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ACRONYMS

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 Participants 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

ACKNOWLEDGMENTS

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 sister RECs including Mulago REC, School of Medicine Research Ethics Committee (SOMREC), and Makerere School of Public Health (MakSPH) REC for their contribution during the revision process of this SOP.

We recognize and thank all UCIREC members who participated in revising these guidelines. Special thanks go to Dr. Nixon Niyonzima (Head Research and training), Dr. Clement Okello (UCIREC secretary), Sr. Maria (member of UCIREC) and Mr. Brian Tumushabe (Administrator UCIREC) for their extra effort devoted towards completion of revision of the revision exercise of these SOPs. It is our sincere hope that the process and revised SOPs will be an opportunity for UCI, UCIREC and investigators to enhance the protection of research participants.

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 different collaborators, UCI's human resource capacity is expanding, and accessing better technologies. This is indeed a time and opportunity to make the care for cancer patients better through research and personal responsibility.

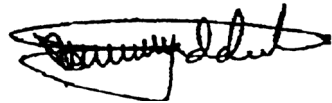
The establishment of the Uganda Cancer Institute Research and Ethics Committee (UCIREC) was an important milestone in ensuring that research done at and/or in collaboration with the UCI is at the highest ethical standards. Moreover, SOP guidelines serve as the first reference in the execution of responsibilities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

work with and at the UCI. After 3 years of operation since its inception, and considering the changing environment and context under which research is conducted, it was imperative that the UCIREC revises its SOPs to keep pace with the changes and need to protect human participants involved in research.

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. Jackson Orem
Executive Director
Uganda cancer institute



Dr. Kyaddondo David
Chairperson UCIREC

1.0 GENERAL PROVISIONS

1.1 Introduction:

The 2014 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 is 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, and is independent in its reflection, advice, and decision making.

1.2 Rationale

To improve the UCI's and any other institution's research oversight of research studies involving its 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.

GUIDING PRINCIPLES:

1. Respect: Autonomy:

Each individual is autonomous and has moral status and their wishes and interests must be protected during research processes.

2. Beneficence/ Malfeasance:

Individuals must be protected from exploitation.

Individuals must be protected from harm

3. Justice

Obligation to treat all individuals fairly and equitably.

1.3 Roles of the REC members

The responsibilities for all REC members include among others:

1. Enforcing adherence to the ethical standards for the conduct of human participants' research so as to

protect safety, rights, interests, values and welfare of all study participants.

2. Ascertaining that implied benefits of research to the participant, community, institution and the general population are realized.
3. To ensure valid scientific and ethical basics and methods of research, and are of the highest standard.
4. Conduct continuous review of protocols, reports, Adverse Events to ascertain compliance with all applicable regulations (local and international).
5. Build capacity for ethical conduct of research especially in cancer and other non-communicable diseases.

1.4 General Guideline:

The operation of UCIREC members is guided by standard procedures that were developed at its inception. These SOPs 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 UCIREC members, Secretariat staff and Relevant Investigators
- e) Confidentiality and Conflict of Interest Calling and conducting UCIREC Meetings
- f) Determining Review category of protocols and reports for Scientific and ethical review
- g) Informed Consent Process
- h) Community engagement Process
- i) Expedited Review of research protocols
- j) Review of Research Using' Stored Data and Specimens
- k) Taking minutes and communicating decisions to Investigators
- l) The Transfer of Human Materials
- m) Reporting of adverse events and Non-compliances
- n) Monitoring and Tracking of studies approved by UCIREC

1.5 Scope of Application:

The Standard operating procedures in this SOP are applicable to all UCIREC activities and will be followed by UCIREC members, UCIREC Secretariat, Co-opted members and investigators.

UCIREC

1.6 Responsibility:

The appointing authority (UCI Executive Director), the REC members and secretariat have the responsibility to implement these SOPs. Therefore, they must read, understand and respect the guidelines set by the REC in this SOP.

SOP# 2.0: Confidentiality by REC members and Secretariat

2.1 Purpose

To protect participants' confidentiality by UCIREC members and Secretariat.

2.2 Scope

This SOP applies to all REC members and REC Secretariat

2.3 Responsibility:

It's the responsibility of the appointing authority, THE UCI REC chair and all REC members to follow this SOP during UCIREC activities.

2.4 Confidentiality:

All REC members must ensure integrity and confidentiality of research protocols, data collected within the research and the privacy of all information relating to research participants.

2.5 Procedures

- a. The REC member has an obligation to protect information entrusted to them regardless of source including but not limited to verbal, written and electronic. Members may not communicate REC deliberations and decisions directly to investigators.

Reading and signing of the Confidentiality Agreement forms. All REC members appointed to UCIREC complete two copies of the conflict of Interest Agreement Form

- (i) Read through the text of the form very carefully.

- (ii) Direct questions to the REC Chair and or Administrator, if any part is unclear
 - (iii) The members fill in their names and their designation on the REC
 - (iv) Sign and date both copies of the document before a member of the Secretariat.
 - (v) Give the forms back to the UCIREC Administrator to sign and date.
- c. The members keep a copy for their record.
 - e. The REC Administrator keeps a copy of the signed Agreement as the Institute's records in the Confidentiality /Conflict of Interest Agreement file.
 - f. Maintain the originally signed on UCIREC file in a secure lockable cabinet with limited access

SOP # 3.0: Constituting and functioning of UCIREC - SOP Ref No: UCIREC 001/2023

3.1 Purpose

The standard operating procedure describes the procedure for constituting the REC, its roles and responsibilities, functioning, how members are appointed and replaced. This SOP is further supported by the other UCI general SOPs.

3.2 Scope:

Applies to all activities for constituting and functions of UCIREC.

3.3 Procedure

a. Composition of the REC

- (i)** The UCIREC is comprised of at least 15 regular voting members; and two alternating community representatives.
- (ii)** The members must have various backgrounds to promote a complete and adequate review of research activities submitted to UCIREC, and conducted by the research investigators under their auspices. Professional qualifications/specialties include physician,

pharmacist, nurse, social scientist, oncologists, statistician, biomedical scientist, paramedic and/or layperson (gene expert; gynecologist???)

- (iii) The members 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 not affiliated to UCI.

b. Membership appointment

- (i) The UCI Director (Head of the Institution) is responsible for appointing UCIREC committee members including the chairperson, Vice Chair and the Administrator.
- (ii) Members are selected in their personal capacities, based on their professional background, interest, ethical and/or scientific knowledge and expertise, as well as their commitment and willingness to volunteer the required time and effort for REC activities.
- (iii) Members are appointed for a period of 3 years. Their appointments may be renewed by the Executive Director / Head of Institution of UCI upon satisfactory performance.

c. Conditions of Appointment and term duration

The appointed members are expected to fulfill the following conditions:

- (i) All REC Members and Independent Consultants must sign Confidentiality/Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.
- (ii) At the end of three-year term, the REC chairperson may retire their position or may have his/her appointment renewed.
- (iii) To foster REC independence, the Director UCI will only appoint the chairperson, Vice Chairperson and REC Administrator at the beginning before the committee membership has been constituted. But in the event that the chairperson resigns, or his term ends the vice chairperson automatically becomes the chairperson.

d. Compensation

- (i) REC membership is voluntary. However, UCIREC members receive facilitation for their participation in REC meetings, monitoring and other activities in recognition of their time,

data, and transport. Facilitation support and stipends are determined based on member's involvement in REC activities.

(ii) REC attendance is completed per REC meeting and maintained as part of UCIREC meeting minutes that include, declaration of member's conflict of interest, a summary of members' discussion point per type of submission reviewed.

e. Membership requirements

- i. Should have expertise in relevant areas
- ii. Willingness to volunteer as a REC member.
- iii. Members are required to sign a conflict of interest and confidentiality agreement at the start of their term. The confidentiality agreement protects the privacy and confidentiality of all REC activities and should not be disclosed to people outside of the REC.
- iv. Members must disclose in writing any interest or involvement – financial, professional or otherwise – in any research proposal under review.

f. The REC chair/vice determines the extent to which members with conflict of interest may be part of the discussion.

g. Resignation, Disqualification, Replacement of Members:

- (i) The chairperson and all REC members may resign their positions by submitting a letter of resignation to the UCI Executive Director (the appointing Official) through the REC Chairperson.
- (ii) Members may be disqualified from continuing with UCIREC activities if found that their performance is unsatisfactory as determined by the REC chairperson and UCIREC members.
- (iii) Members that have resigned or have been disqualified may be replaced by the appointing authority.
- (iv) If a member resigns from the UCIREC, a letter of recognition of services and a certificate of appreciation signed by the UCI Executive Director is given to that member.

f. Co-opted experts

The UCIREC may be further supported in its activities and reflections on specific protocols or requests for advice on specific ethical /scientific issues by Independent reviewers.

- (i) Co-opted experts are identified by the Chairperson/members of the REC.
- (ii) Their professional qualifications may be in the areas of Expertise for a given protocol.
- (iii) Signs a confidential agreement.
- (iv) Declare conflict of interest.
- (v) Co-opted experts do not vote during for reviewed protocols review.

3.4. Role and functions

The UCIREC members act independently in all their roles and activities to ensure ethical conduct of research.

a. REC membership

The following are roles of UCIREC members through their respective Ethical and Scientific review, to contribute to the good functioning of the REC:

Chairperson

- (i) Responsible for chairing all UCIREC meetings and liaise directly with the UNCST, report the REC meeting outcomes to UNCST, invite co-opted experts
- (ii) The REC Chairperson, with support from the REC Administrator conducts annual reviews of each member's role according to qualifications, REC requirement, record of participation, and contribution to the REC. Those who regularly fail to meet the expectations may be requested to step down prior to the end of their term, in which case an alternate or new member will be appointed by the UCI Executive Director.
 - iii) Providing updates on relevant and contemporary issues related to ethics in research
 - iv) Make sure that all REC members contribute during the meeting discussions.
 - v) Chairperson shares the annual progress report and any other related correspondences in regard to that report with the institutional Executive director.

Vice-Chairperson

Performs functions of the chairperson in his/her absence.

REC Secretary

The REC Secretary will be responsible for the minutes of the REC meeting and work in liaison with the REC Administrator.

REC Administrator

Is responsible for administrative aspects of the REC and works on REC Chairperson's instructions.

Roles of Administrator:

- i. The REC administrator is composed of the UCI staff member appointed by the Executive Director of UCI to support the REC office activities.
- ii. The Administrator is responsible for the daily functioning of the REC. Also performs the function of organizing effective and timely efficient reviews, and maintains a tracking spreadsheet for research proposals submitted for UCIREC review.
- iii. Prepares, maintains and distributes Research documents submitted for UCIREC review.
- iv. Organizing UCIREC meetings.
- v. Supporting the Chairperson to prepare the meeting agenda and minutes.

- vi. Maintaining the REC's documents (hard copies and soft copies) and ensures proper archival of these records.
- vii. Communicating with the REC members and investigators.
- viii. Arranges trainings for REC members.
- ix. Work with members to review and revise UCIREC SOPs in line with local and international research guidelines.
- x. Providing the necessary administrative support for REC related activities to the Chairperson of the Committee (e.g., communicating a decision to the investigator).
- xiii. On weekly basis, present to the Chairperson a summary of the submitted protocols for planning on distribution of the appropriate review category and support the decision of scheduling REC meetings.
- xiv. Support the Chair by providing the required information to help in conducting annual performance reviews of REC members and providing annual reports to the UCI Executive Director.
- xv. Coordinate requisition, payment and accountability for REC members' allowance.

Roles and responsibilities of UCIREC members

- i. Declaration of conflict of interest
- ii. Participate in the UCIREC meetings
- iii. Review, discuss and ensure completeness of research proposals submitted for evaluation.
- iv. Monitor serious adverse event reports and recommend appropriate action(s) for participants' safety, rights and wellbeing.
- v. Reviewing the investigator submitted progress reports.
- vi. Monitoring approved research especially high risk and clinical trials as appropriate
- vii. Review of final research reports and outcomes
- viii. Maintain confidentiality of the documents submitted to and deliberations during REC meetings.
- ix. Ensure taking part in continuing research education activities in research involving humans as participants to remain current.

3.4.1 Conduct of REC meetings reviewing protocols

a. Quorum Requirements

- i. A minimum of 50% of the members are present at a REC convened meeting.
- ii. Presence of a community representative to ensure interests of the community are represented. If the community representative is absent the meeting should not convene.

b. Ethical basis

- i. The REC recognizes that the approved protocols should be approved by the National Council for Science and Technology and National Drug Authority (for clinical trials) prior to research implementation in approved specific localities.
- ii. In evaluating scientific and ethical issues for protocols, the UCIREC awareness and consideration is taken about the diversity of laws, cultures and practices governing research and the Ministry of Health medical practices around the world.

- iii. The requirements and conditions of the various localities where proposed research is to be conducted is also put in consideration.
- iv. The UCIREC also seeks to be informed, as appropriate, about the impact of the research it has approved.
- v. The UCIREC is guided in its reflection in regard to the Belmont Ethical research principles (Respect, Beneficence and Justice) as reflected in the UNCST National Guidelines for Research Involving Humans as Research Participants of Uganda.
- vi. During the review the UCIREC makes further references is made to the National and International Ethical Guidelines for Biomedical Research Involving Human as participants (CIOMS), the European Convention on Human Rights and Biomedicine and the Declaration of Helsinki and other international guidelines, WHO and ICH E6.
- vii. The UCIREC fulfills the requirements for the International Assurances office of research protection (OHRP) and functions in accordance with the National laws.

SOP #4.0: Development and maintenance of SOPs-

SOP Ref No: UCIREC 4.0/2023

4.1 Purpose

To ensure consistent procedures for development of UCIRECSOPs.

4.2 Scope

Applies to all SOPs for the different UCIREC activities as they are developed, revised and maintained.

4.3 Responsibility

The Executive director of Uganda cancer institute and UCIREC Chairperson is responsible for ensuring that this SOP is followed during the development, implementation, review, approval and maintenance of all UCIREC SOPs.

4.4 Procedure:

The Chairperson is responsible for ensuring that this SOP is reviewed and revised according to relevant current research information.

All REC members are responsible for review of current SOPs.

4.4.1 Format

i. Cover page

- a. The UCIREC SOP has the UCI logo, the UCISOP REC title, Version and effective date.

ii. Approval Signature

- a. Each version of the UCIREC SOP has an approval signature & Date indicating its review and approval by the Chairperson and the secretary.

iii. Numbering

Numbering of the SOPs in sequential order. Each SOP has a reference number.

Purpose:

- a. To ensure that each of the SOPs entails the function for which it's formulated.

iv. Scope

- v. Each SOP specifies the scope to which it applies. In general, UCI SOPs are broadly applicable. Where appropriate, citations for relevant guidelines and regulations are included.

vi. Procedures

- a. Each SOP clearly spells out the procedures to be followed to ensure compliance.

vii. Attachments

- viii. Where applicable, UCIREC SOPs include sample forms. If not included, the SOP makes reference to those that can be used. Forms which have been provided as samples or templates are identified as such.

4.4.2 Preparation and Content

- (i) These SOPs were developed/reviewed by UCIREC members, in a participatory workshop and follow-up meetings.
- (ii) SOPs were reviewed and finalized by a quorum of UCIREC members.
- (iii) The finalized UCIREC SOPs were approved by the institutional executive director and UCIREC Chairperson [signed].
- (iv) Copies of finalized SOPs were distributed to REC members
- (v) All investigators submitting to UCIREC are mandated to have copies of these SOPs, also can be found on the UCI Website

4.4.3 Revision renewal and revocation.

- i) UCI-REC SOPs shall be revised as necessary.
- ii) The UCIREC Chairperson shall designate an individual(s) to ensure that SOPs are complete and accurate on a periodic basis or as new guidelines are developed based on new research information.
- iii) SOPs shall be reviewed for content and applicability periodically or whenever the National or International regulations affecting working SOPs are revised.
- iv) As the SOPs are reviewed in case of any urgent required revision, an addendum to the SOP will be made indicating the specific areas of SOPs that are no longer applicable and will be revoked.
- v) Revocation or implementation will be accomplished by memo or electronic communication from the Chairperson and addressed to the Executive Director. The investigators submitting to UCIREC shall also be informed.

SOP#5.0: Submission of Protocols and Reports for review to UCIREC SOP Ref No: UCIREC 05/2023

5.1. Purpose

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

5.2. Scope

This SOP applies to the Chairperson and all REC members' investigators submitting to UCIREC and UNCST.

5.3 Responsibility

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

5.4. Procedure

- (i) The investigator(s) must fill the relevant UCIREC form(s) available at the research administration office/or through NRIMS online.
- (ii) The investigator(s) must submit proof of payment for ethical review fees/waiver of payment on submission of protocol. Investigators may contact the research

administration office, or check online for the UNCST standard REC fees structure and details of where to pay account number 9030006331911 in names of Uganda cancer institute; bank name is Stanbic bank.

5.4.1 Initial (New Application)

- a. The following must be submitted to the research administration office at the UCIREC secretariat or online; Please note that UNCST requires Investigators to make research application for review on the UNCST Portal to NRIMS at <https://nrims.uncst.go.ug/>; Upload the protocol on NRIMS, and you will receive an acknowledgment of receipt and assigned UCIREC Protocol reference number.
- b. Upload approval letter from the REC of a collaborating institution
- c. Upload letter of approval from departments and /UCI scientific committee or the REC of the collaborating institution(s) in case of collaborative research.
- d. For students a letter of approval/recommendations from their department or institution of affiliation and supervisor's approval.

- e. Uploaded Study Protocol must be with signed Investigator page and dated)
- f. Provide Protocol summary
- g. Upload Data collection instruments both in English and translations to local language where applicable.
- h. Investigator and co- investigator's Curriculum Vitae (CVs), copies of Professional certifications, Practicing licenses, HSP and GCP training certifications [initialized on each page].
- i. Advertisements, videos, press release, social media posts, flyers, scripts, emails, films, brochures and any other letter that maybe used (where applicable)
- j. Material Transfer Agreement (where applicable)
- k. Data Sharing Agreement between the Sponsor and Investigator).
- l. Informed Consent Forms translated in the local language depending on where the study is to be implemented.
- m. Study budget.
- n. Community Engagement Plan
- o. A dissemination plan.
- p. investigator brochure, or device specifications (where applicable)

- q. Any other supporting informed consent materials like flip charts, videos, assessment of understanding and films.
- r. Treatment plan (observation studies)

5.4.2 Continuing Annual review.

An application form uploaded in NRIMS/obtained from the UCIREC office.

- i. Cover letter specifying request.
- ii. Proof of payment
- iii. Previously approved and stamped documents.
- iv. Copy of current UNCST approval.
- v. Progress report (using the UCIREC template) giving a brief summary of relevant aspects of the study; preliminary findings, status of recruited study participants, violations, deviations, monitoring and audit reports (if applicable), copies of letters of previous approvals by all regulatory bodies with study oversight and collaborators, copy of current protocol and study related documents (ICFs, participant information sheets and other protocol specified documents, study related literature if applicable **{with document versions and dates specified}**), future plans and activities and challenges. (Ref to UCIREC Progress report template)

- vi. Clean copy of previously approved documents being requested for approval.
- vii. Copies of letter of previous approval, approvals from relevant regulatory bodies and collaborators.
- viii. Proof of payment.
- ix. A copy of working protocol

5.4.3 Amendments request

- i. an application uploaded on NRIMS
- ii. Summary of changes
- iii. Research proposal with track changes
- iv. Amended/clean copies Research protocol and related documents **{with document versions and dates specified}** (e.g., consents, questionnaires etc.) and previously approved protocol.
- v. Soft copy of amended protocol (clean) and related research documents for review and approval.
- vi. Proof of payment (Ref: to UNCST standard fee structure).
- vii. Revised Study budget
- viii. Sponsor and investigator communication if applicable.
- ix. Any other documents that may be required.

5.4.4 Protocol Deviations / Protocol Violations

- i. Any other documents that may be required.
- ii. Uploaded completed to NRIMS
- iii. Upload approved protocol.
- iv. Follow up reports

5.4.6 Study close out

- i. Form uploaded to NRIMS.
- ii. Full close out report, manuscript, conference presentation or newspaper report if available.
- iii. Upload the study progress report on NRIMS

5.4.7 End of study follow up

Upload end of study follow up report including copies of notifications to the sponsor.

Upload the progress report temperate.

**SOP #6.0: Training REC members, Secretariat
staff and Relevant Investigators SOP Ref No:
UCIREC 006/2023**

6.1 Purpose

The purpose of this SOP is to inform the Uganda Cancer Institute Research and Ethics committee (UCIREC) 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, Science and ethics.

6.2. Scope

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

6.3 Responsibility

Chairperson, Executive Director, REC members, secretariat and relevant investigators

6.4 Procedure

6.4.1 Training and Orientation of new REC member

- i. New members will have an orientation by the REC Chairperson, REC administrator prior to their first meeting.
- ii. A copy of the approved UCIREC SOP's will be given to each new member to read and understand the REC procedures.
- ii. New REC members who have not completed Human Participant Protection training within 3 years must attend an online Human Participant Training course and Good Clinical Practice course as soon as possible but within 90 days from the REC membership appointment date. These training sessions should be updated periodically.
- iii. The chairperson and REC administrator will identify the new member's area of expertise and update the REC committee Roster.
- iv. Every time the roster is updated, the REC administrator updates the study investigators to update their Essential documents.

6.4.2 Continuing Training and Education

- (i) REC members and chairperson have the 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 of value.
- (iii) The REC Chair and Administrator to organize training for the REC members periodically.

6.4.3 Training of Researchers;

Training in the Human Participants protection of human research participants is required for investigators and study staff team members involved in one or more of the following activities:

- (i) **Study Design** - developing the research concept, scientific method, or objectives for a study that involves intervention or interactions with a human participant or the use of identifiable data or tissue derived from a human participant.
- (ii) **Study Conduct** - implementation and management of research involving human participants. 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 participants.
- (iii) If the Principal investigator of a study fails to meet the training requirements; the REC may recommend training in that identified gap.
- (iv) If the investigator fails to undertake the recommended training, then the REC may suspend the study. The suspension may be lifted when the investigator/team completes the training.

6.4.4 REC Members 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 UNCSST guidelines

- (iii) Ethical Issues and research ethics issues
- (iv) Study monitoring and audit procedures.
- (v) Responsible Conduct of Research
- (vi) Development in relevant science, technical, environmental, health and safety aspects.
- (vii) Relevant requirements of health, safety and environmental laws and regulations and related documents
- (viii) Any other topics that may emerge due to changing context and policies.
- ix) New Technologies

6.4.5 Keeping the training records

- (i) Each REC member should provide a copy of the training certificate to the administrator for archiving in the REC file.
- (ii) Sharing of training records to UNCST for continuous assessment and accumulation of credit points by UCIREC members

- (v) Individuals who fail to meet their training requirements may no longer be involved in REC work or human research. Similarly their credit points at UNCST may not meet

the minimum requirements. 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 may be re-instated when they complete their training.

6.4.6 Annual REC Committee Meeting.

- (i) The REC holds an annual meeting with the Executive Director of UCI and other staff that are concerned with research and REC operations – in particular the research and training directorate.
- (ii) It is the routine for ED to interface with UCIREC members and share their experiences as they reflect on the year's review activities. It's also a forum where discussions are held about different relevant issues, including what went well, challenges and strategies for improvement of the UCIREC operations.
- (iii) The UCI executive Director works hand in hand with the UCIREC Chair and Administrator to oversee the coordination of the annual REC Committee Meeting.

**SOP # 7.0: Determining Review category of
protocols and reports for ethical review SOP Ref
No: UCIREC 07/2023**

7.1 Purpose

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

7.2 Scope

Applies to all protocols and reports submitted to UCIREC.

7.3 Responsibility

UCIREC Administrative staff

7.4 Background

UCIREC has a mandate to conduct the following.

- i) Initial reviews,
- ii) continuing reviews,
- iii) protocol amendments,
- iv) serious adverse events,

- v) progress reports,
- vi) protocol deviations/violations of any research activities involving the use of human participants conducted by, in collaboration with or at Uganda Cancer Institute. The review process can be by:
 - i) full committee,
 - ii) expedited, fast track,
 - iii) Exempted from further REC review.
 - iv) Deferred to another REC or to UNCST
 - v) Joint review (organized by UNCST)

7.5 Procedure for Determining Review Category:

After receiving and checking for completeness of a new application or report, the REC administrator evaluates the application/report to the Chairperson to determine which category of review the application will take, using the information indicated on the application form, the chairperson reviews the protocol according to the criteria below and determines the category of review.

7.5.1 Convened review meeting

In determining applications for review by a full committee (convened), attention will be given to the following:

- (i) High risk studies (more than minimal risk studies)
- (iii) Research intended to use vulnerable populations (children, prisoners, terminally ill, prisoners, disabled, participants and the dead etc) or in case the population to be studied warrants additional protection.
- (iv) Use of placebo
- (v) Complex study designs e.g. use of artificial intelligence and genetic research.
- (vi) Drug/Device clinical trials
- (vii) Research in emergency situations
- (viii) Unethical deviation from standard of care
- (ix) Use of existing data, documents, records, pathological specimens or diagnostic specimens with personal Identifiers.
- (x) Research involving materials (data or specimens) that are readily available to the public (with special emphasis to confidentiality issues).

7.5.2 Fast track

This is a full board review category held off routine REC scheduled meetings. It reduces REC turnaround time and offers chances for timely REC approval timelines. This category of review is financed by the Principal Investigator.

7.5.3 Expedited Review Ref: CIOMS guidelines

This is the review process through which research is reviewed without convening a full board meeting. The REC Chairperson identifies 2-3 qualified and experienced members in the area of research.

- i) Research involving no more than minimal risk is reviewed expedited for example:
 - (i) Minor revisions to previously approved research e.g., Administrative changes
 - (ii) Annual renewals at the stage of data analysis
 - (iii) Research involving materials (data or specimens) that have been collected solely for non-research purposes.

The UCIREC does not grant exemptions from further review.

SOP #8.0: Calling and conducting UCIREC Meetings- SOP Ref No: UCIREC 08/2023

8.1 Purpose

To document the procedure for calling and conducting UCIREC meetings.

8.2 Scope

This SOP applies to all UCIREC activities.

8.3 Responsible persons

UCIREC Chairperson, Administrative staff, UCIREC members and Investigators.

8.4 Background

UCIREC meetings are held monthly.

Schedule of meetings may however be dictated by the number of submitted applications and need for interim meetings for a defined reason.

UCIREC meetings are conducted at the UCI boardroom. In case of change of venue, alternative space is communicated to both the investigators and UCIREC members well before the scheduled time of the meeting.

UCIREC meetings are chaired by the chairperson or the vice and in their absence; one of the UCIREC members is designated by the chairperson.

In case the chairperson/Vice/designated member has a conflict of interest, this is declared and documented ahead of time before the meeting. The individual makes a declaration and steps out of the meeting.

8.5 Procedure

8.5.1 Preparation for the meeting

The Administrator develops a listing of the complete submitted protocols for review.

The chairperson/vice determines the review category for each submission.

The chairperson/Vice together with the Administrator assign reviewers for each submission depending on the member's area of expertise.

The Chairperson/Vice may also Co-opt reviewers if there is need in the area of research.

The Administrator, using the information from the Chairperson/Vice develops a meeting agenda using UCIREC agenda template.

8.5.2 Meeting invitations

- a. The administrator confirms with REC members to determine their availability 3 weeks prior to the scheduled meeting. The Chairperson invites members for the meeting in writing by email or hard copies/soft copies are sent. The invitation includes the agenda of the meeting with the following:
 - I. Protocols for Initial applications
 - II. Protocols for Annual Renewal
 - III. Application for amendment
 - IV. Adverse Events (AEs) and Serious Adverse Events (SAEs),
 - V. Protocol deviations/Violations
 - VI. Approved Protocol monitoring reports
 - VII. Other issues (Training and any REC updates)
- b. Together with the invitation letter, UCIREC members receive all documents listed on the agenda for review 2 weeks before the meeting.
- c. In some cases, an investigator may be invited to the review meetings to present and clarify

unclear information in his/her application.
This is done in writing.

8.5.3 Composition.

UCIREC is composed of 60% of the members including a community representative nonaffiliated to UCI.

Co-opted members do not constitute a quorum.

In case a member abstains from voting he/she is used to establish quorum.

A member with conflict of interest MUST recuse him/herself from making deliberations and voting.

If a member excuses him/herself from deliberations, it is used to establish a quorum.

The Chairperson calls the meeting to order once quorum is attained. All REC members present record their names indicating the capacities by which they are attending the meeting (in person or virtual).

Any investigator invited for a face to face complete attendance log should indicate their names and capacity.

8.5.4 Conducting the meeting

The Chairperson calls the meeting to order and the agenda is reviewed for adoption or revised.

- a. Review of previous meeting minutes by all members present and necessary edits are done before final sign off by the chairperson and secretary.
- b. The research documents are reviewed according to the agenda. The primary reviewer presents their review findings followed by the secondary reviewer and then other members share their review comments as well.
- c. Decision is made by consensus and voting by show of hands whether in person or via zoom where this fails; the chairperson gives the casting vote.

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

Recording of meeting minutes: The Administrator records minutes of each meeting using the UCIREC meeting minute's template. During the meeting, the discussions are written down or recorded using an audio recorder.

After the meeting the administrator uses the recording to ensure completeness and accuracy of the meeting minutes.

The REC secretary and the Chair may also use the recorded information before finalizing and signing off the meeting minutes.

Once the meeting minutes are reviewed in the subsequent review meeting. The previous meeting minutes are deleted from the recording.

8.5.5 Decision options

The following decisions may be made after review of each protocol;

- (i) Approve
- (ii) Conditional approval/Needs minor revisions; in such a case a UCIREC member will be nominated to review the revised protocol;
- (iii) Rejected
- (iv) Resubmit/Needs major revisions i.e. change in the title, methods or objectives; in this case, the proposal may require a resubmission to the committee. Priority may be given to these at the next scheduled meeting.
- (v) Invitation for face-to-face meeting.

SOP#9.0: Review of Research Using Participants' Stored Data and Samples

9.1 Purpose

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

9.2 Scope

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

9.3 Responsible persons

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

9.4 Background

Often, human biological samples or data are obtained from patients during clinical practice or from targeted groups of research participants during retrospective and prospective studies designed to study new study outcomes or events. Such samples and data are stored

at research sites and sample repositories. The should be available at the time research is proposal development and initiated and may remain after the initial study has ended.

9.5 Procedure

This SOP outlines procedures for Scientific and ethical review of research that shall involve reviewing stored data, documents, records (soft copy or hardcopies), or biological samples collected in the past or present research. These may include medical records, school records, employment records or biological specimens that are in existence at the time the research is proposed and initiated. Such research may be retrospective or prospective record reviews or studies that look at stored biological samples.

The UCIREC may review such research following procedures provided in this SOP for scientific and ethical review (refer to SOP for determining review category).It should be noted that retrospective studies using existing materials occasionally entail significantly greater than minimal risks and require review by the convened UCIREC meeting (e.g. where the research reveals genetic results, previously undisclosed illicit behavior such as prostitution, drug

abuse or where the expedited review had concerns about infringement of participants’ privacy and/ or the adequacy of confidentiality protections proposed by the investigators)

9.5.1 Research Utilizing Existing Data Sets

When the data sets are publicly available, their use is exempt as may be determined by UCIREC.

If the existing data contains identifiable private information about a living individual, the research will require UCIREC review determination considering risk/benefit ratio. In cases of identifiable private information, UCIREC must determine whether the information can be used without additional informed consent from the targeted study 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.

9.5.2 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. Identification of the collectors of data or samples
- b. The bank/repository storage and data management Center
- c. The sharing of data i.e. recipients of the data
- d. Duration of storage of data/samples

e. Considerations of Intellectual Property Rights
UCIREC shall oversee all the activities involved in the above elements such as, setting the conditions for collection, secure storage and its duration, maintenance, and appropriate sharing of the data and/or samples, or intellectual property with external investigators.

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

- i. Determine whether the informed consent under which the samples or data was collected is adequate to cover their use in the proposed study
- ii. Determine whether the donors of the samples are traceable/identifiable.
- iii. Determine whether the repository administrators can effectively anonymize the samples/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 sample 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.

9.6 For studies conducting Genetic/Genomic research?

The Chair/Vice makes determination of the REC to review complex studies e.g. Genetics, Adaptive and complex study designs based on REC members expertise. Such Protocols may be referred to another REC or to UNCST for Joint review.

9.7 Reference(s)

Current UNCST guidelines for Human Participants research

SOP#10: UCIREC MINUTES MANAGEMENT.

10.1 Purpose

To describe the procedure of writing, recording UCIREC meeting minutes and communicating decisions made to investigators at all meetings.

10.2 Scope

Writing, recording of minutes and communicating REC decisions to investigators.

10.3 Responsibility

UCIREC chairperson, Secretary, and Administrator.

10.4 Procedure

- a. Minutes will be taken at all UCIREC meetings including adhoc meetings. Both soft and hard copies of the minutes including recordings and other UCIREC documents will be securely kept for a minimum of 20 years for clinical trials, 5 years for other non-clinical trials after the primary objectives of the study have been answered and then archived. The minutes of UCIREC meetings will include but not limited to the following:

- b. The minutes will be taken in writing and recordings format.
- c. The minutes will capture the members present, absent, minute number, the verbatim/ what was discussed and the resolution.
- d. The UCIREC administrator drafts the meeting minutes and shares it with the secretary and chairperson within one week. The secretary and the chairperson checks for completeness and accuracy of the recordings.
- e. The minute's captures: declaration for conflict of interest, study title, REC reference number, review category, deliberations, actions and decisions made for each of the applications being reviewed including amendments and protocol deviations.
- f. Meeting minutes are archived after REC member's approval during subsequent REC committee meetings.

10.4.1 Communicating decisions to investigators.

- a. Investigators whose protocols are reviewed receives communication about the REC decisions and reasons in writing, within two (2) weeks

SOP#11.0: Transfer of Human Materials

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 out of the country.

11.3 Responsibility

UCIREC members, secretariat and the investigators.

11.4 Procedure

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

11.4.1 Samples obtained with intention to conduct research

There must be a 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 specimens and any information for use in future research. The ICF should include a description of the procedure for providing results to participants which are deemed important to their health care.
- f) If future tests 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. Using sample obtained without intention for research

Identifiable specimen:—these specimens include participant details that make it possible to trace the source of the human material. In such instances, 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 (<https://www.uncst.go.ug/>)

SOP#12.0: Identification and Reporting of adverse events and Non -compliances- SOP Ref No: UCIREC 012/2023

12.1 Purpose

- i) This SOP describes the process for identification, documentation and reporting requirements and obligations in case of an unanticipated problem or adverse event in the course of human participants' research approved by the UCIREC.
- ii) Adverse events should be reported for both observation studies and Clinical trials.
- iii) 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 research reviewed by UCIREC

12.3 Responsibility

UCIREC chairperson, members, Administrator and Principal Investigators

12.4 Definitions

- a. Unanticipated Problems Involving Risks to the participants 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 describe in the approved protocol-related documents, such as the REC approved research protocol and informed consent document; and
 - (b) The characteristics of the participant population being studied.
 - (ii) Related or possibly related to a participant's participation in the research; and suggests that the research participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research that was previously known or recognized as may be detailed in the investigators Brochure.

(iii) **Adverse event (AE)** - is any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporarily associated with the participation in the research, whether or not considered related to the participant's participation in the research. Adverse events encompass both physical, psychological, economic and social harms and occur most frequently in all study designs. Adverse events that are unanticipated should be reported according to the specified protocol or this procedure.

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

a) Results in death;

b) Is life threatening, (places the participant at immediate

Risk of death from the event as it occurred)

b) 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 participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events may include but not limited to 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

g) Unexpected Adverse Event is any adverse event occurring in one or more participants in a research protocol, the nature, severity or frequency of which is not consistent with either:

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

disease, disorder or condition of the participants(s) experiencing the adverse event and the participant(s)' predisposing risk factor profile for the adverse event.

iv) Safety reports - From the perspective of one particular institution engaged in a multicenter clinical trial, External adverse Events are those adverse events experienced by participants enrolled by investigators at other institutions engaged in the clinical trial

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

The relatedness of serious adverse events and unexpected events to an intervention is

Graded as follows:

Definitely: When the event is directly caused by the intervention.

Probably: When the event is most likely explained by the research intervention but when definite proof of causality is not evident.

Possible: When explanation for event is equally due to research intervention or Other cause (experience or outcome may have been caused by the Procedures involved in the research).

Unlikely: When the event is more likely explained by another cause.

Not related: When the event is clearly due to another cause.

12.5 Management of Serious Adverse Events and Unexpected Events

- vii. The research protocol should clearly state how the researcher will identify, manage and report serious adverse events and unexpected events.
- viii. The study site clinicians make the initial assessment of relatedness of AEs to the study product. These shall be reviewed by an independent local monitor for verification of the relatedness.

- ix. Before the determination of relatedness of all AEs, care shall be provided to the research participant at the study's cost.
- x. The clinical facilities where research is going to be conducted shall be adequate and appropriately licensed for patient care.

Where a participant cannot be adequately treated at the site, the researcher shall link the participant to more advanced or specialized facilities for better management.

For AEs that are at least possibly related the study shall meet the treatment costs at the site facility and at the referral site.

- c. The investigator must properly document occurrence of serious adverse events or unexpected events using a standard format acceptable to the REC.

12.6 Reporting Serious Adverse Events and Unexpected Events

All serious adverse events and unexpected events shall be reported to the REC. reporting requirements specifically include:

- a. All serious adverse events regardless of relationship to the intervention;
- b. All unexpected events of greater than moderate severity regardless of relationship to the intervention.

All serious adverse events and unexpected events must be reported to the local REC as soon as possible and in any case no later than seven (7) *calendar* days of becoming aware of the event. A detailed report of the serious adverse event and unexpected event should be submitted within seven (7) *calendar* days from the date it is reported to the REC. A notification to the UNCST of these events should be made to the UNCST.

- Certain categories of interventions with potential long-term effects may require extended follow up and monitoring for serious adverse events. This may include investigations

involving genetically modified substances, gene therapy and DNA-based compounds.

- The extended follow up and monitoring period shall be determined by the REC on a case by case basis, but may usually be for a minimum of two years.

12.7 - Other events:

- All other reportable events are defined as unanticipated problem involving risks to participants or communities or serious or continuing noncompliance to the established national research regulatory standards.
- These could include notifiable diseases, criminal acts, deaths and life threatening events in non-clinical trial studies and any other event deemed reportable by the law and the investigator.

Other events are reported to UCIREC as soon as possible and in any case not later than fourteen (14) *calendar* days. These include:

- a. All events associated with protocol violations regardless of severity and relationship to any intervention;

- b. Reference to criteria for stopping or pausing a study as stipulated in the protocol are met
- c. Any event stipulated in the protocol as reportable to the regulatory bodies.

Note: This section on other reportable events shall apply to non-interventional studies

12.5 Procedure

- a. The Principal investigator is responsible for identifying, documenting and reporting serious adverse experiences to research sponsors, UCIREC and other regulatory bodies overseeing the research.. However, may delegate the data collection and communication of such events to appropriate clinical research personnel. The principal investigator or another investigator on the clinical study signs the SAE report for submission to UCIREC with justification.
- b. The Sponsor and the Investigator are responsible for reporting all unexpected adverse events and serious adverse events related to the research,
- c. Fatal or life threatening events are reported to the REC within 3 working days of site awareness or

- according to the study protocol and should follow the most stringent reporting timeline.
- d. All other unexpected serious adverse events should be reported no later than ten working days from the day the Investigator becomes aware of the event
 - e. The Investigator uses the Adverse Event Reporting Form for UCIREC for this reporting. Information should include the details of the event, including:
 - i) The date of event,
 - ii) Date of site awareness
 - iii) Medical history of the participant (including date screened, consented and enrolled),
 - iv) The Medicare provided by the research team and care provider for participant's safety
 - v) The event relationship to the test intervention or underlying condition,
 - vi) Action to avoid re-occurrence,
 - vii) Whether the event provides new risk information that should be added to the informed consent and protocol amendment.
 - 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 research that involves 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 relatedness.

- g. In case of deaths, the investigator or designee submits to the sponsor and UCIREC and other regulatory bodies any additional requested information.
- h. The investigator should notify UCIREC of any safety reports, DSMB reports or reports from the sponsor concerning safety from other research sites as safety reports.
- i. In 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 participants the sponsor may require the investigator to:
 - i) Discontinue the investigation and in such cases, the investigator informs UCIREC and clinical site research personnel that the study is being discontinued.
 - ii) Such reporting should be expedited; could be done by email followed by detailed reporting not later than 7 calendar days after sponsor's notification and receipt of the information of

any unexpected fatal or life- threatening experience associated with use of the intervention..

I. Return all outstanding stock of Clinical Trial Materials (CTM)

In order to resume a previously terminated study of a significant risk device, the investigator submits a request to UCIREC with justification for study resumption including sponsor communication.

12.8 Protocol Violations and Deviations

Any change in the stated procedure, activity or any provision of the protocol without prior approval except for the purposes of intervening when a person's life is in danger constitutes a protocol violation or deviation. Violations tend to be more serious than deviations. When any of these occur, the researcher shall notify the REC.

The report should contain the following information:

- a. Title of the study,
- b. Name of researcher,
- c. Organizational affiliation,

- d. Date of report,
- e. Date(s) when violation occurred,
- f. Brief description of what happened,
- g. Any effect on the study,
- h. Any adverse events arising from the violation,
- i. Management and follow up of violation and steps to avoid recurrence of the violation.

Notification to the REC and where applicable the collaborating organization's REC or any other regulatory bodies should be made by the researcher within seven (7) *calendar* days of becoming aware of the event

12.9 Reporting Non-compliance to the REC

The Principal Investigator ensures that all serious or continuing non-compliance is reported to the REC not later than 10 calendar days from date of site awareness. Such non-compliances include:

- i) Failure to obtain REC approval of human participants'

Research when required under the applicable laws and regulations.

- ii. Enrolling a research participant who does not meet the

- Inclusion and exclusion criteria in the protocol.
- iii. Failure to obtain or document informed consent process.
 - iv. Administering study 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 immediate hazards to the research participant.

12.10 How to submit an Adverse Event and Noncompliance Reports.

- i. Investigators overseen by UCIREC uses the UCIREC Adverse Event Reporting Form.
- ii. Each adverse event or record of noncompliance should be done on a separate form or report.
- iii. Incomplete forms should be returned to the investigator for
by the REC Administrator for completion.
- iv. Upon receipt of a serious adverse event report, or non-compliance report, the UCIREC administrator logs the report into the database for the study and sends a copy of the report to the Chairperson of UCIREC who may review it or designate a UCIREC member to review it.

- v. The designated UCIREC member should review the Adverse Event or noncompliance report. In case one of the Reviewers recommends a temporary suspension of a study in their opinion if continuation is likely to further expose participants to undue risk yet suspension will reduce such risk, an ad-hoc meeting should be called by the Chairperson for a consensus on the decision. However, the Reviewers cannot terminate a study. This action is reserved to a properly convened meeting of the UCIREC.
- vi. The reviewer prepares a report on the review which will be presented at the next convened UCIREC meeting.
- vii. Should UCIREC require additional information, a letter is sent to the investigator requesting for additional information.
- viii. All serious adverse events or non-compliance reports not reviewed by the designated reviewers should be reviewed by the full Board.
- x. A copy of all correspondence/reports is maintained as part of study UCIREC records.

**SOP#13.0: Conflict of Interest -SOP Ref No:
UCIREC 012/2023**

13.1 Purpose

The purpose of this SOP is to explain the guidelines for Managing conflict of interest by UCIREC members and secretariat.

13.2 Scope

This SOP covers the agreements on Conflict of Interest to be followed by UCIREC members.

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 UCIREC meeting or before accessing confidential documents of UCIREC.

13.4 Definition of COI:

A situation in which a person is in a position to derive personal benefit from actions or decisions made in their official capacity or a close personal or professional association with submitting

Investigator(s); direct participation in the research (e.g., protocol development, Principal or Co-investigator); or any significant financial interest in the sponsoring institutional, manufacturing company.

13.5 Procedure to be followed in case the UCIREC member has Conflict of Interest

- a. If it is recognized that there is potential for conflict of interest UNCSST trusts that UCIREC will ably identify and manage conflict of interest.
- b. UCIREC Chairperson identifies and manages the conflict issues so that the ultimate outcome is the protection of human participants
- c. 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.
- d. The undersigned immediately discloses to the Chairperson of the UCIREC any actual or potential conflict of interest that he/she may have in relation to any particular research submitted for review by the Committee, and to

abstain from any participation in discussions or recommendations in respect of such research.

- e. If an investigator 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.
- f. 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.
- g. When a member has a conflict of interest, the member should notify the Chairperson and should not participate in the REC review or approval except to provide information requested by the Committee.
- h. UCIREC members and staff are required to participate in education and training activities related to financial conflict of interest issues including those required by their institution.
- i. For online reviews, the declaration of COI must be checked before access to any protocol

- j. The repercussions of failure to disclose of conflict of interest will fall on the REC members.
- k. Declaration of conflict of interest is documented in the meeting Minutes per research protocol reviewed.

13.5.1 Procedures for review of protocol sections on Participant confidentiality

The UCIREC application forms include questions about privacy and confidentiality. The responses are reviewed by the UCIREC chair or UCIREC members 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, as soon as possible

once 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 a locked cabinet only accessible by the investigator, authorized staff and others like monitors and should be clear in the research protocol and consent documents.

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

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 research should include an approach

to avoid coercion and an invasion on participant's confidentiality and 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 avoiding 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.

f. The intermediary does not obtain consent from the prospective research participant but refers to the investigator for possible consent. G. g) 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.

h) Use of public list: When the investigator obtains names through a publicize e.g. telephone book), the name of the source should be included in the approval letter.

g. Use of Questionnaires, scales, inventories, and interviews: A description 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 approved 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.

Use of records: photographs, films, video tapes , and Audiotapes:

All information to a participant in any form should be submitted, reviewed and approved by the REC members. 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

ii) Potential participant should be notified about intended use,

Storage and destruction

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 in writing unless required by law.

SOP#14.0: Monitoring and Evaluation SOP Ref No: UCIREC 014/2023

14.1 Purpose

This SOP describes the procedures relating to monitoring of Human Participants research approved by UCIREC. It describes monitoring 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

14.4 Procedures

14.4.2 Study Monitoring Reviews

UNCST mandates all RECs to monitor reviewed and approved research Studies.

Types of Monitoring:

- i) Routine monitoring as stipulated in the UNCST guidelines.
- ii) For cause: due to participant's complaint, Whistleblower or based on submitted reports and non-compliance by the investigator } or.

iii) Passive monitoring

- i. Relies on reports submitted by the investigators. UCIREC administrative staff are responsible for entering and maintaining a list of all studies approved.

Procedure:

- i) The UCIREC Administrator compiles a list of studies approved by UCI REC.
- ii) In collaboration with the Chairperson, the administrator generates and sends notification letters reminding the investigator to submit their progress report at least 4 weeks before expiry.
 - xi. The expected response will include a completed UCIREC application forms as specified in each Submission type.

b. Active monitoring

- i. May be routine or prompted by repeated protocol violation or reported research deficiencies of approved research.
- ii. The Chairperson of UCIREC in consultation with the REC members and the administrative staff randomly selects sites that are to be monitored for routine monitoring at a least a month before the date of the visit.
- iii. For each site selected, the Chairperson assigns two or three members of UCIREC to conduct the site visit.
- iv. The Chairperson UCIREC informs the investigator in writing, about the planned visit indicating the date.
- v. The selected UCIREC members conduct the site visit and carries out the monitoring using M&E checklist (Refer to UNCST 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 initiates a site monitoring visit within no more than 14 days from the day of awareness.

- i. The Chairperson or his/her designee, together with at least two other UCIREC members conducts the site monitoring visit.
- ii. The monitoring team holds a meeting prior to the visit to discuss the reported deficiency and come up with a monitoring plan.
- iii. Depending on the gravity of the deficiency (as determined by the REC members) and the time available, the investigator may or may not be notified about the intended visit
- iv. The UCI monitoring team visits the site and makes 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 targeted participants. The frequency of such visits

depends on the magnitude of risk such research presents.

(ii) The administrative staff generates a list of studies that are scheduled for site monitoring and presents it to the UCIREC Chairperson.

(iii) The Chairperson UCIREC writes to the investigator about the planned visit indicating the date and areas the visit is likely to focus on.

c) During the inspection

The monitoring team will do the following:

(i) The team holds an introductory meeting with the investigator and study team staff and requests for:

(ii) A copy of the approval letter including all correspondences with the REC.

(iii) The version of protocol approved together with its appendices.

d). Action to be taken after Monitoring Visits

After the monitoring visit:

i) 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

ii) The monitoring team compiles the report and through the REC administrator is sent to the chairperson of UCIREC for review and action plan.

iii) The Chairperson shares the report at the subsequent convened UCIREC meeting.

(iii)The report is discussed and decisions made by the committee.

(iv) The administrative staff communicates the decisions of the committee to the investigator within 2 weeks after the combined REC meeting.

(v) May decide to withdraw approval, suspend study activities pending further scientific and Ethical decisions in consultation with UNCST & NDA where applicable.

(vii) The monitoring report may be shared with UNCST

15.0 appendices

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; participant to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use research Confidential Information for any purpose outside the UCIREC 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 UCIREC roles 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 a 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 UCIREC 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 Recipient

Date

