

AUREC Standard Operating Procedures (SOP's)

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These standard operating procedures (SOPs) outline how AUREC conducts its activities as mandated by the Medical Research Council of Zimbabwe (MRCZ)

1. DEVELOPING AND UPDATING OF SOPs No 001

(i) PURPOSE

This procedure describes how to develop a new Standard Operating Procedure (SOP) or update an existing one.

(ii) SCOPE

This SOP applies to any development of the AUREC SOP or amendment of the existing ones.

(iii) RESPONSIBILITY

It is the responsibility of the Chairperson of AUREC to:

- a) Nominate SOP team(s) to formulate new SOP(s) or to revise/amend existing SOP(s)
- b) Approve SOP (s)
- c) Sign and date the SOP (s)

Note that the SOP team shall be notified by the University Registrar.

AUREC should approve each new or updated SOP and the Chairperson signs it/them.

(iv) INSTRUCTIONS

a) Numbering of SOPs

When a new SOP is developed, a unique identifying number is allocated.

When a SOP is no longer in use, its status is changed to "inactive". It will not be reused. All guidelines are named and numbered in the following way :

AUREC 001,AUREC 002, AUREC003.....etc

b) Version control

Versions will be controlled by the AUREC Secretariat who will number versions as listed below and previous ones will be retrieved.

Number SOP versions as follows:

Draft versions: *use decimal figures and the word “draft”*

For example: **Version 0.1, draft**

Final versions: *use integer and the word “final”*

For example: Version 1.0 final

For minor changes on a final version: *change only the decimal part of the version number*

For example: version 1.0 final becomes version 1.1

For major changes on a final version: *change the integer part of the version number*

For example, major changes on “version 2.1, final” will be indicated as “version 3.0, final”.

A Log of Copies for the original copy of the guideline must be maintained.

It is the responsibility of the Secretariat to maintain version control.

Only the Secretariat is allowed to make copies of SOPs.

(c) Contents and Layout

i Identification details

The Identification details section has the following information:
title, and number of the SOP and effective date of the SOP

Name and signature of approving person (Chairperson)

ii Main Text

Purpose of the SOP should be explained in summary form.

The scope and responsibility of the SOP should be spelt out.

Detailed description of the procedure should be given

The text should be short and clear.

Appendices

Appendices replace long and complex descriptions.

Effective Date

Chairperson
(Name)

.....
Signature

(i) PURPOSE

The purpose of this SOP is to outline the administrative process and provide instructions for the preparation, review, approval, and distribution of meeting agenda, minutes, invitation, and notification letters of meetings.

(ii) SCOPE

This SOP applies to administrative processes concerning the preparation of all regular AUREC meetings, in three stages: before, during, and after the meeting.

(iii) RESPONSIBILITY

It is the responsibility of the Secretariat to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the minutes sent to him/her for circulation. The committee adopts and approves the minutes in its subsequent meeting.

BEFORE EACH COMMITTEE MEETING

The Secretariat:

(a) Checks for completeness of the form

Documents the review by completing the appropriate checklist. If incomplete, the secretariat obtains the information from the person who submitted the application package.

(b) Assigns protocol to reviewers

Assign protocols to reviewers and include a protocol assessment form with the protocol package and wait for comments

- Allow at most 2 weeks for the review process.
- Specify the due date for the return of comments
- Record the name of the assigned reviewer in the protocol register (annex)

If comments are late, these are to be followed up in preparation for the next committee meeting.

A summary and reviewer's comments sheet is to be prepared so that it is included in the committee agenda.

(c) Prepares meeting agenda

Schedule the review process as soon as possible after submission, either at the time of the next scheduled meeting or *within 4 weeks after submission*.

Prepare the meeting agenda, according to the format shown in Annex 1 (AUREC FORM 01-).

Place protocols on the agenda in the first-come first-serve basis.

Place also "request to appeal" items on the agenda, upon receipt of the correspondence, in the next convened AUREC meeting.

(d) Distribution of protocol packages to the AUREC members

Keep in mind Procedure for Maintaining Confidentiality of AUREC documents (AUREC SOP#) when preparing and distributing documents.

Distribute copies of the protocol submission packages to the assigned reviewers and AUREC members by either electronic mail (if electronic

submitted protocols), telefax, or by post *two weeks in advance of the scheduled meeting*.

Keep copies of “sent” e-mail, fax cover memos and/or letters accompanying posted materials in the correspondence section of the respective protocol file. Confirm (verbally, by e-mail, by fax or by mail) with the members that the protocol packages have been received.

(e) Preparation for the meeting

An agenda should be sent to members at least a week before the Meeting.

Make a room reservation for the scheduled meeting date and time.

Make sure that the room, equipment and facilities are available in good conditions.

(f) During the meeting

The AUREC may allow investigators, project managers, sponsors, etc., to attend a portion of the Committee meeting related to their studies when the need arises. At the discretion of the Chairperson, guests may be allowed to observe the committee meetings.

These guests may include a potential client, students, etc. Guests are required to sign a confidentiality agreement (AUREC FORM , see Annex).

The Secretariat records the meeting discussions and the decisions. The Chairperson may inform members and attendees of the rules of the meeting and any remaining unsolved issues. The meeting proceeds in the order organised in the agenda, however, the Chairperson may allow some switching depending on the situations. The approval process starts when primary reviewers` comments about the new study are presented in the meeting Discussion and comments among members then open right after the presentation. Investigators may be allowed to present their projects in brief and clarify any questions the committee members may have.

(g) Voting

In order to avoid conflict of interest, only those committee members who are independent of the investigator and the sponsor of the trial/study will vote on the trial/study-related matters. All voting will take place after the observers / presenters / committee members with a conflict of interest leave the meeting room.

(h) After the committee meeting

As soon as possible after each meeting, a copy of the minutes is sent to the chairperson or designee for quality control review and approval for circulation and approval in the next meeting.

The Chairman indicates approval by signing and dating the minutes.

A member of the AUREC secretariat staff maintains the official copies of the minutes in accordance with departmental archiving procedures.

(i) Preparing the minutes and the decision

- Assembling the meeting minutes and the decision form.
- Use the format as shown in Annex AUREC FORM to write minutes.

- Compose the summary of each meeting discussion and decision in a concise and easy-to-read style.
- Make sure to cover all contents in each particular category.
- Check spelling, grammar, and context of the written minutes.
- Contents of the AUREC meeting minutes
- The official minutes of the committee meetings consist of, but are not limited to, the following:
 - Name of person preparing the minutes
- Location where the meeting is held
- Meeting date
- Attending committee members and guests
- Agenda items
- Individual serving as Chairman of the meeting
- Determination of a duly constituted quorum by the Chairman to proceed with the meeting
- Required for each study or activity requesting approval:
 - Sponsor name;
 - Protocol number/date/version of protocol, when available;
 - Investigator name;
 - Advertisements;
 - Name of AUREC member presenting study materials;
 - Discussion as deemed appropriate by the Chairman;
 - Number of members voting ‘yes’, ‘no’,
 - Number of abstentions and the reason for the abstention;
- Required for each study or activity requesting Expedited approval:
 - Sponsor name;
 - Protocol number, if applicable;
 - Investigator name;
- Required for each Continuing Review Report:
 - Sponsor name;
 - Protocol number, if applicable;
 - Investigator name;
- Indication of the Committee’s determination to continue, terminate, or amend the study;
- Lists of recommendations or actions to take with the investigator, if applicable.
- Required for each Adverse Event notification and Final Report:
 - Sponsor name;
 - Protocol number, if applicable;
 - Investigator name;
 - Actions deemed appropriate by the Committee’s review.
- Required for Termination of Approval:
 - Sponsor name;
 - Protocol number, if applicable;
 - Investigator name; reason for termination
- Approval of the minutes and the decision
- Check the correctness and completeness of the minutes.

- Get the Chairperson to sign and date the relevant sections of the minutes of the AUREC meeting.

Filing the minutes

- Place the original version of the minutes in the AUREC files.
- Place all correspondence in the appropriate file.
- Place a copy of the approval letter in the “minutes” file to inform the AUREC members of the expedited approval.
- Document the appeal requests in the meeting minutes.
- Distributing the minutes and the decision
- Send a copy of the relevant sections of the minute and the decision form to the applicants for their records by mail.
- Send the approved minutes to the members.
- Send the decision of the Committee for an appeal request to the requester in writing.
- Record the receivers and the delivery date.

Effective Date

Chairperson
(Name)

.....
Signature

3. **CONFIDENTIALITY AND CONFLICT OF INTEREST SOP No 003**

(i) PURPOSE

The purpose of this procedure is to provide a form of Confidentiality / Conflict of Interest Agreement, who should read, keep in mind and sign it, when and where to sign and how the signed document should be kept.

(ii) SCOPE

This SOP covers the Agreement on both Confidentiality and Conflict of Interest concerning activities and information of AUREC.

(iii) RESPONSIBILITY

It is the responsibility of all newly appointed AUREC Members and AUREC Secretariat to read, understand, accept and sign the agreement stated on the Confidentiality / Conflict of Interest form before beginning their tasks on conducting activities with AUREC to protect the rights of the research participants.

(iv) DETAILED INSTRUCTION

Read the content carefully and thoroughly.

Newly appointed members obtain two copies of the Agreement Form.

Read through the content of the form very carefully.

The members fill in their names in the blank spaces.

Ask questions, if any.

Ask questions if any part or sentences are not clear.

Let the Secretariat explain or clarify the context.

Consent

Sign and date both copies.

The Secretariat signs and dates.

The members keep a copy as their records.

Honour the Agreement.

The Compliance Office keeps a copy of the signed Agreement as the Institute's records.

Keep the copies in a Confidentiality/Conflict of Interest Agreement file.

Store the file in a secure cabinet with limited key holders.

(v) GLOSSARY

Confidentiality

The non-occurrence of the unauthorised disclosure of information:

An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned of them. Confidentiality Agreements, sometimes called Secrecy or Nondisclosure agreements. The type of information that can be included under the umbrella of confidential information is virtually unlimited.

Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement.

An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information.

The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.

Conflict of Interest

A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties. There are three key elements in this definition: financial interest; official duties; professional interest.

A conflict of interest occurs when: An individual's private interest differs from his or her professional obligations to the institute. Professional actions or decisions occur that an independent observer might reasonably question.

A conflict depends upon situation and not on the character or actions of the individual. Potential conflicts of interest must be disclosed and managed as per policy.

(vi) Confidentiality / Conflict of Interest Agreement Form

In recognition of the fact...*member's name, and his/her affiliation*.....herein after referred to as the "Undersigned", and as a member of the AUREC has been asked and appointed to assess research studies involving human subjects in order to ensure that the studies are conducted in a humane, ethical manner, with highest standard of care according to the applied national, local regulations, institutional policies and guidelines.

You have been appointed as a member of the AUREC as an individual, not as the advocate or representative of your home province / territory / community nor as the delegate of any organisation or private interest. Your fundamental duty is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions you review.

AUREC must meet the highest ethical standards in order to merit the trust and confidence of the communities in protection of rights and well-being of human subjects. As a member of the AUREC you are expected to meet the same high standards of ethical behaviour as you carry out your mandate.

This Agreement, thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with duties as a member of the AUREC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for

review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the AUREC.

The Undersigned agrees not to disclose or utilise, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It is recognised that the potential for conflict of interest will always exist but has faith in the AUREC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.

It is a policy of the AUREC that no member may participate in the review or approval of an activity in which that member has a conflicting of interest except to provide information as requested by the Ethics Committee.

You will immediately disclose to the Chairperson of the Ethics Committee any actual or potential conflict of interest that you may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an EC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the EC review or approval except to provide information if the Committee requests such.

Conflict of interest cases include, for examples:

A member is involved in a potentially competing research programme.

Accesses to funding or intellectual information may provide an unfair competitive advantage.

A member's personal biases may interfere with his or her impartial judgment.

Members who may have a conflict of interest may not be counted toward a quorum and may not vote.

Effective Date

Chairperson
(Name)

.....
Signature

4. MANAGEMENT OF RESEARCH PROTOCOL/PROPOSAL SUBMISSIONS TO THE AUREC SOP No 004

(i) PURPOSE

This standard operating procedure is designed to describe how the AUREC Secretariat manages protocol submissions to the AUREC.

(ii) SCOPE

Protocol submissions include:
Initial Review Application
Resubmission of Protocols Approved with Stipulation
Protocol Amendment
Annual Continuing Review of Approved Protocols
Protocol Termination

(iii) RESPONSIBILITY

It is the responsibility of the AUREC secretariat to manage protocol submission, distribute for review and get the submission packages approved by the AUREC, as well as to deliver the review results to the protocol applicants.

(iv) DETAILED INSTRUCTIONS

Receive Submission Packages
Receive two (2) paper based and one electronic copy (PDF) of the proposal or on CD.
Check that all copies are identical.
Check for completion using checklist
Stamp and allocate a protocol number

Distribute the packages to the relevant offices
Liaise with chairperson to allocate reviewers
Distribute the packages to reviewers

Store the received packages
File master copy according to AUREC filing system refer to relevant SOP.

Effective Date

Chairperson
(Name)

.....
Signature

5. PROCEDURES FOR INITIAL REVIEW OF RESEARCH PROTOCOLS SOP No.00 5

(i) PURPOSE

This standard operating procedure describes how the AUREC manages initial review of research protocols submitted.

(ii) SCOPE

This SOP applies to the management of research protocols as they go through the initial review process.

(iii) RESPONSIBILITY

It is the responsibility of the AUREC secretariat to receive, manage, distribute for review and get the submission packages reviewed by the AUREC, as well as to deliver the review results to the protocol applicants.

(iv) DETAILED INSTRUCTION

Obtain the distributed protocol packages

Check the distributed packages.

Sign and date an acknowledgement form upon receiving the packages.

Return the receipt form back to the delivery person / AUREC secretariat.

Verify the contents of the packages

Look for an Assessment Form.

Look for the due date for the review.

Check for availability of the meeting date.

Notify the AUREC secretariat for any missing documents or unavailability for the meeting or review due date.

(V) REVIEW THE PROTOCOL

a) Initial Review Application Form

Check the form for completeness of the information and signatures,
Attach an Initial Review Application Form and the AUREC study review form.

Contact reviewer to ascertain availability to review.

State expected timeframe for the review.

Track the review

Compile comments for inclusion in agenda.

NB: Reviewer's name will not be disclosed to researcher.

b) AUREC Meeting

The internal (AUREC) reviewer presents a brief oral or written summary of the study design and his/her comments, plus other reviewers' comments.

The Chairperson or designee entertains discussion on each document under consideration (e.g., protocol, informed consent, investigator's and site qualifications, advertisements).

Recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the Committee are noted in the meeting minutes as 'with modifications made by AUREC' and will be communicated to the investigator.

The Chairperson or designee calls for a separate vote on each element in review. The Committee votes to either:

Approve the study to start as presented with no modifications

Approve the study to start with Committee approved modifications to the consent. = *Approved with recommendation*

Require modifications to items noted at the convened meeting and follow-up with the Chairperson, after receipt of the requested modifications. = *Approved with recommendation*

Require modifications to the items and full committee review of the materials. = *Approved with stipulation or Resubmission*

Request further information regarding the item and full committee re-review of the material. = *Approved with stipulation or Resubmission*

Not approve the study, stating the reason.= *Disapproved*

Approved

If the study is approved, the AUREC reviews the study activities annually. The AUREC Secretariat sends an approval letter along with the approved documents to the investigator.

The letter contains, at a minimum, a listing of each document approved, the date set by the technical committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.

An approval and expiration date is placed on every page of each consent form approved by the AUREC

Not approved

If the Committee votes not to approve the study, the Chairperson or AUREC Secretariat immediately notifies the investigator in writing of the decision and the reason for not approving the study.

If the investigator wishes to appeal this decision, he/she may do so by contacting AUREC. This process is stated in the action letter provided to the investigator.

Modification

If the Committee votes to require modifications to any of the documents, the AUREC secretariat either generates the revisions to the documents, or sends a written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the AUREC.

vi) Final Communication of the Decision of the AUREC and Documentation

a) The action letter

Draft an action letter to inform the investigator or project manager about the AUREC decision.

State clearly the actions that need to be taken.

For the disapproved decision, a letter to notify the investigator and project managers should be drafted to state the following:
“If you wish to appeal this decision, please contact AUREC and submit your appeal in writing, addressed to the AUREC Chairperson with justification as to why the approval should be granted”

b) Store Original Documents

Place the original completed documents along with the other documents in the protocol submission package in the file for the protocol.

Place the original version of the signed form in the AUREC files for the specific protocol.

Keep the file in the cabinet labelled.

c) Distribute Documents to the applicant

Send the action to the applicant within 7 working days after the Committee meeting.

Keep a copy of the letter in the AUREC correspondence files and the study protocol file.

(vii) GLOSSARY

Initial Review

The first time review of that protocol made by two or three individual reviewers (AUREC members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.

Effective Date

Chairperson
(Name)

.....
Signature

6. EXPEDITED REVIEW - SOP No. 00 6

(i) PURPOSE

The purpose of this SOP is to provide instructions on management and approval of **expedited** review process.

(ii) SCOPE

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes to currently approved studies.

(iii) RESPONSIBILITY

It is the responsibility of the Chairperson, AUREC Secretariat, and AUREC members to define or determine which study protocols should be reviewed and approved through expedited channel.

(iv) DETAILED INSTRUCTION

Receive the submitted documents.

Receive the application documents.

Use a checklist form to check the items received.

Stamp the received date on the letter and the documents.

Sign the receiver`s name on the received documents.

(V) DETERMINE PROTOCOL FOR EXPEDITED REVIEW

AUREC Secretariat determines the protocol using the following criteria:

Modification /amendment of protocol.

administrative revisions, such as correction of typographic errors.

addition or deletion of *non-procedural items*, such as the addition of study personnel names, laboratories, etc.

non-significant risk research activity.

the research activity includes only *minor changes* from previously approved protocol.

Proposals involve interviewing of a *non-confidential nature* (not of a private eg. related to sexual preference *etc.*), *not likely to harm* the status or interests of the individual and *not likely to offend* the sensibilities of the people involved.

Those that involve *collection of small amounts of blood samples e.g.* by finger, heel or ear stick.

Those that involve collection of biological specimens for research purposes by *non-invasive means* (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

Collection of data for research purposes through *non-invasive procedures* (not involving general anaesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However procedures involving the *use of x-rays or microwaves are NOT recommended for expedited review.*

Research involving data, documents or specimens that have already been collected or will be *collected for ongoing medical treatment* or diagnosis.

Continuing review of research previously approved with no modifications to the original protocol and studies have taken place and *no additional risks* have been *identified*.

If the protocol satisfies any of the criteria for expedited review, the secretariat will send the protocol to Chairperson.

(vi) Process of Expedited Review

Chairperson nominates 1 AUREC member/or reviewer to review the revised protocol.

The selected member is normally one who reviewed the previous version of that protocol, if it is not submitted for the first time.

The secretariat sends the revised protocol to the selected member.

Carry out the expedited review.

The review may be made through either by circulation of comments through email, discussion or meeting.

If the consensus cannot be reached, the chairperson will refer the proposal back to the AUREC for a full review

The expedited review should normally not take longer than 4 days.

Present to AUREC the proposals approved by expedited review at its regular meeting for ratification.

If AUREC fails to ratify any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review.

(vii) Communicate with the investigator

Full Committee presentation of items approved through expedited review by the Secretariat is accomplished by providing documentation of the items in the meeting agenda / notes.

The secretariat communicates the AUREC members' decision to the Investigator.

GLOSSARY

Administrative documents

Documents include official minutes of Committee meetings as described in Standard Operating Procedures, both historical and Master Files as described in SOP# AUREC...

Expedited approval

An AUREC approval granted only by the Chairman of the Committee or a designated board member (not the full Board) for minor changes to current AUREC approved research activities and for research which involves no more than minimal risk.

Expedited review

A review process by only one or two designated AUREC members who then report the decision to the full Committee meeting for ratification. An expedited review is a speedy one for minor changes to the approved protocol and for research proposal with minimal risk in nature.

Effective Date

Chairperson
(Name)

.....
Signature

7. EMERGENCY MEETING SOP No. 7

(i) PURPOSE

The purpose of this SOP is:

To identify the administrative process for preparing for an emergency meeting (EC);

To provide instructions on the review and approval of study activities using the Emergency Meeting Procedure

(ii) SCOPE

This SOP applies to emergency AUREC meetings.

Emergency meetings may be scheduled to review/approve new studies, additional investigators, continuing review, protocol amendments and other study activities that require full Committee review.

(iii) RESPONSIBILITY

It is the responsibility of the AUREC Secretariat and the Chairperson to decide whether an emergency meeting should be called or not.

(iv) DETAILED INSTRUCTION

Before the Board meeting

Decide to call an EC based on the following criteria:

Urgent issues, if delay will affect or have impact to the public benefit or national economics.

Occurrence of unexpected serious adverse events.

The matter of life and death

Other appropriate reasons.

Invite all members to participate in the meeting. The quorum is three (3) members. For any speciality studies, a respective specialist should be invited to be in attendance of the meeting.

Prepare packets for distribution to Committee members; include a separate sheet with the following information; meeting date, time, and venue.

Refer to the relevant SOPs (i.e. Approval processes: Initial, Expedited, Protocol Amendments, etc.)

During the meeting

Follow the related SOPs. e.g.

SOP# AUREC – Constituting an EC

SOP# AUREC – Management of Protocol Submission

SOP# AUREC – Assessment of Application Protocols

SOP# AUREC – Expedited Review

SOP# AUREC – Initial Review of Application Protocols

SOP# AUREC – Review of Protocol Amendments

SOP# AUREC – Annual Continuing Review

SOP# AUREC – Preparation of Meeting, Agenda, Minutes and Action letters

After the meeting

Follow the related SOPs above.

GLOSSARY

Emergency meeting

A Committee meeting that is scheduled outside of a normally scheduled Committee meeting to review study activities that require Full Committee review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion and voting portions of the meeting.

Effective Date

Chairperson
(Name)

.....
Signature

8. STORAGE OF ACTIVE STUDY FILE SOP No. 008

(i) PURPOSE

To provide instruction for maintaining study files and documents of active protocols or studies previously approved by the AUREC.

(ii) SCOPE

This policy applies to new and existing documents and files of any active protocols.

(iii) RESPONSIBILITY

It is the responsibility of graduate interns to maintain documents and files of active studies in order for easy-to-retrieve and confidential matters

(v) FLOW CHART

Combine the Contents of the study active files	AUREC Secretariat
↓	
Maintain the study active files	AUREC Secretariat

(vi). DETAILED INSTRUCTION

- a) Combine the contents of the study active files
The study files contain, at a minimum, the following information:
Original application and any updates received during the study.
Investigator's brochure or similar documents
Approval letters and other correspondence sent to the investigator.
Approved documents (protocol, protocol amendments, informed consent, advertising materials)
Adverse experience reports or safety report received
Continuing review reports
Progress reports
Protocol events/deviations
- b) **Maintain the study active files**
Assign the approved study files with a unique AUREC iref. number (on a sheet of paper) established by an AUREC secretariat member.
Combine related documents of the approved study files and put them in a file.
Label the file with an AUREC ref. number.
Keep all active and potential study packages in the secured file cabinet serially.
Maintain the study files in an easily accessible but secure manner until the final report is reviewed and accepted by the Committee.

Note: For studies with multiple investigators, a member of the AUREC Secretariat maintains the files to allow cross-referencing without unnecessary duplications.

6. GLOSSARY

Active Study File

Any supportive and approved documents, records containing communications and reports that correspond to each currently approved study.

Effective Date

Chairperson
(Name)

.....
Signature

