

Site-Specific Consent Form Guidance

If you are a participating enrollment site in an Emory-led study for which Emory is serving as single IRB, you must create your site-specific consent form by taking Emory's approved model consent template for the study and making the following adjustments:

Generally throughout the form:

- Any reference to "Emory" should be replaced with the name of your site (such as in Header, Introduction section, Medical Records section, etc.)
- Any reference to the Emory study team or PI should be replaced with your study team and PI.
- Any references to phone numbers (such as in the "How will my medicine be provided?" section) should be changed to your local phone numbers.

"What are the possible risks and discomforts?"

- If you are an institution that must follow the Catholic Directives, you may adjust the Risks section as it pertains to reproduction to reflect your site's boilerplate language for reproductive risk.

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

- Replace Emory's language with your site's boilerplate compensation language.

"Certificate of Confidentiality"

- Add your site name along with any reference to "Emory." For example: Emory and [name of your site] will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you.

"In Case of Injury"

- Replace Emory's language with your site's boilerplate injury language.

"Costs"

- Replace Emory's language with your site's boilerplate cost language.

"Authorization to Use and Disclose Protected Health Information"

- Emory uses a combined consent form and HIPAA authorization. Replace Emory's language with your site's boilerplate HIPAA authorization language, but anywhere your site is mentioned in your language, be sure to put "Emory and [name of your site]" instead.

"Contact Information"

- Replace the Emory study team contact information with your site's study team contact information.
- DO NOT remove the Emory Institutional Review Board contact information.

*If your site is not in the state of Georgia, be sure to remove language related to Georgia's laws on genetic testing under the "How is my Genetic Information Protected? What are the Risks?" and Georgia's laws on privilege under the "Privilege" section. You may add boilerplate language from your IRB for these sections if your state has laws related to genetic testing and privilege.