Emory University IRB

External IRB Consent Checklist

Instructions:

* In the **currently approved master consent form**, **replace** sponsor’s cost and in case of injury language with Emory’s required language using **TRACKED CHANGES.**
* Upload the Emory consent form and this completed form in the local site documents section of the smart form. (If there is no approved master consent because Emory is the only site submitting to the IRB (Ex: WCG), then use an Emory consent template from our website.)
* Include this completed checklist with your submission to the reviewing IRB.
* Text in the boxes below in red is instructional text and is not to be added to consent forms.

**Important Note about sponsor edits:**

* The Emory IRB does not allow sponsors to edit Emory’s injury language UNLESS OSP determines that the injury language does not align with the executed Clinical Trial Agreement (CTA). If the sponsor requests edits to Emory’s injury language, please obtain from the sponsor the specific text they object to and route to OSP, copying irb.reliance@emory.edu for a determination as to whether Emory’s injury language aligns with the executed CTA.
* Non-industry Sponsors may add other entities to Emory’s injury language where Emory is mentioned. That is the only allowable change to Emory’s injury language.
* If you must route the consent form to the sponsor for review prior to submission to the external IRB, **please do so before submitting to the Emory IRB**. Routing it back to the sponsor after Emory has issued signoff will result in significant delays for your site.
* Sponsors may add additional confidentiality language **below** Emory’s HIPAA Authorization (such as GDPR and PIPL) but may not revise text within Emory’s HIPAA Authorization other than the two sections that allow additional bullets to be added.

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| **Site-Specific Language** |
| Please check if any of these are site locations for this submission | If research activities will take place at any of the locations listed below, add the names of these additional sites anywhere Emory is referenced in the consent form. For example: “Emory Healthcare and Grady Health System” or “Emory and Children’s Healthcare of Atlanta.” |
| [ ] Children’s Healthcare of Atlanta | * Insert “and Children’s Healthcare of Atlanta” in the consent form anywhere Emory is mentioned.
* Add the sentence below in the section of the consent regarding IRB contact information:

If you are a patient receiving care at Children’s Healthcare of Atlanta and have a question about your rights, please contact the Children’s Institutional Review Board at 404-785-7477. |
| [ ]  Grady Health System | * Insert “and Grady Health System” in the consent form anywhere Emory is mentioned.
* Add the sentence below in the section of the consent regarding IRB contact information:

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.* Add the language below to the injury language:

We will give you emergency care if you are injured by this research. However, Grady Health System has not set aside funds to pay for this care or to compensate you if a mishap occurs.  If you believe you have been injured by this research, you should contact Dr. \_\_\_\_\_\_\_ (Phone \_\_\_\_). |
| [ ]  Saint Joseph’s Hospital and/or John’s Creek Hospital (other than Emory Clinic leased space) | * Add “and Saint Joseph’s Hospital” and/or “and John’s Creek Hospital” in the consent form anywhere Emory is mentioned.
* The consent form must reference “birth control” and not “contraception,” and may not list specific forms of birth control.
* If the study team provides documentation that other language has been approved through ERD review, you can use the language approved by Rebecca Heitkam.

Example Language: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 are a man:You and the study doctor should agree on a method of birth control to use throughout the study. |

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| **Investigational Study Drug**  |
| Does this study involve an investigational drug study for which you HAVE NOT received a waiver?[ ]  Yes[ ]  No (we have a waiver from using IDS.) | If the study involves any investigational drug(s) dispensed by an IDS (Emory, Grady, CHOA), include the following language in the consent form: 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. You may also call the pharmacy if you have questions about the study drug. |

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| **Radiation Language** |
| Is radiation language required for this study?[ ]  Yes (add to the right)[ ]  No | Insert required radiation language below and add to consent form. |

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| **Studies using drugs under REMS** |
| Does the study involve a drug under REMS?[ ] Yes[ ]  No | IMPORTANT NOTE FOR REMS: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 to consent.  |

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| **Participant Compensation** |
| Will participants be paid?[ ]  Yes[ ]  No | Insert the language below in the consent. If participants will receive $300 or more in one year, then use “You will be asked” instead of “You may be asked.” Also do this if you are sure you will be issuing payment via AP check, or any other method that requires a W-9 regardless of amount. Please DO NOT remove this language entirely, unless you are certain that you will be giving less than $300 in cash or gift cards or non-monetary reimbursement.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.  |

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| **In Case of Injury Language** |
| **NOTE:** If research is taking place at Grady – see Grady-specific instructions on page 1Did the reviewing IRB determine the research to be minimal risk?[ ]  Yes – skip this section - this language is not needed in the consent [ ]  No – Mark the option below that was confirmed as the in case of injury language for this study. Insert PI name and contact information and remove “[or device, as appropriate]” if not applicable to the study. |
|  [ ]  Option 1  | 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 <<and 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 a direct 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  | 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  | 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.  |

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| **Cost Language** |
| If there are billables associated with this research, mark one of the options below that was confirmed as the cost option for this study.  |
| [ ]  Option 1 | If the study was determined to be no more than minimal risk, remove the last sentence of this option.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 described in this form, the cost of treatment for those complications may be charged to you or your insurance.  |
| [ ] Option 2 | 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 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. |

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| **Studies with Genetic Testing** |
| Will this study include genetic testing?[ ] Yes[ ] No | If yes, add this language below the GINA language in the master consent.**Georgia Language:**In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions for life insurance and other types of insurance policies. |

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| **Certificate of Confidentiality (CoC)** |
| Is this study NIH funded or has a CoC been requested for it?[ ] Yes[ ] No | CoC language is 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).ONLY ADD THE LANGUAGE BELOW IF THERE IS NO COC LANGUAGE IN THE APPROVED MASTER CONSENT. 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. |

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| Medical Record Language |
| Will the consent/HIPAA form be placed in the medical record? See guidance here: <https://www.ocr.emory.edu/resources/systems/erms.html>Mark yes for clinical trials, studies providing treatment, generating billing etc. or if protocol indicates consent will be placed in the medical record. [ ] Yes[ ] NoIf yes, is the study requesting Sensitive Study Status? [ ] Yes[ ] No | Insert the language below in the consent for studies that will **NOT** have Sensitive Study Status:**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. 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. Insert the language below in the consent for studies that **WILL** have sensitive study status. Revise as needed to accurately describe your study. The important message is that certain study results will be placed into the medical record because it is useful for treating the patient now and in the future. If certain results will not be put in the record and will be available only to the researchers, the subject should know what those are. **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. 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: [List items below.]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. |

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| **HIPAA Authorization or Confidentiality Language** |
| * Utilize your completed HIPAA worksheet to identify the HIPAA language you need to include in the consent.
* If study team is performing study activities at Children's Healthcare of Atlanta, Hughes Spalding, Grady Health System, Saint Joseph's Hospital, or Emory Johns Creek Hospital, customize each instance of Emory with the other location as well.
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| [ ]  HIPAA worksheet indicates HIPAA applies to research (Accessing PHI, treating and billing to third party payor, research at a covered entity) | Insert this HIPAA language:  [HIPAA Applies to Research Records](https://www.irb.emory.edu/_includes/documents/sections/hipaa-applies-to-research-records.docx) |
| [ ]  HIPAA worksheet indicates HIPAA doesn’t apply to data once it’s in my research records (obtaining PHI but no treatment and billing to third party payor for research) | Insert this HIPAA language:  [Obtaining PHI\_No treatment and Billing\_HIPAA doesn’t apply to research records](https://www.irb.emory.edu/_includes/documents/sections/obtaining-phi_no-treatment-and-billing_hipaa-does-not-apply-to-research-records.docx) |
| [ ]  The research is not accessing, using, or storing any PHI from a covered entity | Insert this Confidentiality language: [Confidentiality language when HIPAA does not apply to study at all](https://www.irb.emory.edu/_includes/documents/sections/confidentiality-language-when-hipaa-does-not-apply-to-study-at-all.docx) |