Office of Research, Grants and Contracts
Standard Operating Procedures (SOP)

SOP Title	Membership and Appointment of the Institutional Review Board (IRB)				
Date Last Revised	12/06/2018	**Date Created**		**Revision #**	2.0
SOP Number	26	**Required by:**	☐OHRP ☐Funding Agency ☐OLAW		
Applicability	☐ RGC Internal	☐Researcher	☒Institutional		
Subgroup	☐ NKU Compliance	☒IRB	☐IACUC	☐IBC	

1.0 PURPOSE

The purpose of this SOP is to describe the procedures for appointing Institutional Review Board (IRB) members and for maintaining the Office of Human Research Protections (OHRP) roster.

2.0 GENERAL INFORMATION AND SCOPE

Per federal regulations the NKU IRB has a minimum of five voting members sufficiently qualified through experience and expertise to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The membership includes regular members who may have designated alternates with qualifications comparable to the regular member. While not listed on the OHRP roster, consultants and ex officio members provide guidance and input regarding IRB operations and protocol review.

IRB membership complies with federal requirements outlined in 45 CFR 46.107 to ensure appropriate diversity of the members through consideration of multiple professions/disciplines, ethnicities and cultural backgrounds, gender, and sensitivity to such issues as community attitudes and representation of the general perspectives of human subjects. In addition, the IRB includes members who can determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the IRB regularly reviews research involving a vulnerable category of subjects, the IRB membership includes individuals who are knowledgeable about and experienced in working with those subjects.

The IRB includes at least one member with each of the following primary affiliations: nonscientific, scientific, and nonaffiliated (i.e., not affiliated with NKU and not part of the immediate family of a person affiliated with NKU), and a physician (on IRB committees that review FDA regulated studies).

In addition, the IRB invites individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

3.0 PROCEDURES

A. APPOINTMENT PROCEDURES/TERMS OF MEMBERSHIP

1. Potential IRB members may be identified by the IRB Chair, the Manager of Research Compliance, or the Vice Provost of Graduate Education Research, and Outreach (VP GERO) and are ultimately appointed by the President of Northern Kentucky University.
2. The Manager of Research Compliance submits the recommendation to the Vice Provost of Graduate Education, Research, and Outreach who, if in agreement, submits the appointment letter to the President of NKU.
3. Appointments for IRB Chairs, Vice Chairs (if appropriate), and IRB members (including alternates) are for staggered three-year terms. NKU has no limit on the number of terms IRB Chairs, Vice Chairs, members, or alternates may serve on the IRB.
4. IRB Chairs, Vice Chairs, members, and alternates are responsible for providing the Manager of Research Compliance with an up-to-date curriculum vitae to document expertise, degrees, and/or license number prior to appointment or reappointment. The CV will ultimately be reviewed by the VP of GERO and the President of NKU prior to formal appointment and will be maintained in by the Manager of Research Compliance.

B. CHAIR APPOINTMENT

See SOP #5 (IRB) IRB Chair Appointment

C. ALTERNATES

1. Alternate IRB members replace IRB members who are unable to attend convened meetings of the IRB. Alternate members have qualifications comparable to the applicable regular member and may be alternates for more than one IRB member. The Manager of Research Compliance or IRB Administrator maintains lists of alternate members on the official membership list approved by OHRP. Terms of appointment, length of service, and duties are identical to those for regular members.
2. Alternates attending a meeting or conducting a protocol review have all the authority of regular IRB members and receive the same training and protocol review application materials as the regular members. IF the regular member and his/her alternate attend the same convened meeting, only one individual may vote.

D. CONSULTANTS

1. IRB staff may recruit ad hoc and cultural consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These ad hoc and cultural consultants do not vote with the IRB and do not count toward a quorum at a convened meeting. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting and/or attend the convened meeting to participate in the review. (See SOP #6 (IRB) Initial Review of Research – Convened (Full Board).

E. PRISONER REPRESENTATIVE

1. When the IRB reviews research involving prisoners, a majority of the IRB (exclusive of the prisoner representative) must have no association with the prison involved, apart from their relationship on the IRB.

2. For IRB review of research involving prisoners, at least one voting member at the IRB meeting must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

F. UNAFFILIATED/COMMUNITY MEMBER

1. Unaffiliated community members play an important role on the IRB. They bring fresh insight and perspective to board decisions about how best to protect research participants. The Community Member has the particular responsibility of bringing the perspective of the volunteer research participant to the review of protocols. Community members do not have a current affiliation with NKU. They also must not have an immediate family member (spouse or child) affiliated with either institution.
2. The unaffiliated member must participate in dialogue at convened board meetings if present. While presence at convened meetings is not required, it is strongly encouraged. The member may participate via conference call, go-to-meeting, etc.
3. While the member will not be individually assigned to review protocols, they may be asked to review a project that requires a community member perspective.
4. The member must stay current on all required IRB training and must complete the initial training prior to reviewing any protocols.

G. TERMINATION OF IRB MEMBERSHIP

IRB membership may be terminated in one of two ways:

1. A member may request to end appointment prior to the three year appointment end date. The request should be made in writing or email to the IRB Chair or Manager of Research Compliance.
2. An IRB member may be relieved of their duties as an IRB member if they fail to fulfill the required roles of an IRB member. This may include, but is not limited to:
    a. Failing to respond to three assigned reviews within a 12 month period. If an IRB member is unable to complete an assigned review, they must notify the IRB Administrator as soon as possible. If an IRB member is relieved of their duties, they will be notified in writing by the IRB Chair.
    b. Failing to complete the required training.

H. OHRP IRB REGISTRATION/IRB MEMBERSHIP ROSTER

1. The Manager of Research Compliance or his/her designee completes the OHRP registration forms in accordance with OHRP requirements and updates the registration in a timely manner when the IRB membership changes. The OHRP registration form serves as the IRB roster and denotes in which scientific capacity each member serves.
2. The Manager of Research Compliance or his/her designee maintains the membership records. IRB staff use the OHRP membership list as the official membership list to determine who may attend IRB meetings and count toward the quorum. It includes a list of regular members and their designated alternates and includes scientific status of all members.
3. To meet OHRP registration requirements and in order to hold convened meetings, the scientist and nonscientist member designations are as follows:

a. Nonscientific: members who have had little or nonscientific or medical training or who do not currently hold positions which involve scientific research or clinical practice (e.g. administrative positions).
b. Scientific: members who are physicians or who hold Ph.D. Pharm.D., or other advanced degrees who are actively engaged in the physical, educational, social, behavioral, or biological sciences and disciplines and/or hold regular faculty appointments.

4.0 REFERENCES

45 CFR 46.103
45 CFR 46.115
45 CFR 46.107
45 CFR 46 Subpart E U.S. Department of Health and Human Services (HHS) Registration of an IRB (Notes)

5.0 FORMS OR ATTACHMENTS

6.0 DEFINITIONS

Approvals

Title	Approved	Date Approved	Not Applicable
Manager of Research Compliance	☒	11/15/2018	☐
IRB Chair	☒	11/15/2018	☐
Institutional Official	☒	11/15/2018	☐

Revisions

Title	Approved	Date Approved	N/A	Summary
Manager of Research Compliance	☒	12/06/2018	☐	Addition of revised common rule information.
IRB Chair	☒	12/06/2018	☐	
Institutional Official	☐		☐	