Header:

* Title of Protocol
* Font: Times New Roman size 12
* DO NOT USE ALL CAPS

Document:

* Font: Times New Roman size 12
* Aligned text to both left and right of margins
* *Italics used here indicate Baptist IRB required language*
* The examples provided are NOT required language

Top of first page - centered: *(Required)*

* **INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY INVOLVING GENETIC MATERIALS OR TESTING**

Footer Top Left:

* Sponsor’s Version and Date
* Baptist IRB ICF Template Version and Date
* Font: Times New Roman size 10

Footer Center: Pagination.

* Page # of ##

|  |  |
| --- | --- |
| **Informed Consent** | It is important that you understand this research so that you can decide whether or not you want to take part. This process is called informed consent. To make your decision, you must consider all the information below. You should especially consider:* The purpose of this research.
* How this research differs from standard medical care.
* The procedures involved in this research.
* The risks of confidentiality loss.
* The alternatives to taking part in this research.
 |
| **Voluntary Participation** | You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled. |
| **Purpose** | The purpose of this research is explain the purpose of the study using conversational language. |
| **Number of Participants** | About X people will take part in this research. |
| **Duration** | You will be in this research study for about add duration. |
| **Costs****(See Below)** | Describe any definite costs to the subject.  |
| **Payment** | Describe the payment schedule and or reimbursement OR. You will not receive payment for taking part in this study. |
| **Ending Study Early** | There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reasons if this becomes necessary. If you do leave the study early, you may be asked to have some of the evaluations/procedures described in this form. Describe any other actions that will occur if the subject has to leave the study early.  |
| **Contacts****(See Below)** | A list of people to contact is included later in this form. |

# **INFORMED CONSENT FOR PARTICIPATION IN A REPOSITORY RESEARCH STUDY**

Title of Study:

Protocol No.:

Sponsor:

Investigator:

Participating Investigators:

Telephone:

**INTRODUCTION**

*(Required):*

*You are being given the opportunity to contribute [blood or indicate the type of specimen] to a repository for research. A research repository is a place where [blood specimens or specimens] and personal information contributed by persons like you are stored for future research. The purpose of this consent form is to help you decide if you want to take part in this repository. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this repository.*

*(Required):*

*Include a clear description of the operation of the repository and identifying the individuals and/or entities responsible for the operation of the repository.*

*(Required):*

*Sponsor (specify) is paying Site (specify), who then in turn pays PI (specify) and other parties that provide services as part of the conduct of this study.*

*(Required):*

*Describe the kinds of medical research for which it is anticipated that specimens from the repository will be used. In addition, indicate whether it is anticipated that currently undetermined, secondary uses of specimens might also be permitted.*

For example:

“Your specimen will be used in research studying….”

*(Required):*

*In simple language, include a brief explanation of genes and/or DNA.*

For example:

“Genes are like blueprints in each of your cells that determine traits that you inherit, like eye color and hair color. Genes may also influence what diseases you get and how you respond to treatment. DNA is the substance that makes up your genes.”

**PURPOSE**

*(Required):*

*A statement describing the nature and purposes of the research should be as specific as possible.*

*In simple language, indicate the length of time for which specimens will be retained in the repository, the expected time commitment for the subject, and expected number of subjects to be studied.*

 For example:

 “Your blood and/or specimen and the information derived from it will be kept indefinitely.”

(Optional):

 If genetic research is anticipated, include a statement about the consequences of DNA typing (e.g., regarding possible paternity determinations).

**PROCEDURES**

*(Required):*

*In simple language, explain the following:*

* *How the specimens will be collected, including the types and amounts of specimens, as well as any other interventions involved in the repository (e.g., use of questionnaires or concomitant review of medical records).*
* *How long the visit will take; if research procedures will occur at a standard of care visit, then indicate how much additional time will be required due to the research procedures.*
* *The amount of blood to be drawn for research purposes at each visit should be given in teaspoons/tablespoons; if there are multiple draws, the total amount of blood to be drawn should also be provided in teaspoons/tablespoons.*
* *List the information that will be collected from your medical record.*

For example:

“If you choose to take part in this repository, approximately 2 tablespoons of blood will be drawn from your arm.”

If applicable, add the following statement, “This blood will be used for the removal of DNA.”

In addition, the following information will be collected from your medical record:

* Date of birth
* Medical history
* A list of your current medications

**[OR]**

For example:

 “If you choose to take part in this repository, a small specimen (provide lay terms for size of specimen) of [type of] tissue will be removed [during the surgery to remove the tumor…].”

If applicable, add the following statement, “This specimen will be used for the removal of DNA.

In addition, the following information will be collected from your medical record:

* Date of birth
* Medical history
* A list of your current medications

 All of this will take 30 additional minutes during your routine doctor visit.”

*(Required):*

*In simple language, explain what entities will have access to specimens from the repository. Specimens might be available to personnel from commercial entities or purchased by….”*

For example:

“Blood specimens or Specimens from this repository may be shared with researchers at other institutions or commercial entities.”

*(Required):*

*Explain who will have ownership of the specimens, data associated with it, data generated from analysis of it, and immortalized cell lines developed from specimens.*

For example:

"You are authorizing that your DNA specimen, the information associated with the specimen, and the information generated from analysis of the specimen to be used by [the name of the sponsor] for the sole purpose of the research described above."

*(Required):*

*Indicate whether profit-making activities might result from commercialization of the research use of the specimens (e.g., the development of a marketable diagnostic test), and whether subjects will share in any profits deriving from these activities.*

For example:

“Successful research using your DNA could result in commercial products, such as a treatment for your disease. You will not share in any financial rewards associated with the development of these products.”

*(Required):*

*In simple language, indicate whether, under certain circumstances, results of studies conducted with the specimens might be relevant to the health of the subjects, and whether these results might be shared with subjects. If such circumstances are anticipated, indicate that subjects will be asked whether or not they want to receive this information. Also, indicate what provisions will be made for counseling subjects about the meaning of the results for their health.*

For example:

“Due to the types of future research that will be conducted with your blood and/or specimen, you will not be informed of any individual results.”

**[OR]**

For example:

“If results of the studies conducted with your blood and/or specimen are relevant to your health, the study doctor or study staff may offer to share this information with you. Please check the appropriate box below indicating whether or not you want to receive such information:

\_\_\_\_\_ Yes, I do want to receive the results of the studies that are performed on my blood and/or specimen.

\_\_\_\_\_ No, I do not want to receive the results of the studies that are performed on my blood and/or specimen.

The study doctor and/or the study staff will explain the test results and what they mean for your health.”

*(Required):*

*In simple language, indicate whether or not some studies using specimens from the repository might require re-contacting subjects for follow-up regarding their health status.*

For example:

“You will not be contacted again to obtain additional information about your DNA specimen.”

*(Required):*

*In simple language, indicate the length of time for which specimens will be retained in the repository. If the length of storage is indefinite, this should be stated.*

For example:

“Your blood and/or specimen and the information derived from it will be kept indefinitely.”

**POSSIBLE RISKS**

*(Required):*

*In simple language and in a bulleted format (whenever possible), describe any risks involved in collecting the blood and/or specimens, which are not already associated with procedures being performed as part of the participant’s standard of care. If there are no additional risks, this should be stated.*

For example:

“The potential risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, lightheadedness, and/or fainting are also possible, although unlikely. “

**[OR]**

“There are no additional physical risks associated with donating a specimen for this repository, as we will be using blood that is left over from a standard of care blood draw (a blood draw that is not being performed for research purposes).”

*(Required):*

*“There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Participating in the repository may involve risks to you which are currently unforeseeable.”*

*(Required):*

*Include a statement explaining the procedures for protecting the privacy of subjects and maintaining the confidentiality of data.*

*(Required):*

*In simple language, describe the possibility that, if results of studies using the specimens are relevant to the health of subjects, then disclosure of the information to subjects may have adverse psychological and/or social consequences.*

For example:

“If test results show that you are positive for \_\_\_\_\_ and you are made aware of this result, it may cause mental stress, unfair treatment from other people, problems with getting insurance or finding a job, or other unanticipated problems.”

**ALTERNATIVE TREATMENT & CHOICES**

*(Required):*

*In simple language, explain that prospective subjects have the option of not contributing specimens to the repository.*

For example:

“You have the option of not donating a specimen to this repository.”

*(Required):*

*For repositories associated with a main treatment study, explain whether subjects may participate in the main study without participating in the repository.*

For example:

“You may take part in the main study without donating a specimen to this repository.”

**POSSIBLE BENEFITS**

*(Required):*

*In simple language, indicate the possible benefit for both the subject and the ways in which the repository has the potential to develop medical knowledge important to society. If there are no direct benefits to subjects associated with participation in the repository, then this should be clearly stated.*

For example:

“There are no direct benefits to you for donating a specimen to this repository.”

**[OR]**

“Your participation in this repository may provide additional information regarding the possible causes of \_\_\_\_\_\_\_\_\_.”

**COSTS**

*(Required):*

*State whether there are any costs to the subject/legally authorized representative for donating a specimen to the repository.*

For example:

“The study may include tests and procedures that are conducted solely for the research study as well as tests and procedures that are conducted as part of your routine care (meaning you would receive this care whether or not you are in the research study). Some of the tests and procedures may be paid for by the study Sponsor while others are billable to you and your insurance company. Your insurance company may or may not agree with this determination. If your insurance company feels that the charges are for tests and procedures related to the research study they may deny payment, making you responsible for any charges that are not paid for by the study Sponsor. There is never any guarantee with any service that you will not incur some financial liability.

The Principal Investigator or his/her representative will discuss the tests and procedures with you. They will tell you what will be paid for by Sponsor and what will be billed to you and your insurance. They will also discuss any additional tests and/or procedures that may be required due to changes in your condition during your study participation. You have the right to refuse to have any additional tests or procedures. If you feel that you have been billed in error, please contact the Principal Investigator or his/her representative whose name and telephone number is included on this consent form.

A summary of the routine and investigational study‐related procedures is included below together with an indication of those items that will, or may, be the patient’s financial responsibility.”

NOTE: The summary may be a narrative or a table formatted description with the headings of “Covered by the Study” and “Payable by You or Your Insurance”

**COMPENSATION FOR INJURY**

*(Required):*

*Compensation statement outlining what will be paid and by whom.*

For example:

If you think you have been hurt by taking part in this study, tell the study doctor immediately.

Baptist Memorial Hospital (specify BMH facility i.e., Desoto, Collierville, Memphis, etc.) and/or [insert clinic name] will provide medical and ancillary services ordered by your physician at the established charges for those services and either Sponsor, you, or your insurance will be billed.

(As Applicable):

The sponsor will pay for the treatment if your injury is the direct result of your participation in the study, use of the study drug/device and properly-performed research procedures. If the sponsor pays for the treatment of your injury, you will be obligated to provide them with some personal information such as your social security number as they must report the payment to CMS.

*(Required):*

*Neither [insert clinic name] nor Baptist Memorial Hospital (specify BMH facility i.e., Desoto, Collierville, Memphis, etc.) has funds for patient compensation of any kind. Therefore, they cannot provide payment for study injuries.*

*If you think you have been hurt by this research, let the study investigator know right away by calling <<insert PI name and contact number>> or << 24 hour number when applicable>>*

*You do not waive any legal rights by signing this consent form.*

**COMPENSATION FOR PARTICIPATION**

*(Required):*

*If compensation is not provided to subjects associated with participation in the repository, this should be stated.*

For example:

“You will not be paid for donating blood and/or specimen to this research.”

*(Required):*

*If payment will be made, explain the following:*

* *the amount of the payment, or of each payment if there is more than one*
* *the total possible payment*
* *in what form payments will be made (cash, check, type of gift card)*
* *when payments will be made*
* *whether payments will be made to the participants OR their legally authorized representatives*

 For example:

 “You will receive a check for $\_\_\_\_ for contributing your blood and/or specimen to the repository. The check will be mailed to you after the visit where you provide your specimen for the repository.”

**[OR]**

 “You will receive a $\_\_\_\_\_ gift card to [name of store or entity] for contributing your blood and/or specimen to the repository. You will be given the gift card at the visit where you provide your specimen for the repository. The gift card will be given to you or your legally authorized representative for use.”

**COSTS FOR PARTICIPATION**

*(Required):*

 *In simple language, state whether there are any costs to the participant/legally authorized representative for donating a blood and/or specimen to the repository.*

 For example:

 “There is no cost to you for contributing your blood and/or specimen to this repository.”

**CONFIDENTIALITY (HIPAA)**

**Research records/specimens**

*(Required):*

*Explain how paper research records will be maintained.*

For example:

“All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and the specified entities listed in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”

*(Required):*

*Explain how electronic research records will be maintained.*

For example:

“All your electronic research records will be computer password protected and accessible only to research personnel and the specified entities listed in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”

**[OR]**

“All your electronic research records will be kept on an encrypted computer where your information is replaced with a code and password only known to the research personnel, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”

*(Required):*

*If the repository includes specimens that will be maintained at the local site, explain whether or not the specimens will be labeled with a code.*

For example:

“Your [type of tissue, blood, etc.] specimen will be labeled with a code.”

**[OR]**

“Your [type of tissue, blood, etc.] specimen will be labeled with your [name, social security number, etc.].”

*(Required):*

*If any individual research records or specimens will be transmitted to an external site for the repository, explain whether or not the data will contain identifiers, be sent using an encrypted method, and whether specimens will be labeled with a code.*

For example (research records):

“Your identifiable research records will be transmitted to [name the investigative site, data center, etc.] using an encrypted method (not regular email), where your information is replaced with a code and password only known to the entities below).”

**[OR]**

“Your research records will be transmitted to [name the investigative site, data center, etc.] and will be labeled with a code (will not contain any identifiable information about you).”

For example (specimens):

“Your [type of tissue, blood, etc.] will be transmitted to [name the investigative site, data center, etc.] and will be labeled with a code.”

**[OR]**

“Your identifiable [type of tissue, blood, etc.] will be transmitted to [name the investigative site, data center, etc.].”

*(Required):*

*If coded research records or specimens will be sent to an external site(s) during for the repository, explain whether or not the master key/list that links the subject’s name with the code will be maintained at the local investigative site.*

For example:

“A master key/list which links your name with the code on your [research record and/or type of tissue, blood, etc. specimen] will be maintained at [name the local investigative site].”

**Use of Data**

*(Required):*

*This section applies to any research involving collection of identifiable biospecimens or identifiable private information. Prospective subjects are informed that either:*

1. *Identifiers might be removed from data and that non-identified data could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from subject.*

***[OR]***

1. *Subject’s data collected as part of research would not be used or distributed for future research.*

NOTE: If option 2, then institutions and investigators must develop a tracking system and provide evidence to the IRB for their acknowledgement and approval.

*(All Three Statements Are Required):*

1. *A statement that subject’s biospecimens may be used for commercial profit and whether subject will share in profit.*
2. *A statement whether clinically relevant results will be disclosed to subjects and if so, under what conditions.*
3. *A statement for research involving biospecimens, whether research (if known) or might include whole genome sequencing.*

(Optional statement):

1. A statement for subjects to consent or refuse to consent to re-contact for additional information or biospecimens or participation in another research study.

**Medical Records**

*(Required):*

*“A copy of this signed consent form is required to be present on your medical chart throughout your treatment at any Baptist facility and be made a permanent part of the your index medical record. Subsequent treatment can refer to the index medical record for the informed consent.”*

**GINA**

*(Required):*

*A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:*

* *Health insurance companies and group health plans may not request your genetic information that we get from this research.*
* *Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding eligibility or premiums.*
* *Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of employment.*

*Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination against all employers.*

**Presentations/Publications**

*(Required):*

*Explain whether or not individual subjects will be identified in any presentations or publications based on the research.*

For example:

“While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.”

**Authorization to Use and Disclose Information for Research Purposes**

*(Required):*

*Under federal privacy regulations, you have the right to determine who has access to your personal health information (called “protected health information” or PHI). PHI collected in this repository may include your medical history, the results of physical exams, lab tests, x-ray exams, and other diagnostic and treatment procedures, as well as basic demographic information. By signing this consent form, you are authorizing the researchers to have access to your PHI collected in this study (if the repository will use PHI in the possession of another covered entity, add) and to receive your PHI from (either) your physician (and/or) facilities where you have received health care.*

**Entities with Potential Access to your PHI**

*(Required):*

*In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including:*

* *Researchers at multiple institutions (add the researchers and the name of the institutions)*
* *Name of the cooperative group if it is a cooperative group study*
* *People responsible for auditing and monitoring the study*
* *Add the Food and Drug Administration (FDA) if the research involves an FDA-regulated drug, device or biologic*
* *Add third party payers if claims for some of the procedures performed during the will be submitted to third party payers.*

(Optional Statement): If the research is sponsored, add the following sentence.

“Your PHI may also be shared with [name of sponsor], which sponsors and provides funds for this research; [name of CRO, if applicable] which has been hired by the sponsor to coordinate the study; and a Data and Safety Monitoring Committee (if applicable).”

**Limitations of that Access**

NOTE: The next two paragraphs are required if the above optional statement was used.

*However, these latter organizations may not have the same obligations to protect your PHI. The Baptist Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines. The mission of the IRB is to protect the rights and welfare of human research participants. The Baptist Institutional Review Board (IRB) may review your PHI as part of its responsibility to protect the rights and welfare of research subjects.*

*Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies (e.g. the FDA, the Office for Human Research Protections), or for other research for which the use and disclosure of your PHI has been approved by the IRB.*

*(Required):*

*Your PHI will be used only for the research purposes described in the Introduction of this consent form. Your PHI will be used*

[ ]  *Until the study is completed (include an end date)*

[ ]  *If the research is FDA regulated and for as long as the sponsor reports study data to the FDA*

[ ]  *If the research is without a foreseeable end-point, such as a repository or a registry) indefinitely.*

NOTE: Choose only one of these, not all three.

**Cancellation of Authorization**

*(Required)*

*You may cancel this authorization in writing at any time by contacting the principal investigator or study staff. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this research.*

(Optional)

If the research study includes treatment of subjects, add the following sentences.

“However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.”

**CONTACT FOR QUESTIONS**

*(Required):*

*If you would like to speak with the investigator to discuss any questions, concerns, problems, or injuries, please call [fill in name and contact info]*

*(Required):*

*If you would like to speak to a person who is not affiliated with this research study to discuss problems, concerns or questions, or to obtain information or offer input please call Rev. Anthony Burdick, Director of Pastoral Care, Baptist Memorial Health Care Corporation at 901-226-5025.*

**VOLUNTARY PARTICIPATION**

*(Required):*

*“Your participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you would otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.”*

*A description of this clinical trial will be available on* [*http://www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov) *as required by US 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.*

**STUDY WITHDRAWAL**

*(Required):*

*Indicate that subjects may discontinue their involvement by having their specimens and related data destroyed, without any loss of benefits to which they are otherwise entitled. Explain the procedures by which this can be accomplished, including who to contact.*

For example:

“You may withdraw or take away your permission for [sponsor] to use your specimen for future research. You do this by contacting the study doctor or study staff and indicating your wishes. Your personal information and specimens will be removed from the repository, but it will not be possible to secure their return from investigators to which they have already been provided.”

**CERTIFICATE OF CONFIDENTIALITY**

*(Required):*

*The repository should include a federal Certificate of Confidentiality, add the following 4 paragraphs.*

*“To help us further protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS).”*

*“With this certificate, the investigators cannot be forced (for example, by court subpoena) to disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.”*

*“The Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note, however, that if an insurer or employer learns about your participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.”*

*“Finally, the investigator is not prevented from taking steps, including disclosure of your research information to authorities, in order to prevent serious harm to yourself or others.”*

**NEW FINDINGS**

*(Required):*

*“Any new findings that may impact your decision to continue participation will be [fill in method].”*

**CONFLICT OF INTEREST**

(Optional):

In simple language, state in the consent form only if, with respect to the sponsor of the repository if a financial conflict of interest exists among the principal investigator or co-investigator and include a brief description of the financial interest.

For example, [PI’s name], the Principal Investigator for this study, has financial interests in the study sponsor, [Sponsor’s Name].This disclosure is made so that you can decide if this relationship affects your willingness to participate in this study. If you have questions, tell the Study Coordinator and he/she will put you in touch with someone to talk to about this.

**CONSENT TO PARTICIPATE**

The research study, procedures, risks and benefits have been explained to me. I have read and understand all of the above, been given the opportunity to ask questions, and my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I will be given a copy of this signed and dated consent form for my own records. I do not give up any of my legal rights by signing this consent form.

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

Name of Adult Participant (printed)

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

Signature of Adult Participant Date/Time

Or

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

\*Legally Authorized Representative Date/Time

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

Relationship to Participant

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

Name of Person Obtaining Consent (printed)

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

Signature of Person Obtaining Consent Date/Time

\*If authorization is to be obtained from a legally authorized representative (e.g., parent(s), legal guardian or conservator) a description of his/her authority to act for the participant is also required.