ACCESS AFRICA 2

Joint Scientific and Ethical Review Guidelines in East Africa

Dr. Christopher Ddamulira (PhD)
Co-Investigator, Uganda National Council for Science and Technology (UNCST)

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

ACCESS AFRICA 2

- Rationale for the Joint Review Guidelines
- General Provisions of the Guidelines
- Role of National Regulatory Agencies (NRAs)
- Roles & Responsibilities of Joint Review Participants
- The Joint Review Process

Christopher Ddamulira

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Rationale for the Joint Review Guidelines

- Increase in the number of drug development clinical trials conducted in Sub-Saharan Africa (SSA).
- Complexity of trials often requires a multi-disciplinary approach.
- Unfavorable timelines for ethical and regulatory approvals of trials during public health emergencies.
- Gaps exist in skills and knowledge in providing adequate regulatory oversight, and efficiency of the regulatory and ethical review processes.
- EDCTP through the AccessAfrica2 Project is supporting the development of Joint Scientific and Ethical Review Guidelines in East Africa.

Christopher Ddamulira

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

General Provisions of the Guidelines

- The Joint Scientific and Ethical Review Guidelines set forth a **framework** for which National Regulatory Agencies (NRAs), Research Ethics Committees (RECs), Institutional Animal Care and Use Committees (IACUCs), subject matter experts, and appropriate stakeholders consider while conducting joint scientific and ethical reviews.

- The guidelines have been adapted from the framework of the African Vaccine Regulatory Forum (**AVAREF**) of the World Health Organisation (WHO).

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Joint Scientific and Ethical Review Guidelines is intended to:

- Enhance **Quality of reviews**
- **Optimize timelines** for review and approval
- **Exchange and validate findings** between NRAs ,Research Ethics Committees (RECs),IACUCs, IBCs and Experts
- **Capacity** strengthening platform

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCTP3 Joint Undertaking and its members.

Criteria for Joint Scientific and Ethical Review of Research (JoSER)

1. New and or complex study designs
2. Invasive and or investigational medical devices intended to treat, diagnose or prevent
3. Innovative treatments, investigational products, or procedures for diseases.
4. Research in Public health emergencies (Interventional trials)
5. Unregistered products with limited information on its use in humans, animals or plants in terms of risks and benefits
6. New and emerging technologies with limited information on their use in humans, plants in terms of risks and benefits

Christopher Ddamulira

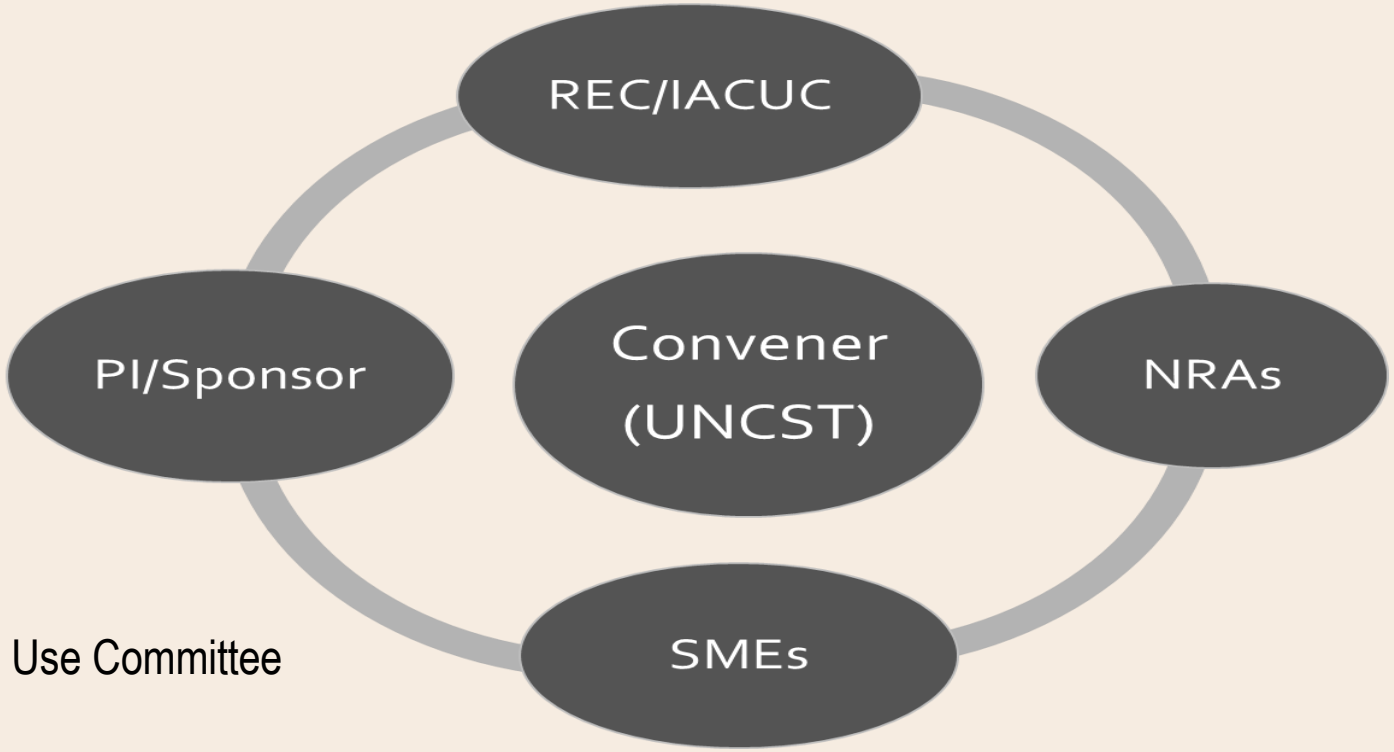
This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCTP3 Joint Undertaking and its members.

Criteria for Joint Scientific and Ethical Review of Research (JoSER)

7. Emerging and re-emerging infectious agents and toxins
8. Potentially hazardous material such as radioactive material
9. Genetic testing and modification in humans, plants, organisms, and animals
10. Invasive and endangered species
11. Use of human stem cells or fetal tissues in the prevention, treatment, and diagnosis of disease.
12. Use of complementary and alternative medicinal products in research for the prevention, treatment, and diagnosis of diseases
13. Any other reason as deemed necessary by the ICs and/or NRAs

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Roles & Responsibilities of Joint Review Participants



IACUC=Institutional Animal Care& Use Committee
NRA=National Regulatory Agency
REC=Research Ethics Committee
SME=Subject Matter Expert
NRAs=Uganda National Council for Science and Technology (UNCST), National Drug Authority (NDA), Uganda National Health Research Organization (UNHRO)

Christopher Ddamulira

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCTP3 Joint Undertaking and its members.

Convener (UNCST Secretariat)

- Managing stakeholder representation for the Joint review meetings
- Distributing research applications to reviewers
- Responding to reviewer requests and providing information exchange
- Appointing a Chairperson
- Compiling comments for the Joint review process
- Coordinating post-approval processes.

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

National Regulatory Agencies

- Pre-screening submitted documents
- Nominating representatives for the Joint review meetings
- Reviewing the research application package, and raising comments
- Issuing regulatory decisions
- Conducting ongoing review of the study, and undertaking other relevant tasks related to the Joint review process

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Institutional Committees (ICs)

- Recommending protocol submission to UNCST for Joint review consideration
- Pre-screening documents
- Ensuring quorum of the IC
- Reviewing research application packages
- Obtaining study approval
- Conducting reviews, and participating in joint monitoring

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCTP3 Joint Undertaking and its members.

Institutional Committees (ICs)

- Ensure PIs receive approval and proceed to the UNCST for registration and the NDA (where applicable) to obtain a certificate for the conduct of the clinical trial

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Invited reviewers and Interested Parties

- Subject matter experts and Interested Parties shall be identified by the UNCST in collaboration with other NRAs

- Provide subject expert opinion and raise queries on the submission

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

PI and Sponsors

- The PI and sponsors must submit the necessary study documents
- Attend the Joint review meeting
- Present an overview of the study, and respond to comments
- Addressing the comments generated in the joint review meeting

Christopher Ddamulira

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

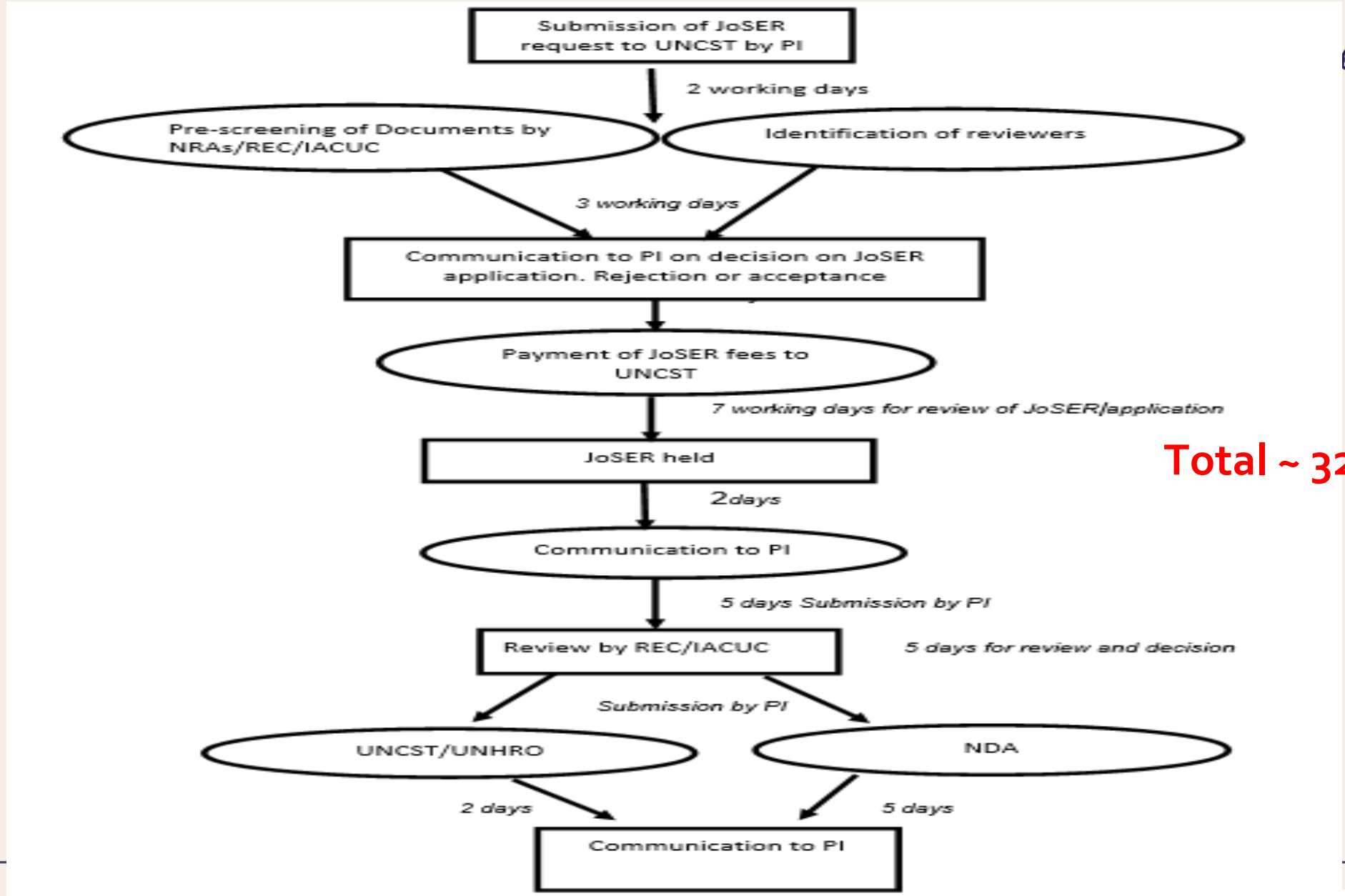
Procedure for Joint Scientific and Ethical Review of Research (JoSER) Applications

- The researcher/PI submits to the REC/Institutional Animal and Care Use Committees (IACUC)/National Biosafety Committee (NBC), and then the REC/IACUC/NBC forwards to the UNCST for JoSER consideration.

- The final decision on whether a protocol is eligible for the joint review is made by the UNCST, based on the assessment by the REC/IACUC and/or any other reason as determined by the NRAs.

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Schema for the Review Process



Total ~ 32 days

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCTP3 Joint Undertaking and its members.

Other aspects for consideration

Joint Monitoring & Inspection

All protocols approved through a joint review process are monitored through a joint inspection by UNCST, UNHRO, NDA, and REC.

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Conclusion

- The guidelines are intended to streamline and ensure the smooth completion of the Joint review process, requiring all participants to comply with the specific provisions in these guidelines.

This project has received funding from the European Union's Horizon Europe under GA No 101103296.
This project is supported by the Global Health EDCPT3 Joint Undertaking and its members.

Global Health
EDCTP3

European
Commission

Thank you!