**Checklist for Study Teams**

**Instructions**

The purpose of this checklist is to make sure that all required elements of consent from the revised common rule are included in your informed consent form.

* Copy and paste the checklist below to a different Word document.
* Submit the checklist **separately** with your consent forms.
* **Delete this checklist** from this consent form template, which begins below with the “concise presentation.”
* We will not stamp the checklist.
* One checklist can apply to all consent forms for the study.
* Remember to add a **version date** to the footer of each informed consent form.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 research  and research subjects’ rights, and whom to contact in the event of a research-related injury to  the subject |  |  | |
| 8 | A statement that participation is voluntary, refusal to participate will involve no penalty or  loss of benefits to which the subject is otherwise entitled, and the subject may discontinue  participation at any time without penalty or loss of benefits to which the subject is otherwise  entitled |  |  | |
| 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 information  or identifiable biospecimens and that, after such removal, the information or biospecimens  could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally  authorized representative, if this might be a possibility; or |  | |  |
| 9(ii) | A statement that the subject’s information or biospecimens collected as part of the  research, even if identifiers are removed, will not be used or distributed for future research  studies. |  | |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **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 used for 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 individual research 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 choice to join 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 choose, take time to learn about the study.

**What do you have to do if you choose to join this study?**

If you qualify and choose to join the study, you will participate for XXX (XXX study visits). The researchers will ask you to do the following: INSERT PROCEDURES. 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. This study is not intended to benefit you directly. INSERT OTHER BENEFITS IF APPLICABLE.

**What are the risks or discomforts you should know about before deciding?**

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. Risks for this study include:

* [risks of the DRUG/DEVICE/PROCEDURE, SOME OF WHICH INCLUDE]
* loss of privacy
* breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled “What are the possible risks and discomforts?”

**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**

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.

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.

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.

There is more information in the “Costs” section further below.

**What Should You 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 such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

**Emory University**

**Consent to be a Research Subject / HIPAA Authorization**

**Title**:

**IRB #:**

**Principal Investigator:**

**Faculty Advisor:**

**Sponsor:**

**Investigator-Sponsor:**

**Study-Supporter:**

If you are the legal guardian of a child who is being asked to participate, the term “you” refers to the child.

## Introduction

You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

* Read this form or have it read to you
* Listen to the study doctor or study staff explain the study to you
* Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not 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.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

## What is the purpose of this study?

The purpose of this study is to…

## What will you be asked to do?

**How will your study drug be provided**?

The study drug 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 study drug to you.  If you have questions about the study drug, you should ask the principal investigator or study nurse.  You may also call the pharmacy if you have questions about the study drug. The number for the pharmacy is included on your study drug package, if given one.

Note: The research team for this study includes non-licensed team members who may obtain your consent, or help guide you through the study. There are some kinds of questions only licensed clinicians can answer. For example, detailed questions about drug interactions. If you have questions like these, the non-licensed coordinator will ask a licensed study team member to answer your questions.

## Who owns your study data and samples?

## If you join this study, you will be donating your samples and data. You will not be paid if your samples or data are used to make a new product. If you leave the study, the 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 it is biologically possible for you to become pregnant**: to protect against possible side effects of the study drug, people 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 person 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 people will be taken out of the study.

**If it is biologically possible for you to make someone pregnant:** the effect of the study drug on sperm is not known. To protect against possible side effects, 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 take 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.

Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

## Will you benefit from the study?

You may not benefit from joining the study. Your condition may improve while you are in this study or it may get worse. This study is designed to learn more about… The study results may be used to help others in the future.

##### Will you be paid for your time and effort?

You will not be compensated for being in this study.

*OR SOMETHING LIKE*

You will get $\_\_\_\_ for each completed study visit, 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 with your Social Security or Taxpayer Identification Number depending on the amount and method of payment. If your payment will be sent to your house in the mail and could be seen by others in your household you can choose not to be compensated. You can decline payment if you are concerned about confidentiality, or you can talk to the study team if there are other ways to be compensated.

##### What are your other options?

If you choose not to join this study, you can get care outside of this 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 your condition.

If you choose to join this study, you may not be able to join other research studies. Discuss this with the researchers if you have concerns. You may wish to look on websites such as clinicaltrials.gov and ResearchMatch.org for other research studies you may want to join.

**How will your private information be protected?**

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.

# 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**

We will store all the data [and specimens] that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data [and specimens] may be useful for other research being done by investigators at Emory or elsewhere. We may share the data [or specimens], linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

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 may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your [specimens 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.

**Returning Results to Participants/Incidental Findings**

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

**Medical Record**

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

OPTION 1 FOR NON-SENSITIVE Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study.

OPTION 2 FOR SENSITIVE: We will take reasonable steps to keep copies of this form out of Emory’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 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 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.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in 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.

## 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 (note: this is the default for federally-funded studies).

If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory <<, the Federal Government (including but not limited to the National Institutes of Health as applicable)>> do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

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 get ill or injured from this research, contact the person listed in the contact section of this form.

Emory will help you get immediate medical care. However, Emory does not have a program to pay for this medical care or to compensate you if you are hurt from being in this study.

The sponsor has agreed to pay the usual and standard costs of treatment or hospital care you receive as a direct result of a study-related injury if the costs are not the result of care required to treat your underlying disease or condition.

Any costs that are not covered by the study sponsor or your insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

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 get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory does not have a program to pay for this medical care or to compensate you if you are hurt from being in this study. The sponsor has agreed to pay the usual and standard costs of treatment or hospital care you receive as a direct result of study-related injury that are not the result of care required to treat your underlying disease or condition.

## Any costs that are not covered by the study sponsor or your insurer will be billed to you.

## 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.

## 

## You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

## 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 last planned study visit, the researchers may ask you to complete some of the final steps such as lab work or imaging as applicable.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

These are some reasons why the researchers may take you out of the study:

**INSERT APPROPRIATE HIPAA OR CONFIDENTIALITY LANGUAGE HERE**

**Contact Information**

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact [study contact person(s)] at [telephone number(s)]:

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or [irb@emory.edu](mailto:irb@emory.edu).

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at [**https://tinyurl.com/ycewgkke**](https://tinyurl.com/ycewgkke)**.** 

## Consent and Authorization

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

**Print** your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. 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**

# Optional Study Information

Your data and/or specimens will be protected the same way as the data and/or specimens for the main study. There are no additional risks or costs for joining the optional study than the ones already described for the main study (see sections above).

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

The purpose of this study is to…

**What will I be asked to do?**

**Will I benefit directly from the study?**

This substudy 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 substudy.

*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, if joining the substudy increases your annual compensation over the taxable amount.

**What are my other options?**

You can participate in the main study and not take part in this substudy.

**Withdrawal from the Substudy**

You have the right to leave this substudy at any time without penalty. You may stay in the main study even if you leave this substudy.

The researchers also have the right to stop your participation in this substudy 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**

See contact information for the main study, above.

**HIPAA Authorization for Optional Substudy**

You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not, you can still be in the main research study.

Your PHI will be used in the Optional Substudy the same way it will be used and disclosed for the main study, with the following differences:

* The following types of PHI may be used or disclosed for the optional substudy:
* The purpose of the use and disclosure is for the optional substudy described above
* The following *additional* people may use or disclose your PHI:

## Consent and Authorization

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

Please **print** your name, **sign**, and **date** below if you agree to be in the optional study(ies) described above. By signing this 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**