



Institutional Signoff and Local Context Review Form

Study Title:

Reviewing IRB PI:

Reviewing IRB
Study ID:

Emory PI:

Emory Study ID:

Emory IRB Contact:

Email and Phone:

1. Engagement

Emory University **does** consider the role of its study team engaged in human subjects research.

Emory University **does not** consider the role of its study team engaged in human subjects research. **Stop here and sign the last page of the form.**

2. Study Team Qualifications and Education

All study team members **have** completed all of their required training including current training in human subjects protection and have the experience and expertise to conduct this research.

All study team members **do not have** all of their required training including current training in human subjects protection and the necessary experience and expertise to conduct this research
Provide details:



3. Investigator Conflicts of Interest

The investigators **have not** identified any financial interests related to this study.

The investigators **have** identified any financial interests related to this study. The COI Management Plan has been provided to the study team and is to be submitted to the reviewing IRB with this form.

4. Site-Specific Informed Consent Forms

N/A - This site is not enrolling participants.

All necessary site-specific language **has** been inserted into the model Informed Consent form(s) including contact information, cost, compensation and subject injury language, HIPAA authorization, and conflict of interest disclosure, if applicable. Emory embeds HIPAA Authorization within our site-specific consent form.

5. Recruitment and Informed Consent

The study team is requesting a partial HIPAA waiver for recruitment purposes.

Emory University **does not** have concerns regarding recruitment procedures and informed consent process as described in the protocol.

Emory University **does** have concerns regarding recruitment procedures and informed consent process as described in the protocol.

Provide Details:



6. Ancillary Reviews

Upon completion of all ancillary reviews required by Emory University, information **was not** identified that may assist the reviewing IRB in its review of the research.

Upon completion of all ancillary reviews required by Emory University, information **was** identified that may assist the reviewing IRB in its review of the research.

Provide Details:

7. Local Cultural Concerns

Emory University **has not** identified any specific ethical concerns pertaining to the community from which research participants will be recruited.

Emory University **has** identified any specific ethical concerns pertaining to the community from which research participants will be recruited.

Provide Details:



8. State Laws and Institutional Policies

Emory University **has not** identified state or local laws, regulations, or institutional policies relevant to this study.

Emory University **has** identified state or local laws, regulations, or institutional policies relevant to this study.

Provide Details:

Emory Institutional Signoff Language