**Statement of Policy**

The REC shall designate a team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

**Objectives of the SOP**

Writing and revising SOPs ensures continuing quality assurance of REC functions.

**Scope/Applicability**

This SOP applies to all REC activities involved in the development of its SOPs and their revisions as published and distributed by the institution. This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the inclusion of the new or revised SOP in the SOP Manual and its dissemination.

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Proposal and approval for revision or writing of a new SOP | Any REC Member or Staff | 1-2 days |
| Step 2: Designation of the SOP Team | Chair | 1-3 days |
| Step 3: Drafting of the revision or new SOP | SOP Team | 1-15 days |
| Step 4: Review and finalization of SOP | REC Members | 1 month |
| Step 5. Submission of finalized SOP to the institutional authority | Chair | 1-3 days |
| Step 6: Inclusion of the new or revised SOP in the SOP Manual and its dissemination | REC Staff | 1-3 days |

**Description of Procedures**

Step 1 - Proposal for a revision of an SOP or a new SOP and its approval: Any REC member or staff can propose the revision of an SOP or creation of a new SOP. A request for amendment or revision is accomplished. The Chair is responsible for initial review of the request, procurement or relevant information, recommendation of further action as follows: Confirm need for amendment or revision, forward to SOP Team; Request further information (state); Forward to content expert for opinion. This will be during a special meeting.

Step 2 - Designation of the SOP Team: The SOP Team will be designated by the Chair. Three to five REC members would compose the team.

Step 3 - Drafting of the revision or new SOP: An SOP template would be utilized. This would greatly harmonize the writing of SOPs. In designing this template, the following contents are included:

* 1. Title, which is descriptive of contents
  2. Policy statement
  3. Objective/s of the activity, which defines the purpose and intended outcome
  4. Scope, which defines the extent of coverage of the SOP and its limitations
  5. Workflow provides a graphic representation of the essential steps to implement the SOP and the responsible person for each step.
  6. Detailed instructions, which elaborates the steps listed in workflow
  7. Glossary – acronyms and terms which need to be defined
  8. Forms, documents to be accomplished by different parties as required by the SOP,
  9. Document history which tabulates the different versions (from draft to final versions) of the document by author, version, date, and description of main changes
  10. References, which lists the instruments use to draft the Guideline such as other SOPs, guidelines, or policies

REC code would be SOP XX/YY where XX can refer to the SOP number, YY the Version of the SOP (starting from 01),

Step 4 - Review and approval of SOP: It is submitted by the SOP Team leader to a REC members. The review require an REC meeting. The review require deliberation, collection of comments, or voting. The details involved are determination of favorable action, deferment, documentation of action. This should be accomplished in one month. The new SOP will be effective a month after the final version has been approved. The Chair signs as he/she approves the final version.

Step 5 – Submission of the SOP to the institutional authority

Step 6 - Inclusion of the new or revised SOP in the SOP Manual and its dissemination: The SOP is made available both hard and E-copy. The E-copy is downloadable in the Research Ethics Committee section in the ADZU website www.adzu.edu.ph.

In case of amended or revised SOP, the old version is retired or superseded and stored separately from the new version. This step ends with filing of approved SOP.

**Forms:**

Letter of Request for Creation/Revision of an SOP

SOP 27 Form 030 SOP Template

**History of SOP**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 02/28/2017 |  |  |
| 02 | 09/26/2022 | krva | Revision of SOP |