Responsible Conduct of Research in Nepal: Identifying and Addressing the Gaps

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Outline of the Presentation

- Responsible Conduct of Research (RCR)

- Building Blocks of RCR

- Need to do to achieve RCR

- Main Areas of RCR

- Standards of RCR

- What we have

- Responsible Research

- Promoting RCR in Nepal

- Challenges

- Possible Road map

Responsible Conduct of Research

Conducting research in a responsible manner, adhering to the principle of research ethics (autonomy, beneficence, and justice) to maintain research integrity leading to better and credible scientific results for application (NIH, 2023)
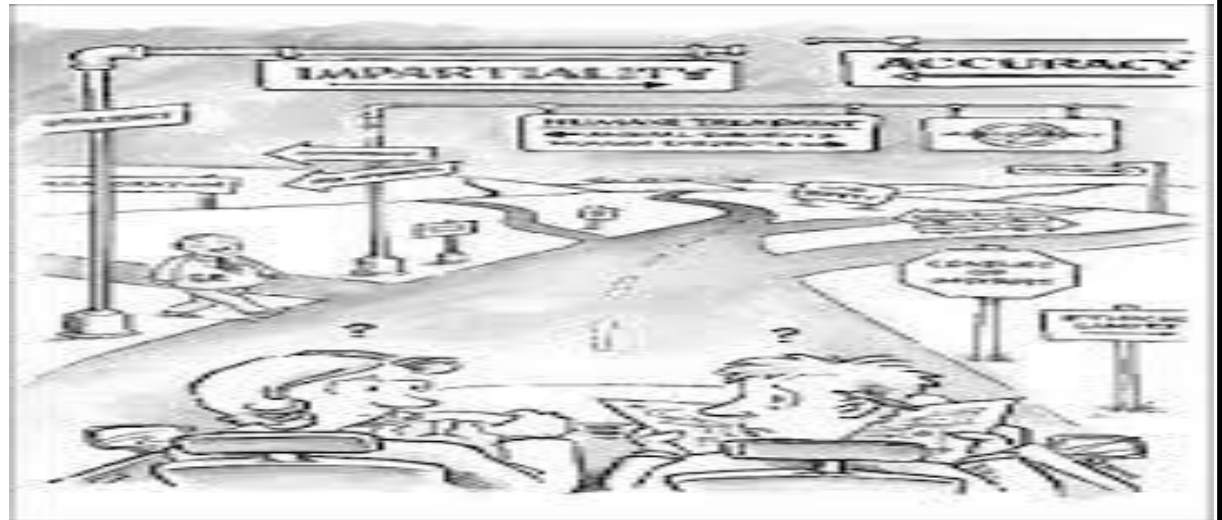
Building Blocks of RCR

- **Objectivity:** Letting facts speak for themselves & avoiding bias

- **Honesty:** Conveying information truthfully and honoring commitments

- **Efficiency:** Using resources wisely and avoiding waste

- **Accuracy:** Reporting findings precisely & taking care to avoid errors

PINCIPLES of RESPONSIBLE CONDUCT of RESEARCH

OBJECTIVITY

HONESTY

EFFICIENCY

ACCURACY
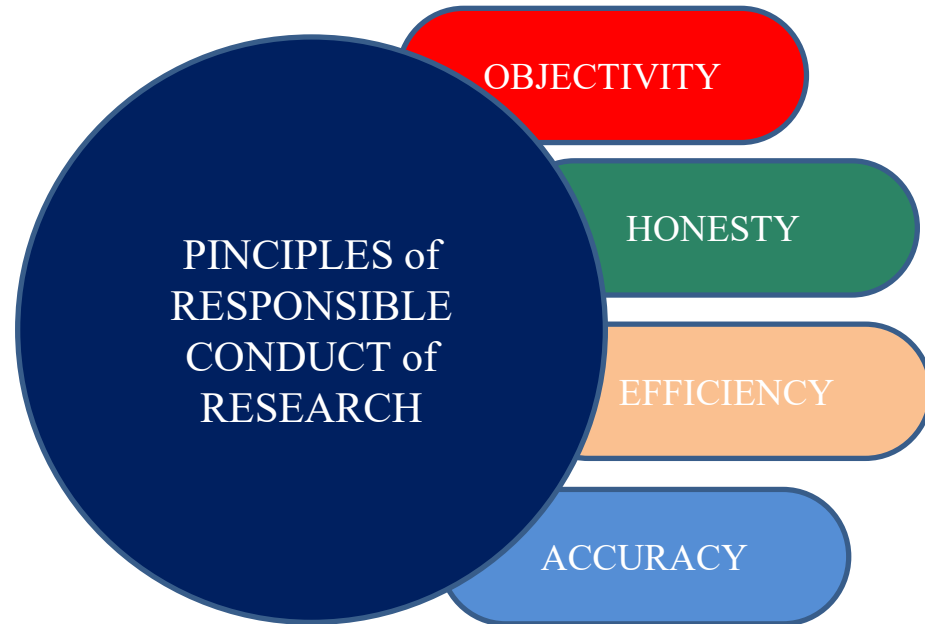
Need to do to Achieve RCR

- Practicing the highest standards of ethics & accountability in each step of the research process from planning to publication and utilization of research findings

- To achieve research integrity i.e. adherence to rules, regulations, guidelines, SoP, and commonly accepted professional codes of conduct

- Simply a practice of good citizenship applied to professional life

Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants

Main Areas of RCR

- Policies and priorities that influence health research;
- Planning and conducting of the research (Conflict of Interest, Data Management, Sharing, and Ownership)
- Professional, legal, and moral responsibilities of researchers, sponsors and institutions; (Nepali PI Should be responsible, Sponsor should have provision for capacity building of the institution and HR, MTA/IPR)
- Research mentoring, monitoring, reviewing, and reporting; (frequent M & E, submission of the final report within 3 Months)
- Research publications and responsible authorship (ICMJE, COPE, and WAME Guidelines)
- Research Misconduct and handling of research misconduct; (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results)
- Collaboration and Networking
- Institutional Research Arrangements
- Clinical trials registration (if needed)

National Ethical Guidelines for Health Research in Nepal 2022

Standards of RCR

- Varies from
  - Discipline to discipline
  - Institution to institutions

But basic principles remain the same

Promoting RCR in Nepal

- Establishment of Nepal Health Research Council by NHRC Act 1991
  - Individuals/organization interested in conducting health research must obtain approval from NHRC
  - Rights to stop/halt the study in case of misconduct

- Publication of National Ethical Guideline 2022 and IRC guideline 2016
  - Ethical Review Board and Institutional Review Committees (56)

How is it done?

- NHRC Executive Committee selects **11 to 15 members** based on the National Ethical Guideline and SOPs with attention to qualification, expertise (medical/non-medical, clinical/non-clinical), affiliated/non-affiliated, and balance of gender

- Agenda preparation and conduction of ERB meetings

- Quorum and CoI requirements

- Group dynamics

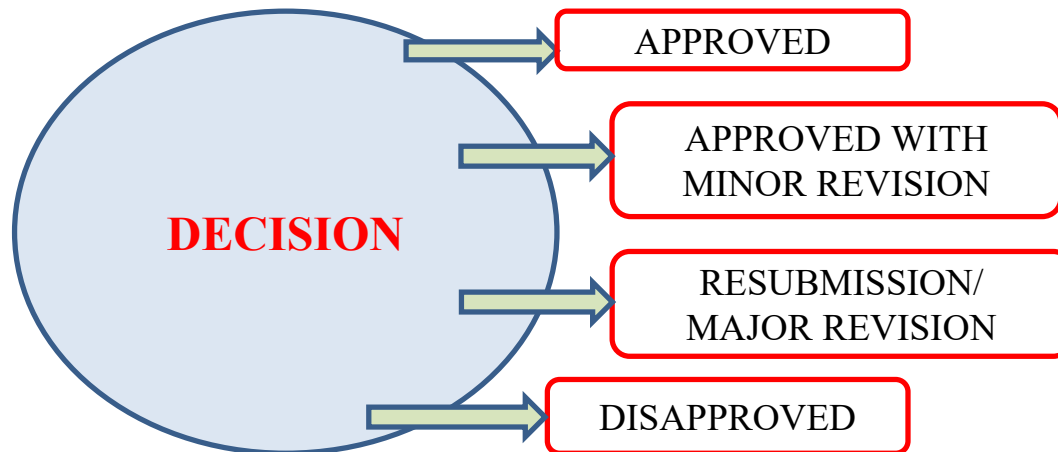- Appropriate reviewers

Types of Review

- Exemption from Review

- Expedited Review

- Full Board Review

Risk Categorization

- Less than Minimal Risk

- Minimal Risk

- Low Risk

- High Risk

- Discussion about science (objectives, design, outcomes, etc.) and ethics (vulnerability, risks, benefits, ICF, etc.)

DECISION

→ APPROVED

→ APPROVED WITH MINOR REVISION

→ RESUBMISSION/ MAJOR REVISION

→ DISAPPROVED

- Communicating the decision and its documentation

Challenges

- Lack of Harmonized System / Procedure
- Inadequate HR and infrastructure
- Less coordination and collaboration with Academia
- Lack of budget
  - To run the IRC
  - Voluntary work
  - Regular capacity-building training and refresher training

Compliance with Guidelines

- **Initial review:** fulfilments of the requirements, identifying the level of risk

- **Implementation:** compliance with the approved protocol, amendment, Guidelines, SOPs

- **Post-approval**: Report submission, dissemination, authorship, post-research access, and benefit sharing

Possible Road Map

- Promoting harmonized system and procedure (Like FERCAP criteria)
  - Develop a single online system for other ECs
  - Joint review and monitoring along with mentoring on research
  - Strengthen the infrastructure and HR capacity, promoting collaborative and multi-disciplinary research in priorities area
  - Open Data Sharing and Ownership/IPR, Post-trial access, and benefit sharing
  - Promote engaging the community in the research process

- Conduct Regular short training programs
  - young researchers and refresher training for EC members and reviewers
- Consider incorporating it in the curriculum in all disciplines
- In-house short talks, discussions, or seminars
- Linkage with international experts and involvement in different activities like open data science, global code of conduct, NIH, FWA

References

- Nuremberg Code 1947
- The Belmont Report 1979
- Council for International Organizations of Medical Sciences (CIOMS) 1982-2016
- WHO Global Health Ethics
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants
- Guidelines for IRCs for Health Research in Nepal 2016
- National Ethical Guideline for Health Research in Nepal 2022
- Standard Operating Procedure
- National guideline for Clinical Trial with the use of Pharmaceutical products 2005
- https://case.edu/gradstudies/current-students/responsible-conduct-research

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