

SOP 034: Human Subjects Protection Program

TITLE: IRB Chair Designations

PURPOSE: IRB Chair duties and transition plan

RESPONSIBILTIES: HSPP Director

PROCEDURES:

IRB Chair membership and rotation must provide continuity of IRB determinations and functions. To achieve this goal, a step-wise approach must be taken to ensure adequate knowledge and training of designated chairs so as to not unduly hinder the IRB's ability to make consistent and ethical decisions to protect human subjects.

IRB Chair duties and structure:

- Biomedical chair This individual must be an MD and have significant expertise in human research activities. Ideal service would involve prior IRB membership and role as an IRB Chair. It is expected that this individual consult with IRB staff throughout each week to make assessments and determinations related to projects involving significant risk, non-compliance issues and IRB agenda and quorum decisions. The Chair serves as the primary designee to run and manage the IRB committee meetings in collaboration with the IRB Coordinator, and attends meetings with faculty and researchers to discuss difficult issues or problems.
- 2. Biomedical Vice-Chairs Two individuals are needed to serve in this role and must have significant experience across a broad spectrum of research activities as they are primarily tasked with review of exempt and expedited human research projects. Given the interdisciplinary nature of research, they will be exposed to Social and Behavioral (SBS) research procedures in addition to medical research activities, and they serve as back-up to the SBS Chairs. A PhD or similar terminal degree would be satisfactory, preferably from a health sciences field, such as Public Health, Pharmacy or Nursing. In addition, the Vice-Chairs run and manage the IRB meetings in the absence of the IRB Chair. They are also tasked with attending meetings with faculty and researchers to discuss difficult issues or problems. The Vice-Chairs interact on a daily basis with the Human Subject Protection Program (HSPP) staff to review proposed exempt and expedited research, and provide consultation on difficult project questions. They are required to be proficient with the use UAccess Research for project reviews.
- 3. SBS Chair and co-Chair The SBS chairs review the majority of research projects from the Social Science colleges. They must have a PhD or comparable terminal degree and have significant research experience in qualitative research methods. The two SBS Chairs serve in tandem on a rotating schedule (as determined in consultation with the HSPP Director) so that the HSPP has continuity throughout the calendar year. They are tasked with difficult issues or problems and non-compliance related to SBS projects. It is expected that they attend IRB meetings periodically throughout the year to a) serve as primary reviewer of SBS projects that require full committee review and b) maintain education and involvement required of other IRB committee members. The SBS Chairs interact on a daily basis with the Human Subject Protection Program (HSPP) staff to review exempt and expedited research. They are required to be proficient with the use of

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UAccess Research for project reviews.

NOTE: All chairs may be assigned as a reviewer on full committee projects during their tenure. They must also be willing to attend national trainings periodically throughout their service.

Requirements for chair transition:

- 1. IRB Chairs that have served for five or more years should be considered for transition.
- 2. Potential chairs must have dedicated time to devote to IRB review to meet the ongoing needs and volume of IRB reviews.
- 3. Potential IRB Chairs should be an experienced IRB member (defined in SOP 001).
- 4. If a potential IRB Chair is not available on the current roster, a suitable replacement should be considered from the general faculty.
- 5. Assistance in finding a replacement Chair must involve Senior Leadership if the HSPP must look at general faculty expertise. In addition, the current IRB Chair will be tasked with evaluating faculty researchers who may be interested in serving in this role through direct communication.
- 6. Any individual tasked with becoming an IRB Chair should be rotated onto committee as described below:
 - a. Attend IRB meetings regularly for at least one year prior to assuming full Chair duties. It is not necessary to have this individual serve as a co-Chair or Vice-Chair, but they must be an active, participating IRB member.
 - b. At one year the individual will be evaluated to assume the chair duties as described above.
 - c. If possible, the outgoing IRB Chair will remain on the IRB for at least one year to further provide continuity of reviews.
 - d. The outgoing Chair may remain as a regular or alternate member of the IRB once their tenure is complete at the discretion of the HSPP Director in consultation with the Institutional Official.

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