The materials/examples here focus on Oral consent processes. Feel free to use any of the text in this document as a template for your oral recruitment and/or consent scripts. This information may also be adapted to form the basis of invitation e-mails or letters for recruitment purposes. Please note that because all research is different, it is just about impossible for the IRB to be able to provide a template that will work for any situation without at least a little bit of editing. Therefore, if you use any of the text below as a template, you will need to edit the words to fit the particulars of your study consent process.

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# Discussion of the Required Elements of Consent

When a researcher plans to obtain verbal consent, participants must still be presented with relevant and required information so that they can make a legally effective “Informed Consent” decision based on that information. In most cases the verbal consent process can be fairly simple and will be what a person would say to a potential participant just out of politeness. Oral consent is sometimes obtained for an early part of a study that will be followed by a more formal consent process later, For example, a research assistant does a telephone screening to make sure that a prospective subject meets eligibility criteria prior to scheduling an appointment for them to come to the office/lab. In such cases, the oral presentation usually needs to deal only with the screening procedures. However, it can, when the researcher and/or IRB determines it is appropriate, contain information about the later portions of the study as well. Usually, for a verbal script, only the basic elements are necessary. The most common additional elements or requirements would be those related to costs and compensation and any other additional elements would be addressed on a case by case basis.

The required basic elements of consent that must be covered are:

1. statement that the study involves research, an explanation of the purposes of the research, and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. description of any reasonably foreseeable risks or discomforts to the subject;
3. description of any benefits to the subject or to others which may reasonably be expected from the research;
4. disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. for research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject;
5. statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject; and
6. The approximate number of subjects involved in the study

In addition to the requirements listed above, the IRB may further require the inclusion of any of the following:

1. A provision for subjects to be given a copy of the consent form, if the consent is written
2. The amount of compensation, and whether payment will be made incrementally or paid in full upon completion
3. When applicable, subjects should be informed that compensation of $600 or more paid to them within one calendar year is required to be reported to the IRS
4. Identification of the sponsor in sponsor-initiated studies
5. A disclosure statement if the Investigator is being directly compensated for conducting the study or has a significant financial conflict of interest
6. If subjects are being followed for survival, the consent form must indicate the investigator’s intent to do so
7. If blood samples will be drawn, information regarding the amount of blood that will be drawn.
8. If material such as a tumor tissue, bone marrow, blood, etc. will be turned into commercial product, subjects should also be informed that they may not benefit from the development of the commercial product

# Example Face-to-Face oral recruitment and screening consent script:

Hello my name is... I am conducting a focus group research study on... in order to learn more about… The focus groups have not been scheduled yet but will be held next month. There is no cost to you except your time and we are compensating people $20 for their participation in a two hour focus group. I was wondering if you might be interested in participating in one these research discussion groups.

If Yes- continue

If No- thank you for your time

I will need to obtain your contact information so that we can get in touch once the times and locations are scheduled but before I do this I would like to see if you meet the eligibility criteria for the study. In order to determine if you might be eligible, I would like to ask you a few brief questions. This will take no more than two minutes. While you may find a few questions a bit personal, all the answers you give will be recorded without your name so there is no risk in participating in this screening. Participation in the screening as well as any later focus groups is completely voluntary and you may choose to stop the screening at any time. You will not be penalized in any way for choosing to stop before we are finished or choosing to not be interviewed at all.

If you would like further information you can ask me at any time and I will also provide you with my contact information in case you have questions later along with that of the UB research participant advocate office that oversees this research at UB in case you have questions about your rights as a participant in research (business card or small slip of paper used for this).

Would it be okay if I asked you a few questions about … now

If No- thank you for your time, here is my contact information (give person contact information/card) in case you have any future questions or change your mind.

If Yes- here is my contact information (give person contact information/card). Do you have any questions before we get started?

# How the Elements are Covered in the Above Script

The following chart illustrates how the above script covers all basic required and some additional elements

|  |  |
| --- | --- |
| Element | Text meeting the element |
| statement that the study involves research, an explanation of the purposes of the research,  and the expected duration of the subject's participation,  a description of the procedures to be followed, and identification of any procedures which are experimental; | I am conducting a focus group research study on...  This will take no more than two minutes  ask you a few brief questions |
| description of any reasonably foreseeable risks  or discomforts to the subject; | there is no risk in participating in this screening  While you may find a few questions a bit personal |
| description of any benefits to the subject or to others which may reasonably be expected from the research; | in order to learn more about… |
| disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; | [As this screening interview is not a treatment there are no alternatives] |
| statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; | all the answers you give will be recorded without your name |
| for research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained; | [As this screening interview is not risky, this is not required]  [But we do tell them about costs and compensation for the focus groups] |
| an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and | I will also provide you with my contact information in case you have questions later along with that of the Institutional review board that oversees this research at UB in case you have questions about your rights as a participant in research.  Do you have any questions before we get started? |
| a statement that participation is voluntary,  refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled,  and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled. | Participation in the screening as well as any later focus groups is completely voluntary  You will not be penalized in any way for choosing to stop before we are finished or choosing to not be interviewed at all.    and you may choose to stop this interview at any time. |

# Example Over-the-Phone Oral Consent Script (when participants call you in response to your advertisement)

Hello thank you for calling the…study. My name is... what can I help you with?

If they are interested in participating in your interview proceed.

Thank you for your interest in our study. Before we get started, one of the ethics requirements of research is that I obtain your informed consent to participate in the study. I am going to read a brief description of the study to you, after that you can ask me any questions you may have and then if you are still interested, we can start the interview.

Our research study is about…We hope to learn about…by asking you questions about… The interview will take approximately 20-30 minutes. While some of the questions are personal, all the answers you give will be recorded without your name so there is no risk in participating in this interview. Participation in the interview is completely voluntary and you may choose to stop at any time. You will not be penalized in any way for choosing to stop before we are finished or choosing to not be interviewed at all. There is no cost to you except your time and we are compensating people a $10 gift card to… for their participation in the interview. If you are interested in the gift card, I will get your mailing address later.

If you have questions, you can ask me at any time and you already have our contact phone number 645-XXXX. If you have questions about your rights as a participant or concerns or complaints about the study and wish to speak with someone who is not directly associated with the study, you can contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu)

Do you have any questions at this time?

If Yes- answer questions

If No- Continue

May we begin the interview now?

If Yes- continue

If No- thank you for your time

# Example Over-the-Phone Oral Consent Script (when you call participants)

[Note that the nature of your contact may result in the need for adaptation to this script based on whether or not the person is expecting your call and if there is a potential invasion of privacy related to the call]

Hello my name is... from the University at Buffalo.

[Occasionally it may be necessary to verify who you are speaking with] I am trying to reach Mrs. XXX?

I am calling because we are conducting a research study on…that you may be interested in. [Provide some information on why you are calling them, i.e. did they respond to you and give their contact information, are they a member of a group that you obtained contact information for, did someone else give you their name as a part of a snowball sample.] If you are interested and this is not a good time, I can call back or leave you with my contact information so that you can call me.

Is this a good time?

Thank you for your interest in our study. Before we get started, one of the ethics requirements of research is that I obtain your informed consent to participate in the study. I am going to read a brief description of the study to you, after that you can ask me any questions you may have and then, if you are still interested, we can start the survey.

Our research study is about…We hope to learn about…by asking you questions about… The survey will take approximately10 minutes. While some of the questions are personal, all the answers you give will be recorded without your name so there is no risk in participating in this interview. Participation in the survey is completely voluntary and you may choose to stop at any time. You will not be penalized in any way for choosing to stop before we are finished or choosing to not participate at all. There is no cost to you except your time and we are compensating people a $5 gift card to… for their participation in the survey. If you are interested in the gift card, I will get your mailing address later.

If you have questions, you can ask me at any time. If you have questions at some later date, our contact phone number is 645-XXXX. If you have questions about your rights as a participant or concerns or complaints about the study and wish to speak with someone who is not directly associated with the study, you can contact the research participant advocate at 716-888-4845 or [researchadvocate@buffalo.edu](mailto:researchadvocate@buffalo.edu)

Do you have any questions at this time?

If Yes- answer questions

If No- Continue

May we begin the survey?

If Yes- continue

If No- thank you for your time

# Invitation announcement to a group or class where an information sheet will be distributed by the research team.

[Note that this announcement does not cover all elements because the information sheet will do so.]

Hello my name is... I am conducting a research study on... in order to learn more about…the study consists of a 5 minute survey. When I pass out the surveys, if you are interested in participating, please take one, read the information sheet describing the study that is on top of the survey, tear it off and retain this top sheet for your records. If after reading the information sheet you still wish to participate please fill out the survey and place it the envelope on the front desk as you leave. Do not put your name anywhere on the survey. If you have any questions, you can feel free to ask me now or contact me later at the e-mail address or phone number on the information sheet.

# Invitation announcement to a group or class by a person who is not a part of the research team.

[Note that this announcement does not cover all elements because the information sheet will do so.]

A researcher has asked me to pass along some information on an opportunity that you may want to take advantage of. I am not involved with this project but wanted to make this available to you in case you are interested. If you are interested in participating, you can access the study or contact the rese4rcher by…If you have any questions about the study, you should contact the principal investigator whose contact information can be accessed on the consent document/information sheet/advertisement.