

**University at Buffalo Institutional Review Board (UBIRB)**

Office of Research Compliance | Clinical Research Institute on Addictions

1021 Main Street | Buffalo, NY 14203

UB Federalwide Assurance ID#: FWA00008824

##  ***[Note- do not edit headers or footers of this document]***

## ***Indicate if this consent document will be used for adults, parental permission, or assent (e.g. entitle it “Adult Consent to Participate in a Research Study”; “Parent Permission for a Child to Participate in a Research Study” etc.)***

## Title of research study: ***[insert title of research study here with protocol number, if applicable. The title must match the study title in CLICK.]***

## Version Date: ***[insert a version date here corresponding to the date of submission to the IRB]***

## Investigator: ***[insert name of principal investigator]***

## Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

## Why am I being invited to take part in a research study?

You are being invited to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research.]

## What should I know about a research study?

1. Someone will explain this research study to you.
2. Whether or not you take part is up to you.
3. You can choose not to take part.
4. You can agree to take part and later change your mind.
5. Your decision will not be held against you.
6. You can ask all the questions you want before you decide.

## Why is this research being done?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

Note: If this research involves an investigational drug or device (i.e. the drug or device is not approved by the FDA for the indication (i.e. the purpose and/or the population for which it is used in this study)), this information should be included in this section.

## How long will the research last and what will I need to do?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

You will be asked to \_\_\_\_\_\_\_\_\_ ***[include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]***

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

***Is there any way being in this study could be bad for me?***

***[This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study.]***

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

***Will being in this study help me in any way?***

***[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document.]***

***[Include if there are benefits to participation. Otherwise delete.]*** We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***[First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]***

***[Include for a study with no benefits to participation. Otherwise delete.]*** There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. ***[Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]***

***[Include for research involving prisoners.]*** Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## What happens if I do not want to be in this research?

Participation in research is completely voluntary. You may choose not to enroll in this study. [Include if there are alternatives other than participating. Otherwise delete.] Instead of being in this research study, your choices may include: [List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]

***[Include if there are no alternatives other than participating.]*** Your alternative to participating in this research study is to not participate.

***Detailed Information:*** The following is more detailed information about this study in addition to the information listed above.

## Who can I talk to?

**If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at** [Insert contact information for the research team]. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). An IRB is a committee that provides ethical and regulatory oversight of research that involves human subjects. You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:

1. You have questions about your rights as a participant in this research
2. Your questions, concerns, or complaints are not being answered by the research team.
3. You cannot reach the research team.
4. You want to talk to someone besides the research team.
5. You want to get information or provide input about this research.

## How many people will be studied?

[Delete the second half of sentence if not multi-center.]

We expect about \_\_\_\_\_ people here will be in this research study out of \_\_\_\_\_ people in the entire study nationally ***[or internationally].***

## What happens if I say yes, I want to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The drugs or biologics that will be given to the subject
* All devices that will be used
* All hospitalizations, outpatient visits and telephone or written follow-up
* The length and duration of visits and procedures
* If blood will be drawn, indicate the amount [in English units] and frequency
* With whom will the subject interact
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* How often procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard care
* What procedures are part of regular medical care that will be done even if the subject does not take part in the research
* ***When applicable, indicate if a pregnancy test will be administered and to whom the results will be disclosed.***
* ***Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen***
* When applicable indicate that the subject will be contacted for future research.

[Include for a clinical trial that involves randomization. Otherwise delete.] The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [equal/one in three/etc.] chance of being given each treatment. [For double-blinded research add] Neither you nor the study doctor will know which treatment you are getting. [For single blinded research add] You will not be told which treatment you are getting, however your study doctor will know.

## What are my responsibilities if I take part in this research?

[Delete this section if there are no subject responsibilities.]

If you take part in this research, you will be responsible to: [Describe any responsibilities of the subject.]

## What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research, [Describe the adverse consequences.] If you decide to leave the research, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the subject, if any.]

[Include for FDA-regulated research. Otherwise delete.] If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. ***[Note: The consent document cannot give the subject the option of having data removed on an FDA-regulated study.]*** If you agree, this data will be handled the same as research data. ***[Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.]***

***[For research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]***

## Is there any way being in this study could be bad for me? (Detailed Risks)

[If there are no known risks including confidentiality issues then state:] There are no known risks associated with these procedures.

[The risks of procedures may be presented in a table form.

Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.

* Physical risks
* Psychological risks
* Privacy risks
* Loss of confidentiality
* Legal risks
* Social risks
* Economic risks

If identifiable information is collected, there is a risk of loss of confidentiality, which should be included in this section. See suggested verbiage:] There is a small chance that someone who is not authorized could see your private study information. We are taking steps so that does not happen. More information can be found in “What happens to the information collected for the research?”]

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.] In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise delete.] The procedures in this research are known to hurt a pregnancy or fetus in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Omit the previous sentence if there are no known risks.] The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. [Omit the previous two sentences for research whose risk profile in pregnancy is well known.] You should not be or become pregnant [include as applicable “***or father a baby”]*** while on this research study.

***[***Include for research that ***may result in additional costs to the subjects. Otherwise delete.]*** Taking part in this research study may lead to added costs to you. [Describe what these costs are.]

[Include for a clinical trial. Otherwise delete].

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research is FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[Describe study-specific methods to maintain the confidentiality of records identifying the participant. ***Explain where the data or specimens will be stored, who will have access to the data or specimens, whether they will be stored in a de-identified manner or linked/associated with identifiers, and how long the data or specimens will be retained.]***

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

***[Include if data or specimens will be retained after the study for future research.]***  Your data or specimens will be retained after the study for future research. ***[Explain where the data or specimens will be stored, who will have access to the data or specimens, whether they will be stored in a de-identified manner or linked/associated with identifiers, and how long the data or specimens will be retained.]***

***[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:]*** If information that identifies you is removed from your study information, it could be used for future research studies or given to other researchers without your additional consent. ***[OR]*** Your study information will not be used for future studies, even if information that identifies you is removed.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the study sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include for FDA-regulated controlled drug and device trials (except Phase I drug trials), FDA-regulated pediatric post-market surveillance trials of devices, or if this is otherwise relevant to your study. Otherwise delete.] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

## Can I be removed from the research without my OK?

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the subject may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

[Include sub-section below for sponsored research. Otherwise delete.]

**Who is paying for this research?**

This research is being funded by [Insert name of sponsor].

***[Include sub-section below if explanation of medical costs is necessary. Include the appropriate language as needed.]***

**What medical costs am I responsible for paying?**

***[Include if subject will be paying for standard of care medical expenses.]*** The tests or procedures required by the research study that would not otherwise be part of your standard care will be covered by the sponsor of this study. The tests or procedures that would be provided to any patient with your condition, regardless of whether he/she was participating in the research study, are considered standard care and will be billed to you or your private or public health insurance company. You will still be responsible for the cost of your usual ongoing medical care, including deductibles and co-payments. If you have any questions about what expenses are covered by the sponsor and what expenses are the responsibility of you or your health insurance provider, please contact a member of the study staff and/or your health insurance provider.

***[Include for a device study where the study device and procedures will be paid by subject and insurance companies. Please modify the language below to match the actual billing requirements for study.]*** Your private or public health insurance company (for example, Medicare) will be billed for the study device, the procedure to implant the device, and any other necessary procedures required by the study. You will be responsible for paying for any co-payment, co-insurance, or deductible.

***[Include if subject will not be paying for any medical expenses.]*** You and your private or public health insurance company will not be charged for any of the tests or procedures done for this study.

[Include ***sub-section below*** for research involving more than minimal risk or involves intervention in medical care. Otherwise delete:]

**Who will pay for my medical care if participating in this research harms me?**

[Include for research involving more than minimal risk or involves intervention in medical care. Otherwise delete.] It is important that you tell your study doctor if you feel that taking part in this study has injured you or caused you to become ill.

You will receive medical treatment if you are injured or become ill as a result of this study. Your doctor will explain the treatment options to you and tell you where you can get treatment.

***[Insert the name of applicable institution(s)-usually the University at Buffalo, Kaleida Health and/or ECMC]*** makes no commitment to provide free medical care or payment for any unfavorable outcomes that result from your participation in this research. Medical services will be billed at the usual charge and will be your responsibility or that of your third-party payer but you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research including ***[the University at Buffalo, Kaleida Health and/or ECMC]****.*

[Include below for industry sponsored research. Typically Phase 4, post-market, observational, or registry studies do not require injury language. If you are unsure if your study requires injury language, call the Clinical Research Office for assistance.] ***[Use the following to describe compensation available for research related injury.]***

However, the Sponsor of this study will pay for the reasonable and necessary costs of medical care for research-related illness or injury where the illness or injury:

* results from this research study and not from a pre-existing medical condition, unless the condition was worsened by the study; and
* did not result from the negligence or misconduct of the study personnel, or their unjustified failure to follow the study protocol or instructions; and
* is directly related to the study drug or device or study procedure

[Include for all studies when “Who will pay for my medical care if participating in this research harms me?” subsection applies.] By accepting medical care or accepting payment for medical expenses, you are not waiving any of your legal rights.

**Will I get paid for my participation in this research?**

[Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[Include if subjects will not be paid. Otherwise delete.] You will not be paid for participating in this study.

***[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise delete.]*** Military personnel should check with their supervisor before accepting payment for participation in this research.

***[Delete entire section if the U.S. Bank Card program is not being used as a payment method. If the study is unable to utilize the US Bank Card program, the study staff will contact the research foundation for other payment options. For more information http://www.buffalo.edu/research/research-services/administering-your-award-set-up-to-closeout/managing-your-award.html ]***

***[When U.S. Bank Cards are being used as a payment method, include the description below that matches the type of card that you are using. There are three options. Delete the options that you are not using.]***

The Study Card Program Group, under The University at Buffalo’s Office of Financial Management, in conjunction with U.S. Bank, will manage study compensation by providing a Reloadable Focus Blue Card, which is a prepaid debit card. When you complete a visit, the amount outlined in the Informed Consent Form will be automatically approved and applied to your U.S. Bank Focus Blue Card balance. If you receive your bank card at the study visit, your payment will be available no later than the next business day. The Study staff will provide you with additional information about how the bank card works. In order for U.S. Bank to be able to reimburse you using the Focus Blue Card, only your first and last name (required), physical address (required), and birth date (required) ***[delete if you were given an exception to the birth date requirement]*** will be shared with U.S. Bank. The Study Card Program Group, under The University at Buffalo Office of Financial Management, will also have access to this information ***[delete the remainder of this statement if you were provided with your own Adjustment Account]*** and UB affiliated Researchers and staff, within the same university department as the Investigator of this study, may also have access to this information. By agreeing to use the U.S. Bank Card service, you are authorizing the release of this information to U.S. Bank and authorizing access to this information to Study Card Program Group, under The University at Buffalo Office of Financial Management ***[delete the remainder of this statement if you were provided with your own Adjustment Account*]** and other UB affiliated Researchers and staff. No protected health information will be shared with the U.S. Bank or the Study Card Program Group.

**Please note that a fee of $2 per month will be deducted from your card balance after 365 days of card inactivity. Your card will be considered activated as of today's date.**

**Please also note that U.S. Bank may use your personal contact information to market the bank’s other products and services to you. You may limit U.S. Bank’s direct marketing to you by visiting U.S. Bank online at http://www.usbank.com/privacy.**

***[If the U.S. Bank Card is being utilized as the study’s payment method and the study is not offering an alternative payment option, then delete the following two lines]***

By initialing here, you affirm to utilize the US Bank Card program for payment. \_\_\_\_\_

By initialing here, you choose not to utilize the US Bank Card program for payment and you will be paid by ***[insert the alternative payment option approved by the IRB]*** \_\_\_\_\_\_\_\_

  ***[or]***

The Study Card Program Group, under The University at Buffalo Office of Financial Management, in conjunction with U.S. Bank, will manage study compensation by providing a One-Time Digital Reward Card. When you complete a visit, the amount outlined in the Informed Consent Form will be automatically approved and applied to your digital reward. The Study staff will provide you with additional information about how the digital reward card works. In order for U.S. Bank to be able to reimburse you using the One-Time Digital Reward Card, your email address will be collected and provided to U.S. Bank.The Study Card Program Group, under The University at Buffalo Office of Financial Management, will also have access to this information ***[delete the remainder of this statement if you were provided with your own Adjustment Account]*** and UB affiliated Researchers and staff, within the same university department as the Investigator of this study, may also have access to this information. By agreeing to use the U.S. Bank Card service, you are authorizing the release of this information to U.S. Bank and authorizing access to this information to the Study Card Program Group, under The University at Buffalo Office of Financial Management ***[delete the remainder of this statement if you were provided with your own Adjustment Account*]** and other UB affiliated Researchers and staff.

**Please note that U.S. Bank may use your personal contact information to market the bank’s other products and services to you. You may limit U.S. Bank’s direct marketing to you by visiting U.S. Bank online at http://www.usbank.com/privacy.**

***[If the U.S. Bank Card is being utilized as the study’s payment method and the study is not offering an alternative payment option, then delete the following two lines]***

By initialing here, you affirm to utilize the US Bank Card program for payment. \_\_\_\_\_

By initialing here, you choose not to utilize the US Bank Card program for payment and you will be paid by ***[insert the alternative payment option approved by the IRB]*** \_\_\_\_\_\_\_\_

  ***[or]***

The Study Card Program Group, under The University at Buffalo Office of Financial Management, in conjunction with U.S. Bank, will manage study compensation by providing a One-Time Plastic Reward Card. When you complete a visit, the amount outlined in the Informed Consent Form will be automatically approved and applied to your One-Time Plastic Reward. If you receive your bank card at the study visit, your payment will be available no later than the next business day. The Study staff will provide you with additional information about how the One-Time Plastic Reward Card works. No personal information will be collected in order for U.S. Bank to be able to reimburse you using the One-Time Plastic Reward Card.

**Please note that an inactivity fee of $2 per month will be deducted from your card balance after 365 days of card inactivity.  This is in addition to a $2 per month maintenance fee that will be deduced from any remaining balance beginning 12 months from the date of your card's activation. You card will be considered activated as of today’s date.**

**Please also note that U.S. Bank may use your personal contact information to market the bank’s other products and services to you. You may limit U.S. Bank’s direct marketing to you by visiting U.S. Bank online at http://www.usbank.com/privacy.**

***[If the U.S. Bank Card is being utilized as the study’s payment method and the study is not offering an alternative payment option, then delete the following two lines.]***

By initialing here, you affirm to utilize the US Bank Card program for payment. \_\_\_\_\_

By initialing here, you choose not to utilize the US Bank Card program for payment and you will be paid by ***[insert the alternative payment option approved by the IRB]*** \_\_\_\_\_\_\_\_

***[When applicable include the following language.]*** If you receive a single gift card deposit of $100 or greater (this does not include U.S. Bank Prepaid Debit Cards), you will be asked to complete an IRS Form W-9. This form will be held confidentially by the research team and those responsible for administering research funds.

Payments that you receive for your participation in this research are considered taxable income. If the amount of payment that you receive reaches or exceeds $600.00 in a calendar year, you will be issued a form 1099.

[Include ***sub-section below*** for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.]

**What happens when I’m released from incarceration?**

If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

***[Include sub-section below for a clinical trial.]***

**What are my alternatives to participating in this research study?**

Instead of being in this research study, your choices may include: ***[include alternatives.]*** The important risks and possible benefits of these alternatives include: ***[Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]***

***[Include sub-section below when applicable.]***

**What will happen to my information and samples?**

Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans ***[or replace with plans when using identifiable information/samples]*** to tell you, or to pay you, or to give any compensation to you or your family.

***[Include sub-section below when applicable.]***

**What will I be told about clinically relevant research results?**

***[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens.]*** Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers [will/will not ***(select one)***] contact you to let you know what they have found.

***[Include when applicable.]*** If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

***[DELETE entire HIPAA section if HIPAA does not apply. Note: HIPAA Authorizations for the release of psychotherapy notes may not be combined with other authorizations, such as informed consent. HIPAA Authorizations for psychotherapy notes must be stand-alone documents.]***

**HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes**

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information and to use or disclose it for the purposes of the research described in this document. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

1. **What individually identifiable health information will be collected about you as part of this research study?**

***[Check all that apply and DELETE any option that does not apply]:***

\_\_\_\_\_ Information from your full medical records: \_\_\_\_\_\_\_\_***[Provide a description of the information that will be collected in a specific and meaningful fashion]***

\_\_\_\_\_ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

**B. Who is authorized to create or provide this information for research use? *[Must include all legal entities creating or providing the information to the researcher; Check all that apply and delete the option(s) that do not apply:]***

\_\_\_\_\_ KALEIDA Health, Buffalo NY

\_\_\_\_\_ ECMC Healthcare Network, Buffalo NY

\_\_\_\_\_ UBMD Clinical Practice Plan(s) (identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_ University at Buffalo School of Dental Medicine

 \_\_\_\_\_ Principal Investigator or designee ***[May only be checked when data is being created by the UB researcher or designee as part of their UB job function; this cannot be checked for data created or provided by legal entities external to UB that the researcher may also belong to, such as UBMD practice plans or affiliated hospitals.]***

\_\_\_\_\_ Other(s) (identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**C. Who is authorized to receive the information from the information providers identified in (B)?**

***[Check all that apply and DELETE the option(s) that do not apply]:***

\_\_√\_ Principal Investigator or designee

\_\_\_\_\_ Other(s) (identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**D. With whom may your protected health information be shared?**

Your health information may be shared with others outside of the research group for purposes directly related to the conduct of this research study or as required by law, including but not limited to:

 ***[Check all that apply and DELETE the option(s) that do not apply]:***

\_\_\_\_\_ Clinical staff not involved in this research study who may become involved in your care if it is potentially relevant to your treatment

\_\_\_\_\_ The sponsor of this research study ***(list specific sponsor),*** cooperative group, etc., or its agents ***[insert list]***:

\_\_\_\_\_ The organization(s) responsible for administering this research ***[insert list – e.g., Research Foundation of SUNY, UB Foundation Services, Inc.]***:

\_\_\_\_\_ Other medical investigators/centers/institutions participating in this research study ***[insert list of centers, institutions]****:*

\_\_\_\_\_ The following ***[insert list of all other specific organizations, people, etc.]***:

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law.All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

Although safeguards are in place to prevent accidental disclosure of your information beyond the purposes described above, the information disclosed through this authorization is no longer protected by HIPAA. There is the potential for this information to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

**E. How long are the information providers listed in (B) authorized to provide your information for this research project?**

***[Choose one (a, b, or c) THEN delete the other 2 options]***

\_\_\_\_\_ a. This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

***[-or-]***

\_\_\_\_\_ b. This authorization will expire at the end of the research study. After that time, this authorization may not be used to acquire additional information about you.

***[-or-]***

\_\_\_\_\_ c. This authorization will expire and your protected health information will no longer be collected for the purposes of this study after ***[date]***

 ***[ALSO check (d) if applicable. DELETE (d) if not applicable.]***

\_\_\_\_\_ d. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.

**F. What are your rights after signing this authorization?**

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

***[Insert name and address of individual or position associated with the research study that will be responsible for handling such requests.]***

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information. ***[Providing copies of such written authorization revocations to the institutions providing information, which are identified in section B, is mandatory unless their contact information has been provided in the previous paragraph]***

**G. What will happen if you decide not to sign this authorization?**

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.

[The following sections in other parts of this template must be present in order for this document to constitute a valid HIPAA Authorization:

* A description of each purpose (the research purpose) for the disclosure of information being requested from entities in section B. Addressed in “Title of research study” section.
* Signature of the individual and a date. If the authorization is signed by a personal representative of the individual, a description of such representative’s authority to act for the individual must also be provided. Addressed in “Signature Block” sections.
* Copies of every signed authorization must be provided to each external institution that will rely upon them to release their information to researchers. Consult with those institutions for the procedures governing how to accomplish this.]

[For studies where the consent form will be uploaded into the EMR, include the following language:]

Should you agree to participate in this research, this consent document will be placed in

your medical record.

[There are four signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB requires that you make separate consent documents for each signature page to be used. (Exception: one consent document may be used when the IRB approves the use of an LAR signature page & assent of an adult legally unable to consent.)]

[Omit the signature page if there is no written documentation of consent.]

**Signature Block for Capable Adult**

|  |
| --- |
| Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. \*Note: you must have prior IRB approval to utilize the short form of consent* documentation*.]***

|  |
| --- |
| **□** My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
|  |
| Printed name of person witnessing consent process |

**Signature Block for use with the LAR of an Adult Unable to Consent**

|  |
| --- |
| ***[When approved by the IRB, this section should be used if the participant does not have the decisional capacity to consent to his/her participation.]*** The following are considered to qualify as Legally Authorized Representatives and may act on behalf of decisionally incapacitated adults in New York State (listed in descending order of priority). Please select the category that describes your relationship with the study participant. [CHECK ONE][ ]  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; or[ ] A close friend: “an adult (l8 years or older) who has a close personal relationship with the subject and provides a signed written statement that they are a close friend of the subject and that they have maintained such regular contact with the subject as to be familiar with the subject’s activities, health, religious or moral beliefs, and some means of corroborating such familiarity”. Briefly explain your relationship as a “close friend” of the study participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Your signature documents your permission for the named subject to take part in this research. |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |
|  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

|  |  |  |
| --- | --- | --- |
| ***[The Assent Box, which is applicable to the subject named in this consent document, must be checked.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

 |

***[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. Note: you must have prior IRB approval to utilize the short form of consent documentation.]***

|  |
| --- |
| **□** My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
|  |
| Printed name of person witnessing consent process |

**Signature Block for Parental Permission**

|  |
| --- |
| Your signature documents your permission for the named child to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise.**[Note: if the IRB determines that the permission of two parents is required, you will be directed to add a second parent signature line.]** |

 ***[The Assent Box, which is applicable to the subject named in this consent document, must be checked]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent  |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***[Check the below box and obtain the signature of the witness if a witness will observe the consent process, e.g. illiterate subjects or short form of consent documentation. \*Note: you must have prior IRB approval to utilize the short form of consent documentation.]***

|  |
| --- |
| **□** My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
|  |
| Printed name of person witnessing consent process |

**Signature Block for Assent of Adults who are Legally Unable to Consent**

***[When the IRB Requires, add the following block if assent will be obtained from an adult who is legally unable to consent]***

|  |
| --- |
| Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |
|  |  |
|  |  |  |
| Signature of person obtaining assent |  | Date |
|  |  |  |
| Printed name of person obtaining assent |  |  |