Emory University/NCI CIRB Consent Guidance Form

* No Changes can be made to CIRB’s master consent form, except as noted below.
* The following table shows what language must instead be placed into the Emory Site-Specific Consent/HIPAA Addendum document (see also the Addendum template)

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| --- | --- |
| Overview and Key Information | No change to CIRB’s template. |
| Contact Information | Insert appropriate contact information in the designated spaces throughout the CIRB template. |
| “How will my study drug be provided?” | **Add** to the Site-Specific Consent/HIPAA Addendum only. |
| “What risks can I expect from taking part in this study?” | **Pregnancy Risk:** For studies taking place at Emory Saint Joseph’s and/or Johns Creek Hospitals:   * Replace all references to “contraception” (or variants of that word) with “birth control”. * Remove reference to specific forms of birth control, unless the study involves thalidomide-type drugs.   No other changes are permitted to CIRB’s template or risk tables.  **Dosimetry information** related to research imaging or research radiation should be **added via the Study Specific Worksheet,** except where radiation levels are standard of care.  **Radiation Risk language:** No changes to CIRB’s template. But **Add** to the Site-Specific Consent/HIPAA Addendum (see template), **only** if there are research-driven scans, and only if the main consent does not include any risks of that radiation. |
| “What are the costs of taking part in this study?” | No change to CIRB’s template.  But: **Add** Emory’s boilerplate cost language to the Site Addendum/HIPAA form (see template). IRB Staff will receive correct Cost Option from OCR directly. (Emory language may or may not contradict NCI CIRB’s language; our language includes a statement that it overrides the NCI CIRB language.) |
| Compensation | No changes to CIRB’s template |
| “What happens if I am injured because I took part in this study?” | Emory boilerplate injury language should be **added** to the injury section (Emory IRB assumes “Option #1,” below, 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 does 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.   * If Grady is a site, please add this language to the end of 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 \_\_\_\_). |
| Medical Records | Add Emory language to the Site-Specific Consent-HIPAA Addendum form (see template) |
| Optional Studies and Contact for Future Research | Institutions can change the circling Yes or No to checking Yes or No.  Institutions can add a sentence that an Optional Study is not offered at their institution or is closed to accrual. Text that is in the model consent form must remain. |
| Conflict of Interest | If applicable, **add** to CIRB’s template.  COI disclosure language must be included in its own section at the end of the document, before the signature block. |
| Genetic/Privacy Language | No change to CIRB’s template.  **Add** Emory-required language to the Site-Specific Consent-HIPAA Form (see template). |
| If Grady is a site… | Add this Grady contact information section:  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. |
| Signature agreeing to take part in the study | No change to CIRB’s template (even for Winship studies). |