

Biomedical Research Consent Guidance

INSTRUCTIONS FOR THIS FORM:

Unless otherwise instructed, do not edit or remove **BLACK** text that is already populated in this document.

Areas in **BLUE** are to be edited to reflect your project.

Areas in **RED** are to be included if you are performing MRI scans as part of your protocol.

Do not copy/ paste from your protocol. Remove all citations and references.

Be certain to write information in plain language. Do not use jargon or abbreviations without explainers.
Include *all* risks, research activities, and incentives.

Remove this page prior to uploading this form.

Informed Consent for Participation in a Biomedical Research Study

Study Title: *(Complete title of the project as it appears on the protocol)*

Principal Investigator (PI): *(Only one person may be named as the PI)*

Other Investigators:

FAU IRB#

Contact for Questions about the Study	Contact for Questions about your Rights as a Research Participant, concerns or complaints that are not answered by the research team, or if you wish to talk to someone independent of the research.
PI/ Contact name: Phone Number: Email:	Florida Atlantic University Research Integrity Office (561) 297-1383 researchintegrity@fau.edu

This form contains information about a research study we want you to participate in. It may have words or processes that you may have questions about. We will answer all your questions and concerns before we ask for your signature. If you do decide to enroll in the study, if you still have questions, please let us know.

KEY INFORMATION

{Should not exceed one page}

You are being asked to take part in a research study about ... (include general description of study). This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

What is the purpose of this study?

Briefly describe the purpose if the study in lay terms. Put detailed descriptions in the main consent document (next pages).

This study will use magnetic resonance imaging (MRI) to evaluate the structure and function of the **body part**. By doing this study, we hope to learn how the **body part** works ...

What are the reasons you might choose to participate in this study?

State the most important reasons {benefits} a person may want to participate in this study. For a complete Description of benefits please refer to the Detailed Information section below.

What are the risks to participating in this study?

MRI Risks

MRI scanners are machines approved by the Food and Drug Administration in the US for diagnostic and research purposes. You will have the scan performed by lying on the scanner table and being moved into the main part of the scanner with the goal of placing your **body part** inside the scanner. MRI scanners use strong magnet fields. Due to the strength of the magnetic field of the MRI, there is a risk of being injured by receiving a burn on your skin or if an unsecured metal object flies into the MRI scanner. In order to minimize this risk, you will be asked to remove all metal objects from your person. In addition, all metal objects will be cleared from the area prior to the scan. This is the standard practice when patients/subjects undergo MRI exams.

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MRI scans are generally well tolerated, but an important exception is for those people who have electrically, magnetically or mechanically activated implants, or metal in or on their bodies. Such individuals might not be able to undergo MRI scanning since it might harm them or the device. In order to make sure the MRI procedure will be safe, you will be asked to complete an MRI Screening form before starting the study. It is important that you tell the researchers in this study if you have any history of the following:

- Any history of metal fragments in your body, eyes or face.
- Ear implants
- Implantation of any electronic devices such as (but not limited to) cardiac pacemakers, cardiac defibrillators, cochlear implants or nerve stimulators.
- Surgery on the blood vessels of your brain or the valves of the heart
- Surgically placed metallic clips (aneurysm clips)
- Claustrophobia (fear of enclosed places)
- Body piercing or tattoos

Some persons may experience some discomfort while lying flat on the table for MRI scans. The scanner may also feel confining and you should let the staff know if you have any specific problems with claustrophobia. The MRI scan does not involve any radiation exposure. There may be risks that are currently unforeseeable.

[[FOR CONTRAST STUDIES ONLY]]

Your MRI scan is going to be performed with intravenous contrast which helps to see parts of the body more clearly. For the intravenous (IV) contrast, prior to going into the scanner, a small needle will be placed in your arm and attached to an IV line that will allow us to inject the contrast. Anytime a needle is inserted into the skin, there is the risk that bleeding or infection can result. However, the procedure is done by trained personnel using appropriate antiseptic techniques that minimize the risk of bleeding and infection. The contrast agent, called gadolinium, will be injected through this IV line during the scan. The injection of gadolinium contrast may cause a cool sensation at the injection site. There is a small risk of an allergic reaction, which can range from mild (rash, itching) to severe (difficulty breathing). If you require medical assistance, we will have a doctor available to treat your symptoms, and if they are severe, we may call 911 in order to take you urgently to the hospital. Rarely, gadolinium can cause a condition called nephrogenic systemic fibrosis (NSF) in patients with severe kidney disease.

Risks of Discovering an Incidental Finding

IMPORTANT: This project is for research purposes only and is not directed or designed for clinical diagnosis as part of medical treatment, and the scans performed in this study are not optimal to find abnormalities. The MRI conducted for research studies is not intended to replace the Standard of Care suggested by physicians. You should not expect that the investigators review the MRI in a way that could detect an abnormality. You should not participate in the study if you want or expect to obtain a clinical diagnosis.

The general results of the scans will be described in a clinical report by a trained specialist. If an unknown abnormality (also called an incidental finding) is discovered on the MRI scan, the MRMD and/or Principal

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Investigator (if a physician) will counsel you about the abnormality and will help refer you to your primary care physician or a specialist who can further evaluate the abnormality and help you manage it. Such a finding may make you feel anxious or depressed. However, the information and scans will be made available to your primary care doctor or referring physician to help you address the incidental findings in a timely manner. However, the decision as to whether to proceed with further examination or treatment from a physician independent of this research study will be your responsibility and decision. The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

What to Do If You Experience Any Adverse Effects

You should call the study Principal Investigator as soon as possible at *phone number* if, during the course of this study. You develop any symptoms from exercise or if your medical condition worsens. If it turns out that being in this study is not in your best interest, you will be taken out of the study.

Do you have to take part in this study?

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

Add the following for student volunteers and/or employees: As a student/employee, if you decide not to take part in this study, your choice will have no effect on your academic status or class grade(s) or employment status.

DETAILED INFORMATION

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?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- Participation is voluntary; whether you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from FAU providers.
- You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

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[Any applicable trials initiated on or after March 7, 2012, must include a specific statement that refers subjects to the publishing of the study data on www.ClinicalTrials.gov. The Food and Drug Administration (FDA) provides the following language that must be used in all consent forms word-for-word]

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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. Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research.]

How long will I be in the study?

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

How many people will take part in this research study?

We expect about _____ people will take part in the entire study.

What happens if I agree to be in this research?

MRI Scans

Before the MRI scan, we will ask you a number of questions to make sure you do not have any metal in your body that might affect the scanner. The MRI scanner has no radiation, but does make loud banging noises for which you will be given ear plugs and/or ear phones to block the sound.

The MRI scan will require you to lie quietly on the scanner table with your *body part* in a [special coil for your *body part*] that enables us to take pictures of your *body part* for approximately XX minutes while in the scanner. It is important that you remain as still as possible during the study. This MRI will allow us to take a picture of your *body part* during different states. The scanner will make a variety of different loud noises which are related to the various measures or sequences that the MRI scanner performs. You will be given ear plugs and/or head phones in order to minimize the sounds. While in the MRI scanner, you may be asked to perform certain tasks *[if tasks will be performed specify below]* or movements but otherwise you will be asked to rest quietly. If any of the procedures are uncomfortable, you can notify the researcher in charge of the scan using an emergency squeeze ball. We will give you this squeeze ball to squeeze in order to indicate at any time that you wish to stop. The MRI staff member will temporarily stop the scan and will help resolve any issues you may have with the scan. If you continue to feel uncomfortable, you can opt out and stop the scan at any time. This will likely terminate your participation in the study.

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

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- *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*
- *When applicable indicate that the subject will be contacted for future research.*

[Include for a clinical trial 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 people conducting the research will know which treatment you are getting. **[For single blinded research add]** You will not be told which treatment you are getting, however the people conducting the research 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].***

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What other choices do I have besides taking part in the research?

[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 clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option. If drug/device/treatment is available as standard of care, state so here].*

What happens if I agree to be in research, but later change my mind?

[Include for research involving students or employees. Otherwise delete] If you are a student or employee at Florida Atlantic University, your academic standing/employment status will not be affected in any way should you choose not to take part or to withdraw at any time.

[Include for all research] You may refuse to participate, or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

[Include if there are potential adverse medical 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, please contact the research team so that they 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?

[Please note that all research study has some risk.]

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. The risks may be presented in a table form]

- *[Physical risks]*
- *Psychological risks*
- *Privacy or confidentiality 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 unknown ways. These may be a minor or 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].

FOR WOMEN: Although the majority of data suggests that MRI scans are safe for pregnant women, as well as embryos or fetuses, there is still much that remains unknown. For this reason, we believe that it is safer not to allow anyone who suspects they might be pregnant to participate in MRI scanning. We will ask all women of child bearing potential if they might be pregnant. If you are pregnant or you feel that there is any chance that you may be pregnant, you should not participate in this study at this time. You do not need to tell us why you have chosen not to participate. Not participating is your right. If there is no chance that you might be pregnant, please let the staff know and you can proceed with the scan. If you think you might be pregnant, and

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would still like to participate, we can perform a pregnancy test to be certain. You will be informed of the result of the pregnancy test, positive or negative.

[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.

[Include for a clinical trial where subjects are randomized to 2 standard of care procedures. Otherwise delete]. The risks and potential complications are similar if you decide to not participate in the study. One potential risk of participating in the study is that you may receive a different *[procedure, treatment, drug, device]* than you would if you do not participate. While these *[procedures, treatments, drugs, devices]* are currently believed to be safe, there may be additional risks discovered in the future. Your care will be identical whether you decide to participate in this study or not. If you do not participate in the study, the decision to have *[procedure, treatment, drug, device]* is up to the personal preference of you and your doctor.

What happens if I believe I am injured because I took part in this study?

The researchers have taken steps to minimize the known or expected risks. In spite of all precautions, you still may experience medical complications or side effects from participating in this study. You should promptly notify the study doctor in the event of any illness or injury as a result of being in the study.

[Include if compensation for research related injury is not available. Otherwise delete and insert language detailing compensation and medical treatment available.] If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment from your physician or treatment center of choice. Care for such injuries will be billed in the ordinary manner to you or your insurance company.

You will not receive any financial payments from FAU for any injuries or illnesses. You do not waive any liability rights for personal injury by signing this form.

Will being in this study help me in any way?

[Include if there are no benefits to participation. Otherwise delete]. You will not receive any benefits from participating in this research.

[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 a clinical trial 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 and should be described in a later section].*

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[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.

Can I be removed from the research without my permission?

[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 happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information. Others include *[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].*

[Use one of the following statements about any research that involves the collection of identifiable private information or samples (biospecimens)]:

Your information *[or samples, if applicable]* collected as part of this research will not be distributed or used for future research studies.

-or-

Your information *[or samples, if applicable]* with identifiers removed might be distributed or used for future research studies without additional informed consent.

[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]. The privilege of confidentiality does not extend to information about sexual or physical abuse of a child. If any member of the research team has or is given such information, he or she is required to report it to the appropriate authority or agency, such as child protective services, a law enforcement agency, or your State's toll-free child abuse reporting hotline. The obligation to report includes past and current alleged or reasonably suspected abuse as well as past or current known abuse. Examples of such abuse include physically harming your child or having inappropriate sexual contact with your child.

[Include if requesting a Certificate of Confidentiality. Otherwise delete]. To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, *[except as explained below]. [Use the following language as applicable]* The Certificate cannot be used to resist a

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demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

[Language such as the following should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.] The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*.

[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.

[The following language is recommended when samples of tissues, cells, blood, or body fluids (hereafter referred to as tissues) will be taken or banked for use in current or future research. This includes testing the sample for purposes of collecting genetic or other information. Investigators should choose the appropriate provisions to be included in their informed consent form and may vary any of the following language as appropriate.]

Tissue Sampling for Research

Research using tissues is an important way to try to understand human disease. You have been given this information because the investigators want to include your tissues in a research project and because they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

Your tissues will be stored *[insert how samples will be stored - and if appropriate how samples will be linked] e.g., under diagnosis and medical record or code number and unlinked*.

[If linked]: You have the right to refuse to allow your tissues to be studied now or saved for future study. You may withdraw from this study at any time. The investigators might retain the identified samples, e.g., as part of your routine clinical care, but not for additional research. De-identified information or biospecimens may or may not be used or shared for future research.

[If unlinked]: Because your samples will not be linked to your name after they are stored, you cannot withdraw your consent to the use of the samples after they are taken.

[Optional]:

The results of the study of your samples will be used for research purposes only and you will not be told the results of the tests. *[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].*

[Or]

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You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

Tissue Sampling for Genetic Testing

[Include the following language if samples in study will be used for genetic testing or if future research on samples will include genetic testing.]

As part of the analysis on your samples, the investigators (may/will) do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

[If investigators will not share the research results with the participant, the following language can be added]

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests.

[If investigators will allow participants to choose whether they want to receive test results and/or will contact participants in the future, the following language (two choices of language) can be added]:

Regarding informing you of the test results, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

Please circle [yes or no] as to whether you wish to be told the test results.

Please circle [yes or no] as to whether you wish your family members to be told the test results.

[Or]

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following:

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- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;
- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

[If you would like to contact participants about future studies, include the following statement]:

*May we contact you about future studies that may be of interest to you?

____ Yes ____ No

How will my privacy and health information be protected?

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form

The use and release of protected health information is for the purpose of collecting data for this study.

Protected Health Information to be shared: *[list all PHI that will be used or disclosed for this specific study]*

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

Hospitals: <List by name>

Clinics: <List by name>

Other Providers: <List by name>

Health Plan: <List by name>

And from hospitals, clinics, health care providers, and health plans that provide health care to you during the study.

By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Other healthcare providers such as labs which are part of the study;
- A safety monitoring board {include only if applicable};
- Institutional officials who are responsible for compliance;

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Some of the tests in this study would have been done as part of your regular care. These test results will be used both to treat you and to complete this research. The test results will be recorded in your medical record. These study results will be included in your medical record. Results of tests and studies done solely for this research study and not as part of your regular care will *[also] OR [not]* be included in your medical record.

[for use this alternative statement:]

All tests are being done only because you are in this study. The study results will *[not]* be *[given to you to send] OR [sent]* to your physician to include in your medical record.

Once your health information has been disclosed to others outside of the hospitals and medical practices *[customize this part of the phrase to fit this study]*, the information may no longer be covered by the federal regulation that protects privacy of health information.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.

This Authorization does not have an expiration date.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission.

To cancel your permission, you will need to send a letter to [name Principal Investigator] stating that you are canceling your authorization. This letter must be signed and dated and sent to this address: [enter the name and address of the Principal Investigator].

[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.

[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.

Are there any costs for participating in this research?

[Include any costs that may be incurred due to the research. Indicate whether participants will be financially responsible for any clinic/hospital charges.]

Will I be paid or otherwise compensated for my participation in this research?

[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 if subjects will be paid \$600 or more during the course of the study. Otherwise delete.] Your name and social security number will be reported to the appropriate Florida Atlantic University (FAU) employees for purposes of making and recording the payment. You are responsible for paying income taxes on any payments

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provided by the study. If you receive \$600 or more from the University, FAU must report the amount you receive to the Internal Revenue Service (IRS) on the form 1099-Misc. This form tells the IRS that payment was made to you, but it does not say that you were paid for taking part in this research study. You should talk to your tax advisor regarding the proper use of this form 1099-Misc.

[If the subject's biospecimens (even if identifiers are removed) may be used for commercial profit, include the following statement: (Modify if subjects will share in commercial profit.)]

Your specimens (even if identifiers are removed) may be used for commercial profit. You will not share in this commercial profit.

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 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 that the investigator believes that the biologic specimens obtained could be part of or lead to the development of a commercial product].

[When applicable indicate when and how the subject will be informed of the results of the research. Include a statement that indicates whether clinical results, including individual research results, will be returned to the subject, and if so, under what conditions].

[Include if investigators have a conflict of interest, and tailor to specific conflict. Otherwise delete.] An individual responsible for the conduct of this research study has a financial interest in the study drug or the medical device being used in this research study.

Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. (Delete duplication)A copy of this document will be provided to you.

Printed name of subject

Signature of subject

Date

[Signature of person obtaining consent is optional for minimal risk studies. If your project meets these criteria, you may delete.]

Name of Person Obtaining Informed Consent _____

Signature of Person of Obtaining Informed Consent _____

Date _____

**Informed Consent for Participation in a
Biomedical Research Study**

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