

Emory University XIRB Consent Form Checklist

Instructions: Language below must be inserted into model consent template as applicable to the study to create the Emory site-specific consent form. Please fill this out to determine which Emory-specific language should be added to the master consent template for our site. Language should be either added or replaced in the master template based on the instructions in [purple](#) below. Please also see the HIPAA section for instructions on how to create your HIPAA authorization language.

<p>Please check if any of these are site locations for this submission.</p>	<p><input type="checkbox"/> <i>Children’s Healthcare of Atlanta</i></p> <p><input type="checkbox"/> <i>Grady Health System</i></p> <p><input type="checkbox"/> <i>Saint Joseph’s Hospital</i></p> <p><input type="checkbox"/> <i>Emory Johns Creek Hospital</i></p> <p><input type="checkbox"/> <i>None of the above</i></p> <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> <p style="font-size: small; color: blue;">NOTE: If the study team is performing study activities at any of the sites above, the documents should include the site name as listed above every place that states “Emory Healthcare” or “Emory.”</p> <p style="font-size: small; color: blue;">Ex: For Grady, you will use “Emory Healthcare and Grady Health System” and “Emory and Grady” throughout the documents.</p> <p style="font-size: small; color: blue;">Also see other required language for these sites in various sections below.</p> </div>
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<p>Procedures</p> <p>Is this an investigational drug study requiring IDS, for which you HAVE NOT received an IDS waiver?</p> <p><input type="checkbox"/> Yes (if yes, include this language at the end of the procedures section)</p> <p><input type="checkbox"/> <i>No</i></p>	<p style="color: magenta;"><u>If applicable, ADD this language to the master template:</u></p> <p><u>How will my medicine be provided?</u></p> <p>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, if given one.</p> <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> <p style="font-size: small; color: blue;">NOTE: Choose “Yes” if the study involves any investigational drug(s) dispensed by an IDS (Emory, Grady, CHOA). Choose “No” if you have received a waiver from using the IDS, or when using non-oral formulations (e.g. I.V. infusion).</p> </div>
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<p>FOR ST JOSEPH'S AND JOHNS CREEK (Catholic sites) ONLY: Risk Language related to pregnancy + contraception</p> <p>Is either Saint Joseph's Hospital or Emory Johns Creek Hospital a site location?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes: does study involve drug under a REMS for reproductive risk?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p><u>If applicable, replace Reproductive Risk language in the master template. In the event that Emory has submitted multiple locations in addition to the St. Joseph and/or Johns Creek sites (see first page list of sites), use the contraception language detailed in this section only:</u></p> <p>If you are a woman of childbearing ability, you and the study doctor must agree on an adequate method of birth control or abstinence for the duration of the study.</p> <p>If you are a man: You and the study doctor should agree on an adequate method of birth control or abstinence for the duration of the study.</p> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>For studies including SAINT JOSEPH'S and/or JOHNS CREEK studies only (Catholic Hospitals) reference to birth control must not go beyond the language in yellow above.</p> <p><i>Important:</i> Regardless of Catholic Directives, if this study utilizes a drug under the FDA REMS program related to reproductive risk (e.g. thalidomide-type drugs), then information on registration, methods of contraception, risks, etc. must be added. HOWEVER, for all other studies at Saint Joseph's Hospital or Johns Creek Hospital, the ONLY reference to birth control may be: "use an adequate birth control method or abstinence for the duration of the study" (no specific forms of birth control may be listed).</p> </div>
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<p>CoC Provisions</p> <p>Is this Study NIH-Funded (whether directly or via subaward), or Applying for a CoC?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p><u>If there is no CoC language in the master template, add this language. If there is already CoC language in the master template, you can leave the language that is there:</u></p> <p><u>Certificate of Confidentiality</u></p> <p>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.</p> <p>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.</p>
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	<p>The Certificate does not stop Emory from making the following disclosures about you:</p> <ul style="list-style-type: none"> • 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. <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> <p>For Certificate of Confidentiality (CoC) studies only, must inform subjects there is a CoC. Use sample language if none is provided by Sponsor (otherwise use Sponsor's language instead of the above).</p> <p>REQUIRED if project is NIH-funded (whether direct or subaward) and is obtaining consent. If not NIH-funded but study team is applying to obtain a CoC for the study, no one should be enrolled until the CoC is approved by the NIH, unless the IRB specifically allows it (in which case a consent form without this language must be used until the CoC is in place).</p> </div>
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<p>Medical Record</p> <p>Will this study access <u>or</u> add data to the Emory or affiliated <u>Medical Record</u> system?</p> <p><input type="checkbox"/> Yes (if yes, this can be placed anywhere in the consent form)</p> <p><input type="checkbox"/> No</p> <p>Has this study been granted "Sensitive" status from the Emory IRB as part of local context?</p> <p><input type="checkbox"/> Yes</p> <p><input type="checkbox"/> No</p>	<p><u>If applicable, add this language to the master template:</u></p> <p><u>Medical Record</u></p> <p>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.</p> <p><input type="checkbox"/> <i>ONLY NON-SENSITIVE STUDIES (used if study is NOT applying for sensitive study status and consent/HIPAA form will be placed in the medical record):</i> Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.</p> <p><input type="checkbox"/> <i>ONLY SENSITIVE STUDIES (if consent/HIPAA form to be kept out of medical record because of sensitive nature of the study, as approved by IRB):</i> We will take reasonable steps to keep copies of this form out of Emory Healthcare 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.</p> <p>Emory Healthcare may create information about you that can help with your health 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</p>
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	<p>HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.</p> <p><input type="checkbox"/> If checked, the following paragraph should be included: 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: <i>[Emory study team must include specifics.]</i></p> <p>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.</p>
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<p>In Case of Injury (AS DETERMINED BY EMORY IRB): check one box at right</p> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>Study team: only select an option if Emory IRB has determined the correct option OR you and Sponsor agree to submit an amendment later if the study is approved with incorrect option. The Emory IRB selection is considered final and may override your selection.</p> </div> <p><input type="checkbox"/> If you are awaiting Emory's institutional signoff for the appropriate option, check here.</p>	<p><u>Replace the master template's injury language with the correct Emory injury option below:</u></p> <p><u>In Case of Injury</u></p> <p><input type="checkbox"/> OPTION 1: <i>The sponsor will not pay for Subject Injury Costs for any subject, no matter if the subject is insured, or how he/she is insured:</i></p> <p>If you believe you have become ill or injured from this research, you should contact the study doctor at the telephone number listed on the first page of this form. You should also let any health care provider who treats you know that you are in a research study.</p> <p>If you get ill or injured from being in the study, Emory will help you get medical treatment. Neither Emory nor the sponsor will pay for your 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.</p> <p>Emory and the sponsor have 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.</p> <p><input type="checkbox"/> OPTION 2: <i>The sponsor will pay for Subject Injury Costs for all subjects, no matter if the subject is insured, or how he/she is insured:</i></p> <p>If you believe you have become ill or injured from this study, you should contact the study doctor at the telephone number listed on the first page of this form. You should also let any health care provider who treats you know that you are in a research study.</p> <p>If you get ill or injured from being in the study, Emory will help you to get medical treatment. Emory and the sponsor have 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.</p> <p>If you get ill or injured as the direct result of a study drug, device, or study procedure, the sponsor will pay the costs for your medical</p>
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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:

- from medical conditions you had before you started the study;
- from the natural progression of your disease or condition;
- from your failure to follow the study plan; or
- 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 will 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 the study doctor at the telephone number listed on the first page of this form. 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 and the sponsor have 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 a study drug, device, or 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:

- from medical conditions you had before you started the study;
- from the natural progression of your disease or condition;
- from your failure to follow the study plan; or
- 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 (AS DETERMINED BY EMORY IRB): Check one box at right.

Study team: only select option if Emory IRB has determined the correct option OR you and Sponsor agree to submit amendment if study is approved with incorrect option. The Emory IRB selection is considered final and may override your selection.

If awaiting Emory's institutional signoff for the appropriate option, check here.

Replace the master template's cost language with the correct Emory injury option below:

Costs

- OPTION 1:** *If there are no costs for research or standard of care related to 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.

- Only if medical procedures involved:* 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:** *If the sponsor will pay only for certain item or services related to 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:** *If the sponsor will not pay for any items or services related to 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,

	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
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<p>Payment / Reimbursement to Subjects</p> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;"> <p>Language needed unless certain no tax form collection will be required.</p> </div> <p><input type="checkbox"/> Check if subject will receive \$300+ in one year.</p> <p><input type="checkbox"/> Check if payment AP check or other method requiring W-9.</p>	<p><u>If applicable, add this language to the master template's compensation language:</u></p> <p>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.</p>
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<p>Contact Information (GRADY ONLY)</p> <p>Is Grady a site location?</p> <p><input type="checkbox"/> Yes (if yes, include this language at the end of the contact information section)</p> <p><input type="checkbox"/> No</p>	<p><u>Where Grady is a site, add this paragraph to the end of the contact information section:</u></p> <p>If you are a patient receiving care from the Grady Health System and have a question about your rights, you may also contact the Office of Research Administration at research@gmh.edu.</p>
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<p>HIPAA Authorization</p> <p><input type="checkbox"/> Check if your study has treatment/billing procedures.</p> <p><input type="checkbox"/> Check if your study will be obtaining PHI from a covered entity, but there will be no treatment/billing.</p>	<p><u>See last page of this checklist for Emory's HIPAA template language. There are two types of template language: one for treatment/billing studies and the other for non-treatment/billing studies that will be using IHI. Please copy and paste the one that is relevant for your study into the master template and fill in your study information using the instructions within the template language.</u></p>
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<p>HIPAA Authorization: Optional Sub-study.</p> <p>Is there an optional study described in the main consent form (if separate sub-study consent form, that would have its own HIPAA language)?</p>	<div style="border: 1px solid red; padding: 5px; margin-bottom: 10px;"> <p>Note: Section below titled "People that will Use and/or Disclose Your PHI for Optional Study" can instead say "The same people that may use and/or disclose your PHI for the main study may do so for the optional sub-study. You may replace "Study" with "Storage of [Data and/or Specimens] for Future Research" if applicable</p> </div> <p><u>If you have a sub-study, add this language.</u></p> <p>Optional Study Authorization: We will also ask for your separate authorization to <i>[insert brief description of optional study(ies) described elsewhere in this consent form]</i>.</p> <p>PHI that will be Used/Disclosed for Optional Study: The PHI that we will use and/or disclose (share) for the optional research study includes: <i>[Describe PHI that will be collected for the sub-study]</i></p>
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<input type="checkbox"/> Yes <i>(if yes, include the information to the right in your consent form in addition to the main HIPAA text)</i> <input type="checkbox"/> No	<p>Authorization to Use PHI is Required to Participate in Optional Study, but not in the Main Study: You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you can still be in the main research study.</p>
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<p>Other special language or instructions?</p> <p><i>(This section is for study-specific language that needs to be added or replaced, such as when the Radiation Safety Committee or the Conflict of Interest committee gives you language to include in your consent form.)</i></p> <input type="checkbox"/> Yes <i>(if yes, include the information to the right in your consent form in addition to the main HIPAA text)</i> <input type="checkbox"/> No	<p><u>If specific language needs to be added anywhere else for some reason or if master template language needs to be replaced with our language in the consent form, make sure to do that.</u></p>
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SEE NEXT PAGE FOR TWO VERSIONS OF EMORY HIPAA LANGUAGE. PLUG THE CORRECT VERSION INTO CONSENT FORM.

HIPAA language for studies where Emory engaged in treatment/billing procedures

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your “protected health information” or “PHI.” To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the “Privacy Rules.” Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study. [ADD ANY OTHER PURPOSES FOR WHICH PHI WILL BE USED/DISCLOSED]

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- _____ is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

Commented [HH1]: As per HIPAA instructions above, insert this language above the consent signature blocks, into the body of the main consent. Remove the sponsor's HIPAA/PHI and insert Emory's.

Commented [HH2]: Use the term “main” if there is a main study and optional sub-studies or optional storage of PHI for future research. DELETE the word “main” if there are no additional options

Commented [HH3]: Include this text if there are optional studies/storage of PHI in which the subject may choose to participate.

Commented [HH4]: DELETE this header if there are no optional substudies or optional storage for future research

Commented [HH5]: Note: PHI refers to health information, not the identifiers attached to that information. DELETE any inapplicable descriptions and add descriptions of any additional PHI that will be collected.

Commented [HH6]: If this is a repository/database study only, then replace with “for the conduct and oversight of this repository [or other term], and of future studies that are covered by this consent and authorization.

Commented [HH7]: Include this language if the sponsor will be paying for all, or any part of, costs relating to subject injury.

Commented [HH8]: Delete this section if there is a certificate of confidentiality.

Commented [HH9]: Delete if N/A

Commented [HH10]: Replace “Sponsor” with “supporter” if applicable, throughout this section; remove references to Sponsor if there is no external funder or study supporter.

Commented [HH11]: Remove if N/A

Commented [HH12]: Remove if N/A

- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- [ADD ANY OTHERS WHO MAY HAVE ACCESS TO PHI].
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
 - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
 - Other researchers and centers that are a part of this study.
 - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration; Veterans Administration.
 - The IRB of Record
 - Public health agencies.
 - Research monitors and reviewer.
 - Accreditation agencies.
 - ADD ANY OTHERS.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Commented [HH13]: Include this language if sponsor has agreed to pay for all or any portion of subject injury. Remove reference to Sponsor if N/A

Commented [HH14]: Add names of other institutions and their offices if collaborating sites will use our consent/HIPAA form.

Commented [HH15]: Delete those that are not applicable; add others if needed.

Optional Study: [Enter very brief description of substudy here; fuller description should appear earlier in the form] (or replace "Study" with "Storage of [Data and/or Specimens] for Future Research:

PHI That Will be Used/Disclosed for Optional Study:

The PHI that we will use and/or disclose (share) for the optional research study includes:

Purposes for which your PHI will be Used/Disclosed for Optional Study:

We will use and disclose your PHI for the conduct and oversight of the optional research study, including the administration and payment of any costs relating to subject injury.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:

You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:

The following people and groups will use and disclose your PHI in connection with the optional research study:

- [Use template bullets from same part of the Main Study authorization above, modified for the Optional study. You may replace these bullets with "The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the optional research study/storage of PHI for future research". Then, if applicable, add, "In addition, the following people and groups may also use and disclose your PHI for the Optional Study:" (Include future researchers etc, if there is a chance that identifiable data/samples will be shared with future researchers)]

Commented [HH16]: DELETE this section if there are no optional substudies or banking for future research. Otherwise:
 - Edit Heading leave only one ("Study" or "Storage of Data/Specimens for Future Research").
 - Insert name/summary of optional activity (just enough so that subjects remember what it is, e.g. "Optional Study: Genetic Testing of Blood Samples" or "Optional Storage of Samples for Future Research").
 - The optional stud(ies) must have been fully described in detail earlier in the consent. If they are instead described in a separate consent form, then that document should instead contain this HIPAA language and it can be left out of this main consent form.

Commented [HH17]: Or "storage and future research use of your PHI"

Commented [HH18]: Describe PHI that will be used/disclosed only for the optional study. Replace "study" and "research study" with "storage and future research use of your PHI" if applicable.

Commented [HH19]: Or "storage and future research use of your PHI"

Commented [HH20]: Include this language if the sponsor will be paying for all, or any part of, costs relating to subject injury.

Commented [HH21]: You may replace these bullets with "The same people and groups who will use and disclose your PHI for the main study will also do so in connection with the optional research study". Then if applicable add, "In addition, the following people and groups may also use and disclose your PHI for the Optional Study:" (include future researchers etc, if chance that identifiable data/samples will be shared with future researchers)

Commented [HH22]: Or "storage and future research use of your PHI"

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, **you must contact the study team at:** _____.

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the **main** study.

Commented [HH23]: Delete this word if there are no optional studies.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. **The Sponsor, and people and companies working with the Sponsor on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.**

Commented [HH24]: Add this text if the sponsor is a pharma company or device manufacturer that is not covered by HIPAA; otherwise delete.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, **contact:** _____

Commented [HH25]: Add Reviewing IRB contact information here

You may also 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 questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at <http://www.surveymonkey.com/s/6ZDMW75>.

Consent and Authorization

Commented [HH26]: Please make sure all signature lines appear on one page (i.e., do not break across two pages)

Consent and HIPAA Authorization for Optional Study/Studies:

Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

[OPTIONAL STUDY TITLE] _____ Initials]

HIPAA language where Emory is obtaining PHI from a covered entity but no treatment/billing for research

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you (“individually identifiable health information” or “IIHI”). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your IIHI. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

OR

Research-Related Treatment

This study involved research-related treatment that will not be electronically billed to any insurance company or government benefits program (e.g., Medicare, Medicaid). You may not receive the research-related treatment unless you sign this authorization. You may receive any non-research related treatment whether or not you sign this form.

Commented [A27]: Retain the section that applies to your study, and delete the other.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Commented [A28]: Delete any inapplicable descriptions and add descriptions of any additional PHI that will be collected.

Purposes for Which Your IIHI Will be Used/Disclosed:

We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

[ADD ANY OTHER PURPOSES FOR WHICH IIHI WILL BE USED/DISCLOSED]

Commented [A29]: Add any other purposes for which IHI will be used or disclosed here.

Use and Disclosure of Your IIHI That is Required by Law:

We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

Commented [A30]: Delete this section if there is a certificate of confidentiality.

People Who will Use/Disclose Your IIHI:

The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.

Commented [A31]: Replace “Sponsor” with “supporter” if applicable; remove references to Sponsor if there is no external funder or study supporter.

Commented [A32]: Remove if N/A

- Emory may use and disclose your I/IIHI to get payment for conducting the study and to run normal business operations.
- The Principal Investigator and research staff will share your I/IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your I/IIHI with people and groups at other sites who are helping conduct the study.
- [REDACTED] is the Sponsor of the study. The Sponsor may use and disclose your I/IIHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your I/IIHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- [ADD ANY OTHERS].
- The following people and groups will use your I/IIHI to make sure the research is done correctly and safely:
 - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
 - Other researchers and centers that are a part of this study.
 - Government agencies that regulate the research including: [Office for Human Research Protections; Food and Drug Administration; Veterans Administration].
 - The IRB of Record
 - Public health agencies.
 - Research monitors and reviewer.
 - Accreditation agencies.
 - [ADD ANY OTHERS].
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your I/IIHI may be shared with that new institution and their oversight offices.

Commented [A33]: Remove if N/A

Commented [A34]: Insert Sponsor's name., or delete bullet if N/A

Commented [A35]: Add any other persons or entities who will have access to the PHI and the purpose of their access, e.g., data monitors, computer administrators, data analysts, etc.

Commented [A36]: Add names of other institutions and their offices if collaborating sites will use our consent/HIPAA form.

Commented [A37]: Delete those that are not applicable; add others if needed.

Commented [A38]: Add any other persons or entities who will have access to the I/IIHI for safety or oversight purposes, including other IRBs which may have access to I/IIHI

Optional Study: [Enter very brief description of substudy here; fuller description should appear earlier in the form] (or replace "Study" with "Storage of [Data and/or Specimens] for Future Research):

Authorization for This Use of I/IIHI is Required to Participate in Optional Study, but Not in Main Study:

You do not have to authorize the use and disclosure of your I/IIHI for the optional study(ies). If you do not authorize the use and disclosure of your I/IIHI for the optional study(ies), then you may not participate in the optional research study, but you can still be in the main research study.

Additional People Who Will Use/Disclose Your I/IIHI for Optional Study:

The following people and groups will use and disclose your I/IIHI in connection with the optional research study:

Commented [A39]: DELETE this section if there are no optional substudies or banking for future research. Otherwise:
 - **Edit Heading** leave only one ("Study" or "Storage of Data/Specimens for Future Research").
 - **Insert name/summary of optional activity** (just enough so that subjects remember what it is, e.g. "Optional Study: Genetic Testing of Blood Samples" or "Optional Storage of Samples for Future Research").
 - The optional stud(ies) must have been fully described in detail earlier in the consent. **If they are instead described in a separate consent form, then that document should instead contain this HIPAA language and it can be left out of this main consent form.**

Commented [A40]: Only if this differs from the main study – otherwise delete this section

Commented [A41]: Or "storage and future research use of your PHI"

Expiration of Your Authorization

Your I/IIHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your I/IIHI. If you want to do this, you must contact the study team at:

Commented [A42]: Insert contact information; normally this is a mailing address.

At that point, the researchers would not collect any more of your I/IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers, the Sponsor, and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

Commented [A43]: If the sponsor is a pharma company or device manufacturer that is not covered by HIPAA, then the word "sponsor" should remain; if the sponsor is covered by HIPAA, then "sponsor" should be deleted.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

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, concerns or complaints about the research

Commented [A44]: A 24-hour contact should be provided when appropriate (e.g., high risk studies).

Commented [A45]: Remove if N/A

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 questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at <http://www.surveymonkey.com/s/6ZDMW75>.

Consent and Authorization

Commented [HH46]: Please make sure all signature lines appear on one page (i.e., do not break across two pages)

Consent and HIPAA Authorization for Optional Study/Studies:

Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

[OPTIONAL STUDY TITLE] _____ Initials