



INSTRUCTIONS:

- *If your study qualifies for **Expedited or Full Board Review**, and requires a consent process with an adult population, you must submit this form, HRP-502, as an informational sheet for use with study participants. Use HRP-502b, for studies with subjects under the age of 18.*
- *This form may be provided electronically to study participants by email or as page one of an electronic survey.*
- *Instructions for completing are provided below in italics, with example wording.*

Delete all red text and italics before submitting this form in the IRB system. Attach a clean copy (i.e., no track changes, comments) in M.S. Word format. Attach the form in the Consent section of Local Site Documents page in the IRB system.

Title of research study: *[insert title of research study here]*

Investigator: *[insert name of principal investigator]*

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

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.]*

Why is this research being done?

[In simple, lay terminology, tell the subject the purpose of the research. Briefly explain the background of the research problem. Explain any potential benefits to others. (2-3 sentences)]

How long will the research last and what will I need to do?

We expect that you will be in this research study for _____. *[list the amount of both active participation time and overall duration--hours/days/months/weeks/years, until a certain event]*

You will be asked to _____. *[include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]*

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

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

[This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study. If risks are minimal, state: The risks to participation are minimal and do not exceed the risks associated with activities found in daily life.

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)[Delete if not applicable]***

Will being in this study help me any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits and should not list compensation, reimbursement, or course credit as a benefit.]

[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 _____ . ***[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 a study with no benefits to participation. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include _____. ***[Describe any benefits to others. 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 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.

OR

[if you are recruiting UCF students or employees. Otherwise delete.] Your participation in this study is voluntary. You are free to withdraw your consent and discontinue participation in this study at any time without prejudice or penalty. Your decision to participate or not participate in this study will in no way affect your continued enrollment, grades, employment or your relationship with UCF or the individuals who may have an interest in this study.

[Include if there are alternatives other than participating.] Instead of being in this research study, your choices may include: ***[List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]***

[Include if there are no alternatives other than participating.] Your alternative to participating in this research study is to not participate.

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

What should I know about a research study?

- Someone will explain this research study to you.
- 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.
- 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 PI. If the PI is a student, include both the student PI and Faculty Advisor name and contact information]***

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at 407-823-2901 or irb@ucf.edu if:

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

How many people will be studied?

We expect ____ people will be in this research study.

OR

We expect about _____ people here will be in this research study out of _____ 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***
- ***The drugs or biologics that will be given to the subject***
- ***All devices that will be used***
- ***All hospitalizations, outpatient visits and telephone or written follow-up***
- ***The length and duration of visits and procedures***
- ***If blood will be drawn, indicate the amount [in English units] and frequency***
- ***With whom will the subject interact***
- ***Where the research will be done***
- ***When the research will be done***
- ***List experimental procedures and therapies and identify them as such***

- *How often procedures will be performed*
- *What is being performed as part of the research study*
- *What is being performed as part of standard care*
- *What procedures are part of regular medical care that will be done even if the subject does not take part in the 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)*
- *When applicable indicate that the subject will be contacted for future research.*

[Include if there will be audio or video recordings. Otherwise delete.] You will be [audio or video as appropriate to the protocol] for recorded during this study. If you do not want to be recorded, you will <not> [Delete or add the “not” as appropriate to the protocol] be able to be in the study. Discuss this with the researcher or a research team member. If you are recorded as part of this study, the recording will be kept in a locked, secure place. The recording will be erased or destroyed when [Explain when the tape will be erased or destroyed. If the tapes will be kept indefinitely, explain this.]

[Include for a clinical trial or any study that involves randomization. Otherwise delete.] The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an _____ *[equal/one in three/etc.]* chance of being given each treatment. *[For double-blinded research add]* Neither you nor the study doctor will know which treatment you are getting. *[For single blinded research add]* You will not be told which treatment you are getting, however your study doctor will know.

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

[Delete this section if the research is not a clinical trial.]

If you take part in this research, you will be responsible to: *[Describe any responsibilities of the subject.]*

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.]*

[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 data 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. *[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.]*

[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.]

Is there any way being in this study could be bad for me? (Detailed Risks)

[Delete this section if there are no risks or discomforts, or if the risks listed in the beginning of the consent form are minor and do not require further detail.]

[The risks of procedures may be presented in a table 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, including all research involving an investigational product. 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.]* You should not be or become pregnant *[include as applicable “or father a baby”]* while on this research study.

[Include for research that may result in additional costs to the subjects. Otherwise delete.] Taking part in this research study may lead to added costs to you. *[Describe what these costs are.]*

[Include for a clinical trial. Otherwise delete.] You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

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 *[delete if no 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 Food and Drug Administration, when the research is FDA-regulated, 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.]

[Explain what identifiable private information [or identifiable samples] will be collected, who will have access to the information, and how long the information or links will be retained.

[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 identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:

If identifiers are removed from your identifiable private information ***[or identifiable samples]*** that are collected during this research, that information [or those samples] could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

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.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

[Include for FDA-regulated controlled drug and device trials (except Phase I drug trials) and FDA-regulated pediatric post-market surveillance trials of devices. Otherwise delete.] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

[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, contact the investigator and medical care will be made available. 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.]***

[Include if subjects will be paid or provided course credit. Otherwise delete.] If you agree to take part in this research study, we will pay you _____ ***[indicate amount, list the method of payment (cash, gift card, and when the compensation will be provided)]*** for your time and effort. ***[Indicate if the amount is pro-rated for research visit completion.]***

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[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.

[Include for a clinical trial.] Instead of being in this research study, your choices may include: ***[include alternatives.]*** The important risks and possible benefits of these alternatives include: ***[Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]***

[Include when applicable.] Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans ***[or replace with plans when using identifiable information/samples]*** to tell you, or to pay you, or to give any compensation to you or your family.

[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.] 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. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

[There are two 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.]

[In general, minimal risk studies may qualify for a Waiver of Written Documentation of Consent and the signature page can be deleted. Omit the signature page if you have requested a Waiver of Written Documentation of Consent in the study protocol.]

Permission to Take Part in a Human Research Study

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

[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

Permission to Take Part in a Human Research Study

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

[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