OSH Research Committee Manual

I. Purpose

A. The purpose of the OSH Research Committee is to promote internal research, recruit external research, and guide appropriate research through the OSH system.

1. Promoting internal research might include, but is not limited to, providing research education or training to staff, developing staff research expertise, and helping with protocol or grant writing and preparation.

2. Recruiting external research might include, but is not limited to, communicating with area schools and universities, developing contacts and relationships with external entities, providing a research point of contact for OSH, and actively pursuing research projects and collaboration in order to create a dynamic research program at OSH.

3. Guiding research through the OSH system might include, but is not limited to, ensuring that researchers have the materials and information they need to proceed with research at OSH; providing feedback to interested parties on protocols, consent forms, surveys, etc.; working with researchers to make the correct connections within OSH in order to carry out their research; overcoming barriers to research within OSH; facilitating a relationship between researchers and staff, administration, and hospital stakeholders; and approving a protocol for IRB submission.

II. Authority

A. The RC is the authorized body responsible for all research at OSH. As such, the RC has authority over the following:

1. As a point of contact for outside institutions, to speak on behalf of OSH with regard to research matters,

2. The responsibility to monitor and review all research being conducted or proposed within OSH,
3. Approve or withhold recommendation for a protocol to proceed to an IRB or to be implemented once approved by the IRB,
4. Immediately upon written notice modify, terminate or suspend a project at any time if there is a threat to the health, safety, or welfare of any DHS/OHA client.

III. Reporting

The RC shall report to the Clinical Executive committee quarterly, or as needed.

IV. Meetings

A. The RC shall hold monthly meetings (or as needed) in order to complete its charge.

1. A simple majority of the membership listed in the most current RC roster constitutes a quorum, and is required for each vote on a protocol. If at any time during the meeting a quorum is lost, the committee may not vote on submitted protocols until a quorum is reestablished. The Chair or designee shall establish that the requirements for a quorum are met if a vote occurs at a meeting. Votes that have been sent to the RC Chair by electronic media or by phone shall count toward the quorum requirement.
2. In order to maintain a viable and efficient process for researchers, the RC may choose to hold virtual meetings by email. The Chair shall email proposals to each member for comment. A quorum vote is still required for recommendation to the IRB. Votes shall be emailed to the Chair.
3. The RC shall maintain meeting minutes and approve the proceeding meeting minutes at the beginning of every meeting. The results of virtual meetings shall also be captured in the committee minutes.
4. The RC shall keep a log of current IRB authorization agreements on file.

V. Membership

A. The RC shall be made up of a multidisciplinary team of OSH staff, a patient, and may include external individuals with appropriate research backgrounds.

1. The RC shall have an elected Chair responsible for facilitating regular meetings, reporting to the Clinical Executive committee, maintaining and creating external contacts, and providing leadership to the committee.
2. The RC Chair shall be elected by a majority vote from within the membership body of the RC to a term of one year, and may be reappointed.
3. The RC shall strive to maintain a diversity of membership appropriate to the committee charge. Additional members may be recruited by the committee for membership to address particular research needs.
4. The RC shall be sufficiently qualified through the experience, diversity, and expertise of its members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitudes.
5. The RC shall include membership by a patient, or if unavailable, a patient advocate.
6. Those interested in RC membership, shall submit a biographical sketch (the form shall be provided by the RC) with a statement of interest. If available, a curriculum vitae (CV) with statement of interest will suffice. The current RC committee shall vote upon the membership candidacy; a simple majority shall approve the candidate for membership. The patient or patient advocate is exempt from this provision.
7. Members shall maintain their Protection of Human Subjects education certificate regardless of whether they are currently involved in active research at OSH.

i. The RC member shall provide proof of an active certificate if obtained through another organization.

ii. If the member does not have an active certificate, they shall complete one of the recommended courses approved by the committee, and provide proof of completion.

iii. The RC shall audit its membership yearly to confirm current certification of its members.

8. The committee shall maintain a membership of five with term limits of two years. The term limits should be staggered, if possible, and individual members can be reappointed.

9. Conflicts of Interest

i. The RC Chair shall not allow a member to participate in the discussion or vote of any research study in which the member has a potential or actual conflict of interest, except to provide information as requested by the RC.

ii. At the beginning of each meeting, the RC Chair shall remind members to recuse themselves if they have an actual or potential conflict of interest with any submission under review.

VI. Review

a. When reviewing study protocols, the RC shall consider federal, state, and hospital policy.

1. The RC shall consider the “Common Rule” 45 CFR part 46 (DHHS), DHS Policy AS-100-06, and National Bioethics Advisory Commission reports and recommendations. Final approval for research and the consideration of the protection of human subjects shall reside with the IRB.

2. The RC shall consider the proposed benefit to OSH and OSH patients. This consideration will not be the deciding factor when determining whether to guide a proposal through the OSH system, but shall be considered in relation to other factors such as the burden on the hospital or infrastructure.
3. The patient committee member shall review all proposed research surveys for content and appropriateness for OSH patients. In addition, the committee or the patient member can convene a patient review panel to review surveys directed at patients specifically.

B. Prior to Submission:

1. The researcher shall consult with the appropriate OSH stakeholders relevant to the project and show evidence in their protocol that this input was sought, barriers and risk have been addressed, and the stakeholder has acknowledged the capacity to support or accommodate the study.
2. The RC shall be available to consult with researchers regarding contacting potential stakeholders.

C. Submission: The researcher shall submit the Research Submission Form and study protocol.

1. The submission form shall include the IRB to be authorized for this project.
2. The RC shall review the IRB listed against OSH's current list of IRBs with signed authorizations on file.
    i. If the IRB has a signed authorization on file, the review process shall continue
    ii. If the IRB does not have a signed authorization on file, or the authorization is out of date, the researcher is responsible for providing the RC with the documentation needed to complete the authorization process.

3. The RC shall formally review a proposal once the Research Submission Form and completed study protocol has been submitted to the Committee
4. The RC review shall culminate in one of three outcomes:
    i. Provisional Approval, to submit to the authorized IRB;
    ii. Not Approved, revisions recommended;
    iii. Not Approved, protocol is not appropriate for OSH at this time.
5. Once a provisional approval has been granted, the RC:
    i. Shall provide the researcher with a letter of approval, and
    ii. Shall submit the project to Clinical Executive for ratification.
6. Once a provisional approval has been received, the researcher shall submit the study to the authorized IRB.
7. Once the researcher receives approval from the authorized IRB, they shall submit the approval letter and approved study documentation to the RC.
8. The RC shall review the IRB approval and final study documentation, and provide one of three outcomes:
    i. Approval for implementation;
    ii. Not Approved, revisions recommended ;
    iii. Not Approved, protocol is not appropriate for OSH at this time.

D. Post-Approval:

1. The researcher shall forward all documentation between themselves and the authorized IRB, including but not limited to:
    i. Continuing review,
    ii. Protocol deviations,

iii. Protocol amendments,

iv. Unanticipated Problems involving risks to subjects or others,

v. Serious adverse events,

vi. Serious or continuing noncompliance with the applicable US federal regulations or the requirements or determinations of the IRB,

vii. Suspension, termination or closure.

2. The research shall forward a summary of study findings or all publications resulting from the approved research.

3. The RC shall be available for consultation and problem-solving efforts at all times.