HRP 580 – HRPP Consent Form Template (v.04/01/2022)

**This template is for research conducted at all Penn State University campuses, including Penn State Health and the Penn State College of Medicine.**

**Note:** Suggested consent language can be found in the [Penn State HRPP Consent Glossary](https://pennstateoffice365.sharepoint.com/:w:/s/VPR-ORP/EeSBXJXF6XpLtrMQinFTA00BkxPcWT9X2P0cPQVB3SoFLg?e=kWmejr).

Use low-literacy techniques to the extent possible throughout the consent form.

• Explain medical terms and complex words in lay terms and simple language.

• Avoid long sentences and paragraphs.

• Use bulleted lists and incorporate white space, where appropriate.

See the following key to distinguish instructions and campus specific language from the body of the consent. Remove all color-coding and delete all gray text boxes, suggested language that is not applicable, and instructions before submitting this form.



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| --- |
| **CONSENT FOR RESEARCH**  The Pennsylvania State University |

Title of Project: <<Complete title of the project as it appears on the research protocol>>

Principal Investigator: <<Only one person may be named as principal investigator. No other investigators are to be listed.>>

Address: <<List principal investigator’s address>>

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (xxx) xxx-xxxx. *{If research is greater than minimal risk, add the following.}* +After hours call (717) 531-8521. Ask for the <<division>> doctor on 24-hour call.

Faculty Advisor: *<<Only one person may be named as a faculty advisor. If the PI is not a student, delete this section>>*

Faculty Advisor Telephone Number: *<<List telephone number where the advisor can be contacted>>*

Subject’s Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**We are asking you to be in a research study.**

**Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.**

**This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.**

Instructions: Include the following paragraph only when enrolling adult subjects unable to provide consent and permission will be sought from their legally authorized representatives.

Some of the people who are eligible to take part in this research study may not be able to give consent to take part because of their medical condition. Instead we will ask the person’s legally authorized representative to give consent. Throughout the consent form, “you” always refers to the person who takes part in the research study.

Instructions: Include the following paragraph only when enrolling children (less than 18 years of age) and permission will be sought from their parent(s)/guardian(s).

Some of the people who are eligible to take part in this research study may not be able to give consent because they are less than 18 years of age (a minor). Instead we will ask their parent(s)/guardian(s) to give permission for their participation in the study, and we may ask them to agree (give assent) to take part. Throughout the consent form, when we say “you”, we mean you or your child.

Key Information Instructions:

* The revised Common Rule human subjects regulations require subjects be given a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent, as well as the entire document, must be organized and presented in a way that facilitates comprehension.
* This section is required for studies approved by the Penn State HRPP on or after 01/21/2019. This section is optional for studies whose initial IRB approval was granted before 01/21/2019.
* **You may DELETE this section if the consent document without this section and without the signature lines is less than 2,000 words (approximately 5 pages, single-spaced, 1-inch margins)**
* This Key Information section should, for most studies, be **≤ 2 pages long**.
* Check with the HRPP if you are unsure if this section is needed.
* Federal agencies expect that, in general, the Key Information section will include a concise explanation of the following: (1) That consent is being sought for research and that participation is voluntary; (2) A brief summary of the purpose of the study; (3) Duration of participation; (4) A brief description of the procedures to be followed in the research; (5) A summary of the most important risks; and (6) Appropriate alternative procedures or courses of treatment, if any that might be advantageous to the potential subject.
* However, federal agencies have stressed the key information should be meaningful within the context of the study and have therefore avoided strictly defining what information should be included.

**KEY INFORMATION**

**The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.**

**Why am I being invited to take part in this research study?**

We are asking you to take part in this voluntary research study because <<state why the subject was selected, e.g., disease diagnosis or healthy volunteer>>.

**What is the purpose of this research study?**

The purposeof this voluntary research study is to <<insert brief purpose of study>>.

**How long will the research study last?**

<< Explain the time commitment to complete the research study>>.

**What will I need to do?**

<<Provide a brief, high level description or summary of the main research activities, such as investigational treatments or extra procedures that are performed for research purposes>>.

**What are the main risks of taking part in the study?**

For this study, the main risks to know about are: <<Identify the most important risks for making a decision about study participation>>.

**What are the possible benefits to me that may reasonably be expected from being in the research?**

Example for a study without benefits to subjects: There are no benefits to you from taking part in this research. Results of the study may benefit other people in the future by helping us learn more about <<describe potential scientific/societal benefits>>.

Example for a study with possible direct benefits for subjects: We cannot promise any benefits to you from taking part in this study. However, possible benefits include <<describe the possible direct benefit to the subject>>. Results of the study may benefit other people in the future by helping us learn more about <<describe potential scientific/societal benefits>>.

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

Participation in research is completely voluntary. You can decide to participate or not to participate.

[Include the following if there are alternatives other than participating] Instead of being in this research study, your choices may include: <<List alternatives procedures, including supportive care if applicable>>.

[Include if there are no alternatives other than participating.] You may choose not to take part in this research study.

**DETAILED INFORMATION**

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

**1. Why is this research study being done?**

Instructions: Include the following information when applicable:

* Briefly summarize the purpose, e.g., “this research study is being done to …”.
* Indicate the FDA status of any drugs or devices that are being tested in the research, and specify “investigational” when applicable.
* Indicate the approximate overall enrollment unless these numbers are not important to a decision to take part in the research.

This research is being done to find out <<state purpose of research study>>.

Approximately <<number>> people will take part in this research study <<nationwide or worldwide or at Penn State >>.

**2. What will happen in this research study?**

Instructions: Include the following information when applicable:

* Outline the procedures in lay terms and in order of occurrence and how often they will be performed.
* Be sure to include:

- screening procedures that occur after signing the consent form

- treatment assignment/randomization

- procedures during treatment

- final visit and follow-up

* **Use lists, tables or flow charts whenever possible.** If practical, prepare a time line chart or schematic to accompany description of procedures and test for research that requires more than 1 or 2 steps/visits.
* Identify all drugs or biologics (dose, frequency, and route of administration), devices, and procedures that are experimental or that are used in an experimental manner.
* Indicate which are standard procedures (standard of care) versus research procedures. Identify any procedures which are experimental. Identify what procedures are part of regular medical care that will be done even if the subject does not take part in the research.
* Indicate whether the research will include any hospitalizations or outpatient clinic visits or telephone or written follow-up.
* Include the length and duration of visits and procedures.
* If the research involves blood collection, indicate the amount [in English units, teaspoons/tablespoons] and how often and if any special preparation is required (e.g., fasting). Common blood and urine tests should be described as “common blood tests to determine your health status.” List any tests that are out of the ordinary for the specific condition being studied in the research.
* Indicate with whom the subject will interact, where the research will be done and when the research will be done.
* If applicable, describe in lay terms randomization procedures, probability for random assignment to each treatment, double-blinds, emergency unblinding, and use of placebo. Include the following for a clinical trial that involves randomization. “You will be randomly assigned to receive one of the [number] study treatments. This means whichever study treatment you receive will be determined purely by chance. You will have a [give the odds of being in any study group, e.g., equal chance, 1 out of 3, etc.]. [For double-blind studies] Neither you nor the research team will know which study treatment you are receiving, but the research team will be able to get this information quickly if it is needed to ensure your safety. [For single blind research studies] You will not be told which treatment you are getting, however your study doctor will know.”
* If the study involves surveys or questionnaires, include a statement that the subject is free to skip any questions that he/she would prefer not to answer, unless that is not true.
* If the study involves the use of educational records covered under FERPA, please indicate specifically which records the researcher requests to use of research purposes.
* If the research involves a screening visit and includes tests or procedures that would not be done for clinical purposes, then consent must be obtained prior to the screening visit. Avoid wording such as “After the screening visit, if you are eligible to **participate** in the study, you will …” Rather, use wording such as “After the screening visit, if you are eligible to **continue** in the research, you will …” or “…if you are eligible to **receive** the research treatment, you will …”
* Include what will happen to any research specimens once the research is completed.
* When applicable indicate that the subject may be contacted for future research.
* Whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.)

For FDA-regulated clinical trials, include the following sub-section about responsibilities at the end of section 2. Delete this sub-section if the research is not an FDA-regulated clinical trial.

**What are my responsibilities if I take part in this research?**

If you take part in this research, your major responsibilities will include:

* <<List any responsibilities of the subject>>
* <<Include the following if appropriate>> For your safety, you must tell the study doctor or nurse about all the prescription drugs, herbal products, over-the-counter drugs (OTC), vitamins and other supplements you are taking. Check with the study doctor before starting any new medicines (including prescription, OTC drugs, vitamins and herbal supplements) or changing doses of medications that you are already taking.

**3. What are the risks and possible discomforts from being in this research study?**

Instructions: The information in this section should be limited to the risks and discomforts related to the procedures done for research purposes, and should not include those related to research subject’s routine medical care. Include the following information when applicable:

* Describe each of the following risks, if appropriate: physical risks, psychological risks, privacy risks, legal risks, social risks, economic risks.
* If known, describe the probability and magnitude of the risk.
* Use lay terms for the risks and discomforts for each procedure and/or drug.
* If possible, group the risks into categories such as expected, occasional, or rare and quantify these categories (e.g., 5 of 100 people who receive the drug).
* Be sure to list all side effects.
* **The use of a list or a table is strongly recommended.**
* Include risks of procedures that are done as part of follow-up that are not standard of care.
* If addressing risks for standard-of-care procedures, identify these as “risks you would have with or without the research.”
* If the risk profile or any research-related interventions is not well known or the research involves investigational drugs or devices, include a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or becomes pregnant) that are currently unknown or unforseeable.
* If relevant, address the potential risks and precautions related to becoming pregnant or fathering a child.
* If the research includes women of child bearing potential or pregnant women, and the risk profile of any research interventions or interactions on embryos and fetuses is not well known, include a statement that the particular treatment or procedure may involve risks to the embryo or fetus, if the subject is or becomes pregnant, which are currently unknown or unforeseeable.
* If the research involves the use of an investigational device, add device malfunction as a possible risk if appropriate.
* If the research involves randomization, add the risks of randomization. For example: “You will be assigned to a treatment program by chance. The treatment you receive may prove to be less effective or to have more side effects than the other research treatment(s) or other available treatments.”

*{Include the risk of loss of confidentiality for all research studies}* There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

**4. What are the possible benefits from being in this research study?**

**4a. What are the possible benefits to me?**

Instructions: Include the following information in this section:

* Reasonable expected benefits to the subject (if any)
* Do not overemphasize the benefits. Monetary reimbursement for participation is not a benefit.
* If benefits from participation may not continue after the research has ended, describe them here.
* Include the following 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.”
* If the research includes a placebo group, use the following text if appropriate, “There is no guarantee that you will benefit from this research. If you are assigned to the active study drug group, the possible benefits you may experience from this research study include <<list benefits>>. If you are assigned to the placebo group, you are not expected to benefit from this research.”

*{For clinical research studies where direct benefit is possible}* There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include <<list any benefits that may be reasonably expected>>.

*{For research with no direct benefit}* You will not benefit from this research study.

**4b. What are the possible benefits to others?**

Instructions: Include the following information in this section:

* Address potential benefits to others (e.g., “The results of this research may guide the future treatment of… ” or “Medical science may gain further understanding of… ”).

*{Use one of the following to begin this section}* The results of this research may guide the future treatment of… or Medical science may gain further understanding of… .

**5. What other options are available instead of being in this research study?**

Instructions: Include the following information in this section:

* Clarify that the potential subject may decline to participate in the research.
* Include any alternatives other than participating.
* For student subject pools or those receiving extra credit in a course, describe alternatives for course credit.
* For clinical trials, list alternative procedures or treatments, if any, that might be reasonable such as the standard of care and/or other research and/or the choice to receive supportive care. If applicable, include the important benefits and risks of these options.
* Indicate if the research treatment(s)/intervention(s) can be obtained without enrolling in the research.

*{For non-treatment studies}* You may choose not to be in this research study.

{*For approved student subject pools*} Since the <<insert name/location of approved subject pool>> will be used to recruit participants you will receive course credit for participating as specified in the syllabus provided by your instructor. Alternative means for earning this course credit are available as specified in the syllabus.”

*{For treatment studies}* You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

* Receive commercially available treatments, including <<list treatment>>.
* Be part of a different research study, if one is available.
* Choose not to be treated for your medical condition (*optional:* and only receive care to make you more comfortable).

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

*{Explain whether or not the research therapy can be obtained off-study}* The therapy offered in this research is available to you without taking part in this research study. ***OR*** Because it is investigational, the therapy offered in this research is only available to you if you take part in the research study.

**6. How long will I take part in this research study?**

Instructions: Include the following information in this section:

* Explain the time commitment to complete this research study, e.g., “It will take you about 14 months to complete this research study. During this time, we will ask you to make 14 study visits.”

*{For studies with time commitment for subjects}* If you agree to take part, it will take you about <<give length of time of participation>> to complete this research study. You will be asked to visit the research site \_\_\_\_ times.

*{For studies with no time commitment for subjects}* Being in this research study does not require any time on your part.

**7. How will you protect my privacy and confidentiality if I decide to take part in this research study?**

**7a. What happens to the information collected for the research?**

Instructions: Include the following information in this section:

* Explain how research data and/or tissue samples will be labeled and stored at Penn State, and at any outside entities or institution.
* Include information about a Certificate of Confidentiality if applicable.
* Explain how any videos, audio recordings or photographs are labeled and secured, who has access to these materials and when they will be destroyed.
* If the research involves prisoners, add the following statement: “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.”
* 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. For example, “We will use and disclose your research records when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. *{Include the following statement if the study does not have a Certificate of Confidentiality.}* Your research records can be opened by court order. Your records also may be provided in response to a subpoena or a legal request for the production of documents.”

Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

* *{Include the following if applicable}*A list that matches your name with your code number will be kept in a locked file in Dr. << PI’s name>> office.
* Your research records will be labeled with <<list all identifiers that apply: your code number, your initials, your date of birth, etc.>>and will be kept in a safe area in <<PI’s name>> research office.
* *{Include the following if specimens are collected for research purposes and used or stored at PSU.}* Your research samples will be labeled with <<list all that apply: a code number, your initials, etc.>> and will be stored <<list where the samples will be stored and how they are secured>>.
* *{Include the following for clinical studies in which a copy of the signed consent form is included in subjects’ medical records.} +*A copy of this signed consent form will be included in your Penn State Health (PSH) medical record. This means that other PSH healthcare providers will know you are in this study.
* *{Include the following if applicable}* +Results of some of the research-related clinical tests (including but not limited to <<list tests>>) will be kept in your PSH medical record.

*{For research records/samples that are sent outside of PSU, describe methods that will be used to ensure confidentiality. If records and specimens are sent to different entities or labeled differently, describe their confidentiality measures separately}* For research records [and specimens] sent to <<outside entity>>, you will be identified by <<list all identifiers that apply: name, social security number, address, phone number, date of birth, any other direct personal identifier, code number>>.

*{Remember to include separate descriptions for records and specimens if they are labeled differently or stored differently or sent to separate entities. This list must match the identifiers selected in Question #18 of the document “HRP-598 - Research Data Plan Review Form” or provided in the protocol template}*.

*{If the research has a Certificate of Confidentiality, add the following statements. NOTE: As of October 1, 2017, all NIH-funded research that is collecting or using identifiable information is automatically covered under a Certificate of Confidentiality}*

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies you to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to yourself or others. Also, your information may be disclosed in accordance with any consent you provide, including for your medical treatment or use in other research. *{Add the following sentence as applicable}* Additionally, the Certificate of Confidentiality does not prevent your information from being disclosed to << name of sponsoring government agency>> in order for it to evaluate or audit the research, or prevent disclosures required to meet FDA requirements. For additional information ask the principal investigator or a member of the study team or contact the Human Research Protection Program at (814) 865-1775.

*{For all studies}* In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research.

* The Office for Human Research Protections in the U. S. Department of Health and Human Services
* *{For drug/device studies and other FDA-regulated research add:}* U.S. Food and Drug Administration
* *{For sponsored studies, add:}* The research study sponsor*,* <<name of Sponsor>>
* The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
* The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
* +People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
* +Organizations that provide independent accreditation and oversight of hospitals and research
* +Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

*{Add the following paragraph for investigator-initiated research studies if applicable.}*

+Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information and samples may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and authorization.

*{Include the following information if the research involves the collection of Protected Health Information.}* +The research team may use your past, present, and future medical information and records for the purpose of your participation in the research study specifically identified in this authorization. Information that will be disclosed may include information that identifies you and your medical condition, as well as information developed as a result of the research study. Your authorization will remain in effect until you revoke it. You may change your mind and revoke (take back) this authorization at any time and for any reason. However, any information previously disclosed under this authorization may not be retrieved and may no longer be protected by federal or state privacy laws. To revoke this consent and authorization, contact the Principal Investigator using the information found on the first page of this form. Revocation of, or refusal to sign, this consent and authorization will not impact the care you receive at Penn State that is not related to the research, however, you will be excluded from participation in this research study if you do not provide this consent and authorization.

**7b. What will happen to my research information and/or samples after the study is completed?**

* If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.
* If data will be submitted to central databases for use in future research studies, include this information in this section.
* If applicable, explain if clinically relevant research results will be disclosed to subjects and, if so, under what conditions.

*{If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements. If the study has an optional section at the end of the consent form for subjects to indicate their choices regarding use of data and/or samples for future research, you do not need to include one of these statements.}*

We may use your research information and your biological samples in future studies or may share your information or biological samples with other investigators for future research without your additional informed consent. Before we use or share your information or samples we will remove any information that shows your identity.

OR

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

*{If the funding agency, sponsor or journal requires research data be submitted to central databases for use in future research studies, include a paragraph describing this process. The following is suggested text that may be modified according to the specific situation.}* Researchers can do studies that are more powerful when they share with each other the data or information they get from research studies. They share this information with each other by putting it into scientific databases. Your coded research information may be put in one or more databases and used for future research. Your information stored in these databases will not include any identifying information such as your name, address, telephone number, or social security number. Your research data will only be available to researchers who have received approval from data access committees and/or Institutional Review Boards. Some of these databases are maintained by Penn State, some are maintained by the federal government, and some are maintained by private companies and other institutions.

*{When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens. The following is suggested text if it is not known if the research will have clinically relevant research results.}*

Most tests done on samples in research studies are only for research and have no clear meaning for health care.  If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers <<will/will not>> contact you to let you know what they have found. *{For studies involving genetic testing, add the following if applicable.}*  If the researchers return genetic test results to you, it is because they think you could have a health risk and want to recommend that the test be re-done by a certified clinical laboratory to check the results.   If this happens, then it will be recommended that you get a second test from a certified clinical laboratory, consult your own doctor, ​and/or get genetic counseling. You may have to pay for those additional services yourself.

**8. What are the costs of taking part in this research study?**

**8a. What will I have to pay for if I take part in this research study?**

Instructions: Include the following information in this section:

* If there are costs to the subject that may result from participation in the research, include a statement describing any additional costs associated with study participation.
* If applicable clarify that subjects will incur no extra expense for participation or clearly describe any costs to the subject, e.g., “There is no cost to you for taking part in this study.”
* Explain how costs will be covered.
* If research tests/procedures are conducted in a clinical setting, provide specific information about which tests/procedures would be the responsibility of the subject and/or his/her insurance carrier and which tests/procedures are covered by the research study.
* If the sponsor is not paying for research tests or study treatments, add a sentence instructing subjects to check with their insurance carrier prior to deciding whether or not to participate.
* Include the following statements for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. “If you are a prisoner and 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.”

*{For clinical research studies}* For costs of tests and procedures that are only being done for the research study:

* *{Include if this is a drug study}* You or your insurance provider will/will not have to pay for the study agents [\*insert name of study agent(s)\*] while you take part in this study. However, you and/or your insurance plan may need to pay for the costs of preparing these study agents and giving them to you.
* *{Include if this is a device study}* You or your insurance provider will/will not have to pay for the study device [\*insert name of study device(s)\*] while you take part in this study. However, you and/or your insurance plan may need to pay for the costs associated with the implantation of the study device(s).
* You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
* Examples of research-related tests and procedures that may be provided at no cost to you may include: visits to the study site, procedures, research blood draws, and/or questionnaires. Talk to the study team about which items and procedures this includes.

*{For clinical research studies}* For costs of medical services for care you would receive even if you were not in this research study:

* You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
* You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
* You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
* You will be responsible for any charges not reimbursed by your insurance company.
* Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

**8b. What happens if I am injured as a result of taking part in this research study?**

Instructions: Include the following information in this section:

* Include the Penn State mandatory wording for treatment for injury (see below).
* If the sponsor will cover costs of research-related injuries, add a statement regarding the sponsor’s compensation for research-related injuries. This paragraph must be consistent with the subject-injury language in the sponsor contract.
* If there is no risk of injury to the subject, omit this section.

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

*{If there is no sponsor or the sponsor is not a for-profit company (e.g. NIH), include the following}*

Penn State compensation for injury

* There are no plans for Penn State to provide financial compensation or free medical treatment for research-related injury.
* If an injury occurs, medical treatment is available at the usual charge.
* Costs will be charged to your insurance carrier or to you.
* Some insurance companies may not cover costs associated with research injuries.
* If these costs are not covered by your insurance, they will be your responsibility.

***OR***

*{If the research is funded by a for-profit sponsor, include the following}*

Penn State compensation for injury

There are no plans for Penn State to provide financial compensation or free medical treatment for research-related injury.

Sponsor’s compensation for injury

If you suffer an illness, injury, or adverse event from taking part in this research study, medical care will be provided. The sponsor will reimburse your reasonable and necessary medical expenses for diagnosis and treatment of a research-related injury, illness, or adverse event.

*{The paragraph immediately above can be added to or replaced with the sponsor’s template language. This paragraph must be consistent with the subject injury language in the sponsor contract and the following clarifiers will not be accepted and should be removed/revised from the sponsor’s template language:*

* *PSH/PSU has adopted the position that for-profit sponsors must accept responsibility for the payment for all complications and/or injuries sustained by study subjects as a result of their participation in research. Language referencing a for-profit sponsor charging insurance companies for research related injuries must be removed*
* *Language that ties the cause of the research related injury “directly” to the use of the study drug or device. In these cases, the word directly must be deleted.*
* *References to the participant not following instructions or being negligent must be removed or clarified to reference that the failure to follow instructions was intentional.*
* *References to the injury, adverse event, or illness not being covered if it is attributable to the natural progression of an underlying or pre-existing condition or events, must include the clarifier “unless it’s made worse by participating in the study.”}*

*{Always end this section with the following statement}* When you sign this form you are not giving up any legal right to seek compensation for injury.

1. **Will I be paid to take part in this research study?**

Instructions: Include the following information in this section:

* Clearly describe any monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.) and whether payment is travel reimbursement, stipend, or a combination of the two.
* If subject is receiving reimbursement for travel only there is no need to collect SSN as this is not reported as income for tax purposes.
* If subject is paid by check the SSN must be collected. The consent form must state that the SSN will be collected and indicate that the SSN is needed for tax reporting purposes.
* Explain how compensation is pro-rated when a subject withdraws prior to completing the study. (This is mandatory to avoid possible undue influence associated with compensation.)
* If there is non-monetary compensation (e.g., small gift, gift certificate), describe that separately from the monetary compensation statement.
* Include the following statement for Department of Defense (DOD) research that targets military personnel where subjects will be paid. “Military personnel should check with their supervisor before accepting payment for participation in this research.”
* If a previously approved subject pool will be used, indicate “You will receive course credit for participating as specified in the syllabus provided by your instructor.”
* If no compensation of any kind will be offered indicate that subjects will not receive compensation for being in the study.
* If applicable, include information about commercial use of research information or specimens (see below).

*{If subjects receive a****stipend or reimbursement****for participation.}****Instructions:*** *Reimbursement and payment must occur in accordance with Penn State Research Protection Guidelines: RPG03, as outlined below.*

*{If subjects do not receive any compensation for participation.}* You will not receive any payment or compensation for being in this research study.

*{Compensation for participation language is distinct across Penn State campuses. Please see the* [*PSU Standard Consent Language*](https://pennstateoffice365.sharepoint.com/:w:/s/VPR-ORP/ETuaAmBIXsxElfxuVTl7TRsBmIfZH0e1Dc3W8tNrNauVMA?e=XJDMIG) *document for the required language applicable to your campus.}*

**10. Who is paying for this research study?**

Instructions: Include the following information in this section:

* Funding disclosure: Disclose what grantors, institution(s) (e.g., NIH) or companies are involved in the research through funding or grants. If none, say so.
* Conflict of Interest: Include information about any consultative relationships with the sponsor or financial or business interests the investigators may have related to this research.

*{For research with no external funding}* Funds from the <<e.g., Penn State College of Medicine or Department of (name of department)>> will be used to support this research.

*{For research with grant funding}* The institution and investigators are receiving a grant from <<grantor or institution>> to support this research.

*{For funding disclosure}* The sponsor <<sponsor’s name>> is paying Penn State for the research to be done.

**11.** **What are my rights if I take part in this research study?**

Instructions: Include the following information in this section:

* If there are anticipated circumstances under which the subject’s participation will be terminated by the investigator without regard to the subject’s consent, include the anticipated circumstances under which participation may be terminated by the investigator without the subject’s consent.
* If there are adverse consequences (physical, social, economic, legal, or psychological) of a subject’s decision to withdraw from the research, include a statement describing the consequences of a subject’s decision to withdraw from the research.
* If there are adverse consequences (physical, social, economic, legal, or psychological) of a subject’s decision to withdraw from the research, explain procedures for the orderly termination of the research.
* For clinical studies, include a statement that any significant new findings that develop during the course of the research, which may relate to the subject’s willingness to continue participation, will be provided to the subject, unless it is unlikely that there will be significant new findings during the course of the research which may relate to the subject’s willingness to continue participation.
* Describe what will happen to data if a subject withdraws. For FDA-regulated research, see template text below.

Taking part in this research study is voluntary.

* You do not have to be in this research.
* If you choose to be in this research, you have the right to stop at any time.
* If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

*{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>>.

*{Include for FDA-regulated research; otherwise delete.}* If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. *{Note: The consent document cannot give the subject the option of having data removed.}* If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled. *{Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study, and may consult public records, such as those establishing survival status.}*

*{If applicable, for research that is not FDA-regulated, describe what will happen to data collected to the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.}*

*{For clinical trials}* Your research doctor *{Add if applicable:* or the sponsor} may take you out of the research study without your permission.

* Some possible reasons for this are: <<list possible reasons, for example: continuing the research would be harmful, your condition has become worse, you become pregnant, you did not follow the instructions of the study doctor, you experience serious side effects>>.
* Also, the sponsor of the research may end the research study early.
* If your participation ends early, you may be asked to visit the research doctor for a final visit.

*{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 all studies}*During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.

**12. If I have questions or concerns about this research study, whom should I call?**

Instructions: Include the following information in this section:

* Clarify the subject’s right to have questions answered.
* Indicate the person to contact in case of further questions about the research or to report a research-related injury.
* Indicate the person to contact for questions about subject rights and privacy issues.

Please call the head of the research study (principal investigator), <<PI name>> at (xxx) xxx-xxxx. *{if clinical protocol add the next phrase}* or the <<division>> doctor on 24-hour call at (717) 531-8521 if you:

* Have questions, complaints or concerns about the research.
* Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at <https://www.research.psu.edu/irb/participants> if you:

* Have questions or want information regarding your rights as a person in a research study.
* Have concerns, complaints or general questions about the research.
* *{Add the next phrase if using identifiable health information}* Have questions about your privacy and the use of your personal health information.
* You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

*{Add the following statement for applicable clinical trials that are required by law or NIH policy to register in the ClinicalTrials.gov registry}* A description of this clinical trial will be available on <https://www.ClinicalTrials.gov>, as required by U.S. Law or policy. 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.

{See next pages for sub-study consent, statement of consent and signature lines}

Instructions: Use the following text only for optional parts of the research, e.g., storage of leftover tissue for future research, optional sub-studies, etc. For each optional part of the study include statements for subjects to initial regarding their decision about participating in this optional part of the study. Remove this section if there are no options parts of the research.

**Optional part(s) of the study**

In addition to the main part of the research study, there is another part of the research. You can be in the main part of the research without agreeing to be in this optional part.

*{Add information about the optional part(s) of the study.}*

*{Add option statements for subjects to initial to indicate their decision about participating in the optional part(s) of the study.}*

You should initial below to indicate what you want regarding the <<list the optional part(s) of the study>>.

a. <<Option statement 1>>.

\_\_\_\_\_\_ Yes \_\_\_\_\_ No

b. <<Option statement 2>>.

\_\_\_\_\_\_ Yes \_\_\_\_\_ No

*{For research involving optional storage of tissue for future research}*

Optional Storage of Tissue for Future Research

In the main part of this study, we are collecting <<list tissue and/or blood and/or cells>>from you. If you agree, the <<indicate researchers and/or sponsor>> would like to store leftover sample(s) for future research.

* These future studies may be helpful in understanding <<list disease(s)/condition(s)>>.
* It is unlikely that these studies will have a direct benefit to you.
* Neither your doctor nor you will receive results of these future research tests, nor will the results be put in your health record.
* Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(s) <<is/are>> used for this kind of research, the results will not be put in your health record.

*{For linked samples}* Your leftover samples will be labeled with <<list all identifiers that apply: “a code number”, “your initials”, etc. >>.

* These samples will be stored <<describe how the samples will be secured>>.
* The length of time they will be used is unknown.
* You will be free to change your mind at any time.
* You should contact principal investigator if you wish to withdraw your permission for your <<list tissue and/or blood and/or cells>>to be used for future research. Any unused <<list tissue and/or blood and/or cells>>will be destroyed and not used for future research studies.

*{For unlinked samples}* Your samples will not be labeled with any of your personal information, such as your name or a code number. They will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them.

You should initial below to indicate what you want regarding the storage of your leftover <<list tissue and/or blood and/or cells>>for future research studies.

a. Your sample*[s]* may be stored and used for future research studies to learn about, <<describe potential future research uses>>.

\_\_\_\_\_\_ Yes \_\_\_\_\_ No

c. Your sample*[s]* may be shared with other investigators/groups without any identifying information.

\_\_\_\_\_\_ Yes \_\_\_\_\_ No

{For research involving optional storage of photos and/or video recordings for future research}

Optional Storage of Video Recordings for Future Research

In the main part of this study, we are collecting << indicate photos and/or video recordings>> that contain identifiable information from you. If you agree, the researchers would like to maintain these << indicate photos and/or video recordings>> for future research or to be used in publications or at presentations.

* Any future studies may be helpful in understanding <<provide an explanation>>.
* It is unlikely that any future studies will have a direct benefit to you.

Your << indicate photos and/or video recordings>> will be labeled with <<list all identifiers that apply: “a code number”, “your initials”, etc. >>.

* These recordings will be stored <<describe how the recordings will be secured>>.
* The length of time they will be used is unknown <<OR>> the recordings will be kept for <<indicate how long>>.
* You will be free to change your mind at any time.
* You should contact principal investigator if you wish to withdraw your permission for your recordingsto be used for future research or publicly. The recordings will then be destroyed and not used for future research studies or shown publicly.

You should initial below to indicate what you want regarding the storage your << indicate photos and/or video recordings>>for future research studies.

a. Your identifiable << indicate photos and/or video recordings>> may be stored and used for future research studies to learn about, <<describe potential future research uses>>.

\_\_\_\_\_\_ Yes \_\_\_\_\_ No

b. Your identifiable << indicate photos and/or video recordings>> may be shared publicly at presentations or in publications.

\_\_\_\_\_\_ Yes \_\_\_\_\_ No

General Instructions: Use the following statement of consent when requesting a waiver of written documentation of consent (i.e., implied or verbal consent). No signature lines should be included in this document when obtaining implied or verbal consent.

Instructions: For obtaining implied or verbal consent from subjects.

**VERBAL/IMPLIED CONSENT TO TAKE PART IN RESEARCH**

I have read this consent form and the research study has been explained to me. I agree to be in the research study described above. A copy of this consent form will be provided to me or I will print a copy for my records. By agreeing to participate, I have not given up any of the legal rights that I would have if I were not a participant in the study.

General Instructions: Include signature line(s) as appropriate to the subject population and consent process described in the protocol documents. Delete those signature lines that are not applicable.

The persons signing the informed consent/authorization form (subject, parent/guardian, representative, and person obtaining informed consent) must print their own name, sign and write date/time of signature.

Instructions: For obtaining signatures directly from subjects.

**INFORMED CONSENT TO TAKE PART IN RESEARCH**

**Signature of Person Obtaining Informed Consent**

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

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

Signature of person who explained this research Date Time Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

**Signature of Person Giving Informed Consent and Authorization**

Before making the decision about being in this research you should have:

* Discussed this research study with an investigator,
* Read the information in this form, and
* Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

**Signature of Subject**

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

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

Signature of Subject Date Time Printed Name

Instructions: For parent(s) or guardian(s) signature(s) if child subjects enrolled.

**Signature of Parent(s)/Guardian for Child**

By signing this consent form, you indicate that you permit your child to be in this research and authorize your child’s information to be used and shared as described above.

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

Printed name of child

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

Signature of Parent/Guardian Date Time Printed Name

Parent

Individual legally authorized to consent to the child’s general medical care. (See note below.)

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.

Instructions: If required by the IRB, add a second parent signature line.

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

Signature of 2nd Parent or Guardian Date Time Printed Name

If signature of second parent/guardian not obtained, indicate why: (select one)

Second parent/guardian is deceased

Second parent/guardian is unknown

Second parent/guardian is incompetent

Second parent/guardian is not reasonably available (document reason in research record)

Only one parent/guardian has legal responsibility for the care and custody of the child

Instructions: If obtaining signature from legally authorized representative (court-appointed legal guardian, health care power of attorney, or health care representative) for an adult subject.

**Subject’s Legally Authorized Representative**

By signing below, you indicate that you give permission for the subject to be in this research and authorize the subject’s information to be used and shared as described above.

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

Printed name of subject

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

Signature of Date Time Printed Name

Legally Authorized Representative

Check the applicable box below indicating authority to act for subject:

Court-appointed legal guardian

Health Care Power of Attorney

Health Care Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to Subject

Instructions: Include the following signature line if your protocol or protocol site addendum indicates the “short form” consent process will be used to obtain and document informed consent of subjects who speak limited English. All approved translated versions of the short form available in the CATS IRB Library may be used for this purpose without submitting a modification. If you need the short form translated into other languages than the ones available in the CATS IRB Library, contact the HRPP for assistance. An impartial witness who is not affiliated with the research must be present for the consent discussion and sign the following statement. For more information, see the Investigator manual available in the CATS IRB Library.

**Witness to Consent for Limited English Speaking Subjects (Using a “Short Form” written in the subject’s own language)**

**Witness Statement:** As someone who understands both English and the language spoken by the subject or subject representative, your signature indicates that the English version of the consent form was presented orally in the language of the subject or subject representative, and that the subject or subject representative was given the opportunity to ask questions.

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

Witness Signature Date Time Printed Name

Instructions: Include the following signature line when you anticipate enrolling subjects who cannot read or write in any language. An impartial witness who is not affiliated with the research must be present for the consent discussion and sign the following statement.

**Witness to Consent of Subjects Who Cannot Read or Write**

**Witness Statement:** Your signature indicates that you were present during the informed consent discussion of this research for the above named subject, that the information in the consent form and any other written information was presented orally to the subject or subject representative, that the subject or subject representative was given the opportunity to ask questions, that the informed consent decision was freely made by the subject or subject representative who indicated consent and authorization for participation by (check the box as applicable):

Making a mark

Other means: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(fill in above)

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

Witness Signature Date Time Printed Name

Instructions*:* Include this section when assent of children or of decisionally-impaired adult subjects will be obtained. Generally, assent should be sought from age-appropriate and developmentally capable children (about age 7 years and older) unless omission is justified in the protocol.Do not include signature lines if you are requesting a waiver of written documentation of consent (i.e., implied or verbal consent).

**ASSENT FOR RESEARCH**

The research study has been explained to you. You have had a chance to ask questions to help you understand what will happen in this research. *{Add the next statements if the research involves urine drug testing in children}* You will have a urine drug test, and it must be negative to participate in this research study. If you are 13 years of age or younger at the time this consent/assent form is signed, and your urine drug test comes back positive, your parents will be notified of this information. If you are 14 years of age or older at the time this consent/assent is signed, and your urine drug test comes back positive, your parents will not be notified of this information without your consent. However, your parents may find out that you are using drugs as you will not be able to take part in this research. *{Add the next statements if the research involves pregnancy testing in children*} If you are a female capable of becoming pregnant you will be tested for pregnancy. The results of your test will not be shared with your parent/guardian without your permission. However, your parents may find out if you are pregnant because you will no longer be able to take part in this research.

You Do Not have to be in the research study. If you agree to participate and later change your mind, you can tell the researchers, and the research will be stopped.

You have decided: **(Initial one)** \_\_\_ To take part in the research.

\_\_\_ NOT to take part in the research.

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

Signature of subject Date Printed Name

OR

Assent not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.