SRA INTERNATIONAL
ANNUAL MEETING
SEATTLE 2023
OCTOBER 14-18

Research Compliance - A Journey of a Thousand Steps

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OUTLINE

- What is Research
- Core Pillars of Research Compliance
- Principles of Responsible Conduct of Research
- Role of RM for compliance in research
- Status of research in The Gambia
- Status of ethical and regulatory review
- Building ethics and regulatory review capacity
- Preliminary findings
- Contextualising ethical principles
- Promoting research integrity
- Research Outcomes

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What is Research?

The Western Sydney University defines research as:

the creation of new knowledge and/or the use of existing knowledge in a new and creative way to generate new concepts, methodologies, and understandings. This could include synthesis and analysis of previous research to the extent that it leads to new and creative outcomes. This comprises of creative work undertaken on a systematic basis to increase the stock of knowledge, including knowledge of humanity, culture and society, and the use of this stock of knowledge to devise new applications.

https://www.westernsydney.edu.au

What is Research?

- The aim of research is to generate evidence to guide policy and practice, so, the results has to be trusted.
- Trusting result of research will entail it being guided by principles, standards and best practices.
- Successful conduct of research requires professional, technical, administrative support.
- **Research management ensures compliance to responsible conduct of research – good research practices.**

Core Pillars of Research Compliance

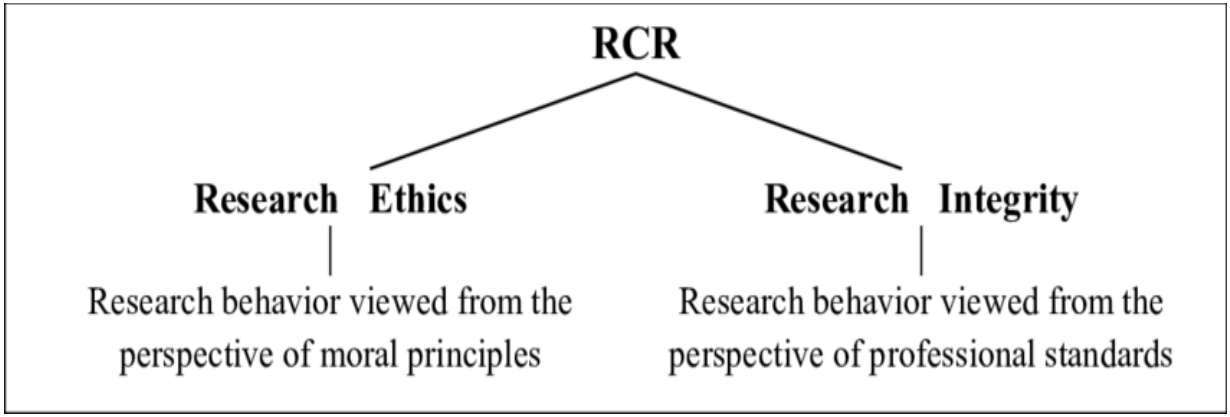
Defining Ethics and Integrity

Ethics helps individuals consider how they should behave from a moral perspective, in other words, what they ought to do (*Vanclay et al, 2013*).

Research ethics provides a set of guidelines for the responsible conduct of research. It differentiates acceptable and unacceptable behaviour and provides the framework that promotes good practice.

Research integrity is defined as active adherence to the ethical principles and professional standards essential for the responsible conduct of research. Active adherence means adoption of the principles and practices as a **personal credo**, not simply accepting them as impositions by rulemakers.

Overview of Responsible Conduct of Research



Steneck, 2006 - Fostering Integrity in Research: Definitions, Current Knowledge, and Future Directions, Science and Engineering Ethics (2006) 12, 53-74

Principles of Responsible Conduct of Research

Responsible conduct of research is underpinned by these core principles:

- Honesty, responsibility and accountability
- Professional courtesy and fairness in working with others
- Good stewardship of research on behalf of others

Promoting integrity and high ethical standards in research, institutions are able to address poor practice and misconduct by:

- Ensuring that research is conducted by competent researchers
- Providing training and support to researchers
- Having a institutional culture base with researchers with the right competences conducting research

Principles of Responsible Conduct of Research

- **Honesty** - in relation to own research and that of others, including ensuring the accuracy of data and results, conveying valid interpretations, acknowledging the contributions of others, and neither engaging in misconduct nor concealing it.

- **Rigour** - conducting the research in line with prevailing norms and standards, using appropriate methods for the study question, adhering to an agreed protocol where relevant, in drawing suitable conclusions and interpretations with respect to the fidelity of the data, and communicating the results of the study.

- **Integrity** - complying with all relevant legal and ethical requirements, declaring any potential or actual conflicts of interest relating to research and where necessary taking steps to resolve them

https://ukrio.org/about-us/what-is-research-integrity/

Principles of Responsible Conduct of Research

- **Transparency, Cooperation, & Open Communication** - promoting the open exchange of ideas, research methods, data and results and their discussion, scrutiny and debate, subject to any considerations of confidentiality.

- **Safety, Care, Respect** - ensuring the rights, safety and wellbeing of all involved in research (i.e., research participants (whether human or animal), researchers, and others), and ensuring that the potential or benefits of the study justify the risks.

- **Accountability** - recognising that ultimate accountability is to the general public and research should be conducted and reported always with this in mind. Ensuring research undertaken complies with any agreements, terms and conditions relating to the project, ensuring proper governance.

- **Training and Skills** - ensuring that those engaged in the research have the necessary skills, training and resources to carry out the research, and report and resolve any unmet needs identified.

Role of RM for compliance in Research

Discussion: As research managers, what is our role in ensuring research compliance.

State of Research in The Gambia

- Priority was not given to **research as a tool** for solving the health and development needs of the country until after **2016**.
- **Weak research capacity** and **inadequate resources** available to research being conducted in the country.
- Investments in research are **insufficient to facilitate research** that commensurate to the needs of the country.
- **Lack of proper setup to govern** the conduct of research at national level – **no research policy, no ethics policy.**
- Low awareness and non-existence of **research management services – (only MRCG at LSHTM has RSO).**

Status of ethical and regulatory review

Gambian Government /Medical Research Council Joint EC

- Established and constituted in 1978.
- Only recognised EC.
- Reviews all research involving human subjects.
- Membership is made up of a cross-section of scientific expertise and lay persons.
- Conducts a dual review process.
- Meet monthly
- Review is done following these guidelines:
    - Declaration of Helsinki – current version
    - Interntional Ethical Guidelines for Health-related Research involving Humans (CIOMS – 2016)
    - The Belmont Report 1979
    - ICH GCP E6 (R2)
    - Local regulatory guidelines

Status of ethical and regulatory review

Medicines Control Agency (MCA)

- Formed by an ACT of Parliament - The **Medicines** and Related Products Act 2014.
- Issues clinical trial approvals, importation licence for medicinal products.
- Mandated to monitor the conduct of trials and stop clinical trials if they do not confirm to procedures and guidelines. They issue fines according to their guidelines.

Building ethics and regulatory review capacity

Title: Building a Robust Ethics and Regulatory Capacity in the Gambia

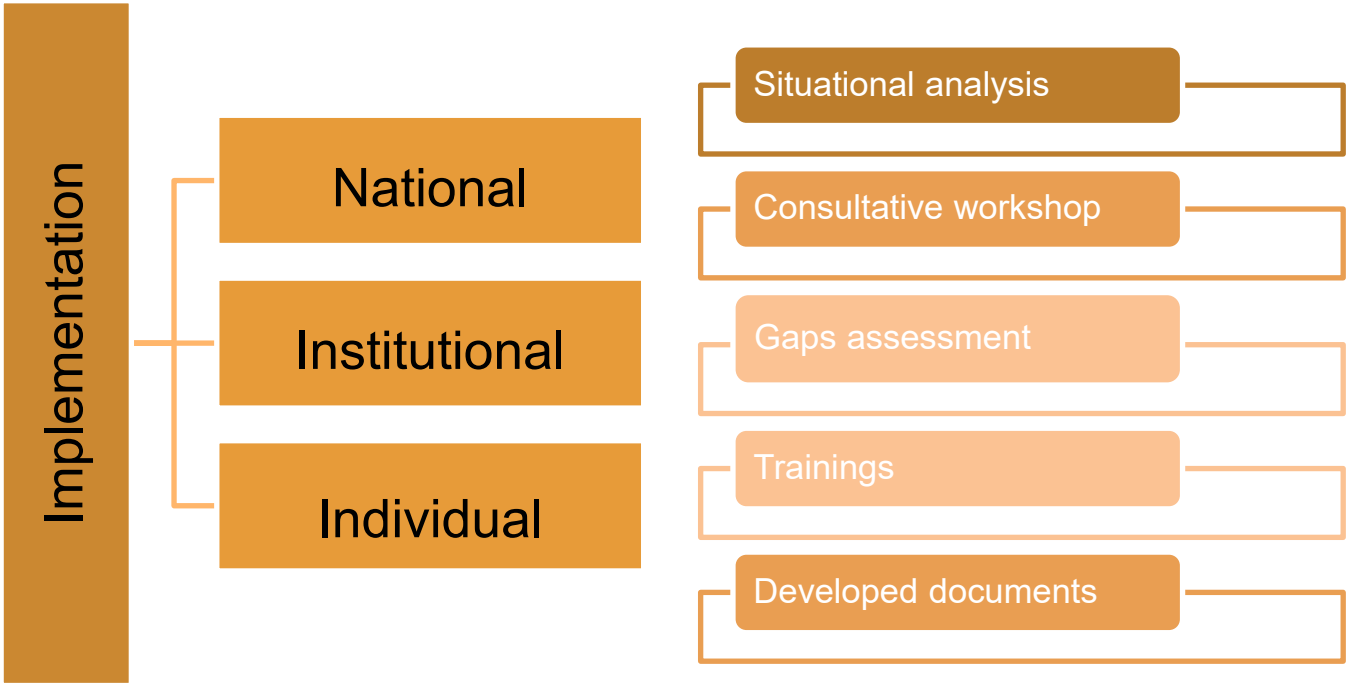
Funder: EDCTP

Aim: To build and enhance ethical and regulatory capacity in The Gambia.

Expected outcomes:

- Introduce an online review platform for EC and MCA.
- Develop national regulatory frameworks for research.
- Introduce standardise tools and guidelines for review.
- Establish a national ethics secretariat.
- Establish IRBs for sectoral and academic bodies.

Building ethics and regulatory review capacity



Building ethics and regulatory review capacity

National Level

- A taskforce was formed and mandated to develop a national regulatory framework.
- Develop a regulatory procedure for approving new IRBs and monitoring their functions.
- Developed review tools, templates and guidelines.
- Developed policy briefs to engage policymakers.

Institution Level

- Development of institutional policies, procedures and guidelines.
- Conduct GCP and Clinical Research training.
- Conduct training on online ethical review system
- Issue license for an online ethical review platform.

Building ethics and regulatory review capacity

Individual Level

Trained on:

- Research ethics principles and role of EC
- Procedures for conducting ethical review
- Conduct of site assessments
- Data protection and applicable clinical research regulations

In addition:

- Will establish a training of trainee programme for ethics administrators for long term continuity.
- Put in place recharging system for the sustainability of the committees.

Preliminary Findings

Respondents

- Two Government Institutions
- Seven Academic Institutions
- Two Multilateral Agencies
- Seventy-five individuals

Findings

- Limited awareness of the existing processes for obtaining ethical and regulatory approval.
- Limited awareness of the international research standards.
- Lack of institutional policies, procedures and guidelines for ethical review.
- Found that there were **SEVEN IRBs** operating without a framework to guide their actions.

Contextualising ethical principles

- Relevance of the research
- Guidelines on inform consent
- Vulnerable populations
- Coercion / compensation / reimbursement
- Contributing human specimens for further research
- Sharing of Data
- Use of clinical data for research purposes
- Guidelines for addressing Incidental Findings and Safeguarding
- Engaging with commercial entities

Promoting Research Integrity

Policy & Practice

- Institution policy on RCR
- Procedure for investigating research misconduct

Advocacy

- Posters on RCR principles
- Run "Speak up"campaigns
- Design flow diagrams for reporting research misconduct

Training

- Train on RCR
- Make RCR training part of staff induction

Promoting Research Integrity

https://www.kuleuven.be/english/research/integrity/culture

Research Outcomes

- Legislation for research and RECs/IRBs*****
- Standard guidelines, templates and review tools
- Online ethics and regulatory review platform
- Availability of fully operational IRBs
- Availability of complete research data***** (work ongoing to develop a national research database).

Acknowledgements

EDCTP

This project is part of the EDCTP2 programme supported by the European Union

Partners:

- **MRCG at LSHTM**
- **EthiXpert – South Africa**
- **MCA – Gambia**
- **Pharmalys**

Beneficiaries:

- **MoHERST**
- **MOH**
- **UTG**
- **EFSTH**
- **IOU**
- **American International University**
- **EUCLIDS University**
- **NARI**

Thank you for your attention