## Informed Consent – Biomedical Template

 **Prospective Biomedical Consent Template**: Below is the template for a prospective biomedical project informed consent form. Please utilize this template as a guide for all prospective biomedical consent forms. The italicized/red text should be replaced with relevant study information or deleted if not applicable. Please be sure to upload your completed informed consent as a separate document in the IRBNet submission.

Informed Consent to Participate in Research [If applicable] and Authorization to Collect, Use, and Share your Health Information

Information to Consider Before Taking Part in this Research Study

**Title:** ***[Title of study, as it appears on the IRB application, grant/contract, or sponsored protocol. Best to bold title so it is more visible.]***

**Study IRBNet # \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***[The 2018 Common Rule requires consent documents to begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding why one might or might not want to participate in research. The first page of this template is designed to assist you with drafting that key information. For minimal risk research, the key information (the “Overview” herein) may comprise the majority of the consent document. Information in the Overview does not have to be reiterated in the sections below the Overview.]***

**Overview:** You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate. The sections in this Overview provide the basic information about the study. More detailed information is provided in the remainder of the document.

Study Staff: This study is being led by *[insert name of PI]* who is a *[list PI’s role]* at/in *[list name of PI’s employer].* This person is called the Principal Investigator. *[The following sentence should be included if there is a faculty advisor involved] [He/She]* is being guided in this research by *[insert name of faculty advisor]*. Other approved research staff may act on behalf of the Principal Investigator.

Study Details: This study is being conducted at*[insert location at which research will be conducted; if at LRH please put “Lakeland Regional health Systems, Inc.” here]* and is supported/sponsored by *[insert name of sponsor].* The purpose of the study is to *[insert brief summary of purpose]*. *Briefly explain in a few sentences, in lay language (understandable at a 7th grade reading level), the purpose of the study and the expected duration of the prospective subject’s participation. Example: The purpose of this study is to find out.... Tell the person, in lay terms, how the research will be carried out and whether the research includes an experimental drug, intervention, or procedure; if applicable, state whether or not the investigational product has been tested in humans before.* *[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.

Subjects: You are being asked to take part because *[explain in lay language the condition(s) or situation that makes the prospective subject eligible for the research. Example: We are asking you to take part in this study because you have had a heart attack. We want to find out if this treatment will help people who have had heart attacks.]*.

Voluntary Participation: Your participation is voluntary. You do not have to participate and may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. Alternatives to participating in the study include: *[If there are alternatives, describe the procedures/treatments/interventions that the subject could receive such as taking a different course of treatment, etc.].*

Benefits, Compensation, and Risk: We do not know if you will receive any benefit from your participation. [*If applicable:* There is no cost to participate.] You *[will /will not]* be compensated *[enter amount if compensated]* for your participation. [*If applicable:* This research is considered minimal risk. Minimal risk means that study risks are the same as the risks you face in daily life.] The most common and most serious risks that may be related to taking part in this research include *[For example most common (occurring in >10% or 20% of the time) and most serious (those that lead to hospitalization, disability or death, etc.).]*

Confidentiality: Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential.

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

### Why are you being asked to take part?

*[Include additional information regarding the purpose of the study and why subjects are being asked to take part beyond what is included in the Overview section.]* This study includes the use of a *[insert drug/device]* for the treatment of *[insert condition]. [Insert drug/device name]* is not approved by the Food and Drug Administration (FDA) for the treatment of *[insert condition]*. It is being used as part of this research study to find out *[insert reason for use of test article in this study]*.

### Study Procedures: What will happen during this study?

*Explain in lay terms what will happen during the study. Make sure your explanation addresses what is being performed as standard of care and what is being performed strictly as part of the research. Explain what may happen at each study visit and at what intervals study visits will occur. Explain the study visit timetable – you may want to complement this description with a table or timeline*. *Explain what the subject will need to do before the first study visit, if anything. For example: You will need to fast (go without food) for 8 hours before your visit.*

At each visit, you will be asked to:

* *Describe the tests and procedures that will need to be performed, including the purpose of each. If there are multiple visits with different procedures occurring at each visit, it is suggested to list each in a separate paragraph and/or as bulleted items.*
* *If blood will be drawn, indicate the amount (in English units) and frequency.*
* *Explain the questions that will be asked and/or interviews/surveys that may be conducted.*
* *Explain the drug, device, or biologic you will use. How much of a dose you will give the person and how it will be administered.*
* *List experimental procedures and therapies and identify them as such.*
* *Explain whether subjects’ regular treatment will change if they take part in the research and if so, how it will change.*
* *If the final visit is different from the others, explain what will happen at that visit.*
* *If audio- or videotaping will be used, the subject must be informed of taping and, if applicable, given the option to agree to be recorded. Explain who will have access to these tapes, whether the information will be identifiable, how long the tapes will be maintained, and how they will be destroyed.*

*[If your study involves storing blood/tissue for future research, include the following]*

In addition to the procedures outlined above, we are asking you to allow us to obtain and store samples of your *[blood/tissue]* for use in future research. These samples may be used for research on your disease or condition and others to assist in the development of new treatments. *[When storing samples for future use, specify where samples will be stored, by whom, for how long, when/how they will be destroyed, and if/how they can be withdrawn by the subject.]* We will take some of your *[blood/ tissue]* in addition to that which has already been obtained for research purposes. *[If extra blood or tissue is being taken, explain how much extra will be taken and how this will impact the procedures for obtaining the samples. Be sure to include any additional risks the collection of blood or tissue will have on the subject.]*

In addition to your sample being used for this study and future research, we would like to share it with other researchers. We will code your sample so that the researcher who uses it for other purposes does not know your identity. We will not release the code that links your sample to your personal identifying information for any reason.

***[If your study involves genetic or genomic testing, use HRP – Genetic/Genomic Consent Addendum as a separate consent.]***

### Total Number of Subjects

About *[number of subjects]* individuals will take part in this study at Lakeland Regional Health (LRH). [*If the study includes multiple sites, add the following statement:* A total of *[number of subjects]* individuals will participate in the study at all sites.]

### Alternatives / Voluntary Participation / Withdrawal

*[Use whichever statement is applicable:]*

You do not have to participate in this research study. *[This statement is sufficient if there are no alternatives for the subject.]*

*[Or]*

Alternatives to participating in the study include: *[If there are alternatives, describe the procedures/treatments/interventions that the subject could receive such as taking a different course of treatment, etc.]*

You should only take part in this study if you want to volunteer. You should not feel that there is any pressure to take part in the study. You are free to participate in this research or withdraw at any time. There will be no penalty or loss of benefits you are entitled to receive if you stop taking part in this study. *[If subjects are students or employees, include as applicable: “decision to participate or not to participate will not affect your student status (course grade) or job status.”]*

You can decide after signing this informed consent document that you no longer want to take part in this study for any reason at any time. If you decide you want to stop taking part in the study, tell the study staff as soon as you can.

* We will tell you how to stop safely. *[Specify if there are any medical consequences of a subject’s decision to withdraw from the research.]*
* If you decide to stop, you can continue getting care from your regular doctor.
* *[Describe the procedures for the orderly termination of participation by the subject.]*

Please note, even if you want to stay in the study, there may be reasons we will need to withdraw you from the study. You may be taken out of this study if we find out it is not safe for you to stay in the study or if you are not coming for the study visits when scheduled. We will let you know the reason for withdrawing you from this study.

### Benefits

*[Use whichever statement is applicable:]*

You will receive no benefit(s) by participating in this research study.

*[Or]*

We are unsure if you will receive any benefits by taking part in this research study.

*[Or]*

The potential benefits of participating in this research study include:

*[List and explain any anticipated benefits the person may have from taking part in this study. Please note that compensation for participation IS NOT considered a benefit.]*

### Risks or Discomfort

*[Use whichever statement is applicable:]*

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day. There are no known additional risks to those who take part in this study.

 *[Or]*

The following risks may occur:

* *List and explain the physical, psychological, and social risks/discomforts and when known, indicate the relative chances of occurrence for each.*
* *List and explain the risks/discomforts associated with the experimental drug, device, procedure (including radiation risks), or biologic, and when known, indicate the relative chances of occurrence for each.*
* *When applicable, explain any risks that might be associated with a breach of confidentiality, including risks to employability, insurability, and/or criminal and civil liabilities.*
* *When applicable, include a statement on reproductive risks.*

*[Include language regarding contraception as appropriate for females:]*

Being a part of this study while pregnant may expose your unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a pregnancy test will be performed and it must be negative before you can continue in this study. If sexually active, you must agree to use appropriate contraceptive measures for the duration of the study and for*[specify if applicable]*months/years afterward. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B™, sold for emergency use after unprotected sex, are not acceptable methods for routine use. If you do become pregnant during this study or if you have unprotected sex, you must inform your study physician immediately.

*[Include language regarding contraception as appropriate for males:]*

Your participation in this research may damage your sperm, which may cause harm to a child that you father while on this study. Such harm may be currently unforeseeable. If you are sexually active and have not had a vasectomy, you must agree to use a medically acceptable form of birth control in order to be in this study and for *[specify if applicable]*months/years afterward. Medically acceptable contraceptives include a condom used with a spermicide. You should inform your partner of the potential for harm to an unborn child. She should know that if pregnancy occurs, you will need to report it to the study doctor, and she should promptly notify her doctor.

### Compensation

**[If compensation for participation is available, include the dollar amount per visit and payment upon study completion of study activities. Explain any other costs you may be able to remunerate, such as parking fees, bus or taxi fare; childcare costs, or time away from work.]**

You will be compensated *[enter amount]* if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be compensated *[enter $ amount here]* for each study visit you complete.

*[LRH investigators must include the following for studies where compensation is more than $75 per payment or $300 per calendar year:]*

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not tell them what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

**[If no payment for participation is available, include the following:]**

You will receive no payment or other compensation for taking part in this study.

**[If commercial development is expected to arise from the study, include the following:]**

**The findings from this research, which may include your biospecimens (even if identifiers are removed), may result in and be used for the future development of products that are of commercial value and/or profit. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.**

### Costs

*[Use only the following statements that apply to your research]*

It *[will / will not]* cost you *[amount / anything]* to take part in the study.

*[If the costs of the research are being paid by the study sponsor the following statement is required:]*

There will be no additional costs to you as a result of being in this study. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

*[If there are costs associated with the study:]*

You or your insurance company will be expected to pay the costs for the following: *[list all procedures which will be the responsibility of the subject outside of routine care.]*

### Compensation for Research Related Injuries

*[must be included for all studies that are greater than minimal risk]*

If you are experiencing an emergency, call 911. If you believe you have been harmed as a result of participating in this study, you should call *[PI’s name]* at *[insert telephone number]* as soon as possible. Lakeland Regional Health has not set aside money to pay for illness or injury that may result from your participation in research.

*[If a study is industry-sponsored, please include the following language.]* The sponsor of this research has agreed to pay LRH for the cost of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury as a direct result of participation in the Study in accordance with the protocol. Any costs not reimbursed by the sponsor or your health insurer will be billed to you.

*[If the study is investigator initiated or not sponsored, please include the following language.]* The cost of illness or injury that may result from your participation in research will be billed to your insurance company or to you in the event you do not have health insurance.

*[Include for all studies regardless of funding/sponsor]* Before you agree to take part in this study, you may want to find out whether your insurance will cover injuries that result from taking part in research. You may be responsible for any deductible, co-insurance, or co-payments that result from such care. If you are injured, Lakeland Regional Health has also not set aside money for lost wages, discomfort, or disability you may experience as a result of a research-related injury. By signing this form, I acknowledge Lakeland Regional Health will not pay for the costs of medical care and treatment, or any associated costs such as lost wages, due to injury arising from participation in this study. You do not give up your legal rights by signing this form. In addition to contacting the study investigator, you should also contact the LRH Institutional Review Board (IRB) at 863-687-1100 x7214 or IRB@myLRH.org if you believe you have been injured as a result of taking part in this study.

### Affiliate Statement

*[If applicable, insert your Institution-approved injury statement here.]*

### Sponsor Statement

*[If applicable, insert the Sponsor Statement consistent with the industry contract here.]*

### Conflict of Interest Statement

*[Include the language outlined in your COI Management Plan. If there are no conflicts, delete this section.]*

### Privacy and Confidentiality

We will do our best to keep your records private and confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Certain people may need to see your study records. These individuals include:

* The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff. *[Modify to match your study. Do not list the actual names of individuals, just their job class.]*
* Certain government and institutional people who need to know more about the study. For example, individuals who provide oversight on this study may need to look at your records. This is done to make sure that we are doing the study in the right way. They also need to make sure that we are protecting your rights and your safety.
* Any agency of the federal, state, or local government that regulates this research. This includes *[List all federal, state, or local agencies/individuals authorized to access records including:* the Department of Health and Human Services (DHHS) and the Office for Human Research Protection (OHRP).*]*
* The LRH Institutional Review Board (IRB) and its related staff who have oversight responsibilities for this study, and staff in LRH Corporate Integrity Services.
* *[Include the name the sponsor(s) or others. If not applicable, please delete this item.]*

*[Please include one of the following statements if the research involves the collection of identifiable private information or biospecimens.]*

Your identifiers might be removed from your private records or your samples. Your information or samples could be used and/or distributed to another investigator for future research studies without additional consent from you or your Legally Authorized Representative *Or;*

Your information or samples collected as part of the research, even if identifiers are removed, will NOT be used or distributed for future research studies.

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

*[Use the mandatory statement below if conducting an online survey:]*

If completing an online survey, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of data sent via the Internet. However, your participation in this online survey involves risks similar to a person’s everyday use of the Internet. If you complete and submit an anonymous survey and later request your data be withdrawn, this may or may not be possible as the researcher may be unable to extract anonymous data from the database.

 *[For study sites located in the EU or studies that will enroll EU subjects, include the language in the following five paragraphs through “…with the data supervisory authority in your country.”]*

Data collected for this research will be stored at the *[insert name of LRH study site, e.g. the Hollis Cancer Center]*, located at Lakeland Regional Health in the United States.

***The following information may be used and disclosed to others:***

* Your research records
* All of your past, current or future medical and other health records held by your study site
* Your contact information, including your name, e-mail address and your mailing address
* *[Insert any other personal data that will be collected from EU subjects, including, for example, information about subjects’ ethnic or racial background, sexual history or sexual orientation, or political or religious beliefs.]*

Your personal information collected for this research will be kept as long as it is needed to conduct this research. Once your participation in the research is over, your information will be stored in accordance with applicable policies and regulations. Your permission to use your personal data will not expire unless you withdraw it in writing. You may withdraw or take away your permission to use and disclose your information at any time. You do this by sending written notice to the Principal Investigator at the following address: *[Insert appropriate business address.]*

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by LRH policies.

If you have concerns about the use or storage of your personal information, you have a right to lodge a complaint with the data supervisory authority in your country.

 *[If applicable (i.e. for studies involving focus groups, include the following language]*

Please be advised that although the researchers will take every precaution to maintain confidentiality of the data, the nature of focus groups prevents the researchers from guaranteeing confidentiality. The researchers would like to remind you to respect the privacy of your fellow subjects and not repeat what is said in the focus group to others.

*[If your research is NIH funded and you are conducting research involving sensitive, identifiable information, you have automatically received a certificate of confidentiality as a part of the terms and conditions of the award and are required to include this language. If your research is not NIH funded and you have applied for a certificate of confidentiality, insert this language as appropriate.]*

To help us protect your privacy, *[we will obtain/we have obtained]* a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a subject in the research project under certain circumstances. The investigative team will voluntarily comply with Florida Statutes and federal regulations, which may mandate or permit certain disclosures of protected information by the investigative team to appropriate individuals.

*[If this is a clinical trial add:]* A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

### What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in this study. We will notify you as soon as possible if such information becomes available.

*[Please include a statement regarding whether clinically relevant results, including individual research results, will be disclosed to subjects, and if so under what conditions.]*

*[If clinically relevant results will be returned, insert the following:]* We may learn things about you from the study activities that could be important to your health or to your treatment. If this happens, this information will be provided to you. [*Insert a description of the types of research results that may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.]* The results will not be placed in your medical record. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

*[If clinically relevant results will not be returned, insert the following:]* When *[data/biospecimens/images]* are collected and analyzed, there is the chance of finding something unexpected. The results from the *[data/biospecimens/images]* we collect in this research study may not be the same as what you would receive as a part of your regular health care. Because of this, you will not be informed of any unexpected findings. The results of your *[data/biospecimens/images]* will not be placed in your medical record. If you believe you are having symptoms that may require care, you should contact your primary care physician.

### You can get the answers to your questions, concerns, or complaints.

If you have any questions, concerns or complaints about this study, call *[name of principal investigator]* at *[telephone #]*. If you have questions about your rights, complaints, or issues as a person taking part in this study, call the LRH IRB at 863-687-1100 x7214or contact by email atIRB@myLRH.org.

*[The following information can be deleted if you are not part of a covered entity, which must adhere to the HIPAA Privacy Rule Regulations. Otherwise, the following LRH approved authorization language MUST be included in your informed consent document.]*

### Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting Lakeland Regional Health to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than LRH who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

* The medical staff that takes care of you and those who are part of this research study;
* Each research site for this study including *[list all sites who will use and share PHI for this research study]*;
* Any laboratories, pharmacies, or others who are part of the approved plan for this study;
* The LRH Institutional Review Board (IRB) their related staff who have oversight responsibilities for this study, including staff in LRH Corporate Integrity Office and the LRH Department of Research and Sponsored Studies;

 *[Delete additional bullets as applicable:]*

* All designated review committees such as *[Add all that apply e.g. VA Research Services; etc.]*;
* Data Safety Monitoring Boards or others who monitor the data and safety of the study;
* There may be other people and/or organizations who may be given access to your personal health information, including *[List any other persons, classes of persons, and/or organizations (including Tampa General Hospital, Moffitt Cancer Center, etc.). Do not list persons who are likely to change over the course of the study, instead list them by title or category only.]*

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, LRH may collect, use, and share the following information *[Modify to match what data will be collected and used in your study]:*

* Your research record.
* All of your past, current or future medical and other health records held by LRH, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.
* *[List any other needed information not included above. The descriptions should have enough detail that one (or an organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.]*

You can refuse to sign this form.  If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke your authorization at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

* You will no longer be a subject in this research study;
* We will stop collecting new information about you;
* We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
* Staff may need to follow-up with you if there is a medical reason to do so.

To revoke your authorization, please write to:

Principal Investigator

For IRB Study # *[Insert your IRB Study #]*

*[Insert complete business mailing address]*

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by LRH policies.

### Consent to Take Part in Research *[If applicable:]* and Authorization for the Collection, Use and Disclosure of Health Information

 *[Acknowledgment of agreement for use and storage]*

It is up to me to decide whether I want to agree to allow my blood/tissue to be used and stored for future research. I understand that I do not have to agree to the use and storage of my blood/tissue in order for me to take part in the study that has been explained to me. I agree to the choice(s) initialed below.

\_\_\_\_\_\_\_ I agree to provide *[blood/tissue]* for use in this research project.

\_\_\_\_\_\_\_ I agree to provide *[blood/tissue]* for use in future research.

I freely give my consent to take part in this study[*If applicable:* and authorize that my health information as agreed above, be collected/disclosed in this study].I understand that by signing this form I am agreeing to take part in research. I have received a copy of this form to take with me.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Taking Part in Study Date
[*If applicable:* /Authorization]

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Taking Part in Study

### Statement of Person Obtaining Informed Consent andResearch Authorization

I have carefully explained to the person taking part in the study what he or she can expect from their participation. I confirm that this research subject speaks the language that was used to explain this research and is receiving an informed consent form in their primary language. This research subject has provided legally effective informed consent.

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Signature of Person Obtaining Informed Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Informed Consent