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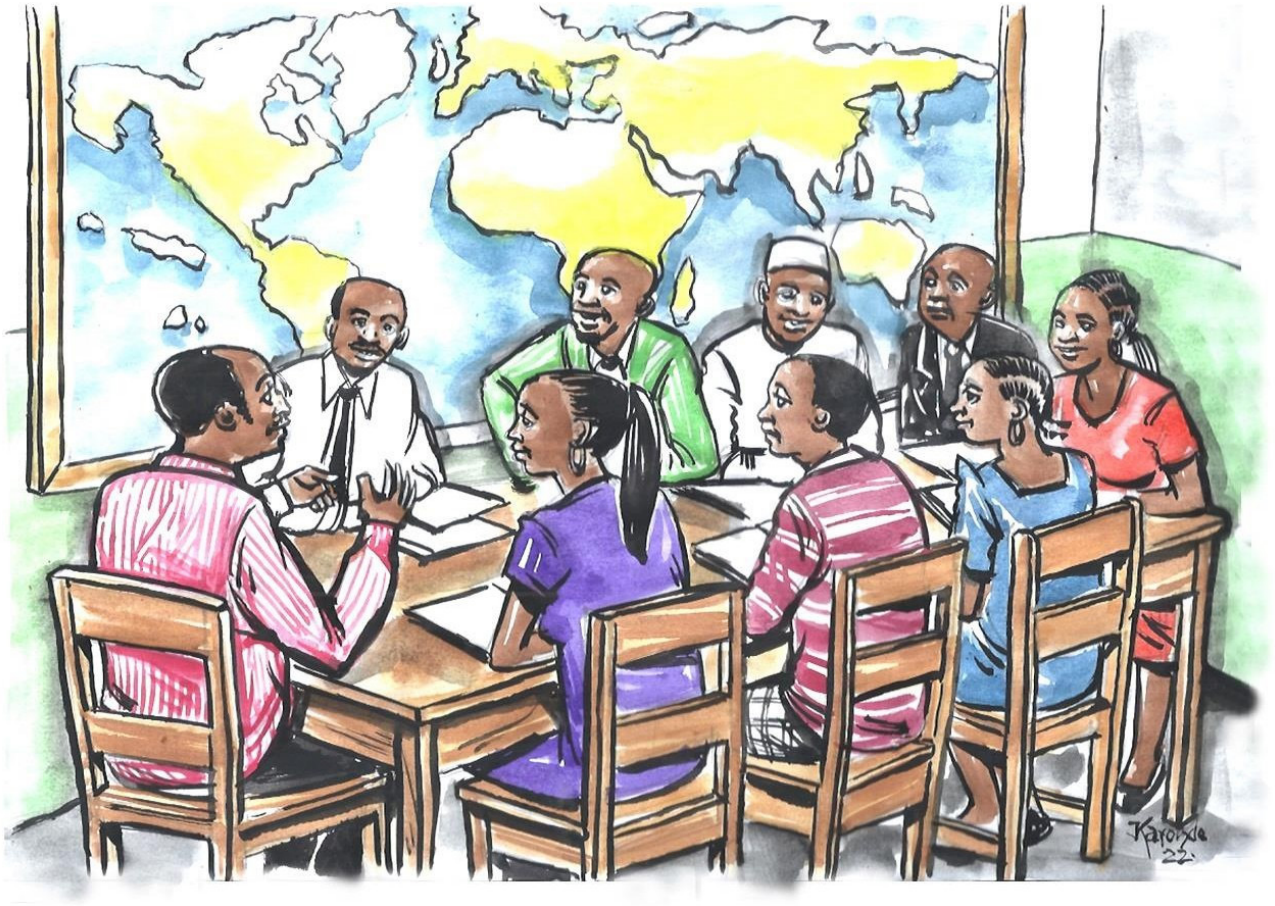

NATIONAL GUIDELINES FOR JOINT SCIENTIFIC AND ETHICAL REVIEW OF RESEARCH

SEPTEMBER 2025

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TABLE OF CONTENTS

HON. MINISTER'S STATEMENT

The Government of Uganda recognizes Science, Technology and Innovation (STI) as a cornerstone of national transformation and a central driver of the Ten-Fold Growth Strategy, as articulated in Vision 2040 and the Fourth National Development Plan (NDP IV). Achieving this ambition demands a robust, predictable, and well-coordinated research and regulatory ecosystem: one that upholds scientific integrity, ethical conduct, and public safety, while simultaneously enabling innovation, industrial scale-up, and competitiveness of Ugandan technologies in regional and global markets.

The National Guidelines for Joint Scientific and Ethical Review of Research (JoSER) mark a significant milestone in strengthening Uganda's research governance and innovation architecture. By institutionalizing collaboration and coordination among regulatory agencies, research institutions, and key stakeholders, the JoSER framework reduces fragmentation, eliminates duplication, and shortens approval timelines. This joint review mechanism improves regulatory efficiency and certainty, critical enablers for investment in research, product development, clinical trials, and commercialization, thereby accelerating the translation of scientific knowledge into safe, high-impact solutions that support socio-economic transformation and industrial growth.

In the context of Uganda's STI agenda, JoSER functions as both a governance reform, and a strategic economic instrument. Efficient and harmonized scientific and ethical review lowers transaction costs for innovators, manufacturers, and investors; de-risks research and development; and strengthens Uganda's attractiveness as a destination for advanced research, clinical trials, and technology-intensive industries. This is particularly critical for high-value sectors such as pharmaceuticals and biotechnology, medical devices, digital health, agri-biotechnology, and emerging data-driven technologies that are expected to contribute significantly to productivity growth, exports, and high-skilled employment.

Aligned with the global health security and innovation agenda championed by the World Health Organization and the Africa Centres for Disease Control and Prevention, Uganda remains committed to building resilient, responsive, and trusted research systems. The JoSER framework strengthens protection of research participants, promotes accountability, and enhances institutional coordination across agencies mandated to regulate scientific research, ensuring that speed, safety, and ethics advance together.

The institutionalization of joint scientific and ethical review further ensures that innovations originating from Uganda comply with regional and international regulatory expectations, including those of the European Medicines Agency and the United States Food and Drug Administration. This regulatory alignment is essential for enabling Ugandan products, therapies, and technologies to access global clinical trial networks, supply chains, and markets, thereby supporting export diversification, technology transfer, and participation in global value chains.

I commend the Uganda National Council for Science and Technology, the Uganda National Health Research Organization, the National Drug Authority, and all collaborating partners for their unwavering commitment to advancing ethical, high-quality, and internationally credible research. Through the implementation of the JoSER Guidelines, Uganda reaffirms its leadership in science-based regulation, leveraging regulatory excellence as a catalyst for innovation, industrialization, investment, and sustainable development under the Ten-Fold Growth Strategy.

Hon. Dr. Monica Musenero Masanza
Minister for Science, Technology and Innovation
Office of the President
The Republic of Uganda

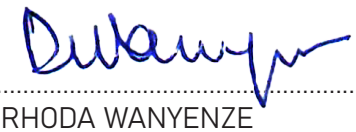
FOREWORD

In the rapidly evolving landscape of scientific research, ensuring the integrity, ethical standards, and societal relevance of research activities is paramount. As Uganda continues its journey towards establishing itself as a hub of scientific excellence, it is imperative that we establish a robust regulatory framework for Science, Technology and innovation to safeguard the rights and welfare of research participants and research subjects. By offering clear and consistent procedures for regulating research, the UNCST intends to enhance the quality of review of research proposals, that provides researchers, sponsors and research regulators with information that will facilitate and fast track the process of submission, and review of research applications in preparation for the mandatory research oversight and clearance process in the country.

The Joint Scientific and Ethical Review Guidelines have been developed to provide a comprehensive framework that supports researchers, Institutional committees, and other stakeholders in navigating the complex ethical and scientific considerations inherent in research activities. They represent a collaborative effort between various stakeholders, all of whom share a commitment to advancing knowledge while safeguarding the well-being of research participants and research subjects.

It is my hope that the guidelines will serve as a valuable resource for all those involved in the research regulatory process, individuals intending to conduct research by providing clarity and guidance as they prepare to over see and conduct research in Uganda. By adhering to these guidelines, we can collectively contribute to the advancement of research in Uganda that meets the highest standards of scientific and ethical rigor while upholding the principles of respect, justice, and responsibility that are at the core of ethical conduct of research.

I commend the efforts of all those who have contributed to the development of this important document and encourage all stakeholders to embrace these guidelines as a foundation for the ethical conduct of research in Uganda and urge researchers, research institutions, and Institutional committees to embrace these guidelines and work together to create a research landscape that benefits both our nation and the global scientific community.



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PROF. RHODA WANYENZE

Chairperson, UNCST Council

PREFACE

The Uganda National Council for Science and Technology (UNCST) is mandated to facilitate and coordinate the development and implementation of policies and strategies for integrating Science and Technology (S&T) into the national development process. To achieve this, the UNCST has developed and implemented several guidelines to promote ethical conduct of research. The UNCST together with the Uganda National Health Research Organization (UNHRO) and National Drug Authority (NDA) are pleased to present these guidelines for joint scientific and ethical review of research in Uganda.

The development of the guidelines was informed by the increasing need to provide facilitatory regulatory environment for the Science, Technology and Innovation eco system. As Uganda continues to advance in scientific research across various fields, it is essential that this progress is guided by robust ethical standards and scientific rigor. The UNCST appointed a multidisciplinary National Taskforce to lead the process of development of the national guidelines which was informed by global best practices, adapted to the unique cultural, social, and economic context of Uganda, ensuring that they are relevant and effective.

The guidelines have been developed in line with the African Vaccine Regulatory Forum (AVAREF) of the World Health Organization (WHO), national and international documents, and they intend to enhance the quality of the joint review of research proposals and provide researchers, sponsors and research regulators with information that will facilitate and fast track the process of submission, and review of research applications in preparation for the mandatory research oversight and clearance process in the country. The review of the guidelines is expected to be a continuous process, intended to take care of new advances in research as they emerge.

The UNCST is grateful to UNHRO, NDA and other stakeholders who were involved in the development of these guidelines. We highly value your ongoing support and look forward to continued collaboration as we promote scientific and ethical conduct of research in Uganda.

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Executive Secretary,
Uganda National Council for Science and Technology

ACKNOWLEDGEMENT

The Uganda National Council for Science and Technology (UNCST) is grateful for the contribution from the government of Uganda through Ministries, Departments and Agencies including: Science, Technology and Innovation Secretariat-Office of the President (STI-OP), Ministry of Health, Ministry of Justice and Constitutional Affairs, Ministry of Finance, Planning and Economic Development, Uganda National Health Research Organization (UNHRO) and the National Drug Authority (NDA). The UNCST recognizes the financial support from the Global Health EDCTP3 Joint Undertaking through the Strengthening Clinical Trial Regulatory and Ethical Review Oversight in East Africa (Access Africa II) Project that enabled the completion of the review and publication of these guidelines.

Sincere appreciation is extended to research institutions, Research Ethics Committees (RECs), Institutional Animal Care and Use Committees (IACUCs), National Biosafety Committee (NBC), academia and all the stakeholders who have contributed towards the successful development of these guidelines. UNCST is particularly thankful to the members of the National Task Force (NTF) for their honorary contribution of time and technical expertise in the development of these guidelines. The members include; Dr. Francis Bajunirwe (Chairperson), Ms. Hellen Opolot, Dr. Samuel Okware, Dr. Helen Ndagijje Byomire, Prof. Noah Kiwanuka, Prof. Stella Neema, Dr. Hannah Kibuuka, Dr. Frederick Nelson Nakwagala, Dr. Racheal Kyeyune Bakyayita, Prof. Pauline Byakika Kibwika, Assoc. Prof. Lawrence Mugisha, Ms. Dorcas Lamunu, Dr. Christopher Ddamulira, Ms. Beth Mutumba Mutebi, Ms. Winfred Nazziwa and Mr. Musa Kwehangana.

ACRONYMS

AVAREF	African Vaccine Regulatory Forum
CRO	Contract Research Organization
CTAs	Clinical Trial Applications
FRECU	Forum for Research Ethics Chairpersons in Uganda
GCP	Good Clinical Practice
IACUCs	Institutional Animal Care and Use Committees
IBCs	Institutional Biosafety Committees
IC	Institutional Committees
JoSER	Joint Scientific and Ethical Review
LMICs	Low- and Middle-Income Countries
LOQ	List of Comments/Questions
MDAs	Ministries Departments and Agencies
NBC	National Biosafety Committee
NCD	Non-Communicable Disease
NDA	National Drug Authority
NRA	National Regulatory Agency
NTF	National Taskforce
PHEIC	Public Health Emergency of International Concern
R&D	Research and Development
RECs	Research Ethics Committees
SOPs	Standard Operating Procedures
UNCST	Uganda National Council for Science and Technology
UNHRO	Uganda National Health Research Organization
WHO	World Health organization

DEFINITIONS

Convener: The UNCST is the convening entity responsible for organizing the joint review and for ensuring that the agreed upon process is respected.

Institutional Committee (IC): This collective term refers to institutional committees accredited by the UNCST and established with the various institutions. These shall include Research Ethics Committees (RECs), Institutional Animal Care and Use Committees (IACUCs), Institutional Biosafety Committees (IBCs), and the National Biosafety Committee (NBC).

Invited reviewers/ Interested Parties: These include representative subject matter experts and appropriate stakeholders in a particular field. The reviewers may include but not limited to disease- specific experts, policy makers, community members, statisticians or individuals with relevant expertise.

Joint Monitoring: is the act of overseeing the progress of a study, and of ensuring that it is conducted, recorded, and reported in accordance with the proposal, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s). The process shall be conducted by representatives of the joint review committee including NRAs, IC's subject matter experts and appropriate stakeholders that were involved in the joint review process.

Joint Inspection: is the act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the study and that may be located at the study site, at the sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

Joint Review Committee: A group of persons appointed by the UNCST and tasked to perform a joint scientific and ethical review.

Joint Scientific and Ethical Review (JoSER): The process of reviewing a research application jointly at a convened meeting by the NRAs (UNCST, UNHRO and NDA), ICs, persons with subject matter expertise and appropriate stakeholders in a given field. This review mechanism is not intended to replace the existing regulatory research oversight process as outlined in the National research guidelines and existing regulatory framework, but rather to optimize review timelines and quality of review.

National Regulatory Agencies: National competent authorities that have the legal mandate and power to regulate the conduct of research studies in Uganda and these include UNCST, UNHRO and NDA.

Principal Investigator: Is the individual responsible for the conduct and oversight of a research project. Such an individual is qualified by education, training and experience to conduct the research study. When a team of individuals conducts a research study, the responsible leader of the team is the principal investigator. In international collaborative research, the local Principal Investigator will be required to make application for a JoSER.

Research: Is a systematic investigation, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Sponsor: An individual, company, institution or organization that takes responsibility for the initiation, management, and/or financing of a research study.

1.0 General Provisions of the Guidelines

1.1 Introduction

The UNCST provides oversight for research ethics and research regulation. The UNCST Act CAP 209 (CAP 211 as amended) mandates UNCST to act as a clearing house for all information on research and experimental development in Uganda. As a national agency with the oversight role for research and development in Uganda, establishing a research governance system is paramount to national development. UNCST serves as a one-stop center for coordination of all research implemented in the country in accordance with relevant international, regional and national guidelines.

Research often involves multiple stakeholders and may entail studies with complex research methodologies and interventions. Examples include international and multiple site clinical trials, novel therapeutic agents and research in public health emergencies. For such studies, the National Regulatory Agencies (NRAs) have traditionally convened a Joint Scientific and Ethical Review (JoSER). In this mechanism, the UNCST, constitutes a panel comprised of subject matter experts, members of Institutional Committees (ICs) and National Regulatory Agencies to perform a joint review. The advantage of this approach is that it shortens the turnaround time of the approval process, provides quality review and shared understanding of the proposal under review among the stakeholders involved in the review process. Although this JoSER process has demonstrated success, there have been limitations due to the absence of comprehensive guidelines regarding; how the process should be initiated, who should initiate the process, the criteria for research that should be reviewed jointly, joint monitoring and inspection, review components and communication of results.

The guidelines set forth a framework for which NRAs, ICs, subject matter experts and appropriate stakeholders in a given field shall consider while submitting proposals and conducting such reviews.

1.2 Rationale

In the past two decades, the number of research proposals registered at UNCST has grown four-fold. Significant growth has especially been observed in the fields of health, agriculture and environmental sciences, physical and biological sciences, humanities and social sciences, industrial and engineering sciences, and information sciences. This growth may be attributed to evolving patterns in science, technology, disease burdens which call for advanced research, emerging academic and research institutions as well as the increased international research collaborations in the country.

The growth has been observed not only in the number of research proposals, but also in their complexity, which often requires review by a multi-disciplinary approach. Feedback from a review process involving multiple regulatory bodies poses unfavorable timelines for ethical and regulatory approvals, especially for time-sensitive projects such as research during public health emergencies. These reviews are sequential, time consuming and may also present challenges with respect to the quality of review. In addition, multiple sequential review processes may produce different or even contradicting results and/or decisions from the respective regulatory bodies thus demonstrating the importance of developing a joint review mechanism.

Considering the above, UNCST, UNHRO and NDA have developed these guidelines to provide a framework for which together with relevant Ministries, Departments and Agencies (MDAs), ICs, subject matter experts and appropriate stakeholders in the different disciplines shall use while conducting Joint Scientific and Ethical Review (JoSER). These guidelines provide a road map to the research regulators, researchers, sponsors and other stakeholders on the JoSER mechanism.

The JoSER process is intended to enhance the quality of the review, optimize review timelines, serve as a platform to allow regulators and ICs to exchange and validate their findings about the application as well as act as a capacity strengthening platform.

1.3 Scope

These guidelines apply to all research that qualify for JoSER in Health, Agriculture and Environmental Sciences, Physical and Biological Sciences, Humanities and Social Sciences, Industrial and Engineering Sciences, and Information Sciences.

2.0 The Role of the National Regulatory Agencies

Three regulatory agencies namely NDA, UNHRO and UNCST have specific mandates for the regulation of research in the country: The specific clauses relevant to their operations with regard to oversight of research studies are described below:

a. The National Drug Authority under section 40 of the NDA Act 1993 mandates it "to issue a certificate to any person for the purpose of carrying out clinical trials in respect of a drug that may be specified in the certificate". No person may carry out any clinical trial in respect of any drug unless he or she is in possession of a certificate issued under this law.

b. The Uganda National Health Research Organization is mandated to "appraise scientifically and ethically and give approval to all research proposals related to health, before the commencement of any biomedical or other health-related research" (UNHRO Act 2011 -Art 6(e); 16(e)" (UNHRO Act (art 6 (2). For expediency, this process will jointly be processed at the UNCST secretariat as discussed below through a joint mechanism.

c. The Uganda National Council of Science and Technology is mandated under the UNCST Act to "act as a clearing house for information on research and experimental development taking place in scientific institutions, centres and other enterprises and on the potential applications of their results; and to work in close cooperation with and co-ordinate all scientific and technological activities of persons, institutions, sectors and organizations".

3.0 Responsibilities and Composition of Participants in Joint Scientific and Ethical Review

a) Convener (UNCST Secretariat):

The UNCST Secretariat will coordinate the JoSER and be present during discussions regarding the research application under review. In particular, the UNCST shall:

i. Coordinate with all stakeholders to identify their representatives to the JoSER and communicate a date for the review meeting

ii. Distribute the research application package to the review committee

iii. Respond to any request for advice or guidance by reviewers or PI involved in the JoSER.

iv. Provide an appropriate platform for the exchange of information between the review committee and the researchers as part of the review process.

v. Nominate a chairperson who will preside over the JoSER meeting. The chairperson of the JoSER shall not be the chairperson of the IC of record.

vi. Compile the List of Comments/Questions (LOQ) from the JoSER and communicate these to the PI. Formally sign off any correspondence to the researcher and or sponsor that arises out of any activity conducted by the JoSER committee

vii. Conduct continuing assessment of the research study including a plan for onsite monitoring of the study.

viii. Coordinate any other post-approval processes that may require joint review such as applications for renewal, amendment and critical notifications such as termination of the study, study halts etc.

b) National Regulatory Agencies

The NRAs shall in accordance with their mandate:

i. Participate in the pre-screening of the submitted documents in a timely manner.

ii. Nominate suitable representatives to the JoSER meeting.

iii. Review the research application package submitted by the Principal Investigator (PI) ahead of the JoSER.

iv.Raise comments and/or recommendations (if any) to the PI for response.

v. Issue a regulatory decision to the PI in line with the NRA Institutional procedures.

vi. Conduct continuing review of the research study. The NRA may participate in a joint inspection and/or monitoring of the approved study upon request by the UNCST.

vii. Undertake any other relevant task and assignment in relation to JoSER process.

c) Institutional Committees

The committees shall:

i. Provide recommendation for the submission of the proposal to UNCST for consideration for JoSER.

ii. Participate in the pre-screening of the submitted documents in a timely manner.

iii. Ensure quorum of its committee for the JoSER meeting.

iv. Review the research application package submitted by the PI ahead of the JoSER.

v. Review the final proposal developed and/or revised by the PI after the JoSER meeting at a convened meeting, and notify the PI in writing about the outcome (approval or rejection) of the review so that he/she can proceed to the UNCST for registration and the NDA (where applicable) to obtain a certificate for conduct of the clinical trial.

vi. Where necessary, request content experts from the JoSER meeting to review responses to the comments from the JoSER.

vii. Issue approval of the study where applicable.

viii. Conduct continuing review of the research study including a plan for onsite monitoring of the study.

ix. The committee may participate in a joint monitoring of the approved study.

d) Invited reviewers and Interested Parties:

Subject matter experts and Interested Parties shall be identified by the UNCST in collaboration with the NRAs to provide additional information in the given field of research. They shall also raise relevant queries on the submission.

e) PI and sponsors: The PI and where applicable sponsors shall:

i. Submit a request for JoSER to the IC of record.

ii. Provide and submit in a timely manner all the necessary documents for the study for review.

iii. Attend the JoSER meeting, make a presentation providing an overview of the study and provide any clarification to the JoSER during the open session of the meeting.

iv. Respond to the list of comments raised by the JoSER meeting and formally submit these responses in a timely manner.

v. Cover the administrative costs of the meeting.

NB: The JoSER shall be constituted according to the field of study in the proposal. The following NRAs maybe involved: NDA, UNHRO and UNCST with a minimum of one (01) person per NRA as required. Based on the nature of the proposal, subject matter experts and representatives from other MDAs shall be invited.

4.0 Criteria for Joint Scientific and Ethical Review

Submission for joint review may be investigator initiated, NRA or IC initiated. The criteria below may be assessed in combination or individually. Consideration for joint review may include but is not limited to research on the following:

a) New and complex study designs.

b) Invasive and/or investigational medical devices intended to treat, diagnose or prevent disease.

c) Research in Public Health Emergencies.

d) Innovative treatments, investigational products or procedures for diseases. This could include new investigational products or registered products proposed for a new indication.

e) Unregistered product with limited information on its use in humans, animals or plants in terms of risks and benefits

f) New and emerging technologies with limited information on their use in humans, animals or plants in terms of risks and benefits

g) Emerging and re-emerging infectious agents and toxins

h) Potentially hazardous material such as radioactive material

i) Genetic testing and modification in humans, plants, organisms and animals

j) Invasive and endangered species

k) Use of human stem cells or fetal tissues in the prevention, treatment and diagnosis of disease.

l) Use of complementary and alternative medicinal products in research for the prevention, treatment and diagnosis of diseases. This includes but is not limited to the use of herbal medicinal products, ayurvedic medicine, naturopathic medicine, body-based practices such as reflexology as part of research.

m) Any other reason as deemed necessary by the ICs and/or NRAs

These criteria are assessed based on Appendix A of this document. The final decision on whether a study is eligible for JoSER is made by the UNCST, based on the assessment by the IC and/or any other reason as determined by the NRAs.

5.0 Joint Scientific and Ethical Review Process

PI initiated: The proposal to initiate a JoSER shall be made by the PI through the IC of record. The initiation will be through the completion of the assessment form (Appendix A) along with the full proposal and all required supporting documents. The chairperson of the IC of record will conduct a preliminary review to determine the eligibility for JoSER. The chairperson will make a decision on whether to proceed to JoSER and communicate to the PI and the UNCST. The final decision on eligibility for JoSER shall be made by UNCST in consultation with the relevant NRAs.

IC initiated: A request for a JoSER may be made by the IC of record. The UNCST in consultation with the relevant NRAs, makes determination for the joint review. The UNCST will then request the PI to submit the additional documents via the portal for the JoSER process.

The joint review mechanism does not intend to replace the existing regulatory research oversight process as outlined in the National Research Guidelines.

5.1 Procedure for Joint Scientific and Ethical Review of Research Applications

a) Pre-consultation: A researcher shall make consultations with the chairperson of the IC prior to submission of the research application via the portal for pre-screening.

b) Prescreening: The prescreening shall take maximum of three (3) working days. After pre-screening of the documents by the NRAs, ICs, administrative comments together with the scheduled date and program for the joint review shall be sent to the applicant within three (3) working days. The request for JoSER may be rejected or accepted.

c) Scheduling the meeting: A research application submitted through the portal, once accepted shall be shared with the NRAs and relevant subject matter experts and Interested Parties. The UNCST in collaboration with the NRAs shall identify subject matter experts and Interested Parties and notify them about the review meeting. In addition, nomination of the IC membership shall be made by the chairperson of the IC of record and names forwarded to the UNCST. This process shall be completed within the three (3) working days.

d) Conduct of a JoSER Meeting: Following identification of reviewers, a joint review meeting will be convened by UNCST within ten (10) calendar days. The UNCST appoints a Chairperson to oversee the review meeting, which commences once a quorum is established, including members of the Institutional Committees. Prior to start of the meeting, all reviewers shall be required to have signed a Confidentiality Agreement and Conflict of Interest declaration forms, copies of these are attached in appendices B and C. All reviewers shall be expected to read and review the application package ahead of the JoSER meeting.

The PI together with his/her selected research team members shall be in attendance. The PI will be required to make a presentation about the study during the meeting to clarify on aspects of the proposal and other documents that might not have been clear to the reviewers. Following the presentation, the review panel convenes privately to discuss and harmonize feedback. Subsequently, the review team and investigators reconvene for a debriefing on the outcomes of the joint scientific and ethical review. The meeting may be held virtually, physically or in a blended mode depending on prevailing circumstances. The decision on the application as either rejection or conditional approval will be made by the JoSER committee.

e) Review of revised proposal and relevant documentation by IC: The UNCST will submit a consolidated list of comments from the joint review within three (3) days after a convened meeting. The PI together with his or her team shall submit a formal response to the comments received at the JoSER and thereafter, submit a cover letter and required documentation to the local IC for decision making. The IC will convene a meeting to review the responses within five (5) working days. The IC shall not undertake re-review of the proposal to generate new comments.

The IC may co-opt some of the experts who took part in the JoSER to review the responses and make decision on whether to reject or approve the proposal. Where an IC fails to reach a conclusion, the Chairperson may request UNCST to reconvene JoSER to provide recommendations that may facilitate decision making on the proposal. The outcome of the Review by the IC may result in approval or rejection of the proposal. In case the proposal is approved, the PI will submit it to the relevant NRAs for regulatory approval.

f) Review by NRAs: Submission of approved documents shall be made by the PI to the UNCST and where necessary made in parallel to the NDA after IC approval. The PI shall make an online registration of the research study within the UNCST research portal for clearance. The UNCST in collaboration with UNHRO shall review the documentation for completeness within two (2) working days after which a research permit may be issued.

The NDA shall review the Clinical Trial Application (CTA) and provide a regulatory decision within five (5) working days after which a certificate may be issued. It should, however, be noted that a clinical trial certificate shall be granted after obtaining a research permit from the UNCST.

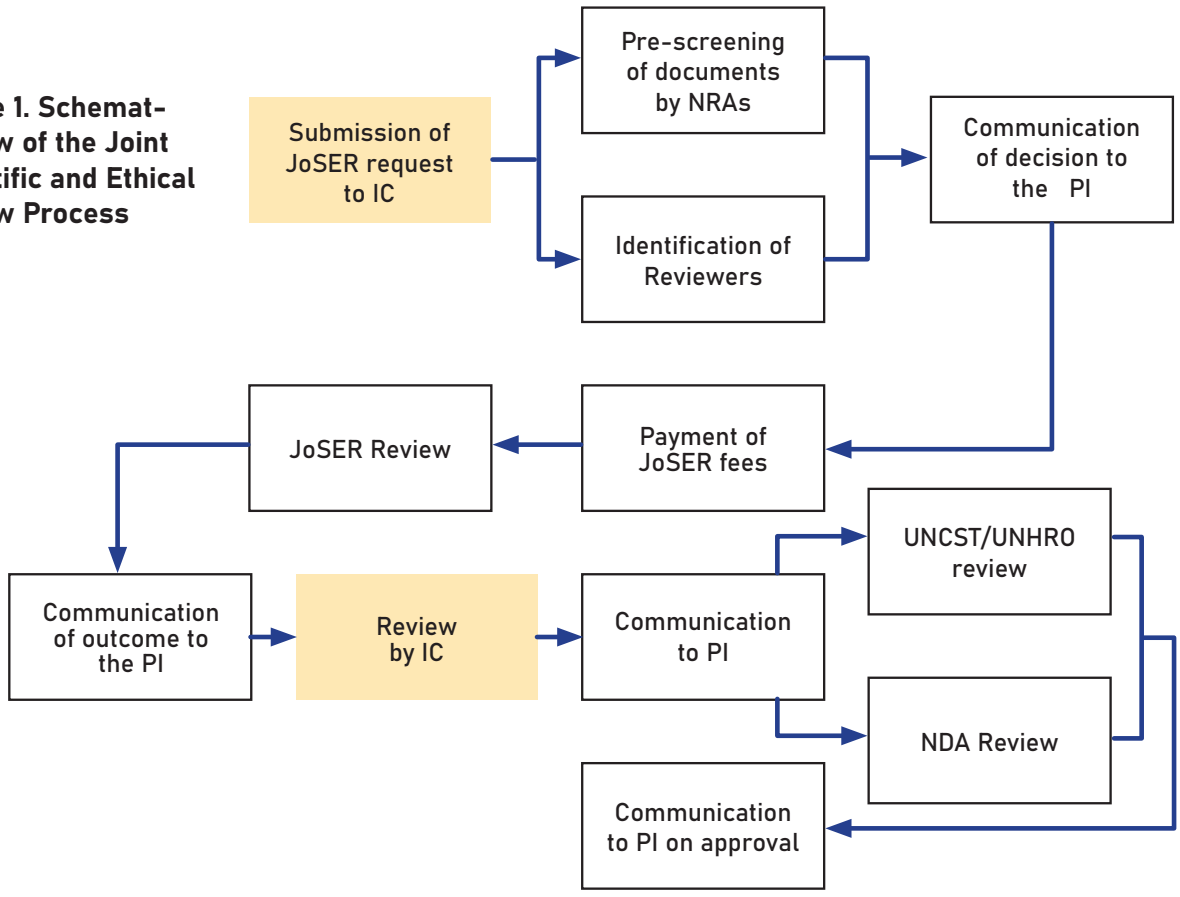
g) Review of Amendments: Any amendments shall be submitted to the IC. The IC shall co-opt at least two (2) members from the JoSER committee in case of any major amendments to the previously JoSER reviewed proposal.

Appeals: A researcher who is dissatisfied with JoSER's decision may appeal to the Executive Secretary of the UNCST within fifteen (15) days from the date of receipt of decision. The UNCST together with the relevant regulatory bodies shall carry out an independent review and make a final decision.

A researcher who is dissatisfied with the IC's decision may appeal to the Executive Secretary of the UNCST within fifteen (15) days from the date of receipt of IC decision. The UNCST shall carry out an independent review in collaboration with other regulatory bodies where applicable.

The summarized procedure is shown in the schema figure 1 below and involves the following steps:

Figure 1. Schematic Flow of the Joint Scientific and Ethical Review Process



6.0 Administrative Fee Structure for Joint Scientific and Ethical Review Process

Research proposals submitted for joint review will require reviewers to dedicate time and effort out of the routine schedule of their institutions to fast-track the review of the application package and provide high level recommendations. Each of the reviewers shall be compensated for their time and effort. These fees are to be paid by the Sponsor/PI and excludes the fees at the respective NRAs and ICs. They may vary from time to time depending on administrative circumstances. The JoSER shall be held at the NRA offices unless the sponsor/PI prefers otherwise. The necessary preparations for the meeting which include logistics, are catered for by the sponsor/PI.

7.0 Monitoring/Inspections by the National Regulatory Agencies

The NRAs and ICs shall make efforts to conduct on-site monitoring/inspections of approved studies across the country with the aim of promoting ethical conduct of research in line with the relevant research guidelines and regulations. Monitoring/Inspection is important because it ensures adherence to the approved proposal and minimizes risk for unethical conduct of research.

The UNCST may coordinate a joint monitoring/inspection where necessary. The UNCST shall convene the NRAs, relevant IC and communicate to the PI about the intended inspection. The monitoring/inspection of the research site will be conducted with the relevant representatives after which a report will be submitted to the PI within twenty-one (21) days from the date of the inspection. The PI shall be required to provide a response to the observations and or non-compliances (as applicable) within fourteen (14) days from receipt of the report.

Proposals approved through a joint review process may be inspected and/or monitored through a joint inspection by UNCST, UNHRO, NDA and ICs

8.0 Conclusion

These guidelines are intended to streamline and ensure the smooth completion of the JoSER process. All participants in the JoSER process are expected to comply with the provisions of these guidelines. It is expected that all participants in the JoSER review comply with the specific decisions made during the JoSER process.

APPENDICES

APPENDIX A: ASSESSMENT FORM FOR PI INITIATED REQUEST FOR JoSER

Section A:		
1.	Name of PI	
2.	Telephone contact	
3.	Email	
4.	Institution of affiliation	
5.	Institutional Committee (REC/IACUC/NBC/IBC) of record	
6.	Title of proposal	
7.	Proposal version date and Number	

Section B: Classification of study (Mark all that apply)		
1.	Health and Medical Sciences	
2.	Social Sciences and Humanities	
3.	Engineering and Technology	
4.	Agricultural Sciences	
5.	Natural Sciences	

Section C: Type of Study Design		
1.	Cross sectional study	
2.	Case Control Study	
3.	Cohort study	
4.	Ecological study	
5.	Experimental study	
	Others (Specify):	

Section D: Reason for Joint Review (Mark whatever applies to the study)				
a)	Research involving uncommon and complex study design	h)	Emerging and re-emerging infectious agents and toxins	
b)	Invasive and or investigational medical devices intended to treat, diagnose or prevent disease.	i)	Potentially hazardous material such as radioactive material	
c)	Research in Public Health Emergencies	j)	Unregistered product with limited information on its use in humans, animals or plants in terms of risks and benefits	
d)	Innovative treatments, investigational products and procedures for diseases. This could include new investigational products or registered products proposed for a new indication.	k)	New and emerging technologies with limited information on their use in humans, animals or plants in terms of risks and benefits	

e)	Invasive and endangered species	l)	Genetic testing and modification in humans, plants, organisms and animals	
f)	Use of human stem cells or fetal tissues in the prevention, treatment and diagnosis of disease	m)	Use of complementary and alternative medicinal products in research for the prevention, treatment and diagnosis of diseases. This includes but is not limited to the use of herbal medicinal products, ayurvedic medicine, naturopathic medicine, body-based practices such as reflexology as part of research.	
Other (provide brief justification for requesting a JoSER): ……				
Section E: Decision to be determined by the IC chairperson/designee				
Recommendation for Joint review (mark where applicable) Yes No				
Joint review mechanism (comments for either decision above)				
Name of the IC Chairperson/designee: …… **Signature**:……**Date (dd/mm/yy):**…….				

APPENDIX B: CONFIDENTIALITY AGREEMENT

In the course of participating in this review as an expert adviser under this Agreement, you will have access to certain information, which is proprietary to research application. You undertake to treat such information (hereinafter referred to as "the Information") as confidential.

In this case you agree:

a) not to use the Information for any other purpose than discharging your obligations under this Agreement; and

b) not to disclose or provide the Information to any person who is not bound by similar obligations of confidentiality and non-use as contained herein.

However, you will not be bound by any obligations of confidentiality and non-use to the extent that you are clearly able to demonstrate that any part of the Information:

a) was known to you prior to any disclosure by UNCST and/or the sponsors or manufacturer(s); or

b) was in the public domain at the time of disclosure by UNCST and/or the sponsors or the manufacturer(s); or

c) has become part of the public domain through no fault of your own; or

d) has become available to you from a third party not in breach of any legal obligations of confidentiality to UNCST and/or the sponsor or manufacturer(s).

You also undertake not to communicate the deliberations and findings of the joint scientific and ethical review of the research application, as well as any resulting recommendations and/or decisions of the joint review team to any third party, except as explicitly agreed by UNCST.

You will discharge your responsibilities hereunder exclusively in your capacity as an expert adviser to UNCST.

Signed**:**

Full Name: .....

Institution: .....

Date: .....

APPENDIX C: DECLARATION OF CONFLICT OF INTEREST

By signing this Agreement, you furthermore confirm that you have no financial interest and/or other relationship with a party, which:

a) may have a vested commercial interest in obtaining access to any part of the Information referred to above; and/or

b) may have a vested interest in the outcome of the review, in which you will participate, including but not limited to parties, such as the sponsors or manufacturer(s) of the candidate product that is (are) to be tested in the application or manufacturers of competing candidates.

In this regard, it should be noted that the sponsors or researchers of the research application under review have the right to object to your participation in the joint review especially when there is conflict of interest.

If such objection cannot be resolved in consultation with research team, the UNCST shall be entitled to terminate this Agreement or cancel participation by you hereunder.

I hereby agree to the conditions and provisions contained in this document. I hereby declare that:

a) I have no pecuniary or other personal interest, direct or indirect, in any matter that raises or may raise a conflict with my duties as a member of the Joint Scientific and Ethical Review Committee.

b) I have pecuniary or other personal interest, direct or indirect, in certain matter that raises or may raise a conflict with my duties as a member of the Joint Scientific and Ethical Review Committee. The particulars of such matter are stated below:

_____

_____

_____

Signed:

Full Name: .....

Institution: .....

Date: .....

APPENDIX D: DOCUMENT CONTROL

DOCUMENT TITLE	National Guidelines for Joint Scientific and Ethical Review of Research in Uganda		
DOCUMENT REFERENCE	**VERSION**	**DATE**	
National Guidelines for Joint Scientific and Ethical Review of Research in Uganda	1.0	September 2025	
DOCUMENT ORIGINS	**NAME**		**DATE**
REVIEWERS	UNCST		**September 2025**
	UNHRO		
	NDA		
DOCUMENT REVISION RECORD			
NEXT REVISION DATE	**DESCRIPTION**	**CHANGES**	**Date**
September 2030	Review the document in relation to: 1.The status of research landscape in the country 2.Comments from the users 3.Provisions of the National Guidelines 4.Conformity with the international guidelines		

NATIONAL GUIDELINES FOR JOINT SCIENTIFIC AND ETHICAL REVIEW OF RESEARCH IN UGANDA

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