Research Ethics and Governance in Sierra Leone

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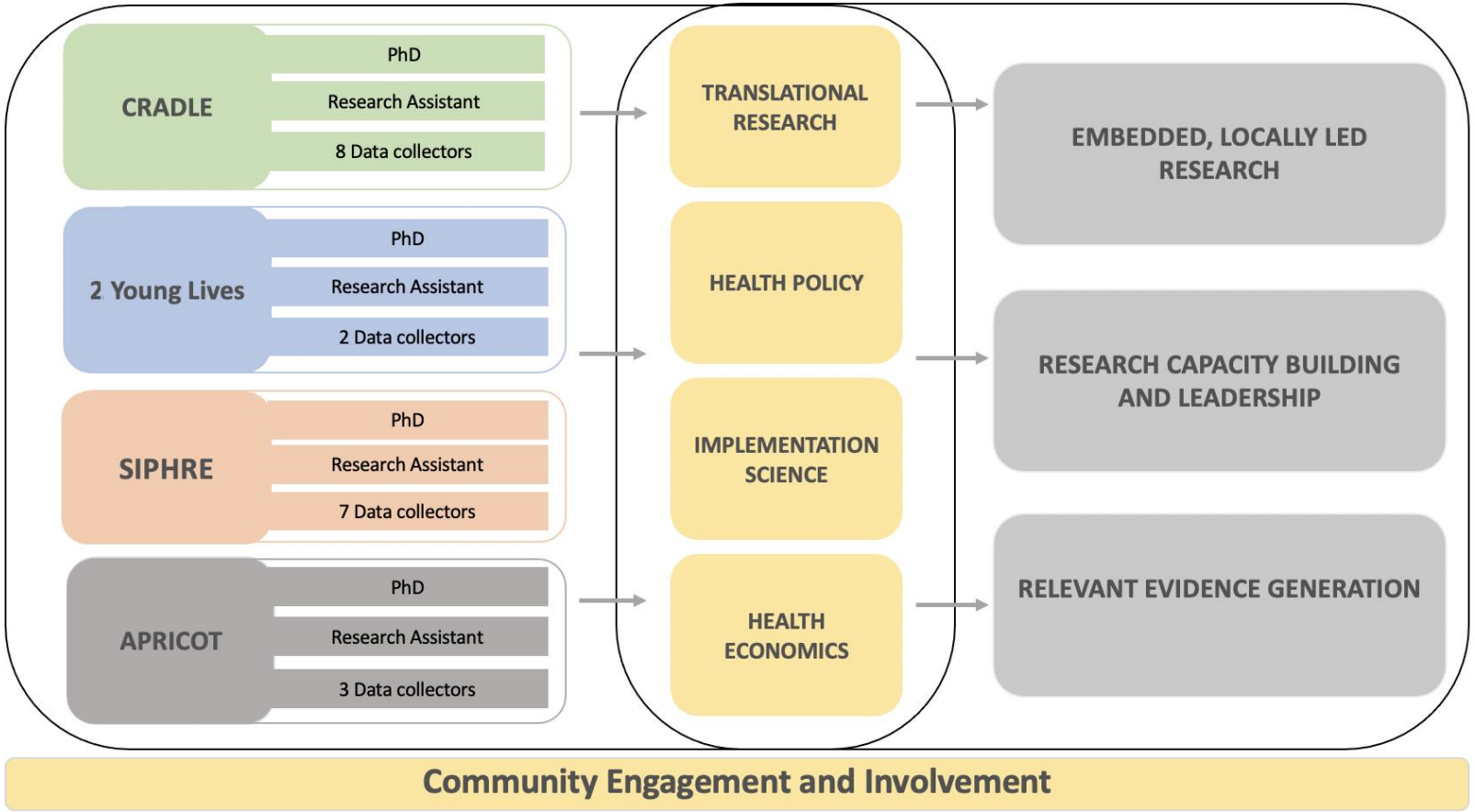
Definitions

- **Research:** A systematic investigation which involves the gathering and analysis of information designed to develop or contribute to knowledge.
- **Sponsor:** An individual, institution, organisation, company that takes responsibility for the initiation, management and or financing of research.
- **Principal Investigator**: The lead investigator or the main holder of the research funding or the project leader. In other words, this individual is the main researcher overseeing/conducting the research process.
- **Researcher:** Any individual conducting/carrying out research.
- **Supervisor:** Any individual(s) responsible for oversight of other researchers.

NIHR CRIBS: Global Health Research Group



Lifeline Nehemiah

THE UNIVERSITY of SIERRA LEONE

KING'S College LONDON

Welbodi PARTNERSHIP

2 Young Lives

CRIBS

CRIBS Global Health Research Group
Capacity. Research. Innovation.
Building maternity Systems in Sierra Leone

Definitions

- **Research Involving Human Participants**: Any social science, biomedical, behavioural or epidemiological activity that entails systematic collection and/or analysis of data with the intent to generate new knowledge.
- **Subjects:** Research participants or individuals recruited into a research project from/about whom data is obtained.
- **Research Protocol**: A detailed plan of a study and includes the project title, project summary, description, ethical consideration, gender issues and references.
- **Personal Data:** Data that relates to a living individual and contains personally identifiable information.
- **Bioethics:** A field of ethical enquiry that examines ethical issues and dilemmas arising from health care, health and research involving humans.

Definitions

- **Beneficence:** This means, participants are not harmed by the research study and that the benefits outweigh risks. It is the obligation to do good to research participants.
- **Nonmaleficence**: Obligation to avoid causing harm to others.
- **Risk**: The potential that a chosen action or activity will lead to an undesirable outcome that may affect research participants or researchers involved in a study. It is a potential harm or probability of an adverse event or outcome.
- **Vulnerable Group**: Person(s) without the capacity to make informed consent decision(s) based on their mental or emotional ability or who may be susceptible to exploitation or significant harm. A vulnerable person may include children depending on their age and some categories of adults.
- **Privacy:** The state or condition of being alone, undisturbed, or free from public attention as a matter of choice or right. It is seclusion, freedom from interference or intrusion, absence, or avoidance of publicity. It also means secrecy, concealment and protection from public knowledge or availability.
- **Confidentiality:** Obligation to keep information secret unless its disclosure has been authorised by the person concerned or in extraordinary circumstances by the appropriate authorities.

Definitions

- **Autonomy (respect for persons):** respecting the person's ability to make own decisions without interference or undue influence and adequately protecting the interest of those who are incapable of making their own decisions.

- **Voluntary:** Performed or done of one's own free will, choice or impulse, not coerced, prompted, or suggested by another. It is free of undue inducement/influence and the participants will be free to participate or continue to participate in a research activity out of their own free will.

- **Informed Consent**: Voluntary agreement of an individual, or his/her authorised representative, who has the legal capacity to give consent and who exercises free power of choice without undue inducement or any other form of constraint or coercion to participate in research. The individual must have sufficient knowledge and understanding of the nature of the proposed research, the anticipated risks, potential benefits, as well as the requirements of the research to be able to make an informed decision.

- **Assent:** this is a term used to express willingness to participate in research by persons who are by definition too young (in Sierra Leone, children below the age 18 years) to give informed consent but who are old enough to understand the proposed research in general, it's expected risks and benefits and the activities expected of them as participants/respondents. It is an agreement by someone below the age of 18 years not able to give legal consent to participate in a research activity.

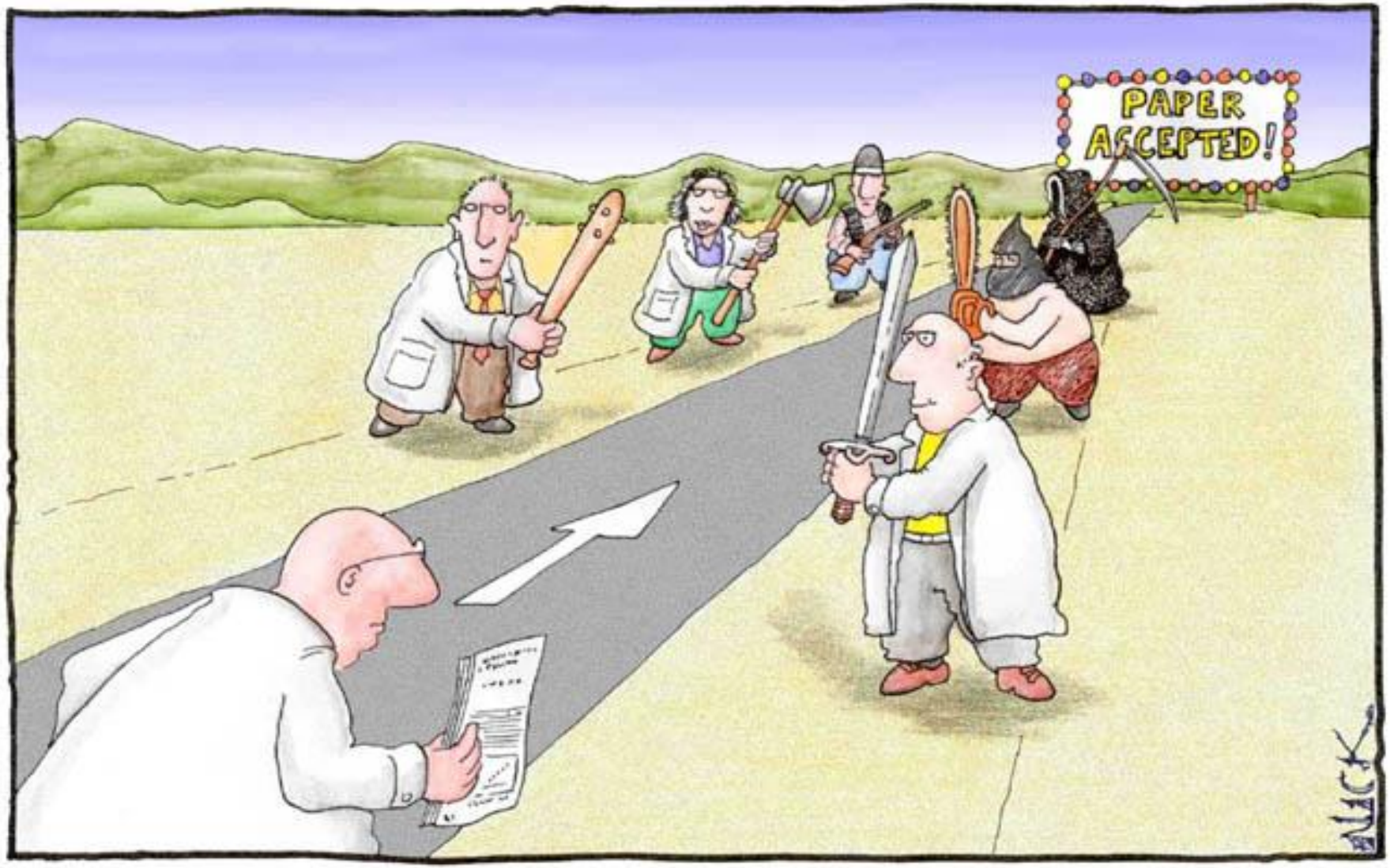
Definitions

- **Conflict of Interest**: This arises if individuals stand to achieve personal gain by failing to discharge their professional obligations, either to protect the welfare of the research participants, or to uphold the integrity of the scientific process.
- **Justice:** This requires that benefits and burdens be distributed fairly among all groups and classes in society without discrimination, taking into consideration diversity and inclusion.

Research ethics committees

- ethical review board (ERB), ethical review committee (ERC), health research ethics committee (HREC), institutional review board (IRB), etc.

- group of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles.



Ethics Review is not a barrier to research

Establishment of RECs

The Nuremberg Code (1949) requires that:

- voluntary consent of the human subject is absolutely essential in any experimentation
- the experiment should be such as to yield fruitful results for the good of society
- the experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
- the degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved
- the human subject should be at liberty to bring the experiment to an end
- the scientist in charge must be prepared to terminate the experiment at any stage if a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

World Medical Association: Declaration of Helsinki (1964)

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental ***protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor*** *provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed*

Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO (2002)

*all proposals to conduct research involving human subjects must be submitted for review of their **scientific merit** and **ethical acceptability** to one or more scientific review and ethical review committees…. The investigator must obtain their **approval or clearance before undertaking the research**. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study*

Need for independent review

- To minimize concerns with regard to researchers' conflicts of interest and to ensure public accountability, ***independent ethical review*** of all clinical research protocols is necessary.

[See Emanuel, E. et al (2000, 2004), What makes clinical research ethical]

Sierra Leone National Ethics and Scientific Committee (SLESRC)

A group of individuals from diverse backgrounds charged with the responsibility to undertake the scientific and ethical review of research protocols applying agreed ethical principles; appointed by the Chief Medical Officer in consultation with the Director of Training and Research in the Sierra Leone Government's Ministry of Health and Sanitation. Review and approve, or withhold approval of, research proposals that involve human participants, human samples, and/or their data

- Review and approve, or withhold requests for amendments to previously approved protocols/studies
- Promote awareness of ethical principles and practices among researchers, the wider health sector, and the general population.
- Promote excellence in scientific, health-related research and innovative practice for the wellbeing of society
- Ensure the interests, dignity, rights, welfare, health, and wellbeing of participants are protected

Membership

11 members from among the following:

- Health professionals
- Biomedical scientist
- MOHS nominee
- Social scientist
- Religious leader
- Gender specialist
- Lawyer
- Community representative

Core values

TRANSPARENCY

ACCOUNTABILITY

INTEGRITY

QUALITY

FAIRNESS

CONFIDENTIALITY

Meetings

Meets once a month or at intervals depending on workload and urgency of the protocol application

Quorum: A quorum is the minimum number of members that must be present to constitute a valid meeting where decisions can be made concerning proposed research applications submitted to the committee for ethical review.

The Committee shall endeavour to reach a decision concerning the ethical acceptability of a protocol by consensus.

The submission process

- The Principal Investigator (PI) or designated administrator shall submit a signed cover letter addressed to the chairperson of the Committee requesting ethical and scientific clearance at least two calendar months before the anticipated commencement of the proposed study
- Submit five hard copies (or utilise portal for submission) of the full research protocol which should include the following:
  - Protocol cover page that shows full and short titles of research (where applicable), full names and qualifications of the Principal Investigator and key investigators
  - Standard research protocol including, but not limited to: background to the study, scope, limitations, research questions and/or objectives, methodology, ethical issues, potential risks and benefits, sampling, specific study locations, funding source, study budget, workplan/timelines, etc.
- Informed consent/assent forms must be attached to each protocol. An Information Sheet, separate from the Informed Consent Form, must also be attached to each protocol. Please note that the Committee does not normally accept verbal consent. In the circumstance where verbal consent is required, the applicant must make a special request in the protocol proffering reasons.

The submission process

- Abridged CV not more than four pages each of the PI(s) and key associates clearly stating their roles as relevant to the research protocol submitted
- Study protocols for academic degrees must be accompanied by a signed letter of confirmation from that University's approved supervisor (on official letterhead) indicating the full title of the study and that it has been approved by the institution's faculty and/or Institutional Review Board (IRB).
- All new applications should include interview guides, questionnaires, and checklists, as the case may be.
- Any mention of collaboration or partnership with other agency (ies) or bodies must be evidenced in the application either through a Memorandum of Understanding (MoU), letter of collaboration or a consortium agreement
- There should be documented evidence of approval for research sites such as institutions, communities, councils etc.
- An electronic copy (MS Word or pdf) of your application (all merged into one file) addressed to slesrcadmin@mohs.gov.sl

Charges

Self-funded individual Sierra Leonean researchers based in Sierra Leone

- Five hundred thousand Leones (Le500,000)

Graduate Students studying in Sierra Leone

- Three hundred Thousand Leones (SLL350,000)

Sierra Leonean students studying abroad

- One Hundred United States Dollars ($100) or its equivalence in Leones

Self-funded Sierra Leonean academics abroad

- Two hundred United States Dollars ($200) or its equivalence in Leones

Self-funded international researchers

- Five hundred United States Dollars ($500) or its equivalence in Leones

National/local/CBOs and Universities conducting non-clinical studies

- Two Million Five Hundred Thousand Leones (Le2,500,000). This does not include collaboration with internationals

International NGOs based in Sierra Leone

- Seven Hundred United States Dollars ($700) or its equivalence in Leones

Group questions

Are their ethical issues in your planned research?

How will you address them?