



## Consent to Participate in a Research Study

[Instructions are shaded and located within [brackets]. Insert the relevant information and remove the instructions, unwanted text, and underlines and reformat the final form to fit the consent template.]

[TITLE OF STUDY]

### KEY INFORMATION

[Include most crucial information from the potential participant's perspective; must not exceed one page.]

You are being invited to take part in a research study about [insert general description of study].

### WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

[Briefly describe the purpose of the study and the procedures to be followed in lay terms. For detailed descriptions, use detailed consent or Appendices.]

By doing this study, we hope to learn [Insert what the study hopes to learn]. Your participation in this research will last about [state in hours, days, months, years].

[If testing Food and Drug Administration (FDA)-regulated products for safety or effectiveness include the following:] The purpose of this research is to gather information on the safety and effectiveness of [state name of drug, device, etc. Indicate if the drug, device, or biologic is FDA-approved and whether it is being used in the study consistent with labeling indications.]

### WHAT ARE KEY REASONS THAT I MIGHT CHOOSE TO PARTICIPATE FOR THIS STUDY?

[State the most important reason(s) {i.e. potential benefit(s)/rewards} a person may want to volunteer to participate in this study?]

For a complete description of benefits and/or rewards, refer to the Detailed Consent.

### WHAT ARE KEY REASONS THAT I MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

[State the most important reason(s) {risk(s)/disadvantages} why a participant may NOT want to volunteer for this study considering the participant's perspective. Discuss alternative treatments/procedures that might be advantageous to the subject. For detailed descriptions, use Appendices.] For a complete description of risks, refer to the Detailed Consent/Appendix.



## **DO I HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits, or rights you would normally have if you choose not to volunteer.

## **WHAT IF I HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?**

The person in charge of this study is \_\_\_\_\_ [Principal Investigator, PI] of the [Enter your Institution and Department]. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [PI contact information].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in Tallahassee Memorial Healthcare, Office of Institutional Review Board (TMH IRB) between the business hours of 8am and 5pm EST, Monday-Friday at 850-431-2522.



## DETAILED CONSENT:

[The following detailed consent template includes sample language for many different types of research. REMOVE TEXT THAT DOES NOT APPLY TO YOUR RESEARCH.]

Use lay language and terminology throughout the document.]

### OVERVIEW

You have been asked to volunteer to participate in a research study. A clinical trial is a type of research study. Clinical trials are voluntary and include only people who choose to take part [remove if this is not a clinical trial]. This consent form gives you information about the clinical trial and what it would involve if you take part. Members of the study team will discuss this information with you.

Please take your time to make a decision about whether to take part. You may discuss your decision with your family and friends. If you have any questions, you should ask your study doctor or your healthcare team for more explanation.

**1. WHAT IS THE USUAL APPROACH TO MY** [insert type of condition and standard of care here]

**2. WHAT ARE MY OTHER CHOICES IF I DO NOT TAKE PART IN THIS STUDY?**

If you decide not to take part in this study, you have other choices. For example:

- You may choose to have the usual approach described above.
- You may choose to take part in a different study, if one is available.
- Or, you may choose not to be treated for your [insert condition or disease here]. But, you may want to receive comfort care to relieve symptoms [remove if not appropriate].

**3. WHY IS THIS STUDY BEING DONE?**

[Insert text here explaining why the study is being done.]

There will be about [insert number] people taking part in this study [Should be removed if study only at TMH]. About [insert number] people will take part in this study at Tallahassee Memorial HealthCare.

**4. WHAT ARE THE STUDY GROUPS?**



Insert text here

## 5. HOW LONG WILL I BE IN THIS STUDY?

Insert text here

## 6. WHAT EXAMS, TESTS, AND PROCEDURES ARE INVOLVED IN THIS STUDY?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Insert bulleted list of procedures, exams etc.

Some **extra** exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

- Insert bulleted list of procedures being performed for research purposes only.

A patient study calendar is attached at the end of this document. It shows how often these (insert appropriate words, e.g., exams, tests, and/or procedures) will be done.

### BEFORE I BEGIN THE STUDY:

You will need to have the following **extra** [Insert appropriate word, e.g. exams, tests and/or procedures] to find out if you can be in the study:

- [Insert bulleted list of exams, tests, and/or procedures that are required for research purposes (only the EXTRA tests, beyond standard of care)]

If the exams, tests, and procedures show that you can take part in the study, and you choose to take part, then you will need the following extra [insert appropriate word, e.g.

exams, tests, and/or procedures]. They are not part of the usual approach for your type of [insert patient condition/disease].

#### **DURING THE STUDY:**

- [Insert bulleted list of exams, tests, and procedures]

### **7. WHAT POSSIBLE RISKS CAN I EXPECT FROM TAKING PART IN THIS STUDY?**

#### **General Risks**

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual.
- You may be asked sensitive or private questions which you normally do not discuss.
- [Use for randomized studies only] The study [drug(s)/device/study approach] may not be better, and could possibly be worse, than the usual approach for your [insert condition/disease].
- [Use for studies that have genetic testing] There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways to tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. [For non-US sites, please verify the existence of such laws before including the following sentence.] There are federal and Florida State laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.
- [Use for studies requiring genetic testing] There can also be a risk of finding out new genetic information about you. New health information about inherited traits that might affect you or your blood relatives could be found during a study.

#### **Side Effect Risks**

The [specify the type of study intervention, such as surgery, radiation therapy, drugs, etc.] used in this study may affect how different parts of your body work such as your



liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/device/study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children. [delete, if not relevant to the intervention and potential side effects]
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of [Enter drug/intervention name here] are:

<b>COMMON, SOME MAY BE SERIOUS</b>

<b>OCCASIONAL, SOME MAY BE SERIOUS</b>



## RARE AND SERIOUS

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

**Reproductive Risks:** You should not get pregnant, breastfeed, or father a baby while in this study. The [specify intervention/drug] used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study [Delete if drug/intervention does not affect pregnancy].

### 8. WHAT ARE THE POSSIBLE BENEFITS TO PARTICIPATING IN THIS STUDY?

[For clinical research studies where direct benefit is possible] The possible benefit you may experience from [insert drug, device, or procedure] described in this research includes [list any benefits that may be reasonably expected]. However, there is no guarantee that you will benefit from this research.

[For research with no direct benefit] You will not benefit from taking part in this research study.

The results of this research may guide future treatment of [insert condition].

### 9. CAN I STOP TAKING PART IN THIS STUDY?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available



- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB, or US Food and Drug Administration (FDA).

## 10. IS THERE A POTENTIAL CONFLICT OF INTEREST FOR THIS STUDY?

This study is funded by [Insert funder's name] and sponsored by [*Insert sponsor name*]. [For investigators with conflicts: Dr. xyz, a researcher on the study team, has a financial interest in [name of company], the company that is paying for this study; that will manufacture the study drug; that will sell the drug; and/or the company conducting part of this study.]

## 11. WHAT ARE MY RESPONSIBILITIES IN THIS STUDY?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
  - all medications and supplements you are taking
  - any side effects
  - any doctors' visits or hospital stays outside of this study
  - if you have been or are currently in another research study.

[Include as appropriate] Write down in your medication diary when you take the study drug at home

## 12. WHAT ARE MY RIGHTS IN THIS STUDY?

Taking part in this study is your choice. No matter what decision you make and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in the study, call the Tallahassee Memorial HealthCare Institutional Review Board at 850-431-2522.

## 13. WHAT ARE MY COSTS OF TAKING PART IN THIS STUDY?

The [study agent/intervention] will be supplied at [*xx charge – either no charge or will be charged to insurance – this is study specific and should represent the terms for your specific study*] while take part in this study. [Use for IV drugs] The cost of getting the [study agent/intervention] ready and giving it to you [As appropriate, add "...is [also] provided at no charge. "Or" is not paid by the study sponsor so you or your insurance





company may have to pay for this.’] It is possible that the [study agent/intervention] may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your current health plan/insurance company will need to pay for all of the other costs of [As appropriate add: “caring for” or “preventing” or “treating”] your [condition/disease] while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless they are listed below:

- [Insert bulleted list of research non-billable items]

Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

[Use only when there are no costs to the participant] There is no cost for taking part in this study.

#### **14. WILL I RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?**

You will receive \_\_\_\_\_ for taking part in this study. [If this is a monetary reward/ payment, explain how this will be pro-rated should the participant choose to withdraw early. If this is not a cash payment, the IRB strongly suggests that the reward be given to the participant regardless of completion of the study.]

If applicable, provide the following statement:

With a few exceptions, study payments are considered taxable income reportable to the Internal Revenue Service (IRS). A form 1099 will be sent to you if your total payments for research participation are \$600 or more in a calendar year.

[OR]

[Add if appropriate] You will not be paid for taking part in this study.

#### **15. WHAT HAPPENS IF I AM INJURED OR HURT BECAUSE I TOOK PART IN THIS STUDY?**

You will get medical treatment if you are injured as a result of taking part in this study. If you think you have been injured as a result of taking part in this research study, you must tell your study doctor or the person in charge of this research study as soon as possible. The names and phone number of the person in charge of this research are listed on this consent form.



[Insert text here]

If you feel this injury was a result of medical error, you keep all of your legal rights.

## **16. WHO WILL SEE MY PROTECTED HEALTH INFORMATION?**

Your privacy is very important to us and the researchers will make every effort to protect it. Trained staff at Tallahassee Memorial HealthCare *and* [enter your organization if appropriate] may review your records if necessary.

If your information from this study is used in any reports or publications, your name or anything else that could identify you will not be used.

Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

## **17. WILL MY INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?**

[Include **ONE** of the following statements if this study collects ANY identifiable sample or ANY identifiable private information]

Your information or samples collected as part of this research study will NOT be used or shared for future research studies, even if we remove identifiable information like your name, medical record number, or date of birth.

OR

All identifiable information (for example: your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

## **18. WILL I BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?**

[If there is potential for incidental findings, describe how incidental findings will be managed and whether findings will or will not be communicated to participant.]



Generally, tests done for research purposes are not meant to provide clinical information.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by \_\_\_\_\_ [specify review by a special committee, an expert consultant] to determine if it is in your best interest to contact you.

If so, \_\_\_\_\_ [the repository, your primary/clinical care provider] will contact you using the information you provided. With the help of a {medical specialist, a genetic counselor}, they will present possible risks or benefits of receiving the information. At that time you can choose to receive or refuse the result or finding. If you would like more information about this, call \_\_\_\_\_ [list person to contact].

OR

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

Yes    No \_\_\_\_\_ Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to \_\_\_\_\_ [provide phone and mailing address].

[Include this statement if there is a potential for commercialization]

The information and/or samples that you are providing no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

### **19. IS MY GENETIC INFORMATION PROTECTED? [DELETE SECTION, IF NO GENETIC INFORMATION IS OBTAINED]**

Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. It does not prevent companies that sell life insurance, disability insurance, or long-term care insurance from using genetic information as a reason to deny coverage or set premiums. **Your blood sample will only be used for research and will not be sold. However, there is no guarantee that the privacy of**



**your personal information can be absolutely protected. Your identity will be kept as confidential as possible as required by law and your researcher will not attempt to identify you.**

## **SPECIAL NOTICE REGARDING USE OF DNA TEST RESULTS UNDER FLORIDA LAW**

The DNA analysis described in this document will be performed as described, and the results will be provided to those individuals and/or groups noted in the section on 'use and disclosure of PHI'. If TMH receives identifiable results of your DNA analysis, at your request, TMH will provide the results of your DNA analysis to your physician. The DNA analysis is performed strictly for research purposes and will not be used by TMH in any decision regarding insurability, employment, mortgage, loan, credit, or education opportunity.

### **20. WHERE CAN I GET MORE INFORMATION?**

A description of this clinical trial will be available at on <http://www.ClinicalTrials.gov> as required by US Law. The 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.

### **21. WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?**

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctors [insert name of study doctor(s)] at [Insert telephone number].

### **22. ADDITIONAL STUDIES SECTION:**

This section is about optional studies you can choose to take part in, if appropriate. Delete otherwise

For optional biological specimen banking: The analysis of your samples may contribute to the creation of new items that may be commercially valuable to the sponsor. The sponsor has no plans to provide you, either now or in the future, any compensation, royalty, or any other financial benefit that might result from any product, procedure, or other item that may be developed from studying your samples or any information or data that is derived from such research.

[Indicate if the research will or might include whole genome sequencing. Suggested language:] Research testing on your sample will include whole genome sequencing. This means we will map your entire genetic code. If you have any questions about this, ask study staff.



## PARTICIPANT INFORMED CONSENT FOR CLINICAL RESEARCH

[Insert Protocol Title Here]

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legal Authorized Representative (LAR). In my judgement and the participant's or that of his/her Legal Authorized Representative, there is sufficient access to information, including risks and benefits to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting Professional Must Personally Sign and Date/Time		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand.		
<input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A (Adult or Child <7)		
Consenting Professional's signature		
Consenting Professional's Name (Print)		Date: Time:

### Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the descriptions of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study and (2) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date/Time		
Participant/LAR Signature		
Participant/LAR Name (Print)		Date: Time:
LAR Relationship to Participant		



Witness signature (If Required)

- Non-English Speaking Participant Witness and/or Interpreter: I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).
- Other: I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: \_\_\_\_\_

Signature of Witness: \_\_\_\_\_ Date: \_\_\_\_\_

Time: \_\_\_\_\_

(If witness used for consent discussion, their name must be documented in the EMR)

The Participant/LAR must be provided with a signed copy of this form.



**RESEARCH AUTHORIZATION FOR THE USE AND  
DISCLOSURE OF PROTECTED HEALTH INFORMATION**

**STUDY TITLE:** *Include the title of the study*

**PRINCIPAL INVESTIGATOR (STUDY DOCTOR):** *Insert name of PI*

Federal law requires Tallahassee Memorial HealthCare [and *Insert Private Practice, if applicable*] to protect the privacy of information that identifies you and relates to your past, present and future medical conditions (“protected health information). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others as explained below. Tallahassee Memorial HealthCare [and *Insert Private Practice, if applicable*] must obtain your permission before using or disclosing your protected health information for research purposes. This form helps make sure that you are informed of how your information will be used or disclosed in the future. Please read the information below before signing this form. By signing this form, you agree to the use and disclosure of your information for this research study.

**1. What protected health information about me will be used or shared with others during this research?**

- a. *Existing medical records*
- b. *Your research records which includes new health information created from study-related tests, procedures, visits, and/or questionnaires*
- c. *Biospecimens which include things like tissue and blood. These will only be shared if you have agreed to this in the informed consent. (\*\*remove bullet if not applicable\*\*)*

**2. Who will use or share protected health information about me?**

- a. Tallahassee Memorial HealthCare [and *Insert Private Practice, if applicable*] will use and share your protected health information. Individuals and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information. These include:
  - i. The study’s Principal Investigator and Co-Principal Investigator(s):  
*Please specify*





- ii. The research team at Tallahassee Memorial HealthCare including the participating investigators, research staff, research nurses, fellows/ residents, and clerical support staff.
- iii. *Insert Private Practice, if applicable*
- iv. Any health care personnel who provides services to you in connection with this study.
- v. The members and staff of Tallahassee Memorial HealthCare's Institutional Review Board and Office of Research.
- vi. The members and staff of *Insert External IRB*. [Only list IF using an External IRB, otherwise delete]

**3. With whom outside of Tallahassee Memorial HealthCare [and *Insert Private Practice, if applicable*] may my protected health information be shared?**

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following:

- a. The sponsor of the study: [Insert Sponsor of the Study],
- b. The funder of the study: [Only list IF different from the study sponsor, otherwise delete]
- c. The sponsor's/TMH's/*Insert Private Practice, if applicable* research collaborators, business partners, subcontractors and agent(s), in the United States or other countries, working with [the sponsor/TMH/*Insert Private Practice, if applicable*] to conduct the study, to monitor the study or to analyze the study information for this study or other research about the study [enter appropriate term(s): drug, device, procedure, intervention]
- d. Other research doctors and medical centers participating in this research [remove bullet if not applicable]
- e. Federal and state agencies and other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. These include:
  - i. Office of Human Research Protection (OHRP)

- ii. Department of Health and Human Services,
- iii. Food and Drug Administration and other regulatory agencies responsible for oversight.
- f. Others: [Please specific: i.e.: drug/device manufacturer, outside Data and Safety Monitoring Board, external payment/compensation companies. DO NOT list outside laboratories, central pathology review, CRO or other research sites – these are covered under the 3c above. Remove this bullet if not applicable]

Some of these organizations who may receive your protected health information may not have to satisfy the same privacy rules and requirements. They, in fact, may share your information with others without your permission.

#### **4. Why will protected information about me be used by or shared by TMH or others?**

- a. The main reasons may include the following:
  - i. To conduct the study, to monitor your health status, to measure the effects of drugs/device/procedures being studied and determine the research results.
  - ii. To ensure the research meets legal and institutional requirements
  - iii. Your study information may be added to research databases so that it can design better research studies in the future, develop other therapies for patients or gain a better understanding of disease.
  - iv. For TMH medical treatment, billing matters, or health care operations. For example, medical information produced by this research study will become part of your hospital medical record.

#### **5. Statement of privacy rights:**

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study. If you do not sign, it will not affect your ongoing treatment or healthcare coverage.



- You have the right to withdraw your permission for Tallahassee Memorial HealthCare [and *Insert Private Practice, if applicable*] to use or share your protected health information for purposes of this study. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the Study Doctor. If you withdraw your permission, you will not be able to continue to participate in the research study.
- You have the right to request access to your protected health information that is used or shared during this research and that is related to the research or payment for the research, but you may access this information only after the study is completed. You can have access to your medical record at any time in accordance with policy. To request this information, please contact the Study Doctor. You may also ask the Study Doctor to correct any study related information about you that is wrong.

**Participant’s (or LAR) HIPAA Authorization Statement**

I have read this form with the descriptions of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am authorizing for the use and disclosure of my/their protected health information.

This Authorization does not have an expiration date [or as appropriate, insert expiration date (note: the study participant will need to be re-consented if the study continues after the expiration date) or event, such as "end of the research study."]

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		
Participant/LAR Name (Print)		Date: Time:
LAR Relationship to Participant		

Witness signature (If Required)

- Non-English Speaking Participant Witness and/or Interpreter: I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).
- Other: I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: \_\_\_\_\_

Signature of Witness: \_\_\_\_\_ Date: \_\_\_\_\_

Time: \_\_\_\_\_

(If witness used for consent discussion, their name must be documented in the EMR)

The Participant/LAR must be provided with a signed copy of this form.



Appendix A:  
Study Schedule and Procedures

Insert Study Schedule/Calendar