IRB Membership

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1.0 Purpose

To aid in assuring knowledge and compliance of all persons involved in any aspect of human subject research by documenting IRB membership requirements.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the Health Sciences Institutional Review Board.
3.0 Policy/Procedure
The Health Sciences IRB (HS IRB) is duly constituted in light of the anticipated scope of
the institution's research activities and the types of subject populations likely to be
involved, the appropriateness of the proposed initial and continuing review procedures in
light of the probable risks, and the size and complexity of the institution. The HS IRB is
composed of at least five (5) regular voting members as mandated by the federal
regulations (45 CFR 46.107(a)). The membership is sufficiently qualified through the
experience and expertise of its members, and the diversity of the members, including
consideration of race, gender, and cultural backgrounds and sensitivity to such issues as
community attitudes, to promote respect for its advice and counsel in safeguarding the
rights and welfare of human subjects. Additionally, the HS IRB is able to ascertain the
acceptability of proposed research in terms of institutional commitments and regulations,
applicable law, and standards of professional conduct and practice.

The HS IRB is comprised of two subcommittees under the leadership of a single IRB
Chair and with assistance of a central IRB administrative office. Each subcommittee is
composed of no fewer than 5 general and lay members representing the health service
professions (medicine, nursing, and health professions), consumers, and members of the
non-scientific community (lawyers, clergy, ethicists, educators, etc.).

Potential new members are identified by recommendation from deans and department
heads in answer to solicitations for new members. The Vice Provost for Research
appoints new members. Routinely, appointments and reappointments of the voting
members of the Board will become effective at the beginning of the academic year
(September 1). At times it is necessary to fill a void in IRB membership during the year.
If the situation arises, a member will be solicited and appointed as soon as reasonably
possible.

Board members
A general Board member will be a respected, active member of the faculty or staff who is
a qualified scientific member of the IRB, is concerned about human rights and ethical
issues and stays well informed in the changing regulations relevant to the use of human
subjects in research. The member is appointed by the Vice Provost for Research to a
three-year term, which is renewed yearly and may be reappointed at the discretion of the
Vice-Provost of the Office of Research.

Responsibilities of the general Board member include, but are not limited to:
• Attend board meetings
• Review meeting material prior to Board meetings
• Serve as primary reviewer on assigned submitted proposals and prepare overview to
  present to Board and recommendation of action to be taken
• Determine whether proposal information is sufficient to allow knowledgeable vote (if
  not, determine if necessary to contact investigator or request review by outside
  consultant)
• Apply regulatory criteria for approval and vote on recommended action to proposal
• Evaluate submitted consent for appropriateness
• Assist in maintaining quorum, leaving only for emergencies
• Maintain confidentiality of Board discussions and all materials submitted for review
• When qualified as an expedited reviewer, conduct review and act on any expeditable project sent for review in a timely manner
• Review and act on requests for amendments and reports of unanticipated problems
• Review and act on compliance issues that require board action
• Remain well informed on the changing regulations relevant to the use of human subjects in research.
• Fulfill all training requirements
• Notify IRB staff of any potential conflict of interest

Required qualifications for expedited reviewers: A board member must demonstrate a consistent and comprehensive pattern of review of assigned protocols and demonstrate a dedication to the protection of human subjects with their actions and comments before being considered for eligibility, to be determined by the chair.

Eligible board members will be noted on the roster. The roster will be updated as needed.

The IRB staff, for all expedited and full board studies, will verify that the primary reviewer has the appropriate scientific and scholarly expertise to perform an in-depth review of the project before a project is assigned.

Lay Members
A lay Board member will be a respected, active member of the community who is concerned about human rights and ethical issues and stays well informed in the changing regulations relevant to the use of human subjects in research. The member is appointed by the Vice Provost for Research to a one-year term, which can be renewed indefinitely. The terms of lay members may continue without limit as long as the member continues to possess the desired qualifications.

The lay member is generally not affiliated with the institution but may be affiliated in a non-scientific capacity. At least one lay member of each Board will be a non-institutional affiliated member and must be present at the meeting for quorum. The Office of Research will query members on appointment regarding the affiliations of their immediate family, and annually thereafter using a Committee Membership Renewal Form, to confirm unaffiliated status or report affiliations of their immediate family.

Responsibilities of the lay Board member include, but are not limited to:
• Attend board meetings
• Review meeting packet prior to Board meeting
• Serve as consent reviewer on assigned submitted proposals and prepare list of any consent concerns to discuss at the Board meeting
• Determine if informed consent is adequate to allow knowledgeable vote (if not, determine if necessary to contact investigator or request review by outside consultant)
• Apply regulatory criteria for approval and vote on recommended action to proposal
• Assist in maintaining quorum, leaving only for emergencies
• Maintain confidentiality of Board discussions and all materials submitted for review
• Remains well informed on the changing regulations relevant to the use of human subjects in research.
• Fulfill all training requirements
• Notify IRB staff of any potential conflict of interest

Non-scientific lay members will be appointed to serve a one-year term and may be reappointed at the discretion of the Vice-Provost. The terms of lay members may continue without limit as long as the member continues to possess the desired qualifications.

**Chair**
The Chair of the IRB has overall responsibility for both IRB boards (middle and end of month boards) and oversight of the IRB Administrative Office.

Qualifications for the IRB Chair are:
• The Chair will be a respected, active member of the faculty from one of the schools
• Is a qualified member of the IRB or has prior experience in research
• Is concerned about human rights and ethical issues and stays well informed in the changing regulations relevant to the use of human subjects in research.
• Fulfills all training requirements (see SOP 1.8.1.2)
• The IRB chair will designate which IRB members are qualified to perform an expedited review.

The Chair is appointed by the Vice Provost for Research to a three-year term, which can be renewed and may be reappointed at the discretion of the Vice-Provost of the Office of Research.

Responsibilities of the Chair include, but are not limited to:
• Approve Board policies and procedures
• Resolve controversial substantive or procedural matters
• Keep current with regulations
• Assist in the education of investigators and board members
• Review and act on requests for emergency use of a test article/compassionate use
• Signatory for all approval letters, termination letters and other Board correspondence
• Reviews and acts on all exemption requests and annual reports in the absence of the Compliance Officer
• Oversight of the Board and IRB Administrative Office activities

**Vice-Chair**
The Vice-Chair of the IRB has responsibility for the IRB Board (either the mid-month or end-month) for which he/she serves as Vice-Chair.

Qualifications for the IRB Vice-Chair are:
• The Vice-Chair will be a respected, active member of the faculty from one of the schools
• Is concerned about human rights and ethical issues and stays well informed in the changing regulations relevant to the use of human subjects in research.
• Fulfills all training requirements

The Vice-Chair is appointed by the Vice Provost for Research to a three-year term, which can be renewed and may be reappointed at the discretion of the Vice-Provost of the Office of Research.

Responsibilities of the Vice-Chair include, but are not limited to:
• Review Board policies and procedures
• Resolve controversial substantive or procedural matters
• Conduct Board meetings
• Keep current with regulations
• Assist in the education of investigators and board members
• Review and act on project amendment requests
• Review and act on requests for emergency use of a test article/compassionate use in the absence of the Chair
• Review and acts on all exemption requests and annual reports in the absence of the Compliance Officer and/or Chair

Additional Consultants
The HS IRB uses consultants who are not regular voting members of the Board to review proposals in their areas of expertise, such as a device specialist or statistical consultant. If a situation arises where a proposal falls outside the expertise of the board members, an individual with expertise, and no conflicts (see conflict of interest SOP) in the necessary area will be identified and asked to serve in the capacity of non-voting member consultant in that discipline.

Additional Members
In order to better meet the needs of some of the affiliated institutions as required each subcommittee will include individuals associated with:

1) Harry S Truman Memorial Veterans Hospital (two individuals per each HS IRB committee as required by VA regulations) appointed by the VAMC Director for a three year term.
2) One member of the HS IRB is a designated prisoner consultant who has the appropriate background and experience to serve in that capacity.

Under the direction of The Office of Research, Compliance Officers are responsible for the distribution of renewal or service completion letters to Board members in August of each year. The content of these letters will be based on time of service and evaluation of performance. Health Sciences IRB staff will meet with Campus IRB staff to review IRB composition for compliance with regulatory and organizational requirements. An update of membership changes to the fully registered IRB will be compiled and submitted online to The Office for Human Research Protection as needed but at least annually.