1. **Policy Statement**

The meeting minutes of the IREB shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

1. **Objective of the Activity**

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in the meeting of the IREB.

1. **Scope**

This SOP includes IREB actions related to the documentation of the proceedings of a meeting, the final output of which is the minutes of the meeting, following the template on Minutes of the Meeting. This SOP begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes.

**4. Workflow**

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| **ACTIVITY** | **RESPONSIBILITY** |
| 1.  Entry of preliminary information on the minutes template | IREB Member Secretary |
| *2*. Preparation of the draft minutes | IREB Member Secretary |
| 3. Notation of the draft minutes | IREB Chair |
| 4. Approval of the minutes in the next IREB meeting | IREB Chair and Members |
| 5. Filing of the approved minutes consistent with SOP No. 23 Managing Active Files | IREB Member Secretary |

1. **Detailed Procedures**

 **5.1 Entry of preliminary information on the minute’s template**: Preliminary or relevant information (e.g. protocol-related information, other matters), are entered by the CVHRDC-REC Member Secretary, supervised by the Chair, in Template on Minutes of Meeting.

 5.2 **Preparation of the draft minutes**: The IREB Member Secretary prepares the draft minutes of the meeting, reviewed by the Chair before the meeting. The IREB Member Secretary documents the proceedings, following the agenda by real time recording and note taking for physical meetings. However, for online and hybrid meetings, the meeting is audio-visually recorded. To ensure the accuracy of the documentation, the Chair may request to the Member Secretary to read an approved motion. Documented discussions include comments, ethical issues, and informed consent form issues without attribution to specific members.

 5.3 **Notation of the draft minutes**: After the meeting, the IREB Member Secretary prepares using the  the draft minutes of the meeting, using the Template on Minutes of Meeting, and submits it to the Chair for notation. The Chair circulates to the members the draft Minutes within one week after receipt for any correction. The following items are included in the minutes of the meeting:

* Date and venue of meeting
* Members attendance (members present and absent)
* Presence of Independent consultants, primary investigators, guests, and observer’s attendance (if any)
* Time when the meeting was called to order
* Declaration of Quorum
* Name of Presiding officer/Chair
* Conflict of Interest (COI) declaration
* Items discussed, issues raised, and resolutions
* REC decisions and recommendations
* Name and signature of person who prepared the minutes/IREB Member Secretary
* Name and signature of the Chair and date of notation

5.4 **Approval of the minutes in the next REC meeting**: The minutes of the previous is approved by the body in the following meeting after a motion and duly seconded, following the order in SOP No. 18 Preparing the Meeting Agenda.

**Step 5 - Storage of the approved minutes**: What type of storage system does the IREB have for the final minutes of meeting? What kind of documentation is necessary to complete this task? It is recommended that the IREB maintain a central file of all meeting minutes by year to facilitate retrieval. See SOP 23 Managing Active Files.

1. **Glossary**

Meeting Agenda-  the list of topics or items to be taken up in a meeting arranged in a sequential manner.  It is an outline of the meeting procedure and starts with a “Call to Order”.

Draft Meeting Minutes – Proceedings of the meeting prepared by the Secretariat under the supervision of the IREB Member Secretary.

Provisional Meeting Minutes – Proceedings of the meeting that have been noted or approved by the Presiding officer or Chair.

Final Meeting Minutes – Proceedings of the meeting that have been approved by the IREB members.

Real-time Recording – the process of documenting the minutes of the meeting as the meeting proceeds simultaneously.

1. **Forms**:

Form Meeting Agenda Template

Form Notice of Meeting

1. **History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
|  |  | IREB Members | First draft |

1. **References**

*CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011*

*National Ethical Guidelines for Health and Health-related Research 2022*

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

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