Protocol Title: Insert Title of Research Study or Acronym

Principal Investigator: Insert Name of the Principal Investigator
Address
Insert Phone Numbers

Emergency Contact: Insert Emergency Contact
Insert Phone Number/Pager, etc.

Why am I being asked to volunteer?

☐ The subject is being invited to participate in a research study and why he/she is being asked to volunteer.
☐ Participation is voluntary.
☐ The subject will get a copy of the consent form and should ask questions.
☐ The subject will be asked to sign this form if consent is given to participate.
☐ Include some information about the study such as “a study of “X” (drug or device, etc.) in participants with “Y” disease.
☐ Ensure subject is aware that they do not have to participate in research being performed by their own doctor.

You are being invited to participate in a research study because (why he/she is being asked to volunteer.). Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research
study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

What is the purpose of this research study?
- A concise explanation of the purpose of the research, incorporating any intent to assess safety +/- efficacy.
- A clarification that the drug/device is investigational. Can note that the drug/device is approved for another indication if applicable, but must clarify that the use of the drug/device in this study is experimental.

How long will I be in the study?
- Expected duration of a subject’s involvement with the study.
- Expected total duration of study.
- (optional) Total number of subjects in study *note: if this information is included add “How may other people will be in the study” to the title of this section.
- (optional) Include number of subjects at Penn *note: if this information is included add “How may other people will be in the study” to the title of this section.

What am I being asked to do?
- A high level overview of the major elements of the study and what is expected of the subject (i.e. note here only the major procedures and milestones).
- Following the overview, provide a full list of procedures/tests by lay-term names. Consider including number of times each test will occur, amount, exposure if appropriate, etc. in easy layman terms.
- Describe each test/procedure in layman’s terms.
- Clearly identify which procedures are experimental.
- (optional) May be complimented by a simple table or chart or other additional materials may be inserted here or given as a handout. Any such materials require IRB approval.

What are the possible risks or discomforts?
- Known risks from the study agent. May also be detailed in chart format and additional material inserted here or given as a handout. Any such materials require IRB approval.
- Risks, discomforts/inconveniences of study-related procedures noted in the section “What am I being asked to do?” If standard of care testing is being changed, describe any resultant effects.
risk, if applicable. May also be detailed in chart format and additional material inserted here or given as a hand out. Any such materials require IRB approval.

☐ Clarify that if the subject is injured, they should inform treating physician that they are in a research study.

☐ Include information on reproductive issues, if appropriate. NOTE: If male contraception methods or warnings are warranted, the appropriate information must be provided in this section as well.

☐ Do not make statements of proven safety unless that safety data is part of FDA-approved labeling. If the labeling safety data does not include data in the proposed study population for this study, make clear that there is no safety data in the population under study.

☐ Include a statement that the research may involve risks that are currently unforeseeable.

☐ If protocol includes MRI for research purposes (with or without IV contrast agents), please refer to the required CAMRIS clause language for all required risk language: http://www.med.upenn.edu/camris/consent.html

Reproductive risks: Because of the effects of this drug/device, there could be serious harm to unborn children or children who are breast-feeding. These effects could also harm the mother. It is also possible that harmful side effects that are not yet known could happen to both the mother and unborn or breast-feeding child. If you are currently pregnant, it is important that you inform the investigator because you will not be able participate in the study. If you are able to become pregnant, you will be given a serum pregnancy test before entry into the study. You are asked to use a medically accepted method of birth control (such as...) while you participate in the study. You should not become pregnant while you are taking this drug/device. If you do become pregnant, you must tell the investigator and consult an obstetrician or maternal-fetal specialist.

Reproductive Risks for studies involving MRIs

☐ If protocol includes MRI for research purposes (with or without IV contrast agents), please refer to the CAMRIS clause language for all required reproductive risk language: http://www.med.upenn.edu/camris/consent.html

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 the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?
If direct subject benefits can reasonably be anticipated as a result of participating in the protocol (section II.16 of application), then describe these possible benefits. Conclude with the following standard clause:

You may not get any benefit from being in this research study.

If direct subject benefits are NOT anticipated, then use the following standard clause:

You are not expected to get any benefit from being in this research study.

(optional) Anticipated benefits to society.

What other choices do I have if I do not participate?

- Information on other treatments available.
- Alternatives to entering the study including, when appropriate, supportive care with no additional disease-directed therapy.
- A statement that they may discuss alternatives with their personal physician.

Will I be paid for being in this study?

- Description of any monetary compensation (*payments/stipend), if subjects are being compensated for their time and travel.
- A break down the total compensation (i.e. clarify if paid after each visit/procedure or upon completion of the study, etc.).
- If there is no compensation for participation in this study, state that here.

[If subjects will receive monetary compensation for their participation by check or an amount of $100 or more, include the following language] Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

- Procedures or tests that will be covered by the study.
- Procedures or tests that are not covered by the study, stating how they will be paid for (i.e., third party payer, etc.).

“You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. The following drug [insert drug name] is approved for [insert condition/disease] and its cost will be billed to your insurance company. Please talk to your doctor and study team about putting you in touch with a financial counselor.
to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance."

What happens if I am injured from being in the study?
(for research that poses greater than minimal risks to participants.)

- Provide contact information for research-related injury (i.e. can refer to the contact information noted in Consent header, if appropriate).
- Describe what treatment will be provided for research related injuries.
- Explain how treatment for research related injuries would be paid.
- Subject's responsibilities relating to research related injuries.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

--- OR ---

[If there is sponsor-specific injury language, add it here. However, for industry-sponsored research, the sponsor must pay for research related injury unless otherwise negotiated with the institution.]

For NCI supported cancer trials, consider including the following information:

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute’s website at [https://www.cancer.gov](https://www.cancer.gov) and type “paying for clinical trials” into the website’s search bar, visit the National Cancer Institute’s website at [http://cancer.gov/clinicaltrials/understanding/insurance-coverage](http://cancer.gov/clinicaltrials/understanding/insurance-coverage). Another way to get this information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

When is the Study over? Can I leave the Study before it ends?

- Define when the overall study is to end.
- Explain what events could lead to early study closure.
- Note that the subject can elect to leave the study at any time.
- If early withdrawal could expose the subject to medical risks, describe and how those risks will be minimized or prevented (e.g. in a hypertensive study, it may be necessary to wean a subject off the study medication or to transition them to alternate therapy).

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your
physician, the study Sponsor, or the Food and Drug Administration (FDA) without your consent because:

• The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
• You have not followed study instructions.
• The Sponsor, the study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

What happens to my collected samples and data?

If there is no future use of data or specimens, this section is not required.

☐ If data or biospecimens will be retained for additional use within the context of this particular study or for any potential additional research in the future please include appropriate language for one of 2 possible scenarios:

☐ SCENARIO 1 - DATA AND/OR BIOSPECIMENS ARE STORED FOR FUTURE RESEARCH BUT WILL BE RETAINED DE-IDENTIFIED
  ▪ Please include a statement to this affect in the consent form that this will occur. No additional information needed about rescinding consent to future use by the participant as this is not possible to do when using de-identified data or biospecimens.

☐ SCENARIO 2 - DATA AND/OR BIOSPECIMENS ARE STORED FOR FUTURE RESEARCH WITH IDENTIFYING INFORMATION.
  ▪ A statement specifically describing what identifiers will be retained with the data or biospecimens will need to be included;
  ▪ A statement noting how a participant may withdraw their consent to future use with identifiable data or biospecimens will need to be included (instructions for withdrawing consent will need to be provided);
  ▪ A statement noting how data or biospecimens will be protected to prevent loss of confidentiality (as this is a risk when storing data or biospecimens with identifiers).

☐ For both Scenarios 1 and 2 the following additional information should be added:
  ▪ A statement that the participant’s biospecimens (even if identifiers are removed as in scenario 1 above) may be used for commercial profit and whether the participant will or will not share in this commercial profit,
  ▪ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to participants and, if so, under what conditions,
  ▪ A statement of whether the research will (if known or if this is a possibility, this should be included) or might include whole genome sequencing.

If future use of specimens is optional, be sure to provide an area within the consent form for subjects to clearly document opting in or out of future use before they sign. If future use is not optional, please clearly state as such, section is not required.
Who can see or use my information? How will my personal information be protected?

[If your study involves testing for infectious diseases, please include the language in paragraphs two/three below]

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

If you test positive for <add any reportable infectious diseases for which testing will be performed specifically for research>, by law we have to report the positive test results to the City of Philadelphia Health Department and/or the PA Department of Health. Personal identifiers such as name, sex, date of birth, address, and phone number will be reported. For more information about the requirements reporting infectious diseases to the City of Philadelphia Health Department, please visit https://hip.phila.gov/ReportDisease. For more information about the requirements for reporting infectious diseases to the PA Health Department, please visit www.health.pa.gov and type 'Reportable Diseases' into the site search bar.


Explain how confidentiality will be maintained. Be specific about how records will be secured to protect the identity of the subject. State the IRB at the University of Pennsylvania will have access to the records. Explain how subjects will be de-identified; will code numbers be used? Please note; the content of this section will vary according to the research design. There may be cause for more or less protections depending on the nature of the research. The language suggested above should be altered when necessary.

Electronic Medical Records and Research Results
What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the University of Pennsylvania IRB with any questions, concerns or complaints by calling (215) 898-2614.
When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)  Signature of Subject  Date

Name of Person Obtaining Consent (Please Print)  Signature  Date

(Optional) Use the authorization line only in studies which are approved by the IRB to use representatives to authorize a subject’s participation in research. Delete if not applicable.

For subjects unable to give authorization, the authorization is given by the following authorized subject representative:

Authorized subject representative [print]  Authorized subject representative Signature  Date

Provide a brief description of above person authority to serve as the subject’s authorized representative.