Ethical Issues in Research: Clearance & Application Process

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Why this orientation?

- Understand the ethical clearance processes.
- Require cooperation/supervision of research
- Increase international collaboration & demand for ethical clearance.
- Address persistent concerns about quality, e.g.:
  - Ethical considerations (informed consent/ checklist; aligned work plan & budget, referencing)
  - Consistency in title, aims & objective, research question, expected outcome
  - Population, sample size, sampling procedure

Context

- Research may involve human, animal participants, environment

- Research raises complex ethical issues

- legal, social, cultural, economic, civil & political

- relevance, moral concerns, especially in institutions involving training for leadership

Ethical Issues in Research

- Discrimination based on gender, religion, ethnicity, association, etc.)
- Cruelty
- Unfair practices (validity)
- Crime
- Direct harm - pain to research participants
- Confidentiality, privacy -trauma

Ethical Issues in Research

A researcher may

- Expose secret experiences, confessions, personal confidential details (illness status, marital challenges, abortions, etc. -appropriate trauma support) = *confidentiality concerns*
- Record participants voices, pictures or videos
- Falsify data & results; Plagiarise
- Coerce participants with diminished autonomy
- Generally “cause trouble” -conflicts in homes, relationships, institutions; invade bodies; privacy, etc.

Background To Ethical Reviews

- The Tuskegee Experiment (1932-1972): USA - Public Health Service experiment on 399 black men in the late stages of syphilis
  - 28 direct deaths
  - 100 related complications
  - 40 wives infected
  - 19 children born with congenital syphilis
- Treatment of Jews at Concentration camps.
- Stanley Milgram's Study on Obedience

3 Basic Ethical Principles (Belmont Report)

1. **Respect for Persons**: a) acknowledge autonomy & b) protect those with diminished autonomy (e.g. children, patients, prisoners)
2. **Beneficence**: a) do not harm; b) maximize possible benefits, minimize possible harm
3. **Justice:** burdens & benefits from research are evenly distributed; people are treated fairly; i.e. researchers should not take from participants without giving back to them

Application of Principle 1- -IRB Goal

Consent Process:

Information: Enough to enable participants make an informed choice whether to participate in study - procedure, purpose, risk, benefit, opportunity to ask questions & to withdraw at any time from the research;

Participants have

- an accurate & realistic expectation of what could happen to them;

-what research options are open to them (especially as patients)

Clarity & Agreement

Consent Process:

- Speak directly to the participants
- Provide interpretation for non-literate participants, minors or others who cannot give consent (e.g. due to incapacitation, ill health or incarceration)
- Witnesses for such participants

Application of Principle 1 -*IRB Goal*

Comprehension: consent form & process - clear language that will enable participants to easily understand contents; avoid technical terms/ jargons, exculpatory language;

Translation-interpretation; *Training* - researchers & assistants

Consideration of respondents' intelligence, maturity, language.

Voluntariness: Clarity re voluntary participation: appropriate autonomy to make reasoned decision; conditions free of coercion & undue influence

Application of Principle 2 - Beneficence

Risk: Do not injure respondents regardless of benefits from the research

- check possibility of any harm: psychological, physical, legal, social, economic i.e. responses do not cause a risk of criminal or civil liability, potential damage to financial standing, "employability", reputation
- minimize risks e.g.by improving research design

Benefit: what is the direct benefit to i) participant, ii) society; **Compensation**

Purpose & Procedure

Clear, simple statements on

- Research purpose
- Procedures - specifics
- Expected duration of participant's involvement

Privacy *refers to persons & their interest in controlling access of others to themselves;*

Confidentiality *refers to data.*

Application of Principle 3: Justice

Selection of participants: appropriateness of

- selection pool
- inclusion/exclusion criteria
- inclusion of vulnerable populations
- recruitment : fair & impartial – contacting procedure?

Provide a statement that there will be

-***notification of significant new findings*** during research period that may affect a participant's willingness to continue in the research

Application of Principle 3: Justice

- "Fairness in distribution" or "what is deserved"
- Injustice occurs when

  - an entitled benefit is denied without good reason

  - a burden is imposed unduly
- Competence, age, deprivation, experience, merit, position may sometimes constitute criteria justifying differential treatment for specific purposes.

ESSENCE OF ETHICAL CLEREANCE PROCESS

- Assess ethical dimensions in proposed study.
- Advice on ethical dimensions as necessary.
- Consider interface of science & ethical dimensions.

INTERFACE OF SCIENCE & ETHICS

Simple measure: *"Bad science is bad ethics"*

- Will the proposed study lead to the achievements of objectives?
- Are the objectives clear enough to ensure good science?
- Can the objectives be achieved with the proposed research approach?
- Are there any deceptions /contradictions in the proposal?

INSTITUTIONAL REVIEW APPLICATION

Arrangements Of Protocol

- Application Letters: *Supervisor(s); Applicant*
- Background Information
- Proposal
- **Attachments:**
  - Informed Consent Forms
  - Checklist
  - Instrument - *FGD's, IDIs, Questionnaire etc.*
  - CV's – Abridged - *PI, Supervisor*

Proposal Format

- Executive summary (Not more than 250words)
- Introduction/Rationale
- Justification
- Aim(s) or Objective(s) of study
- Methodology: Design; Population, Sample size/Sampling Procedure; Instruments; Data collection procedure
  - Ethical issues
- Expected Outcome/Results
- Work Plan; Budget; References

Basic Qualities of Research

- Well structured, according to format.
- Free from language/expression /grammatical errors.
- Obviously “Supervisor reviewed”.
- Submitted in time (about a month to fieldwork)

The Protocol Review Process

- Submission to UCCIRB office (To Administrator).
- Assigning of Reviewers (at least 2).
- Receipt of Reviewers comments by IRBoard Meetings
- Feedback to PIs:
  - Approved
  - Approved after amendments or subject to clarifications
  - Deferred for changes/suggestions to be effected
  - Not Approved

“Extra” Caution

Risks & Discomforts

State:

- Non ***OR*** Reasonably foreseeable risks or discomforts to participants
- Note: Even when a study may seem non-invasive, involving no risk (e.g. observation research) – the actual conduct may result in risk or invasion
- Insurance for research-related injuries

Risks & Discomforts

Provide for

- Planned safety monitoring
- Available medical treatment: if injury occurs, where further information may be obtained
- Trauma support – specific & available
- Compensation for injury

Research Related Injury

Where there is likelihood of more than minimal risk, provide description of

- Availability of compensation; insurance
- Medical treatment of injury
- Further information on alternative courses of treatment, that may be of advantage to a participant

Risk - "Extra" Caution

S**torage of samples** e.g. blood or tissue – for how long; what use; who will have access;

Prior consent from each participant; the future study; Later consent from IRB for future use

Storage institution in Ghana; if outside- proper justification should be given & a material transfer agreement.