UGANDA CANCER INSTITUTE RESEARCH AND ETHICS COMMITTE (UCIREC)

STANDARD OPERATING PROCEDURE (S)

VERSION 1.0 SEPTEMBER 2015

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"Research is Our Resource"

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Acronyms

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ADRs- Adverse Drug Reactions

AE – Adverse Event

CIOMS- Council for International Organization of Medical Sciences

CTM – Clinical Trial materials

UCI – Uganda Cancer Institute

DSMB- Data safety monitoring Board

HSP- Human Subjects protection

ICF – Informed consent form

ICH – International Conference on Harmonization

PAM- Post Approval Monitor

REC – Research and ethics committee

REO- Research and Ethics Office

SAE –Serious Adverse Event

SOP- Standard Operating Procedures

UNCST – Uganda National Council of Science and Technology

WHO- World Health organization

Acknowledgements

The Directorate of research and training of the Uganda cancer institute (UCI) is grateful to the management of the Institute for the support provided in the establishment of the Uganda Cancer Institute Research and Ethics Committee (UCIREC). We also wish to acknowledge our collaborators at Fred Hutchinson Cancer Research Center for the guidance during the process of establishing the UCIREC.

We recognize and thank all REC members who participated in developing these guidelines. Special thanks go to Mr. Paul Kutyabami (consultant), Ms.Annet Nakaganda Muyita (operations manager UCIREC), Innocent Mutyaba (UCIREC secretary) and Ms. Rebecca Kampi Musooko (Administrator UCIREC) for their extra effort devoted to this work.

Preface

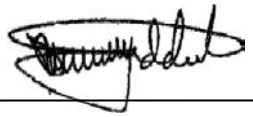
The Uganda Cancer Institute (UCI) has tremendously contributed to cancer research and treatment since 1967. Similar to other institutions in Uganda, UCI suffered remarkable setbacks during the political turmoil the country faced in the 1970s and early 80s, which led to withdrawal of several partners, resulting in severe reduction of its capacity for patient care and research.

However, the UCI has entered into a new era and is rising from the ashes: Currently, the institute is with improved government support and commitment, with the help of our collaborators, its human capacity is expanding, and access to better technologies. This is indeed a time and opportunity to make the care of cancer patients better through research and personal responsibility.

The establishment of the Uganda Cancer Institute Research and Ethics Committee (UCIREC) is an important milestone in ensuring that research done at and/or in collaboration with the UCI is at the highest ethical standards. These guidelines serve as the first reference in the execution of responsibilities by UCIREC members or individuals involved in research work at the UCI.

Readers that identify any form of error in this book are invited to send their corrections and suggestions to UCIREC .Email ***ucirec@uci.or.ug***

Dr. Innocent Mutyaba
Secretary UCIREC



Dr. Kyaddondo David
Chairperson UCIREC

1.0 GENERAL PROVISIONS

1.1 Introduction:

The National guidelines for research involving Humans as research participants issued by the Uganda National Council of Science and Technology (UNCST), recommend that all institutions in Uganda that have a mandate that include conduct of research involving humans may set up RECs but in accordance with the National regulations.

Uganda Cancer Institute (UCI) is a health care institution with a core function of conducting research. UCI is involved in both local and collaborative research and over the years the volume of research at the site are increasing, and it is anticipated that the trend will be consistent with the improvement in infrastructure, staffing and services. UCI set up a REC in relation to the national guidelines. The REC is composed of both scientists and non-scientists. It is independent in its reflection, advice, and decision.

1.2 Rationale

To improve the UCI's oversight of research studies involving its patients, staff and other site resources, the UCI board of governors and director found it necessary to set-up a Research Ethics Committee (REC) at UCI.

1.3 Roles of the REC members

The responsibilities for REC members include among others:

1. Enforcing adherence to the ethical standards for the conduct of human subjects' research so as to protect the rights, interests, values and welfare of the study participants.

2. Ascertaining that implied benefits of research to the participant, community, institution and the general population are realized.

3. To ensure scientific basis and methods of research are valid and of the highest standard.

4. Conduct continuous review of protocols, reports, Adverse Events to ascertain compliance with all applicable regulations.

5. Build capacity for ethical conduct of research especially in cancer and other non-communicable diseases.

1.4 General Guideline:

The operation of REC members is guided by standard procedures that they developed at its inception. The SOPs were developed to guide the following issues among others:

a) Constituting and functioning of UCIREC
b) Development and maintenance of SOPs
c) Submission of Applications, Protocols and Reports for review to Uganda Cancer Institute REC
d) Training REC members, Secretariat staff and Relevant Investigators
e) Calling and conducting UCIREC Meetings
f) Determining Review category of protocols and reports for ethical review
g) Expedited Review of research protocols
h) Review of Research Using Patients' Stored Data and Specimens
i) Taking minutes and communicating decisions to Investigators
j) Transfer of Human Materials
k) Reporting of adverse events and Non compliances

l) Confidentiality and Conflict of Interest

m) Monitoring and Tracking of studies approved by UCIREC

1.5 Scope of Application:

The Standard operating procedures in this hand book are applicable to all UCIREC activities and will be utilized by members, UCIREC Secretariat, co-opted members and investigators.

2.0 Constituting and functioning of UCIREC - SOP

Ref No: UCIREC 001/2015

2.1 Purpose

These standard operating procedures describe the procedure for constituting the REC, its roles and responsibilities, functioning, how membership can be terminated and replaced. This SOP is further supported by the other SOPs of the UCIREC.

2.2 Scope:

Applies to all activities executed at the UCIREC

2.3 Responsibility:

The appointing authority (UCI director), the REC members and secretariat are to implement this guideline. The target group must read, understand and respect the guidelines set by the REC in this SOP.

2.4 Procedure

a. Composition of the REC

(i) The UCIREC will be comprised of 13 regular voting members; and two alternative community representatives.

(ii) The members shall include at least one member whose primary concerns are in medical science, at least one member whose primary concerns are in non-medical/non-scientific areas, and at least a member from outside the UCI

iii) The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the research institutions under their auspices. Professional qualifications/specialties

may include physician, pharmacist, nurse, social scientist, lawyer, statistician, paramedic and/or layperson.

iv) The REC cannot consist entirely of men or entirely of women.

b. Membership requirements

(i) The Head of the Institution is responsible for appointing of committee members

(ii) Members are selected in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the REC's work.

(iii) Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration

(iv) The REC will decide the extent to which members that might have a conflict of interest may participate in bringing out advice /decisions (refer to SOP on Confidentiality / Conflict of Interest Agreement).

(v) Members will be required to sign a confidentiality agreement at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the REC in the course of its work.

(vi) Members are appointed for a period of 3 years. Their appointments may be renewed by the Director of UCI upon satisfactory performance.

c. Conditions of Appointment and term duration

Members are appointed to the REC for a term of three years normally beginning at the time of appointment. The members are also expected to fulfill the following conditions:

(i) Willingness to publicize his/her full name, profession, and affiliation;

(ii) All financial accountability, reimbursement for work and expenses, if any, within or related to the REC should be recorded and made available to the public upon request;

(iii) All REC Members and Independent Consultants must sign Confidentiality/Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

(iv) At the end of three-year term, the REC chairperson may retire their position or may be invited to renew their appointment.

(v) The REC Chairperson, Operations manager and the REC Administrator will conduct annual reviews of each member according to qualifications, needs of the REC, record of participation, and contribution to the REC. Those who regularly fail to meet the expectations may be asked to step down prior to the end of their term, in which case an alternate or new member will be appointed, as necessary.

(vi) The REC Chairperson, Operations manager and the REC Administrator will provide individual performance reviews to the UCI Director at the end of each -year. Reappointments will be based on the needs of the REC and each member's qualifications, record of participation, and contribution to the board.

(vii) To foster REC independence, the Director UCI will only appoint the, chairperson, vice chairperson and REC secretary at the beginning before the committee membership has been constituted. In the event that one of the above offices falls vacant and in subsequent

terms the committee members will vote the leadership. The voting should be conducted at the next meeting of the full committee of the REC after the position falls vacant

d. Compensation

(i) REC membership is voluntary. REC members receive a small amount of facilitation fee in recognition for their time, transport and participation. Facilitation support and stipends are determined based on membership status or attendance at REC meetings according to the REC member compensation schedule. The facilitation shall be agreed upon by the committee as the budget allows. .

(ii) REC roster must be developed. This will include a summary of information about its voting members, and REC secretariat staff e.g. Name, initials, specialty, gender etc

e. Resignation, Disqualification, Replacement of Members

(i) Members may resign their positions by submitting a letter of resignation to the Chairperson.

(ii) Members may also be disqualified from continuance if found that their performance is unsatisfactory as determined by the REC secretariat and the REC chairperson.

(iii) Members that have resigned or have been disqualified may be replaced by the appointing authorities.

(iv) If a member resigns from the REC, a thank you letter and a certificate of appreciation signed by the UCI Director are provided to the member.

f. Co-opted experts

The REC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.

(i) Co-opted experts are appointed by the Chairperson of the REC.
(ii) Their professional qualifications may be in the areas of expertise as may be required.
(iii) Co -opted expert may decline or resign their positions by submitting a letter of notification to the Chairperson.

2.4.2 Role and functions

a. Officers

The following officers through their respective responsibilities contribute to the good functioning of the REC:

(i) **Chairperson**

Responsible to chair all REC meetings and liaise directly with the UNCST, report the meeting outcomes to UNCST, invite co-opted experts

(ii) Vice-Chairperson

Responsible to chair the meetings in the absence of the Chairperson and act as vice-chair during meetings where the Chairperson is present,

(iii) Secretary

The REC secretary will be responsible for the minutes of the REC meeting and work in liaison with REC secretariat**.**

(iv) **Administrator**

Is responsible for the administrative aspect of the REC (see b - below).

b. Secretariat

i. The Secretariat is composed of the REC administrator and the assistant.

ii. The assistant REC administrator is a UCI staff member appointed by the Director of UCI to support in the REC office.

iii. The REC Administrator is responsible for the daily functioning of the REC. The Secretariat shall have the following function organizing an effective and efficient tracking procedure for each proposal received.

iv. Preparation, maintenance and distribution of study files.

v. Organizing REC meetings regularly.

vi. Preparation and maintenance of meeting agenda and minutes.

vii. Maintaining the REC's documentation and Archive.

viii. Communicating with the REC members and applicants

ix. Arrangement of training for personnel and REC members

x. Organizing the preparation, review, revision and distribution of SOPs and guidelines

xi. Providing the necessary administrative support for REC related activities to the Chairperson of the Committee (e.g. communicating a decision to the applicant).

xii. Providing updates on relevant and contemporary issues related to ethics in health

research, as well as relevant contemporary literature to the Committee members.

xiii. Conducting annual performance reviews of REC members and providing an annual report about performance reviews to the UCI Director and REC Secretariat.

c. Roles and responsibilities of REC members

i. Participate in the REC meetings
ii. Review, discuss and consider research proposals submitted for evaluation
iii. Monitor serious adverse event reports and recommend appropriate action(s)
iv. Review the progress reports and monitor ongoing studies as appropriate including site visiting
v. Evaluate final reports and outcomes
vi. Maintain confidentiality of the documents and deliberations of REC meetings
vii. Declare any conflict of interest
viii. Participate in continuing education activities in biomedical ethics and research involving humans as participants
ix. Train other members of the institution in ethics of research involving humans as research participants
x. Advise the institution on policy matters concerning research involving humans as participants

2.4.3 Conduction of REC meetings reviewing protocols

a.Quorum Requirements

i. A minimum of 50% of the members must be present at a meeting in order to issue a valid advice and/or decision.

ii. Professional qualifications of the quorum requirements should consist of:

iii. At least one member who is medical scientist and at least one member who represents interests of the community.

b. Ethical basis

i. The REC recognizes that the protocols it approves must also be approved by the National Council for Science and Technology and/or local ethics committees prior to their implementation in specific localities.

ii. In evaluating protocols and ethical issues, the REC is aware of the diversity of laws, cultures and practices governing research and medical practices in various countries around the world.

iii. It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.

iv. The REC also seeks to be informed, as appropriate, by national/local ethics committees and researchers of the impact of the research it has approved.

v. The REC is guided in its reflection, advice, and decision by the ethical principles expressed in the National Guidelines for Research Involving Humans as Research Participants of Uganda.

vi. It makes further reference to the National and International Ethical Guidelines for Biomedical Research Involving Human as participants (CIOMS), the Belmont Report, the European Convention on Human Rights and Biomedicine and the Declaration of Helsinki

vii. The REC establishes its own standard operating procedures based on the Operational Guidelines for

Ethics Committees that Review Biomedical Research, the WHO & ICH Guidelines for Good Clinical Practice and the National Council for Science and Technology guidelines.

The REC seeks to fulfil the requirements for international assurances and is established and functions in accordance with the national law and regulations

2.5 Reference(s)

- Uganda National council guidelines for research involving Human subjects –July 2014
- ICH guidelines – Nov 2005

2.6 Attachment(s)

None

3.0 Development and maintenance of SOPs- SOP Ref No: UCIREC 002/2015

3.1 Purpose

To ensure consistent procedures for development and formatting of Standard Operating Procedures (SOPs) used by UCIREC

3.2 Scope

Applies to all SOPs for different activities at UCIREC as they are written or revised

3.3 Responsibility

The UCIREC Chairperson and the REC secretariat are responsible for ensuring that this SOP is followed for the development, approval and maintenance of all SOPs applicable to UCIREC

3.4 Procedure

3.4.1 Format

(i) Cover page

The UCIREC SOP handbook should carry the UCI logo, the title, version and effective date.

(ii) Approval Signature

Each version of the guideline book will carry an approval signature indicating its review and approval by the Chairperson and the secretary.

(iii) Numbering

Numbering of the SOPs should be sequential. Each SOP should have the reference number. Version and reference number control is the responsibility of the Chairperson and REC office administrator.

(iv) Purpose:

Each a SOP should entail the function for which it's formulated.

(v) Scope

Each SOP should specify the scope to which it applies. In general, SOPs should be prepared to be as broadly applicable as possible.

(vi) Staff responsibilities

All SOPs should address which REC members that are responsible for the activities described in the SOP. Specific names should be avoided, but job titles or descriptions should be used.

(vii) Procedures

Each SOP should clearly spell out the procedures to be followed to ensure compliance.

(viii) Attachments

Where applicable, SOPs should include sample forms. If not included, SOP should specify none. Forms which are provided as samples or templates should also be

identified as such. Modifications to sample or template forms need to be justified in a memo to file.

3.4.2 Preparation and Content

(i) SOPs should be written broadly and as applicable as possible. Where appropriate, citations for relevant guidelines and regulations should be included.

(ii) SOPs may be written by any REC member at the direction of the Chairperson. REC members involved in the writing and revision of SOPs should seek input and comment from the colleagues likely to be affected by its content.

(iii) SOPs shall be reviewed and modified by a quorum of REC members as part of training before they are finalized by REC office

(iv) SOPs are considered finalized following the review and signature by UCIREC Chairperson and secretary. Copies of finalized SOPs should be distributed to affected staff.

3.4.3 Revision, renewal and Rescission

SOPs should be revised as necessary. The UCIREC Chairperson should designate an individual to ensure that SOPs are complete and accurate on a periodic basis. SOPs should be reviewed for content and applicability periodically but not exceeding 3-years or whether national or international regulations are issued or revised. As the SOPs are compiled to one booklet in case of any urgent revisions made prior to the 3 years an addendum to the

guideline will be made indicating the specific areas of SOPs which no longer apply and will be rescinded. Rescission will be accomplished by memo or electronic communication from the Chairperson and addressed to affected UCIREC members.

3.5 Reference (s)

UNCST Guideline for Research involving human subjects

3.6 Attachment(s)

None.

4.0 Submission of Applications, Protocols and Reports for review to UCIREC SOP Ref No: UCIREC 003/2015

4.1. Purpose

To describe the procedure for submission of protocols and reports for review to the UCIREC

4.2. Scope

This SOP applies to all protocols and reports submitted for review to the UCIREC

4.3 Responsibility

The UCIREC secretariat, REC members and investigators that submit the protocols to UCIREC for review and approval.

4.4. Procedure

(i) The investigator(s) must fill the relevant form(s) available at the research administration office.

(ii) The investigator(s) must pay the ethical review fees. Investigators should contact the research administration office, or check online for the UCIREC fees structure and details of where to pay.

4.4.1 Initial (New Application)

The following must be submitted to the research administration office at the UCIREC secretariat.

i. Filled REC form 101 (2 copies) Research Protocol (14 copies)
ii. Summary of protocol (14 copies)

iii. Evidence of payment of application fees (Photocopy of receipt)
iv. Letter of approval from departments and /UCI scientific committee or the REC of the collaborating institution(s) in case of collaborative research
v. Minutes from departmental presentations for students (where applicable)
vi. Data collection instruments both in English and translations where it is required Curriculum Vitaes (CVs), copies of academic qualifications of the principal investigator(s) and co-investigators, and copies of practicing licenses.
vii. Adverts, press releases, brochures (where applicable)
viii. Soft copy of the above submitted protocol

4.4.2 Continuing Annual review

i. Filled REC Form 102
ii. Annual progress report (Format to be indicated)
iii. Monitoring and audit reports
iv. Copy of letter of previous approval, approvals from relevant regulatory bodies and collaborators.
v. Proof of payment.

4.4.3 Amendments request and Protocol Deviations / Protocol Violations

i. Filled REC Form 103

ii. Research proposal with track changes

iii. Soft copy of submitted proposal

iv. Proof of payment.

4.4.4 Adverse Event/Severe Adverse Event report

Filled REC Form 104

4.4.5 Termination/study close out

i. Filled REC Form 105

ii. Full close out report, manuscript, conference presentation or newspaper report.

iii. The REC Secretariat will cross-check for completeness of the submitted application using the guideline , acknowledge receipt and assign a protocol reference number

Note: The REC administrator will, on weekly basis, present to the Chairperson of the committee a summary of the submitted protocols so as to finally decide on the appropriate review category and guide the decision of scheduling REC meetings

4.5 Reference(s)

- UNCST guidelines July 2014
- ICH-GCP guidelines

4.6 Attachment(s)

None

5.0 Training REC members, Secretariat staff and Relevant Investigators

SOP Ref No: UCIREC 004/2015

5.1 Purpose

The purpose of this SOP is to inform the Uganda Cancer Institute Research and Ethics committee (UCIREC) personnel and members why training is necessary and how the members should seek to occasionally attend training or workshop programs to up-date themselves on the progress of technology, information and ethics.

5.2. Scope

The SOP applies to the UCIREC secretariat, REC members, and investigators from other institutions who submit research studies to the UCIREC for review and approval.

5.3 Responsibility

REC members, secretariat and relevant investigators

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5.4.1Training and Orientation of new REC member

i. New members will have an orientation by the REC administrator and the chairperson prior to their first meeting. An SOP handbook will be given to each new member.
ii. New REC members who have not completed any human subject protection training must attend an online Human Subject Training course and Good Clinical Practice course.

iii. The chairperson and REC administrator will identify the new member's area of expertise and update the REC committee Roster.

5.4.2 Continuing Training and Education

(i) REC members and chairperson are provided opportunities to attend local REC conferences, training and seminars

(ii) An exchange of ideas, information and experiences with overseas institutions and organizations related to research ethics is also good to be carried out.

5.4.3Training of researchers

Training in the protection of human research subjects is also required for personnel involved in one or more of the following activities:

(i) **Design -** developing the research concept, scientific method, or objectives for a study that involves intervention or interactions with a human subject or the use of identifiable data or tissue derived from a human subject.

(ii) **Conduct -** implementation and management of research involving human subjects. Staff conducting research includes principal investigators, research staff working on a research study, and others engaged in research activity supporting the research

Study (e.g., conducting interviews, surveys, data collection).

(iii) **Reporting**- analyzing, summarizing, or preparing manuscripts involving data derived from a research study involving human subjects.

5.4.4 Topics for training

REC members and REC secretariat staff should maintain competence by ensuring updates of their knowledge of:

(i) Good Clinical Practice (GCP)

(ii) International and local research guidelines including UNCST guidelines

(iii) Ethical Issues and research ethics issues

(iv) Responsible Conduct of Research

(v) Development in relevant science, technical, environmental, health and safety aspects.

(vi) Relevant requirements of health, safety and environmental laws and regulations and related documents

(vii) Research monitoring and audit procedures.

5.4.5 Keeping the training records

(i) Each REC member will provide a copy of the training certificate to the administrator for archiving in the REC file.

(ii) Also archive the community sensitization/training reports or any training record

(iii) Individuals who fail to meet their training requirements may no longer be involved in REC work or human research. The REC secretariat will notify the concerned member as appropriate. The member would need to respond to the notification, confirming they would not be involved in REC activities; they can be re-instated when they complete their training.

(iv) If the Principal investigator of a study fails to meet the training requirements; the REC may close the study. It can be re-opened when the lead investigator completes the training.

5.4.5 Annual REC Committee Meeting

(i) The REC committee will hold a meeting annually with the UCI Director and other staff that are concerned with REC operations. It is an opportunity for UCI Director to acknowledge the REC members and offer an opportunity to share their views. It's also a forum to provide additional training to REC members, hold discussions about relevant issues, discuss any resource needs and share experiences.

(ii) The REC operations manager will oversee the coordination of the annual REC Committee Meeting. The REC Administrator will act as the recording secretary. The

draft minutes will be distributed to all the REC members and the UCI Director.

(iii) In the event that this meeting cannot be scheduled separately, the UCI Director will be invited to attend a regularly scheduled committee meeting.

5.4 Reference(s)

- UNCST Guidelines on Research Involving Humans as Research Participants- July 2014
- ICH-GCP guidelines – Nov 2005

5.5 Attachment(s)

Sample of Training Record Form for REC Secretariat staffs and REC members

First name:	Last name:
Staff / Membership since:	Status:
Education Background:	

Training Experience:

#	**Courses / Workshops / Conferences / Meetings**	**Organized by:**	**Where?**	**Duration**	**Source of Funding**

	Attended				
1					
2					
3					
4					

6.0 Calling and conducting UCIREC Meetings- SOP

Ref No: UCIREC 005/2015

6.1 Purpose

To document the procedure for calling and conducting UCIREC meetings

6.2 Scope

This SOP applies to all UCIREC secretariat, UCIREC members and investigators that submit their applications to UCIREC.

6.3 Responsibility

Chairperson UCIREC, REC secretariat, and UCIREC members.

6.4 Procedure

6.4.1 REC meetings

a. Generally, UCIREC meetings will be held monthly except if such a day falls on Public holidays or other major activities at UCI. Schedule of meetings may however be dictated by the number of submitted applications.
b. UCIREC meetings will be conducted in the UCI board room. In case of change of venue, alternative space will be communicated to both the investigators and UCIREC members well before the scheduled time of the meeting.
c. UCIREC meetings will be chaired by the chairperson or the vice and in their absence, one of the UCIREC members will be designated in writing

6.4.2 Meeting invitations

a. The administrator will ask the REC members to determine their availability and confirm their attendance 2 weeks prior to the scheduled meeting. The REC Administrator or a designated person will invite members of UCIREC in writing for the meeting. The invitation will include the agenda of the meeting. The agenda will include of the following:
   i. New protocols
   ii. Applications for renewal of approval
   iii. Research progress reports, Adverse events (AEs) and serious adverse events (SAEs), amendments and protocol deviations.
   iv. Protocol monitoring reports
   v. Other issues
b. Together with invitation letter, UCIREC members will receive full applications package to be reviewed and any other document that will enable them to effectively participate in the meeting at least seven days before the meeting.
c. In case an investigator is to be invited to the review meetings this should be done by email or in writing and when necessary reminders can be sent to the investigator through appropriate media including short messages (SMS). This will also involve the use of notice board.

6.4.3 Quorum

The Chairperson will call the meeting to order when at least 50% of the UCIREC members including the Chairperson (or any designated Chairperson) are present. All members present including the investigators will record their names indicating the capacities by which they are attending the meeting.

6.4.4Conducting the meeting

Initial (new) applications for review will be presented first. Decisions will be made by voting. In case of a stalemate, the chairperson will give the casting vote.

The REC chair leads the discussion of each activity at full REC committee meeting. The REC deliberates and takes action on each item.

6.4.5Review System

a. The REC uses a primary and secondary reviewer system for activities requiring full review. Each REC member has access to all submitted study documents for studies in which he/she has no identified conflict of interest. All REC members are expected to review at a minimum; the Application form, the protocol, consents and recruitment materials prior to the meeting. It's the primary and secondary reviewers' responsibility to review all the documents of their assigned activity and to report their findings at the convened REC meeting. The following decisions may be made after review of each protocol;
   (i) Approve with no suggested changes
   (ii) Approved but pending minor changes; in such a case a UCIREC member will be nominated to review the revised protocol;
   (iii) Major changes required i.e. change in the title, methodology or objective; in this case, the proposal may require a resubmission to the committee. Priority may be given to these at the next meeting.
   (iv) The proposal may be rejected.
b. After all the initial (new) applications have been reviewed, applications for renewal and resubmission will be discussed by the committee.

c. At the discretion of the Chairperson, the investigator may be called upon.
d. The status reports, AEs and SAEs reports will also be reviewed committee before adjourning the meeting.

6.4.6Appeal /Arbitration

(i) A researcher who is dissatisfied with the REC's decision may appeal to UNCST within 30 calendar days after receiving REC decisions.

(ii) When UCIREC disagrees with another REC over the interpretation of guidelines, administration or ethical issues in respect to a given protocol or REC operation UNCST will be approached for arbitration.

6.5 Reference(s)

- SOP Ref No :UCIREC 001/2015 Constituting and functioning of UCIREC

6.7 Attachment(s).

None

7.0 Determining Review category of protocols and reports for ethical review

SOP Ref No: UCIREC 006/2015

7.1 Purpose

To describe the procedure for determining the review category of protocols and reports submitted to UCIREC for ethical review

7.2 Scope

Applies to all protocols and reports submitted to UCIREC.

7.3 Responsibility

UCIREC secretariat and REC chairperson

7.4 Procedure

After receiving and checking for completeness of a new application for ethical review, the REC administrative staff will evaluate the application to determine which category of review process the application will take, using the information indicated on the application form and advise the chairperson accordingly. The chairperson will also review the protocol according to the criteria below and decide whether it's fit for expedited review.

7.4.1 Full committee review

In determining applications that will be reviewed by a full committee, attention will be given to the following:

(i) Significant risk studies (more than minimal risk studies)

(ii) The research intends to use vulnerable participants or the population to be involved in research warrants additional protection.

(iii) Use of placebo
(iv) Deviation from standard of care
(v) Use of existing data, documents, records, pathological specimens or diagnostic specimens with personal identifiers.

7.4.2 Expedited Review

The following kinds of research may be reviewed through expedited review.

a. Research that involves no more than minimal risk Examples of research that may fall under this category may include but not be limited to:
   (i) Research where no investigational drug is used.
   (ii) Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice excluding procedures involving radiation.
   (iii) Research involving materials (data or specimens) that have been collected solely for non-research purposes.
   (iv) Research involving materials (data or specimens) that are readily available to the public.
b. If there are minor changes in the previously approved research during the period for which approval was authorized. Minor changes to previously approved research are those that meet all of the following criteria:
   (i) Involve the addition of no more than minimal risk to participants
   (ii) All added procedures are eligible for initial review using the expedited procedure if considered independently of the research.

(iii) Addition of research activities that would be considered exempt or expedited if considered independently of the main research protocol.

(iv) Minor increases or decreases in the number of participants

(v) Amendments in remuneration to participants.

(vi) Amendments to improve the clarity of statements in the informed consent form research privacy form, or protocol to correct typographical errors, provided that such a change does not alter the content or intent of the statement.

(vii) Changes in the Principal Investigator or Co-investigators.

c. Research previously approved by a full committee will ideally be reviewed under full committee. However, if it falls, under the categories below, such research may, be reviewed under the expedited review process

(i) Research is permanently closed to the enrollment of new subjects.

(ii) All subjects have completed all research-related interventions.

(iii) Research remains active only for long-term follow-up of subjects

(iv) Where no participants have been enrolled and no additional risks have been identified

(v) Where the remaining research activities are limited to data analysis

7.5 Reference(s)

- SOP Ref No: UCIREC 001/2015 – Constituting and functioning of UCIREC.

- ❖ SOP Ref No: UCIREC 004/2015 Submission of Applications, protocols and Reports for review to UCIREC
- ❖ SOP Ref No: UCIREC 007/2015 Expedited Review of research protocols

7.6 **Attachment(s)**

None

8.0 Expedited Review of research protocols - SOP Ref No: UCIREC 007/2015

8.1 Purpose

To describe the criteria for expedited review of protocols for applications that is categorized to be appropriate for such review.

8.2 Scope

Applies to all protocols and reports intended for expedited review.

8.3 Responsibility

UCIREC members, secretariat and the investigators

8.4 Procedure

a. The UCIREC administrative secretariat initially reviews the application to determine which review category the application falls under (expedited review or full board). The UCIREC administrative secretariat will then forward the protocol and the documentation to the UCIREC Chairperson as in SOP for determining review category.
   i. The UCIREC Chairperson will confirm the expedited review determination and may review the application or may designate a member(s) to review the application
   ii. If the expedited review is to be carried out by UCIREC members designated by the Chairperson, the Chairperson will communicate in writing to the member(s) requesting him or her to review the application through an expedited review

process. The communication will include all information that is deemed vital in helping the member to review the application.

iii. Reviewer may exercise all the authority of UCIREC except disapprove the research; if the reviewer decides that the request does not meet expedited review requirements, or if he or she feels the request needs to go before the full committee, the changes must be reviewed by the full committee meeting.

iv. Using the background information in this SOP and other supporting forms, the reviewer will make recommendations regarding the science and ethics of the protocol and any other issues that may arise.

v. Designate a member(s) to review the application.

b. If the reviewer(s) approves the expedited research;

i. His/her recommendation will be communicated in writing to the secretariat that will pass it on to the chairperson.

ii. The chairperson will approve and the secretariat will make copies of the correspondence for the UCIREC files.

iii. The investigator will receive a communication in writing within 2 weeks.

c. If the reviewer(s) decides that the research may not be expedited:

i. They will notify the Chairperson through the secretariat to place the research on the next UCIREC meeting agenda.

ii. The reviewer(s) will then present the decisions and reasons to the convened UCIREC meeting for discussion, approval, disapproval, or for revisions.

d. The full committee will be informed of all expedited review procedures that were done at the next regularly scheduled

meeting and these will be documented in the minutes of UCIREC meetings.

8.4 Reference (s)

- ❖ SOP Ref No.-UCIREC 006/2015 Determining Review category of protocols and reports for ethical review

8.5 Attachment (s)

None

9.0 Review of Research Using Patients' Stored Data and Specimens

SOP Ref No: UCIREC 008/2015

9.1 Purpose

To describe the procedure for reviewing research that is going to utilize patients' stored data and/or biological specimens.

9.2 Scope

Applies to research that involves use of patients' stored data and specimens. Such as medical records, school records, employment records or biological specimens that are in existence at the time the research is proposed and initiated.

9.3 Responsibility

UCIREC members, UCIREC secretariat, Investigators, and custodians of the data and/or the specimens

9.4 Procedure

The UCIREC may review such research following procedures provided in the SOP for ethical review (refer to SOP for determining review category).It should be noted though that retrospective studies using existing materials occasionally entail significant greater than minimal risks and require review by the convened UCIREC meeting (e.g where the research reveals previously undisclosed illicit behavior such as prostitution, drug abuse or where the expedited review had concerns about infringement of subjects' privacy and/ or the adequacy of confidentiality protections proposed by the investigators).

9.4.1 Research Utilizing Existing Data Sets

When the data sets are publicly available, their use is exempt. But if the existing data contains identifiable private information about a living individual, the research will require UCIREC review. In cases of identifiable private information, UCIREC must determine whether the information can be used without additional informed consent from the participants.

a. In making this determination, the UCIREC shall first examine the conditions of informed consent under which the data were originally obtained. It may be that the proposed research is permissible under the original terms of informed consent.
b. In other cases, the UCIREC may determine that the research can proceed only if the investigator obtains and uses "anonymized" data. Under this scenario, codes and other identifiers are permanently removed from the data set before the data are sent to the investigator, and the removal is accomplished in such a manner that neither the investigator nor the source maintaining the data set can re-establish participants' identities.

9.4.2 Research Using Data or Tissue Banks (also called Repositories)

Human data and tissue repositories collect, store, and distribute identifiable information and human materials respectively about individual persons either for research purposes or for clinical care.

The policy is supposed to cover the following components of Tissue bank activities:-

a. Identity of the collectors of data or tissue samples
b. The bank/repository storage and data management Centre
c. The sharing of data i.e recipients of the data
d. Considerations of Intellectual Property Rights

UCIREC, with the guidance of UNCST, shall oversee all the activities involved in the above elements such as, setting the conditions for collection, secure storage, maintenance, and appropriate sharing of the data and/or tissues, or intellectual property with external investigators.

UCIREC after consulting with the site policy on data/specimen repositories shall evaluate the proposal using the following criteria:

i. Determine whether the informed consent under which the specimens or data was collected is adequate to cover their use in the proposed study
ii. Determine whether the donors of the specimen are traceable/identifiable
iii. Determine whether the repository administrators can effectively anonymize the specimens/data before sending them to the investigators, and indeed, if the data the investigator is to receive is effectively anonymized.
iv. Determine whether use of the specimens will offer extra risk to specimen donors.
v. Determine if the proposed study involves genetic studies
vi. Determine whether it is possible to carry out the research without waiving the informed consent.

9.5 Reference(s)

- ❖ SOP Ref No: UCIREC 006/2015 Determining review category of protocols and reports for ethical review.
- ❖ SOP Ref No: UCIREC 010/2015 Samples and specimen transfer

9.6 Attachment(s)

None

10.0 Taking minutes and communicating decisions to Investigators

SOP Ref No: UCIREC 009/2014

10.1 Purpose

To describe the procedure of recording UCIREC meeting minutes and communicating decisions made to investigators

10.2 Scope

Recording of minutes and communicating REC decisions to investigator

10.3 Responsibility

REC Secretariat and the REC secretary

10.4 Procedure

a. Minutes will be taken at all UCIREC meetings including emergency meetings. Both soft and hard copies of the minutes and other UCIREC documents will be securely kept for a minimum of 10 years and then achieved. The minutes of UCIREC meetings will include but not limited to the following:

i. Attendance of research and ethics committee members, co-opted members, REC administrative staff, investigators/presenters, other researchers present and guests.

ii. Separate deliberations, actions and decisions made on each of the applications being reviewed including amendments and protocol deviations.

iii. Votes for each activity as numbers for, against or abstaining.
iv. Report from expedited reviewer and discussion.
v. The name of a member who left the meeting before the end and the reason for leaving. Circumstances in which members with conflict of interest did not participate in deliberation and voting (Ref. to SOP on conflict of interest for details).
vi. The length of time until the next review based on the degree of risk for review of pending issues.
vii. Any other discussions and decisions taken by UCIREC.

b. The UCIREC secretariat / secretary will prepare the minutes of the meeting and copies of will be provided to UCIREC members electronically in a period of one (1) week for their comments.The comments on minutes will be received within 2 days; otherwise it will be assumed that the members are in agreement.
c. Investigators whose protocols were reviewed will receive communication about the REC decisions and reasons in writing, within two (2) weeks.
d. In case the proposal was approved pending minor changes, the reviewer of the corrections will be indicated. The investigator(s) will submit the corrected version of the protocol directly to the UCI Research and Ethics Review Office staff that will relay it to the designated reviewer.
e. In case major changes are required; the investigator shall be advised to resubmit the corrected version of the proposal/protocol.

f. In case of a rejection, the investigator shall be given a summary of the reasons for the rejection.
g. Document the determinations required by the guidelines and protocol specific findings supporting those determinations for research involving:
h. A procedure which waives the requirement for obtaining asigned consent form or the waiver of some or all of the elements of consent.
i. Pregnant women human fetuses or neonates; or children and prisoners (vulnerable populations).
j. At the end of each REC meeting, the edited minutes from the previous REC meeting will be signed

k. Minutes will be kept on file at the UCI Research and Ethics Review administration office and the attached signed confidentiality pledges for guests or co-opted members.
l. Approved proposals and consent forms shall be stamped and archived.
m. Approval letters shall contain protocol version, date and protocol number.
n. Meeting minutes and agendas should be archived after they are approved by the REC committee

10.5 Reference(s)

❖ SOP Ref no: UCIREC 005/2015- Conducting and calling UCIREC meetings

10.6 Attachment (s)

None

11. 0 Transfer of Human Materials - SOP Ref No: \ UCIREC 010/2015

11.1 Purpose

To describe the procedure for transferring human materials between organizations that conduct research approved by UCIREC.

11.2 Scope

This SOP applies to all research involving transfer of human materials from organization to another within Country and overseas.

11.3 Responsibility

UCIREC members, UCIREC secretariat and the investigators.

11.4 Procedure

In reviewing research protocols involving storage, exchange or transfer of human biological materials, the reviewers need to ensure that the following issues are addressed,

11.4.1 Samples obtained with intention to do research

There must be separate consent form for sample storage and future use. The form should include:

a. Purpose of storage
b. Place of storage
c. Measures to protect confidentiality and privacy during storage, transfer and use of specimen in other studies
d. Voluntariness and right to withdraw consent

e. Potential risks and benefits of storing specimen and any information for use in future research. The ICF should include a description of the procedure for providing results to participant which are deemed important to their health care.
f. If future tests will include genetic studies, detailed information on the risks and benefits of genetic testing should be provided. In addition, separate consent for genetic testing should be obtained- either as a subsection of the storage and future use consent form or using a separate consent form.

11.4.2 Using sample obtained without intention for research

Identifiable specimen–these specimen include participant details that make it possible to trace the source of the human material. In such instance, informed consent should be obtained from the specimen source.

Note: When the reviewers are satisfied with the above, they should ensure that the investigator is notified of the requirements of the Uganda National Council for Science and Technology Guidelines on "Procedure for Exchange/Transfer of Human Biological Materials". The guidelines can be accessed from the UNCST website or latest print material (July 2014).

11.5 References

- SOP Ref No: UCIREC 006/ 2015 Determining review category of protocols and reports for ethical review.
- SOP Ref No: UCIREC 008/2015 Review of Research Using Patients' Stored Data and Specimens

11.6 Attachment (s)

None

12.0 Reporting of adverse events and Non compliances- SOP Ref No: UCIREC 011/2015

12 .1Purpose

This SOP describes the process and reporting requirements and obligations in case of an unanticipated problem or adverse event in the course of human subjects' research approved by the UCIREC.It also provides the necessary definitions and reporting period as recommended by the Uganda National Council for Science and Technology and other international Guidelines.

12.2 Scope

This SOP applies to all researches reviewed by UCIREC

12.3 Responsibility

UCIREC chairperson, members, secretariat and Principal Investigators

12.4 Definitions

a. **Unanticipated Problems Involving Risks to the Subjects or Others**:

Refers to any incident, experience, or outcome that meets all the following criteria:

(i) Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the REC approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.

(ii) **Related or possibly related** to a subject's participation in the research; and Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

(iii) **Adverse event (AE)** - is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporarily associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms and occur most frequently in the context of biomedical research, although they can occur in the context of social and behavioral research. Adverse events that are unanticipated must be reported according to this procedure.

(iv) **Serious Adverse Events -** Any adverse event temporarily associated with the subject's participation in research that meets any of the following criteria:

a. Results in death;
b. Is life threatening, (places the subject at immediate risk of death from the event as it occurred)
c. Requires inpatient hospitalization or prolongation of existing hospitalization;
d. Results in a persistent or significant disability or incapacity;
e. Results in a congenital anomaly or birth defect, or
f. any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of

the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).

v. Unexpected Adverse Event is any adverse event occurring in one or more subjects in a research protocol, the nature, severity or frequency of which is not consistent with either

a.the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in (a) the protocol-related documents, such as the REC approved research protocol, any applicable investigator brochure, and the current REC approved informed consent document and (b) other relevant sources of information, such as product labeling and package inserts; or

b. the expected natural progression of any underlying disease, disorder or condition of the subjects(s) experiencing the adverse event and the subject(s)' predisposing risk factor profile for the adverse event.

vi. External adverse event - From the perspective of one particular institution engaged in a multicenter clinical trial, external adverse events are those adverse events experienced by subjects enrolled by investigators at other institutions engaged in the clinical trial

vii. Internal adverse event- From the perspective of one particular institution engaged in a multicenter clinical trial, internal adverse events are those adverse events experienced by subjects enrolled by the investigator(s) at that institution. In the

context of a single-center clinical trial, all adverse events would be considered internal adverse events.

viii. Possibly related to the research- There is a reasonable possibility that the adverse event, incident, experience or outcome may have been caused by the procedures involved in the research.

12.5 Procedure

a. The Principal investigator will be responsible for reporting serious adverse experiences to trial sponsors and UCIREC. However, he/she may delegate the data collection and communication of such events to appropriate clinical site research personnel. The principal investigator or another investigator on the clinical study will sign the SAE report prior to submission to UCIREC
b. The Sponsor and Principal Investigator are responsible for reporting all unexpected adverse events and serious adverse events related to a test intervention to UCIREC.
c. Fatal or life threatening events should be reported to the REC within 3 working days of discovery
d. All other unexpected serious adverse events should be reported no later than ten working days from the day the Sponsor or Investigator becomes aware of the event
e. The Investigator will use the Adverse Event Reporting Form for UCIREC for this reporting. Information should include the facts of the case, including the date of event, medical history of the subject, the event relationship to the test intervention or underlying condition, the likelihood re-occurrence, and whether the event provides new risk information that should be added to the informed consent. Reporting form for ADRs

f. Assignment of relatedness of an adverse experience may not be clear. To ensure that review of all serious adverse events is systematically undertaken, all studies that involve intervention with a diagnostic or therapeutic drug, biological agent, device, or procedure will have all serious unexpected adverse events reported to the UCIREC regardless of the probability of cause.
g. For reported deaths, the principal investigator or designee should supply the sponsor and UCIREC with any additional requested information (e.g hospital records and autopsy reports).
h. The investigator must notify UCIREC of any safety reports, study monitor's reports, DSMB reports or reports from the sponsor concerning safety from other research sites as received from sponsors by submitting such reports to UCIREC within 10 working days of receipt.
i. In the case of investigational drugs, if upon further evaluation of the SAE the sponsor determines that the investigational drug presents a reasonable and significant risk to subjects the sponsor may require the principal investigator to:
   (i) Discontinue the investigation
   (ii) Notify UCIREC and clinical site research personnel that the study is being discontinued. Such reporting should be expedited; could be done by email followed by detailed reporting not later than 7 calendar days after sponsor's receipt of the information of any unexpected fatal or life- threatening experience associated with use of the study drug.
   (iii) Return all outstanding stock of Clinical Trial Materials (CTM)

j. The principal investigator is responsible for immediately discontinuing a trial upon receipt of notification from the sponsor in the event that the sponsor determines that an unanticipated adverse device event presents an unreasonable risk to study subjects. In order to resume a previously terminated study of a significant risk device, the principal investigator must submit a request to UCIREC and copy all UCIREC correspondence/approval to the sponsor.

12.5.1 Reporting Non-compliance to the REC

For each research study the Principal Investigator must ensure that all serious or continuing non-compliance is reported to the REC not later than 10 calendar days after he or she first becomes aware of the problem. Such non-compliances include:

(i) The failure to obtain REC approval of human subjects' research when required under the applicable laws and regulations.

(ii) Enrolling a research participant who does not fit the inclusion and exclusion criteria in the protocol.

(iii) Failing to obtain or document informed consent.

(iv) Administering drugs, radiations, biologics or cell products, or using devices required by the protocol at a dose or schedule that has not been approved by the REC except when necessary to eliminate hazards to the research participant.

12.5.2 How to submit an Adverse Event and Noncompliance Reports.

(i) Investigators should use the UCIREC Adverse Event Reporting Form while reporting adverse events and noncompliance.

(ii) Each adverse event or record of noncompliance should be done on a separate form or report.

(iii) Incomplete forms will be returned to the investigator for completion.

(ix) Upon receipt of a serious adverse event or non-compliance report, the UCIREC administrative staff will log the report into the database for the study and send a copy of the report to the Chairperson of UCIREC who may review it or designate a UCIREC member to review it.

(iv) If designated UCIREC member is used, he will review the Adverse Event or noncompliance report and may approve continuation of the study without modification to the protocol or informed consent, or approve continuation with minor changes to the protocol or informed consent on behalf of the REC. The Reviewer may request a temporary suspension of a study if in his or her opinion continuation is likely to further expose participants to undue risk yet suspension will reduce such risk. However, the Reviewers cannot terminate a study. This action is reserved to a properly convened meeting of the UCIREC.

(v) The reviewer will prepare a report on the review which will be presented at the next convened UCIREC meeting.

(vi) Should UCIREC require additional information, a letter will be sent to the investigator requesting additional information.

(vii) All serious adverse events or noncompliance reports not reviewed by the designated Reviewers will be reviewed by the full Board.

(viii) A copy of all correspondence/reports will be kept in the appropriate UCIREC files and study files.

12.6 Reference(s)

- SOP Ref No: UCIREC 013 /2015 monitoring and tracking of studies approved by UCIREC.

12.7 Attachment (s)

None

13.0 Confidentiality and Conflict of Interest -SOP Ref No: UCIREC 012/2015

13.1 Purpose

The purpose of this SOP is to explain the guidelines for: 1) Managing conflict of interest by UCIREC members and secretariat. 2)Assessing protection of participant confidentiality by research studies, REC secretariat and members.

13.2 Scope

This SOP covers the agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the REC and potential participant confidentiality.

13.3 Responsibility

It is the responsibility of the REC secretariat to ensure that newly-appointed REC members and guests read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before attending procedures of the REC meeting or before accessing confidential documents of the REC.It is the responsibility of investigators, REC members and secretariat to ensure that participant confidentiality is maintained and protected.

13.4 Procedure

13.4.1 Procedures in case the REC member has Conflict of Interest

a. It is recognized that the potential for conflict of interest will always exist, but UNSCT has faith in the REC and its

Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects

b. It is the policy of the UCIREC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the REC.

c. The undersigned will immediately disclose to the Chairperson of the UCIREC any actual or potential conflict of interest that he/she 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.

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

e. 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 REC member(s) in question. The Committee may decide to investigate the applicant's claim of the potential conflict.

f. When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the REC review or approval except to provide information requested by the Committee.

13.4.2 Maintaining Confidentiality by REC members and secretariat

a. The REC member has an obligation to protect information entrusted to them regardless of format; including but not limited to verbal, written and electronic. Members may not

communicate REC deliberations and decisions directly to investigators.

b. Reading and signing of the Confidentiality/Conflict of Interest Agreement forms. Newly appointed members obtain two copies of the Agreement Form.
   (i) Read through the text of the form very carefully.
   (ii) Direct questions to the Secretariat, if any part or sentences is not clear.
   (iii) The members fill in their names and their office on the blanks.
   (iv) Sign and date both copies of the document before a member of the Secretariat.
   (v) Give the forms back to the compliance officer to sign and date
c. The members keep a copy as their records.
d. Keep the Agreement in mind
e. The REC secretariat keeps a copy of the signed Agreement as the Institute's records in the Confidentiality /Conflict of Interest Agreement file.
f. Store the copies in a file in a secure cabinet with limited key holders

13.4.3 Procedures for review of protocol sections on Participant confidentiality

The REC application forms include questions about privacy and confidentiality. The responses are reviewed by the REC chair or REC committee to determine whether the study adequately addresses these issues.

a. **Protections of confidentiality:**

In a research in which participant's participation, response, and the investigator's knowledge of the respondents may be of interest to a court of law, the participant should be informed of this possibility in the consent form.

b. Identification of Research participant

(i) If written consent is not required, any identifiable private information or individually identifiable health care information on data collection forms, questionnaires, and other records should be removed, stricken, or otherwise obliterated as soon as noted by the investigator, even if such use is unintentional.

(ii) In instances where it is necessary to identify research participants, identification of data collection forms, questionnaires and, other records should be by code, with the code translation to be kept separate from the data. A code should be established solely for the purpose of the study. The code translation log and the data should be kept in a secure place, such as locked cabinet only accessible by the investigator, authorized staff and others like monitors or identified by the REC application.

(iii) Where the information will be computerized, no names or other identifying information should be entered .The study code number should be entered. The code translation is not entered into computer.

c. **Approach to research participants**

The most sensitive of all research issues is the approach to research participants. For this reason, the procedures of all studies should include an approach to research participants which avoids coercion and an invasion on privacy.

d. Minimizing the appearance of coercion

The investigators should stress the voluntary nature of participation. Whenever the potential research participants are patients, clients or students under the care of the investigators or employees, measures to minimize coercion must be considered such as a different person talking to the potential participants or avoid the use of persons altogether.

e. Use of intermediary

In order to avoid an invasion of privacy, it may be necessary for the investigator to enlist the cooperation of other professionals and Organizations as intermediaries. This is appropriate when the investigator has not had prior contact with the research participant and has not obtained their names .The intermediary does not obtain consent form the prospective research participant but refer to the investigator for possible consent. The intermediary that is willing to assist the investigator in this way should not take a strong advocacy position in favor of a particular research activity.

f. Use of public list

When the investigator obtains names through a public list (e.g. telephone book), the name of the source should be included in the approach letter.

g. Use of Questionnaires ,scales ,inventories , and interviews

Adescription of the questions to be asked (including where appropriate examples of the most personal and sensitive questions) should be provided to the research participants. Research participants should be informed (in the consent

document) of their right to refuse to answer any questions and an estimate should be given of the length of time needed to complete the activity.

h. Use of records: photographs ,films ,videotapes , and Audiotapes

(i) Photographs, films, videotapes, and audiotapes to be made or to be used for research require the informed consent of the research participant.

(ii) The purpose or intended use of such data should be included in the ICF.

NOTE: Use or disclosure of protected health information for anything other than treatment, payment or health care operations generally requires an authorization from the research participant unless UCIREC –approved waiver is obtained.

13.5 Reference(s)

- SOP Ref No: UCIREC001/2015 Constituting and functioning of UCIREC

13.6 Attachment (s)

Confidentiality Agreement Form for the Research and Ethics Committee Members

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the UCIREC . A copy will be given to you for your records.

In the course of my activities as a member of the REC, I may be provided with confidential information and documentation (which

we will refer to as the "Confidential Information").I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

I,……., have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Undersigned Signature Date

_____ _____

Director Uganda Cancer Institute Date

Confidentiality Agreement Form for Guest Attendees to REC Meetings

I,……., understand that I am allowed to attend the REC meeting as a guest or an observer. In the course of REC meeting , some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as Confidential.

Indicate the details (date and number) of the REC Meeting attended:

…….

…….

…….

_____ _____

Signature of the Guest or Observer Date

_____ _____

Chairperson of the REC Date

Confidentiality Agreement Form

for Non-members Requesting for Copies of REC Documents

I,……., as a non-REC member ,I understand that the copy (ies) of documents given to me by the REC is (are) confidential. I shall use the information only for the indicated purpose as described to the REC and shall not duplicate, give or distribute these documents to any person(s) without permission from the REC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information Confidential.

I have received copies of the following REC documents:

……

……

……

_____ _____

Signature of the recipient Date

14.0 Monitoring and Tracking of studies approved by UCI REC

SOP Ref No: UCIREC 0013/2015

14.1 Purpose

This SOP describes the procedures relating to post approval monitoring of Human Subjects research approved by UCIREC.It also describes notification requirements and procedures regarding progress reports to UCIREC

14.2 Scope

Applies to all research approved by UCIREC

14.3 Responsibility

UCIREC Secretariat and members

14.4Procedures

14.4.1 Administrative Reviews:

a. Administrative reviews are conducted by a Post Approval Monitor (PAM) to measure the effectiveness and/ or efficiency of UCIREC procedures and HSP Procedures.
b. A PAM may conduct periodic assessment of UCIREC procedures by examining databases, records and related materials to evaluate, without limitation, REC performance (i.e. attendance, survey results, etc.)
c. Fullboard, expedited, and exempt processing
d. Processing turn around times
e. Outreach and training activities
f. Completeness of REC minutes

g. Consent processing
h. Documentation contained in research records (i.e. evaluation risks, data and safety monitoring etc.)
i. Numbers/activities reported on the continuing review. All materials reviewed will generally be selected randomly by a PAM. However, the individual initiating the review and the HSP Manager have the authority to identify specific information for review including specific protocols for on-site review. A PAM will conduct the review utilizing a checklist such as those listed in the attachments. Any potential noncompliance identified during the review will be noted on the checklist even if it outside the scope of the review or not on the checklist.
j. After conducting an in-depth review of the databases, REC records, protocols and/or related materials, the results of the review will be reported to the REC Chairperson. The REC Chairperson is responsible for implementing measures to enhance the HSP as appropriate based on the results of the review.
k. The UCIREC procedures will be reviewed at least once every 2 years.

14.4.2 Site Reviews

Site reviews are conducted by a PAM to review an investigator's human subject's research activities. Site reviews / monitoring may be passive or active.

a. Passive monitoring

i. Relies on reports submitted by the investigators. UCIREC administrative staff will be responsible for entering and

maintaining a list of all studies approved by it. Communication of approval to the investigator will indicate the reporting requirement for the specific research.

ii. The UCIREC administrative staff will in the last week of every month generate a list of studies approved by UCI REC whose approvals are due to expire in the following 2 months.

iii. In collaboration with the Chairperson, the administrative staff will generate and send notification letters reminding the investigator to submit their progress report at least 4 weeks before expiry of approval. In case of closing studies, 8 weeks before closure. The communication will be sent along with the required forms and instructions for submission.

iv. If no response is obtained from the investigators, the administrative staff or designee will send repeat notices at approximately two weekly intervals.

v. The Principal Investigator may also be contacted if no response is received. The UCIREC Chairperson, Administrator or designee may perform this function.

vi. A copy of the written requests, email copies, faxes and fax confirmations will be kept in the files of the study.

vii. The expected response will include a completed UCIREC form together with all the necessary review materials. When these are reviewed, the administrative staff and the Chairperson UCIREC will schedule them for continuing review either through expedited or full board review or exempted according to SOP 006.

viii. The investigator will then be notified following procedures in SOP 009.

b. Active monitoring

i. May be routine or prompted by repeated site violation of HSP or reported deficiencies at site.
ii. The Chairperson of UCIREC in consultation with the REC members and the administrative staff will randomly select sites that are to be visited for routine monitoring at a least a month before the date of the visit.
iii. For each site selected, the Chairperson will assign two members of UCIREC to conduct the site visit
iv. The Chairperson UCIREC will inform in writing, the PI of the site about the intended visit indicating the date.
v. The two selected UCIREC members conduct the site visit and carry out the monitoring using M& E checklist (Refer to M & E checklist)

14.4.3 Monitoring after Reported Deficiencies

a. When the Chairperson of UCIREC receives a report of likely deficiencies at particular research sites either from whistle blowers or research participants, or problems identified from submitted reports, he or she will initiate a site inspection in not more than 14 days from the day such a report was received.

i. The Chairperson or his/her designee, together with at least two other UCIREC members will conduct the site inspection.
ii. The inspection team will hold a meeting prior to the visit to discuss the reported deficiency and come up with a site inspection plan.
iii. Depending on the gravity of the deficiency and the time available, the PI may or may not be notified about the intended visit.

iv. The inspection team will visit the site and make an assessment

b. Scheduling site inspections

(i) Monitoring visits may be scheduled at the time of approval of the research if the research presents more than minimal risk to the participants. The frequency of such visits will depend on the magnitude of risk such research presents.

(ii) The administrative staff will generate a list of studies that have scheduled site inspection visits and present it to the Chairperson UCIREC

(iii) The Chairperson UCIREC will write to the PI informing him/her about the intended visit indicating the date and areas the visit is likely to focus on.

c. During the inspection

The monitoring team will carry the following:

(i) A copy of minutes of the meeting where the study was approved.

(ii) The version of protocol approved together with its appendices

d. Action to be taken after Monitoring Visits

After the monitoring visit, the following shall be done;

(i) The monitoring team shall make a report to the chairperson of UCIREC

(ii) The Chairperson shall schedule discussion of the report at the next UCIREC meeting.

(iii) The report will be discussed and decisions shall be made by the committee.

(iv) The administrative staff shall communicate the decisions of the committee to the site not more than 2 weeks after it has been made.

(v) Depending on the gravity of the site deficiencies, the Chairperson in consultation with the monitoring team and other UCIREC members may temporarily make decisions during the visit that they reasonably deem fit to confer protection to research participants.

(vi) May decide to withdraw approval

(vii) Report to UNCST

14.5 Reference(s)

- SOP Ref No: UCIREC 005/2015 Determining review category of protocols and reports for ethical review.
- SOP Ref No: UCIREC 011/2015 Reporting of adverse events and Non compliances.

14.6 Attachment(s)

None