**Statement of Policy**

Meetings shall be presided by the chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review.

**Objectives of the SOP**

Meetings are conducted to provide an opportunity for the REC to arrive at collegial decisions regarding study protocols and REC operations and to be informed of pertinent administrative matters.

**Scope/Applicability**

This SOP describes the manner by which the REC conducts all its meetings. It covers REC actions and activities from the time the meeting is called to order and quorum is declared to the time the meeting is adjourned. This SOP begins with the distribution of meeting materials and ends with the collection, storage, and disposal of meeting materials.

**Flowchart**

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| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Distribution of meeting materials | REC Staff | 1 day (same day) |
| Step 2: Declaration of quorum (formal start) | Member Secretary or Chair | 1 day(same day) |
| Step 3: Approval of the provisional agenda | REC Members | 1 day(same day) |

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| Step 4: Declaration of conflict of interest (COI) | REC Members (who have COI) | 1 day(same day) |
| Step 5: Approval of minutes of the previous meeting | REC Members | 1 day(same day) |
| Step 6: Discussion of “Business arising from the minutes” | REC Members | 1 day(same day) |
| Step 7: Review of protocols and protocol-related submissions (SOP on Full Review (SOP# 05)) | REC Chair and Members | 1 day(same day) |
| Step 8: Report of results of expedited review (SOP on Expedited Review (SOP# 04)) | Designated Reviewers | 1 day(same day) |
| Step 9: Discussion of operations-related matters | REC Chair and Members | 1 day(same day) |
| Step 10: Adjournment | Chair | 1 day(same day) |
| Step 11: Collection, storage, and disposal of meeting materials | Staff | 1 -2 days |

**Description of Procedures**

Step 1 - Distribution of meeting materials: The documents needed would include Meeting Agenda, Approved minutes of the meeting of the previous meeting agenda and related study protocols or study protocol synopses (Research Protocol / Paper, Informed consent, Technical Panel Clearance, Protocol evaluation form, Informed consent evaluation form). These documents should have been prepared ahead in accordance with SOP 17 on Preparing for a meeting. Copies would be provided to all REC members 5 to 7 days before the start of the meeting.

Step 2 – Declaration of quorum: Qourum is declared when 50% of members plus one are present. Including the presence of a non-affiliated and a nonscientist (lay) members as a requirement of quorum. It is the Chair or the member Secretary who will declare qourum. Confirmation of quorum is done at the start of the meeting and reconfirmation is done every time a decision needs to be made.

Step 3 - Approval of the provisional agenda: The Chair invites the members to examine the provisional agenda and to propose addition or deletion of items.

Step 4 - Declaration of Conflict of Interest: The Chair would ask for any declaration of conflict of interest. Any member declaring COI would be a non-participant in the decision making process.

Step 5 - Approval of minutes of previous meeting: The Chair presides over the review of the Minutes of the previous meeting. Any member can declare a motion for approval, which any member can second. The Chair then declares approval of the Minutes of the previous meeting.

Step 6 - Discussion of “Business arising from the minutes”: The Chair or member Secretary reports on „business arising from the minutes“ The Chair encourages all members present in the meeting to actively participate in all the discussions. All actions on study protocol submissions being reviewed are decided upon by majority of votes.

Step 7 - Review of protocols and protocol-related submissions: The REC will allow the principal investigator or researcher to make a presentation if need be. They would be invited for a clarificatory interview. An Independent Consultant may be commissioned by REC of highly specialized areas to attend the part of the meeting related to specific studies for purposes of clarifying issues related to the study protocol only. They will not be counted during determination of quorum and will not be able to vote for full board actions during the meeting.

The sequence of the review would be as follows: technical issues, ethical issues, and informed consent process/form issues. The primary reviewers should be guided by the assessment form in their presentations. See SOP 05 Full Review.

All actions on study protocol submissions being reviewed are decided upon by majority of votes. Either by secret ballot or by raising hands.

Step 8 - Report of results of expedited review: One (1) or both of the primary reviewer will present the results of expedited review to the members. Expedited review results are for the information of the REC members, only, as well as for the documentation of the review results.

Step 9 - Discussion of operations-related matters: The following may be included in the operations-related matters: SOP manual review, revising and writting, Research Ethics trainings, REC composition, REC resources and other related matters.

Step 10 - Adjournment: Before closing the meeting, the Chair calls for any other matters that need attention or action, as the need arises. With no further matters for discussion, the Chair formally adjourns the meeting, with the time noted by the REC Staff who is documenting the meeting. Meeting must be adjourned after all items in the agenda have been discussed and/or resolved. A member must move for the adjournment of the meeting, and seconded, for it to be declared.

Step 11 - Collection, storage, and disposal of meeting materials: The Review Panel Staff collects all meeting materials, including the documentation collected for the Minutes of the meeting; mindful that these materials are confidential and must be handled appropriately. See SOPs on Managing Active Files (SOP# 23) and SOP # 18 Preparation of Agenda

**Forms:**

SOP 6 Form 011 Protocol Assessment Form

SOP 6 Form 012 ICF Assessment Form

SOP 6 Form 008 REC Decision Form

 **History of SOP**

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| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 01/28/2015 | krva | Creation of SOP |
| 02 | 09/26/2022 | krva | Revision of SOP |