1. **Policy Statement**

The Isabela State University-Institutional Research Ethics Board (ISU-IREB) believes the fact that research is collaborative work that demands multi-specialization among its members. Since the research to be submitted for review by the ISU-IREB is diverse in terms of thematic areas, there is a need to appoint Independent Consultants to make an effective review of the research protocols.

The ISU-IREB shall invite an independent consultant whose expertise is not represented in the current membership but is needed in a study under review. He/she need not be affiliated with the institution.

1. **Objective of the Activity**

This Standard Operating Procedure (SOP) aims to describe the appointment of Independent Consultants to ensure that it conforms to the IREB practice and complements the pool of expertise in the ISU-IREB.

1. **Scope**

The SOP specifically pertains to the selection and designation of Independent Consultants in the review of research protocols of the ISU-IREB. It begins with the Identification of the study that requires an Independent Consultant and ends with the inclusion in the pool of Independent Consultant and filing of appointment documents.

1. **Workflow**

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| **ACTIVITY** | **RESPONSIBLE PERSON** |
| 1. Identification of the study that requires an Independent Consultant | Primary Reviewer, Member-Secretary ISU-IREB Chairperson |
| 1. Identification of the Independent Consultant/s | Primary Reviewer, Member-Secretary ISU-IREB Chairperson |
| 1. Invitation of the independent consultant | IREB Chairperson |
| 1. Appointment of the independent consultant | ISU-IREB Staff |
| 1. Receipt of the signed Conflict of interest disclosure and confidentiality agreement | ISU-IREB Staff |
| 1. Inclusion in the pool of independent consultants | ISU-IREB Staff |

1. **Description of Procedures**

1. **Identification of the study that requires an Independent Consultant**

Either the Primary Reviewer, Member-Secretary, or Chair identifies the study requires expertise necessary in the review of a research proposal and that may not be provided by the current members of the ISU-IREB.

**5.2 Identification of the Independent Consultant/s**

         The ISU-IREB Chairperson refers to the roster of specialists in the IREB or other

         Non-affiliate institutions for the necessary expertise and select the appropriate expert. S/he

         instructs the ISU-IREB Staff to prepare the FORM 3A LETTER OF INVITATION.

1. **Invitation of the Independent Consultant**

The ISU-IREB Staff prepares a FORM 3A LETTER OF INVITATION containing the Terms of Reference for the signature of the IREB Chairperson and sends this to the identified expert. The letter of invitation contains a section for acceptance of the invitation.

The independent consultant shall inform his/her institution and request for a special order allowing him/her to perform his/her function as an independent consultant to ISU-IREB.

1. **Appointment of Independent Consultant**

Upon receipt of the acceptance of the invitation, the ISU-IREB Staff prepares FORM 3B LETTER OF APPOINTMENT for the signature of the IREB Chairperson and sends the appointment to the independent consultant together with FORM 2C CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT and FORM 1B CURRICULUM VITAE for signing.

Appointment may be terminated by either resignation of the independent consultant, or by the IREB Chairperson.

1. **Receipt of the signed conflict of disclosure and confidentiality agreement**

    The ISU-IREB Staff receives the signed FORM 2C CONFIDENTIALITY AND CONFLICT

    OF INTEREST AGREEMENT and file this in the appropriate folder.

1. **Inclusion in the Pool of Independent Consultants**

The ISU-IREB Staff enters the name of the new independent consultants in the appropriate database containing name, expertise, institution, and date of appointment. The Independent Consultants File shall contain FORM 3B LETTER OF APPOINTMENT, FORM 2C CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT, and FORM 1B CURRICULUM VITAE.

1. **Glossary**

**Database** – a structured/organized collection of information so that the data can easily be accessed,

managed, and updated.

**Expertise** – a proficiency, skill, or know-how possessed by experts in a certain academic or professional field

**Independent consultants –** Resource persons who are not members of the ISU-IREB, whose expertise is needed in the review of a research protocol/proposal, and who may be invited to attend a committee meeting but are non-voting during the deliberations.

1. **Forms**

FORM 3A LETTER OF INVITATION TO INDEPENDENT CONSULTANT

FORM 3B LETTER OF APPOINTMENT TO INDEPENDENT CONSULTANT

FORM 1B CURRICULUM VITAE

FORM 1D CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

1. **References**

World Health Organization Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011 

National Ethical Guidelines for Health and Health-Related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

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