IRB Standard Operating Procedures		
SOP#: 06 **Revision#: 1**	**Title: Convened IRB Review**	**Effective Date:** **March 8, 2019**
Approved By:	**Institutional Review Board**	**Approval Date:** **March 8, 2019**

PURPOSE

To define policies and procedures for conducting full-board review of human subjects research.

DEFINITIONS

Appeal - request for reconsideration of an Institutional Review Board (IRB) determination in research involving human subjects, including (but not limited to) decisions regarding approval status, conditions for approval, or noncompliance. Note: An appeal is reviewed by the convened IRB responsible for the determination being appealed; for a decision made by expedited review, the corresponding convened IRB may review the appeal. Also: request for reconsideration.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

IRB - an institutional review board established in accord with and for the purposes expressed in the federal regulations for the protection of human research subjects.

Convened review - the review of proposed human subjects research by an IRB that meets the membership requirements specified in federal regulations regarding the number, qualifications, diversity, and affiliation of its members, at which a majority of the members are present including at least one non-scientist. Review by the convened IRB may be referred to as either "full review" or "full board review".

Minimal risk - the probability and magnitude of the harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

PROCEDURES

The IRB typically meets once per month.
IRB meetings are conducted according to SOP IRB Meeting Procedures.

Pre-review Procedures

The principal investigator (PI) will complete the most current application and forms available on the IRB website and submit a complete packet, including all supporting documentation electronically. Instructions for preparing the application are available on the IRB's website.
Incomplete applications will not be reviewed. Missing items will be identified and requested during the administrative pre-review. If the items are not submitted within 1 week following the IRB request, the entire application packet will be sent back to the PI without review.
Once completed application materials have been submitted, IRB staff will conduct an "Administrative Pre-review", and make note of possible issues on a pre-review document.
All application material and pre-review notes from the administrative pre-reviewer will be shared with the IRB chair.
IRB staff in consultation with the chair will assign a primary and secondary reviewer to each new study based on the IRB member's educational background, experience, and expertise. For research requiring expertise in multiple areas of science or ethics, additional reviewers may be assigned as determined by the IRB staff and chair.
Only IRB members designated as scientists may serve as primary reviewers. Non-scientists may serve as secondary reviewers.
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Initial Review

Both the primary and secondary

IRB Determinations

Approval: An approval is granted if the research activities meet the criteria for approval (45 CFR 46.111 and/or 21 CFR 56.111 and, if applicable Subparts B, C, and D) and no changes to the research are required by the IRB. Determination of the approval period for research approved by the convened IRB is made as described in SOP IRB Approval Period and Determination of Expiration.

Modifications Required to Secure Approval: The IRB requires that the investigator (a) makes specified changes to the research protocol or informed consent document(

Review of Investigator's Responses to the IRB

The IRB staff reviews responses from investigators for modifications required to secure approval and notes their pre-review comments