated IDEs used in this study. |
| **B** | | **Holder of the IND/IDE/Abbreviated IDE.** | |
| 1 | Just provide the name of the person or corporation and contact information for all INDs and/or IDEs. |

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| Explain procedures followed to comply with FDA sponsor requirements for the following:   |  |  |  |  | | --- | --- | --- | --- | |  | ***Applicable to:*** | | | | ***FDA Regulation*** | ***IND Studies*** | ***IDE studies*** | ***Abbreviated IDE studies*** | | ***21 CFR 11*** | ***X*** | ***X*** |  | | ***21 CFR 54*** | ***X*** | ***X*** |  | | ***21 CFR 210*** | ***X*** |  |  | | ***21 CFR 211*** | ***X*** |  |  | | ***21 CFR 312*** | ***X*** |  |  | | ***21 CFR 812*** |  | ***X*** | ***X*** | | ***21 CFR 820*** |  | ***X*** |  | | | |
| **Discussion- FDA Sponsor Requirements.**  You will need to consult the regulations directly and provide a description of how the local research will meet the FDA requirements. In corporate sponsored trials, these requirements are usually addressed by the sponsor and therefore do not need to be made a part of the local protocol (but then you would be using HRP-508 for submitting this protocol rather than this HRP-503 form). | | |
| **A** | | **NA type responses** | |
| 1 | **NA.** There will be no drugs or medical devices used in this study. |
| 2 | **NA.** There will be no drugs requiring INDs or medical devices requiring IDEs or abbreviated IDEs used in this study. |
| **B** | | **FDA Sponsor Requirements.** | |
| 1 | Provide the information needed to address the applicable FDA regulations for investigational drugs and devices. |

# Humanitarian Use Devices

**N/A:** This study does not involve humanitarian use devices. This does not apply.

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| For Humanitarian Use Device (HUD) uses provide a description of the device, a summary of how you propose to use the device, including a description of any screening procedures, the HUD procedure, and any patient follow-up visits, tests or procedures. For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use. |
| **Discussion- Humanitarian Use Devices.**  An Humanitarian Use Device (HUD) is a medical device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year. Consult HRP-323-Worksheet-Criteria for Approval HUD to ensure that you are providing the information required for IRB approval of the HUD as you answer the items. |