Designing Clinical Research Maternal Health: "*Ethics and Processes*"

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Research in Maternal Health

Undertaking Clinical Research in Maternal Health: Ethical Considerations!!!

Objectives of the Session

- **Definitions of Research and Ethics**
- **Roles of Ethics Committee, Application process** and Why research ethics regulations are necessary;
- **Increase Knowledge and Understanding:** Relevance of Ethics in Clinical Research in Maternal Health;
- Identify **Critical Elements** of a Scientific study that Researchers must pay attention to.
- **Key Message: Acceptability: How to Succeed in getting your Research Proposal approved.**
- **Assurance of a Ethically Sound Research protocol** that meets the criteria for approval.

What is Research and Ethics??

- **Research** refers to a systematic, scientific investigation which involves the gathering and analysis of information designed to develop or contribute to knowledge.
- **Ethics** is the science relating to **Moral actions** and one's Value system. **Moral principles** that govern a person's behaviour.
- Defines what is **"Right versus Wrong"**. Constitute Good and Bad Conduct. Guide individuals and groups to make good, moral choices, related actions
- Ethics stipulates the **expected standards and behavior** expected of researchers.

Why Ethical Considerations in Research?

- **A MUST!!** Ethics is a Key Aspect of the Scientific process. **Good Clinical Practice!**
- Research Misconduct has Grave consequences: Psychological, Emotional, Physical trauma and loss of lives.
- Human Rights Abuse (Respect for Persons)
- **Credibility: Plagarism, Falsification , Forgery..**
- **Valuable Human Lives involved: Over and Above all:** To ensure that, the **rights, safety, dignity,** and **well-being** of research participants are **protected**.

The Ethics and Scientific Committee

- The Sierra Leone Ethics and Scientific Review Committee (SLESRC) under the Ministry of Health and Sanitation was established in 1992 with the aim of protecting research participants.
- It is charged with the responsibility of giving **Ethical and Scientific approval** for all intended research studies involving human participants and/or their data.

Role of the Ethics Committee

- **Review and Approve, or Withhold** approval of, research proposals that involve human participants, human samples, and/or their data.
- **Review and Evaluate** all ethical and scientific aspects of the research protocol.
- **Promote awareness of Ethical principles and practices** among researchers.
- **Ensure the interests, dignity, rights, welfare, health, and wellbeing of participants are protected . Benefits versus Risks?**

Role of the Ethics Committee…

- The Ethics Committee is also charged with the responsibility of **providing advice, and guidance** to researchers and related authorities as to the **safe conduct of studies** involving humans or their data, and how to respect research participants' privacy, safety, and ensure confidentiality.
- Promote excellence in scientific, health related research and innovative practice for the wellbeing of society.

Application process: Ethical Guidelines - Checklist

- Checklist provides guidance to researchers for submitting applications to the SLESRC for ethical review of research protocols.
- All research applicants are therefore required to familiarise themselves with these to ensure compliance with the expected ethical standards.
- Completed checklist (which forms part of this document). It can also be downloaded from: https://mohs2017.files.wordpress.com/2017/03/guidelines-and-checklist-for-ethical-clearance-2017.pdf
- Ministry of Health and Sanitation: Coordinator Ethics and Scientific Committee

Application process …

- All protocols should be submitted to the administrator for both ethical clearance and review of the science of the research.
- **Documentation requirements:**
- The principal investigator (PI) or designated administrator shall submit a 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 of the full research protocol which should include the following:
- Protocol cover page that shows full and short titles of research, full names and qualifications of the Principal Investigator and key investigators .

Ethical Guidelines

- **Who are You?** Brief CV of the PI and key associates clearly stating their roles - not more than four pages each
- **Why the Study?** Study protocols for award of an academic degree must be accompanied by a letter of confirmation from the supervisor (on official letterhead) indicating the full title of the study and that it has been approved by the institution's faculty and review board (IRB).
- **Supporting Documents:** 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 through Memorandum of Understandings (MoUs), letter of collaboration or consortium agreements
- An electronic copy (MS Word or pdf) of your application addressed to the Coordinator.
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Application process

- 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.

Application Guidelines: Checklist

Sierra Leone Ethics and Scientific Review Committee Checklist
Name of Applicant: _____**Date of application**_____
Category: Local or Int'l Student/NGO/Institution not based in Sierra Leone, etc. _____
If student, state Faculty_____**Start date of data collection**_____

ESSENTIAL ELEMENTS IN THE APPLICATION FOR APPROVAL		YES	NO
1.	Statement that the study involves research		
1.	Explanation of the purpose of the research		
1.	Design and procedures used are described and are sound		
1.	Expected duration of participation in study is given, including detailed activity timelines/workplan		
1.	Selection of subjects described and selection is equitable for all persons targeted		
1.	Method of obtaining informed consent/assent is described and does not involve elements of coercion		
1.	Description of risk(s) involved and how they will be managed. Are risks/discomforts reasonable in relation to anticipated benefits?		
1.	Statement that the subject's participation is voluntary and refusal to participate will not involve a penalty or loss of benefits that the subject is otherwise entitled to		
1.	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent		
1.	If research involves more than minimal risk, is there an explanation as to whether any compensation and/or psychological or medical treatment appropriate to the injury will be made available if injury occurs?		
1.	Statement about how the data will be monitored to ensure privacy and confidentiality of data		
1.	Statement that the subject has the right to contact the ethics and scientific review committee, if the subject sustains a research-related injury, or has issues with the study. The committee's contact details must be indicated		
1.	Statement about how the data will be monitored to ensure privacy and confidentiality of data		
1.	Cover Letter explaining purpose of your application (Not more than two pages)		

	ESSENTIAL ELEMENTS FOR THE INFORMATION SHEET	YES	NO
1	A statement that the study involves research		
2	An explanation of the purpose of the research		
3	Explanation of procedures		
4	Explanation of what will be done to the subject, when and how many times		
5	Description of incentives and the mechanism for distribution.		
6	A statement and description of risks involved and how they will be handled/mitigated.		
7	Statement that the subject's participation is voluntary and refusal to participate will not involve a penalty or loss of benefits that the subject is otherwise entitled to.		
8	Description of what happens to the subject if he/she withdraws from the study		
9	Identification of whom to contact for answers to pertinent questions about the research.		
10	Statement that the subject has the right to contact the ethics and scientific review committee, if the subject sustains a research-related injury.		
11	A statement that the particular aspects of the research involve risks which are currently unforeseeable		
12	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent		
13	Any additional costs to the subject that may result from participation in the research		
14	Statement about how the data will be monitored to ensure privacy and confidentiality of data		
15	Statement indicating who will have contact with subjects		
16	Statement indicating who will have access to data linked to subjects		
17	A statement indicating whether the findings from the study will be helpful to the individual's situation or health		
18	Statement at the end of the consent form giving the name of the PI of the study. If student, then the research faculty with whom the student is working (using his/her data) or supervising the research		
19	Is consent form written at level that the subject can understand, given age and education?		
20	Other comments		

Completing the application process

- Copies of receipts for all payments made shall be attached to the application and all accompanying supporting documentations
- The checklist and consent forms should be filled out completely to complete the application documentation process.
- The completed application should then be submitted to the SLESRC secretariat
- For any further information, please contact: efoday@mohs.gov.sl/slesrcadmin@mohs.gov.slor +23278366493
- **Feedback** from the Committee - Written

Fundamental Ethical principles Researchers Must take note of

- **Autonomy** It involves the right of self determination, independence and freedom, **respect for the individual** (Informed Consent).
- **Beneficence** An obligation to do good and not to do harm, Prevent evil or harm to others. Obligation to do right things
- **Non-maleficence -** Requires intentional prevention of causing harm.

Fundamental Ethical Principles..

- **Justice** Obligation to be fair to all people, just, Requires fair distribution of burden and benefits. All individuals should have equal access to scare resources.
- **Fidelity-** Obligation to be faithful to all agreement, commitments and responsibilities that one has made to oneself and others (privacy and confidentiality).
- **Veracity-R**efers to truth telling and not intentionally deceiving or misleading people. It is grounded in respect for persons. Verify facts in an honest environment. Accuracy and correctness.

Scientific design and conduct of the research

- **Background:** The researcher(s) must have the required qualifications and experience to carry out the research.
- The research study should have a **valid scientific method** for it to be ethically acceptable to ensure that, research participants and their communities are not exposed to risks of harm without any possibility of benefit.
- **The Study methodology should be Scientifically sound.**
- Ethical implications of the research design or strategy.
- **Risks and potential benefits**
- Ensure risks are minimised both by preventing potential harm and minimizing harmful impacts should they occur in relation to the benefits of the study.

Elements of the Review

- **Scientific design and conduct of the study;**
- Adequate background information and literature review
- **The appropriateness of the study design in relation to the objectives, methodology,** the analysis including sample size calculations and the potential to reaching sound conclusions.
- **Justification of predictable risks and inconveniences** against the anticipated benefits for the research subjects and concerned communities. Criteria for suspending or terminating the study as a whole.
- **Adequacy of the site** including the supporting staff, available facilities and emergency procedures.
- Manner in which the results of the research will be reported and published.

Elements of the review ….

- **Recruitment of participants**
- Characteristics of the **population** from which the research participants will be drawn (gender, age, literacy, culture, religion, ethnicity, economic status etc).
- Means by which initial contact and recruitment is to be conducted
- Means by which full information is to be conveyed to potential research participants or their representatives.
- Inclusion and or exclusion criteria for participants

Care and Protection of research participants

- **Competence of the PI(s)** (qualification, experience etc) to carry out the proposed research
- Any plans to withdraw or withhold standard therapies for the purpose of research and the justification for such action
- **Support:** Medical care to be provided to reach participants during the course of the research and at the end.
- The adequacy of medical supervision and psychosocial support of the research participants
- Steps to be taken if research participants voluntarily withdraw during the course of the research
- Description of any financial cost to the research participants (including money, services and or gifts).
- Provisions for compensation/treatment in the case of injury/disability/death of a research participant as a result of participating in the research.
- Insurance and indemnity arrangement if required

Informed consent process

- Full description of the process for obtaining informed consent.
- Adequacy, completeness and comprehension of written and oral information to be given to participants and where appropriate their legal representative(s).
- Assurance that, research participants will receive information that becomes available during the course of the research relevant to their participation (especially their rights, safety and well-being).
- **Queries/Inquiries:** Provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of research

Informed consent…

- **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.
- Persons are entitled to choose/decide freely whether or not to participate in a research study based upon thoroughly understanding the adequate information provided on the proposed research study.

Protection of research participants

Privacy & Confidentiality (HIV Status, Anonymity).

- **Permission:** Access to personal data of the participants including medical records and biological samples.
- Measures to ensure security, protection and confidentiality of personal information about research participants.
- **Biological specimen:** Full description, including quantity or size, of any specimens that will be collected (blood, body fluid, tissue biopsies etc
- Plan for obtaining consent and clearance from participants and SLESRC.

Who decides for Me??

- Clear justification to include individuals who cannot consent and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
- Undue advantage
- Lack of Knowledge

Protection and Rights

- **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, pregnant women, etc. Minors and or adults who lack the mental or physical capacity to provide informed consent, should be obtained by their parents or legally authorised persons/decision-makers.

Key Messages!!

- *A Good Research Proposal which takes into consideration the **Ethical ingredients.***
- *Provides a Detailed and Comprehensive Proposal in such a way that everyone is protected and not abused!!*
- ***Methodological difficulties** creates room for re-submission! Do it right the first time!*
- *Evidence for Action: Engage in Research!!*

Thank you for your Attention!!