1. **Policy Statement**

The ISU-IREB selection of members shall be through direct appointment by the IREB Chairperson that ensures multidisciplinary (scientists and non-scientists, medical and non-medical members), multi-sectoral, (gender- and age-balanced), and member/s who are not affiliated with the consortium. Members shall be classified as regular or alternate members. The eight (8) regular members shall serve for 2 years but may be renewed for several terms. The alternate members shall serve yearly and shall attend meetings whenever called to ensure that meetings are conducted with sufficient members. The selection of members shall be based on the National Ethical Guidelines and the WHO Operational Guidelines.

1. **Objective of the Activity**

The selection and appointment of ISU-IREB members aim to ensure that the composition of the ISU-IREB complies with international, and national guidelines and that appropriate expertise is taken into consideration.

1. **Scope**

This SOP applies specifically to the selection of members of the ISU-IREB. This SOP begins with a call for nomination and ends with the filing of appointment papers and Curriculum Vitae of ISU-IREB members in the membership file.

1. **Workflow**

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| **Activity** | **Responsible Person/s** |
| 1. Call for nomination
 | ISU-IREB Chairperson |
| 1. Submission of nominations
 | Head of Member Institution  |
| 1. Shortlisting of nominees
 | ISU-IREB Chairperson & Members |
| 1. Appoints new ISU-IREB members to include Member Secretary & non-affiliated members
 | ISU-IREB Chairperson |
| 1. Forwarding of appointment letter to the new members
 | New ISU-IREB Members |
| 1. Signing of conforme, confidentiality, and conflict of interest agreements
 | New Member/s |
| 1. Files appointment letters and CVs with supporting documents
 | ISU-IREB Secretariat |

1. **Description of Procedures**

* 1. **Call for nomination**

The ISU-IREB chair shall notify the ISU Executive Director of the vacancy for a member in the ISU-IREB. The call for nominations should be based on qualifications and requirements stated in the international, national, and institutional policies. It shall require the accomplishment of a FORM 1A NOMINATION AND ACCEPTANCE FORM and submission of other documents such as FORM 1B. CURRICULUM VITAE and certificates of training, etc.  The call for nominations is coursed through the IREB Executive Director and sent to the heads of IREB member institutions.

* 1. **Submission of nominations**

The nominators submit FORM 1A. NOMINATION AND ACCEPTANCE FORM and other required documents including FORM 1B. CURRICULUM VITAE and certificates of training, etc. to the ISU-IREB office. The Secretary Staff checks the completeness of the nominations, e.g. CVs of the nominees, Ethics Training Certificates, Endorsement of the Head of Member Institution, etc.

1. **Shortlisting of nominees**

The ISU-IREB Chairperson and Members prepare a shortlist of the nominees for both regular and alternate members based on requirements and qualifications. The shortlisted will be submitted to ISU Executive Director for final review and endorsed to the ISU-IREB Chairperson for approval.

1. **Receipt of Appointment papers of new members**

The ISU-IREB Secretary Staff receives FORM 1C. APPOINTMENT LETTER from the IREB Chairperson and inform the ISU-IREB Chair accordingly. The appointment papers specify the conditions of the appointment including the roles and responsibilities.

**Regular and Non-affiliate member**

a. The role of the scientific and/or medical member is to focus on the review of the study protocol, while the role of the non-scientific/non-medical or lay member is to focus on the review of the informed consent process and form.

b. The roles of the affiliated and non-affiliated members in terms of the review are similar, however, the non-affiliated member is expected to provide an external perspective to ensure the independence of the position of the ISU-IREB, even from possible bias that may the impact rights, safety, and well-being of human subjects in research.

c. Make a timely and thorough review and decision regarding protocols given to him/her for evaluation as defined in SOP#4 and SOP#5

d. Familiarize him/herself with the SOPs of the ISU-IREB, his/her terms of reference, and the international and national guidelines on research ethics

e. Participate actively in the ISU meetings and are entitled to vote for a decision during the meeting. It is expected that a ISU-IREB member will have at least 50% attendance during the period of appointment because attendance is integral to the effectiveness of the ISU-IREB as a review board. Alternate Members will be called upon to attend meetings as a substitute to members who will be absent for purposes of maintaining quorum.

f. Participate in initial review (initial submission and resubmission) and continuing review (amendments, progress reports, final reports, noncompliance reports, early termination reports, and SAE/SUSAR reports) of protocols submitted for consideration of ISU-IREB, and recommend appropriate action on serious adverse events based on monitoring reports from SAE Subcommittee

g. Maintain confidentiality of the documents and deliberations of ISU-IREB meetings

g. Declare any conflict of interest in general and for specific protocols for review

h. Participate in required training as stipulated in SOP 1 Chapter 1.2 – 5.3 with proof of attendance in such training activity submitted to the ISU-IREB Chairman

i. Submit an updated and signed CV at the start of each calendar year

j. Refer to the ISU-IREB Chair any suggestion, complaint, or grievance of research participants, PIs, and/or sponsors before acting on them and after consulting with other ISU-IREB Members

k. Participate in Site Visits and similar activities as needed

         l.

**Secretary Staff**

a. Assist the Member-Secretary in the performance of tasks related to maintenance of ISU-IREB databases and generation of statistical data

b. Assist in the preparing and processing of ISU-IREB administrative documents

c. Assist in tasks related to accounting and release of funds

d. Manage protocol submissions

e. Organize an effective and efficient tracking procedure for each protocol received

f. Prepare and distribute protocol files for review

g. Maintain the ISU-IREB Active Files and Archives, SUBMISSIONS LOGBOOK 1 and SUBMISSION DATABASE 1, References and other document files, especially their security and confidentiality

h. Organize IREB meetings (see SOP19 CONDUCT OF MEETINGS)

i. Prepare and maintain meeting agenda and minutes

j. Inform ISU-IREB review members and personnel about training workshops and arrange for the latter’s participation in such workshops

k. Organize the preparation, review, revision, and distribution of SOPs and guidelines

m. Provide the necessary secretariat support for ISU-IREB -related activities like Site Visits and communicating decisions to the PIs

n. Perform other related functions that may be assigned by the ISU-IREB Chair, Vice-Chair, Member-Secretary and Members

o. Perform other related functions that may be assigned by the ISU-IREB Chair, Vice-Chair, Member-Secretary and Members

1. **Forwarding of Appointment papers to the new members.**

The ISU-IREB-Chairperson signs the appointment papers as noted and dated and then instructs the staff to forward the documents to the concerned new member.

1. **Signing the conforme, and the conflict of interest disclosure and confidentiality agreement.**

The new IREB-REC member/s sign FORM 1D. CONFIDENTIALITY AND CONFLICT OF INTEREST DISCLOSURE AGREEMENTS.

1. **Filing of appointment documents and CVs and signed Agreements in the membership file**

The IREB Secretariat files FORM IA NOMINATION FORM, FORM 1C APPOINTMENT LETTER, FORM 1B CURRICULUM VITAE, and signed FORM 1D CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENTS and FORM 1E TRAINING RECORDS with supporting documents of the new IREB members.

**6. Glossary**

 **Scientists** are individuals whose formal education is at least a master’s degree in a scientific discipline, e.g. biology, social science, etc.

             **Non-scientists** are individuals whose primary interest is not in any of the natural, physical, or social sciences and whose highest formal education is a bachelor’s degree.

**Non-affiliated** **member** – refers to a ISU-IREB member not belonging to the member institutions of the ISU and shall serve as a layperson representing the community.

**Non-scientific/non-medical member** – an individual whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline.

    **Alternate Member**- refers to a member who possesses the qualifications of specified regular members and is appointed in substitution of the regular member who cannot attend the meeting to comply with the quorum requirement.

**Regular Member**- refers to a member who receives official appointments from the ISU

Executive Director and is required to attend the meetings of the committee to form a quorum.

**7. Forms**

FORM 1A NOMINATION AND ACCEPTANCE OF NOMINATION

FORM 1B CURRICULUM VITAE

FORM 1C APPOINTMENT LETTER (ISU-IREB MEMBER)

FORM 1D CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENTS

FORM 1E TRAINING RECORDS

1. **History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
|  |  |  | **-** |
|  |  |  |  |

1. **References**

PHREB National Ethical Guidelines for Health and Health-Related Research

World Health Organization Operational Guidelines

2020 PHREB SOP Workbook

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| --- | --- |
| Prepared by:   |  |
| Recommending Approval:   |  |
| Approved by:   |  |
| Approval Date:   |  |