

# Systematic Determination

SOP 112

Revised: December 18, 2015

## Purpose and Scope

This procedure establishes the process to pre-review and to review requests for approval of research projects inclusive of all activities throughout the life of the projects.

This document applies to all Investigators, Human Studies Program (HSP) staff, and IRB members who submit or review human subject research (new research, continuing review, and modifications) for expedited or full board review.

## Procedure

HSP Staff are responsible for the initial intake and preliminary screening of new research applications submitted electronically. The HSP Coordinators review the submission for completeness and route the application to the appropriate IRB committee for subsequent review.

1. Upon receipt of a new Protocol Application, the IRB administrative staff conducts initial reviews of the application for completeness.
2. The (HSP) Coordinator conducts a preliminary review for protocol completeness and confirms the review and protocol type selected by the Principal Investigator as appropriate for the study (Exempt, Expedited, or Full-Board). IRB Coordinators provide support to their designated IRBs (i.e., Biomedical, Social & Behavioral Sciences, and Cooperative). Protocols or proposals assigned to their IRB committee are reviewed by the Coordinators to confirm or reassign the review type as appropriate for the study.
  - a) Protocols submitted for a review type determined not appropriate are converted to the appropriate review type by the HSP Coordinator.
  - b) If the change in review type requires additional information from the Principal Investigator, the protocol is returned to the Principal Investigator. Continuing Review and Modification applications have only a primary reviewer. If possible, the reviewer for the initial application will be assigned to the submission.
  - c) The HSP Coordinator will use the appropriate checklist to review the application materials ensuring all required protocol documents, supplemental documents and information are provided.
  - d) If the information is not complete, the HSP Coordinator will contact the investigator and offer the opportunity to provide additional information within two (2) weeks, unless there are extenuating circumstances and a mutual agreement on the timing is set.
  - e) The HSP Coordinator will note the missing materials in the appropriate reviewer worksheet.

- f) If the investigator will not provide additional materials, the HSP Coordinator will continue processing.
3. HSP Staff may contact the Investigator to address issues of incompleteness in their application submission before assigning the research protocol or proposal to a Reviewer.
    - a. If the investigator or research staff member is overdue in meeting IRB requirements within the prescribed time frame, the HSP Coordinator will contact the investigator.
    - b. If the investigator will take steps to remove the overdue status before further review, the HSP Coordinator will wait for submission of the materials to remove the overdue status.
    - c. If the investigator will not take actions, the HSP Coordinator will continue processing.
  4. The HSP Coordinator will direct the application to the appropriate path for either an expedited review or for review at a convened IRB meeting.
    - a. The HSP Coordinator will refer to the appropriate IRB Roster and select a designated reviewer who has scientific or scholarly expertise in the area of research.
    - b. To avoid any potential conflicting interest, new protocols are not assigned to an IRB member who is also an investigator on the research project.
    - c. Assignment of protocols to IRB members on the appropriate IRBs is based on the date the protocol was submitted to the IRB. Protocols assigned to the upcoming IRB meeting must be a complete application and submitted by the identified deadline. Protocols submitted after the deadline will be placed on the agenda for the following month.
    - d. New protocols are assigned by the IRB Coordinator to a primary reviewer and a secondary reviewer, with the primary reviewer assigned to present the protocol at the convened meeting. The IRB Coordinator assigns new protocols subject to full board review to a primary reviewer and secondary reviewer, with the primary reviewer to present at the convened meeting.
    - e. If there is not at least one person on the IRB with the appropriate scientific or scholarly expertise, or other expertise or knowledge, to conduct an in-depth review of the protocol, the IRB obtains consultation.
      - i. During deliberation the IRB can determine whether a consultant is needed. The primary reviewer may also consult a consultant prior to the IRB meeting.

## Materials

- APP 01 New Research Protocol/ Proposal for Initial Approval - General Information
- APP 04 New Research Protocol/ Proposal for Initial Approval -Non-Exempt
- APP 05 Modification Request Application
- APP 07 Continuing Review – Non-Exempt Research
- WKSH 303 Non-Exempt Reviewer Worksheet
- WKSH 311 Reviewer Worksheet for Continuing Review, Modification or Study Closure
- GUIDE 608 Informed Consent Checklist – Basic and Additional

- DOC 704 UH IRB “Cheat Sheet” Placemat

## References:

- The IRB has and follows written policies and procedures to conduct reviews by the convened IRB: (AAHRPP Element II.2.D)
  - Element II.2.D.1. – Initial review
  - Element II.2.D.2. – Continuing review
  - Element II.2.D.3. – Review of proposed modifications to previously approved research.
- The IRB has and follows written policies and procedures to conduct reviews by an expedited procedure, if such procedure is used. (AAHRPP Element II.2.E)
  - Element II.2.E.1. – Initial review
  - Element II.2.E.2. – Continuing review
  - Element II.2.E.3. – Review of proposed modifications to previously approved research