1. **Policy Statement**

The Isabela State University-Institutional Research Ethics Board (ISU-IREB) shall consider the perspectives of researchers regarding the acceptability and feasibility of IREB recommendations, including their disapproval. A fully documented researchers ‘appeal must be filed to the IREB 5 working days before the monthly IREB meeting (every last Saturday of the month) for the appeal to be included on the agenda of the IREB monthly meeting. The resolution of the appeal shall be determined through an in-dept evaluation and full review of the well documented appeal and decision is in accordance with the consensus of the committee members. The IREB, through the member secretary shall inform the researcher thru writing regarding the final decision on the appeal discussed at the monthly meeting. The letter shall be transmitted by IREB secretariat within three (3) working days after the monthly meeting thru the official email of the IREB.

1. **Objective of the Activity**

The management of appeals assures the impartiality, transparency, and comprehensiveness of the ethics review, which takes into consideration the researcher's position and perspective.

1. **Scope**

The Standard Operating Procedure on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the committee’s action to the researcher and updating of the protocol.

1. **Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
| 1: Receipt of an appeal | IREB Secretariat |
| 2: Retrieval of pertinent protocol file | IREB Secretariat |
| 3: Notification of Chair and Primary Reviewer/s | IREB Secretariat |
| 4: Inclusion in the Agenda of the next regular meeting | IREB Chair, Secretary and Primary Reviewer |
| 5: Discussion of and deliberation on the appeal | Chair and IREB Members |
| 6: Communication of committee action  (SOP 27 Communicating IREB Decisions) | IREB Chair, Secretary, Secretariat |
| 7: Filing of documents and updating of the protocol database | IREB Secretariat |

1. **Description of Procedures**

Each of the identified steps in the workflow are described in detail as follows:

**5.1. Receipt of an Appeal:** The IREB secretariat receives the letter of appeal and enters the pertinent information into the logbook.

**5. 2. Retrieval of pertinent protocol file**: The IREB secretariat retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

**5.3. Notification of Chair and Primary reviewers:** The IREB secretariat notifies the IREB Chairperson. The primary reviewers, through the member secretary shall be informed about the letter of appeal and a full review and indepth evaluation shall be conducted by the reviewers.

**5.4. Inclusion in the Agenda of the next regular meeting:** The IREB Chairperson through the member secretary instructs the staff to include the appeal in the agenda of the next meeting to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher/s to be available on the scheduled meeting in case there is a need for further clarification.

**5.5. Discussion of and Deliberation on the Appeal:** The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal.  The Chair presents the contents of the appeal and leads the discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides by consensus whether to accept any or all of the points raised in the appeal.

**5.6. Communication of Committee Action:** Based on the deliberations, the Chair summarizes the decision points and instructs the IREB staff to prepare the draft decision letter (Form 15C Decision Letter) for his/her finalization and forward it to the researcher.(SOP 21 Communicating IREB Decisions).

**5.7: Filing of Documents and Update of Protocol Database:** The IREB Secretariat files all the documents into the appropriate folder and updates the protocol database accordingly.

1. **Glossary**

**Appeal** – a request of a researcher/ investigator for a reconsideration of the IREB recommendation.

**Primary reviewer** – is a member of the IREB who is assigned to do an in-depth evaluation of research-related documents using technical and ethical criteria established by the committee.

**Protocol File/Folder** – is an organized compilation of all documents (in physical or electronic form) related to a study.

**Protocol database** - a collection of information (e.g. regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

1. **Forms**

Form 15C Decision Letter

1. **History**

This is the first draft of the IREB SOP through a IREB Standard Operating Procedure (SOP) workshop participated by the DOST IREB Focal Person, the IREB Chairperson, Members and secretariat   conducted on October 25-27, 2023 at Mango Suites, Santiago City.

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| **Version No.** | **Date** | **Authors** | **Main Change** |
| 0 |  | ISU-IREB SOP Team |  |

1. **References**
2. WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
3. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
4. Philippine Health Research Ethics Board Standard Operating Procedures 2020
5. National Ethical Guidelines for Research Involving Human Participants 2022

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