## Title of research study: ***[insert title of research study here with protocol number, if applicable]***

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

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

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research.]

## What should I know about a research study?

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

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (610)957-6150 or irb@swarthmore.edu if:

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

## Why is this research being done?

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

## How long will the research last?

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

## How many people will be studied?

We expect about \_\_\_ people will be in this research study. **[Include if study is mutli-site research. Otherwise delete]** We expect about \_\_\_ people in the entire study nationally **[or internationally]**.

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

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

* A time-line description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* Psychological tests and/or questionnaires
* Description of observations or interviews that will occur as part of the research
* Description of any manipulation of the subject's environment and activities that will take place as a part of the research
* Description of all data to be collected about subjects, and the source of that data (such as data from existing records, data from non-research specific sources such as standardized tests, etc.)
* The length and duration of procedures
* With whom will the subject interact
* Where the research will be done
* When the research will be done
* How often procedures will be performed
* What is being performed as part of the research study
* When applicable indicate that the subject will be contacted for future research.***]***

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

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

[Include if there are alternatives other than participating. Otherwise delete.] Instead of being in this research study, your choices may include: [List alternatives procedures. For student subject pools describe alternatives for course credit.]

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

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

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

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

[Delete this section if there are no risks or discomforts.]

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

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

* [Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks]

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

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

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

[Delete this section if there are no benefits.]

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

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

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

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

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

***[If data will be retained after the study for future research, explain where the data will be stored, who will have access to the data, and how long the date will be retained.]***

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

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

[Delete this section if not applicable.]

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

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

## What else do I need to know?

[Include for sponsored research. Otherwise delete.] This research is being funded by [Insert name of sponsor].

[Include for research involving more than minimal risk. Otherwise delete.] If you need medical care because of taking part in this research study, seek medical attention immediately (if it is a medical emergency, first call 911). Generally, this care will be billed to you, your insurance, or other third party. [Insert the name of the institution] has no program to pay for medical care for research-related injury. [Describe any compensation available for research related injury.] Please contact the investigator as soon as possible to report the event.

It is important that you tell the Principal Investigator [Include full name] if you think you have been injured as a result of taking part in this study. You can call him/her at [Include phone number.]

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

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

***[When applicable indicate when and how the subject will be informed of the results of the research.]***

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

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

**Signature Block for Capable Adult**

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission to take part in this research. | | |
|  |  |  |
| Signature of subject |  | Date |
|  |  | |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | IRB Approval Date |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

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

**Signature Block for Adult Unable to Consent**

|  |  |  |
| --- | --- | --- |
| Your signature documents your permission for the named subject to take part in this research. | | |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  | |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | IRB Approval Date |

***[Add the following block if you will document assent of the subject.]***

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

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

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

**Signature Block for Children**

|  |  |  |  |
| --- | --- | --- | --- |
| Your signature documents your permission for the named child to take part in this research. | | | |
|  | |  | |
| Printed name of child | |
|  | |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care | |  | Date |
|  | | * Parent * Individual legally authorized to consent to the child’s general medical care (See note below) | |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care | |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. | | | |
|  | |  |  |
| Signature of parent | |  | Date |
|  | |  | |
| Printed name of parent | |
| If signature of second parent not obtained, indicate why: (select one) | | | |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]*** * Second parent is deceased * Second parent is unknown | * Second parent is incompetent * Second parent is not reasonably available * Only one parent has legal responsibility for the care and custody of the child | | |

***[Add the following block if you will document assent of children]***

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

***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  | IRB Approval Date |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

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