**Checklist for Study Teams**

**Instructions**

* The purpose of this form is to make sure that all required elements of consent from the revised common rule are included in your inform consent document
* This form needs to be completed and submitted separately with your consent forms.
* Copy and paste the chart below to a different Word document, and **delete it** from the consent template (that should start with the concise presentation). We will not stamp the checklist.
* **One checklist can apply to all consent forms of the study.**

|  |
| --- |
| BASIC ELEMENTS OF INFORMED CONSENT YES N/A |
| 1 | Statement that the study involves research Explanation of the purpose of the research Expected duration of participation Description of the procedures Identification of *research* procedures v. *non-research* | [ ]  | [ ]  |
| 2 | Description of any reasonably foreseeable risks or discomforts | [ ]  | [ ]  |
| 3 | Description of any benefits to the subject or to others that may be reasonably expected from the research | [ ]  | [ ]  |
| 4 | Disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the subject | [ ]  | [ ]  |
| 5 | Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the research staff, IRBs, sponsor, their representatives, and possibly the FDA or OHRP. | [ ]  | [ ]  |
| 6  | For research involving more than minimal risk, a statement that emergency medical care will be arranged for a study-related illness or injury, and an explanation of whether funds are set aside to pay for this care and/or compensation, and if so by whom (e.g., sponsor, subject, insurer). Language must not be exculpatory (i.e. “In case of injury” language) | [ ]  | [ ]  |
| 7 | An explanation of whom to contact for answers to pertinent questions about the researchand research subjects’ rights, and whom to contact in the event of a research-related injury tothe subject | [ ]  | [ ]  |
| 8  | A statement that participation is voluntary, refusal to participate will involve no penalty orloss of benefits to which the subject is otherwise entitled, and the subject may discontinueparticipation at any time without penalty or loss of benefits to which the subject is otherwiseentitled | [ ]  | [ ]  |
| 9  | One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: |
| 9(i) | A statement that identifiers might be removed from the identifiable private informationor identifiable biospecimens and that, after such removal, the information or biospecimenscould be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legallyauthorized representative, if this might be a possibility; or | [ ]  | [ ]  |
| 9(ii) | A statement that the subject’s information or biospecimens collected as part of theresearch, even if identifiers are removed, will not be used or distributed for future researchstudies. | [ ]  | [ ]  |

|  |
| --- |
| **ADDITIONAL ELEMENTS: ONE OR MORE MAY BE APPROPRIATE YES N/A** |
| 1 | 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 may become pregnant) that are currently unforeseeable. | [ ]  | [ ]  |
| 2  | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative’s consent. | [ ]  | [ ]  |
| 3  | Any additional costs to the subject that may result from participation in the research. | [ ]  | [ ]  |
| 4 | The consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject. | [ ]  | [ ]  |
| 5 | A statement that significant new findings developed during the course of the research that may affect the subject's willingness to continue to participate will be provided to the subject. | [ ]  | [ ]  |
| 6 | The approximate number of subjects involved in the study. | [ ]  | [ ]  |
| 7 | (Required for research involving biospecimens) A statement that the subject’s biospecimens (even if identifiers are removed) may be usedfor commercial profit and whether the subject will or will not share in this commercial profit | [ ]  | [ ]  |
| 8 | (Required for research generating any test results) A statement regarding whether clinically relevant research results, including individualresearch results, will be disclosed to subjects, and if so, under what conditions; and | [ ]  | [ ]  |
| 9 | (Required for research involving biospecimens) For research involving biospecimens, 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). | [ ]  | [ ]  |

 **You Are Being Asked to Be in a Research Study**

**Concise presentation of key concepts**

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of INSERT NUMBER people who are being studied, at Emory and elsewhere.

**Why is this study being done?**

This study is being done to answer the question: INSERT QUESTION HERE. You are being asked to be in this research study because INSERT REASON HERE.

**Do you have to be in the study?**

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

**What do I have to do if I choose to participate in this study?**

If you are eligible and want to be part of the study, you will participate for XXX (XXX study visits). The researchers will ask you to do the following: INSERT. Some/ALL/None of these procedures will be paid for by the study.

**How is this study going to help you?**

If you are in the study, you will be helping the researchers answer the study question. INSERT OTHER BENEFITS IF APPLICABLE.

**What are the risks or discomforts I should know about before making a decision?**

The study will take time. The drug/device/procedure that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include [risks of the DRUG/DEVICE/PROCEDURE, SOME OF WHICH INCLUDE], loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

**Alternatives to Joining This Study**

[Describe alternative treatments here, specific to the enrolling institution, or say “Since this is not a treatment study, the alternative is not to participate”).

**Costs**

You WILL / WILL NOT have to pay for some/any of the study procedures, in particular those that are not covered by your medical insurance.

The study team can help you work out how much you might have to pay. There is more information in the cost section below.

**What Should I Do Next?**

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand which parts of the are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

**Emory University**

**Consent to be a Research Subject**

**Title**:

**IRB #:**

**Principal Investigator:**

**Sponsor:**

**Investigator-Sponsor:**

**Study-Supporter:**

*If you are the legal guardian of a child who is being asked to participate, the term “you” used in this consent refers to your child*

## Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

* Please carefully read this form or have it read to you
* Please listen to the study doctor or study staff explain the study to you
* Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

## What is the purpose of this study?

The purpose of this study is to…

## What will I be asked to do?

**How will my medicine be provided**?

The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member.  The principal investigator or health care providers on his/her research team will provide the medicine to you.  If you have questions about the medicine, you should ask the principal investigator or study nurse.  You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

## Who owns my study information and samples?

## If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

## What are the possible risks and discomforts?

There may be side effects from the study drug or procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

The less common risks and discomforts expected in this study are:

Rare but possible risks include:

**If you are a woman**: to protect against possible side effects of the study drug, women who are pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

**If you are a man:** the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug and for \_\_\_\_\_\_\_\_\_\_ days/weeks/months after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

## Will I benefit directly from the study?

This study is not designed to benefit you directly. Your [condition] may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about… The study results may be used to help others in the future.

##### Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

*OR SOMETHING LIKE*

You will get $\_\_\_\_ for each completed study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $\_\_\_\_ total, if you complete all study visits. You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

##### What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. [List the major standard care options and/or possibility of other studies; if the study compares two standard care treatments, state which one the subject would be most likely to get outside of the study, if applicable] The study doctor will discuss these with you. You do not have to be in this study to be treated for [condition].

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

**How will you protect my private information that you collect in this study?**

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Certain offices and people other than the researchers may look at study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include [The Food and Drug Administration, the Office for Human Research Protections, the funder(s), the Emory Institutional Review Board, the Emory Office of Research Compliance]. Study funders may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

# Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

* Giving state public health officials information about certain infectious diseases,
* Giving law officials information about abuse of a child, elderly person or disabled person.
* Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**Storing and Sharing your Information**

De-identified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data [and specimens] from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

OR

Your data [and specimens] from this study will not be shared with anyone outside this study, even if we take out all the information that can identify you.

We will use your sample and data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial cell line, a medical or genetic test, a drug, or other commercial product) that could be sold by a company. You will not receive money from the sale of any such product.

**[No results returned to participants]**

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

**[Participants will receive aggregate results]**

Once the study has been completed, we will send you a summary of all of the results of the study and what they mean. We will not send you your individual results from this study.

**[Participants have option to receive individual results]**

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

**[INSERT OTHER SECTIONS FROM MODULAR CONSENT DOCUMENT HERE]**

**Medical Record**

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

OPTION 1 FOR NON-SENSITIVE: Copies of the consent form that you sign will be put in any Emory Healthcare medical record you have now or any time during the study. We will keep a copy of these documents in a separate research record that we will use for research purposes. We will ask for your authorization if we need to obtain any information from your medical record.

OPTION 2 FOR SENSITIVE: We will take reasonable steps to keep copies of this form out of Emory Healthcare’s medical records system. If we aren’t successful in keeping these forms out, despite our efforts, we will take steps to remove them. If they cannot be removed, we will take steps to limit access to them.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure. We will ask for your authorization if we need to obtain any information from your medical record.

We will also keep a separate research record of all study tests and procedures that we will use for research purposes. This research record will not be a part of your medical record. For this study, those items include:

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

**[INSERT OTHER SECTIONS FROM MODULAR CONSENT DOCUMENT HERE]**

## In Case of Injury

OPTION 1: The sponsor may choose not to pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured.

If you believe you have become ill or injured from this research, you should contact Dr. \_\_ at telephone number \_\_\_. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor have set aside money to pay for this medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

OPTION 2: The sponsor may choose to pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured.

If you believe you have become ill or injured from this study, you should contact Dr. \_\_ at telephone number \_\_\_. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Emory has not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. “Negligence” is the failure to follow a standard duty of care. If you get ill or injured as the direct result of the study drug [or device, as appropriate] or a study procedure, the sponsor will pay the costs for your medical treatment of the illness or injury. The sponsor will not pay for co-payments or co-insurance that your insurer says you must pay. Also, the sponsor will not pay for illness or injury:

1. from medical conditions you had before you started the study;
2. from the natural progression of your disease or condition;
3. from your failure to follow the study plan; or
4. that is directly caused by the negligence of an Emory employee.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment that the sponsor does not pay. Your insurer may be told that you are in a research study.

You will have to pay for any treatment costs that are not paid for by your insurance or the sponsor.

OPTION 3: The sponsor may choose to pay for Subject Injury Costs for uninsured subjects or subjects with Medicare/Medicaid and to pay any part of Subject Injury Costs for privately insured subjects that are not covered and/or paid by their private insurance.

If you believe you have become ill or injured from this research, you should contact Dr. \_\_ at telephone number \_\_\_. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you get medical treatment. Emory has not set aside any money to pay you if you are injured as a result of being in this study. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence. “Negligence” is the failure to follow a standard duty of care.

If you get ill or injured as the direct result of the study drug [or device, as appropriate] or a study procedure, then, depending on what insurance you may have, the sponsor may pay for some of all of the costs of your medical treatment for the illness or injury. If you are uninsured, or if you have Medicare or Medicaid, the sponsor will pay for the costs of your medical treatment for the illness or injury. If you have Medicare or Medicaid, the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

If you have private insurance, Emory will look at your claims for these costs to determine if they can be sent to your insurance for payment. Your insurer may be told that you are in a research study and given information about your treatment. The sponsor will pay for the costs that are not paid by your insurance provider.

The sponsor will not pay for co-payments or co-insurance that Medicare, Medicaid or your private insurer says you must pay. Also, the sponsor will not pay for illness or injury:

1. from medical conditions you had before you started the study;
2. from the natural progression of your disease or condition;
3. from your failure to follow the study plan; or
4. that is directly caused by the negligence of an Emory employee.

You will have to pay for any treatment costs that are not paid for by the sponsor or by any insurance you may have.

## Costs

*OPTION 1: There are no costs, research or standard of care related, associated with the study*.

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury” as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

*OPTION 2: The sponsor will pay for certain items or services associated with the study.*

The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that the sponsor does not cover. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

*OPTION 3: The sponsor will not pay for any items or services associated with the study.*

The study sponsor does not plan to pay for any items or services that you may receive if you take part in this study.

You will have to pay for the items or services that are part of this study. The sponsor will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that are part of this study. Emory will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

## Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor’s advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done, specifically:

* EXAMPLE-Imaging, lab work, etc.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

**Contact Information**

Contact [study contact person(s)] at [telephone number(s)]:

* if you have any questions about this study or your part in it,
* if you feel you have had a research-related injury or a bad reaction to the study drug, or
* if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

* if you have questions about your rights as a research participant.
* if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at [**https://tinyurl.com/ycewgkke**](https://tinyurl.com/ycewgkke)**.**

## Consent

**Consent for Optional Study/Studies:**

Please initial below if you opt to participate in the optional study/studies previously described:

**[OPTIONAL STUDY TITLE] \_\_\_\_\_\_\_\_\_\_\_\_Initials**

***TO BE FILLED OUT BY SUBJECT ONLY***

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

**Name of Subject**

**Signature of Subject (18 or older and able to consent) Date Time**

**Signature of Legally Authorized Representative Date Time**

**Authority of Legally Authorized Representative or Relationship to Subject**

***TO BE FILLED OUT BY STUDY TEAM ONLY***

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Person Conducting Informed Consent Discussion**

**Signature of Person Conducting Informed Consent Discussion Date Time**