Case study on the ethical sound approach (do's and dont's) when working with vulnerable research populations

Daniel Bruce Sarpong (PhD)

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University of Ghana Ethics Committees/Boards and focus

- Noguchi Memorial Institute for Medical Research Institutional Review Board (NMIMR-IRB) located within the NMIMR;
- Ethical and Protocol Review Committee (EPRC) located within the College of Health Sciences, Korle-Bu;
- Ethics Committees for the Humanities (ECH) located within the Institute of Statistical, Social and Economic Research (ISSER);
- Ethics Committee for Basic and Applied Sciences (ECBAS) located within the College of Basic and Applied Sciences;
- Institutional Animal Care and Use Committee (IACUC) located within NMIMR reviews proposed studies involving animals to ensure their responsible and ethical use for research purposes considering appropriate ethical guidelines

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Outline

- Define Vulnerable Populations
- Why Protection of vulnerable?
- Ethical Principles of Research
- Categories of vulnerable Research Participants
  - Ethical Issues
  - Special Protection
- Some Case studies of involving Vulnerable Research Participants (Do's & Don'ts) from ECBAS

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Vulnerable Population

- Defined as groups of people who, due to factors usually considered outside their control, do not have the same opportunities as other, more fortunate groups in society

- Vulnerable subjects are also those whose ability to provide voluntary consent for research purpose may be compromised by social pressures, among others

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3. Vulnerable research participants in Ghana considered by UG

The UG recognizes vulnerable groups to include:

- Children: <18yrs,
- prisoners,
- pregnant women,
- mentally disabled persons, elderly people
- People who use drugs
- People who are ill or immuno-compromised
- Economically disadvantaged persons
- Educationally disadvantaged persons(students, etc
- etc

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Why Special Protection?

- Past abuses of the rights of vulnerable participants

  Notable among them:

- Nazi atrocities and the Nuremberg trials (1947)
- The Tuskegee Syphilis Study (1932-1972)
- Trovan Study in Kano, Nigeria (1996)

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Ethical Principles

- 1947 The Nuremberg Code
- 1964 Declaration of Helsinki
- 1974 National Commission for the Protection of Human Subjects
- 1979 Belmont Report
- 1982 CIOMS Guidelines
- 1991 The Common Rule (45 CFR 46)
- 1995 Advisory Committee on Human Radiation
- 1995 National Bioethics Advisory Commission

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Belmont Report (1979)

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Principle 1: Respect for Persons

- Treat Individuals as autonomous agents
- Protect persons with diminished autonomy

Ethical Consideration

- Participants voluntarily participate in research
- Obtain informed consent
- Privacy and confidentiality are protected

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Principle 2: Beneficence

- Do unto others as you would have them do unto you (Trade-offs between individual and societal benefit require IRB Members to make difficult choices

Ethical Consideration

- The risk of research are justified by potential benefits to the individual or society
- The study is designed so risk are minimized
- Conflicts of interest are managed adequately

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Principle 3: Justice

- Distribute the risks and potential benefits of research equally among those who may benefit from the research

Ethical Consideration

- Vulnerable participants are not targeted for convenience
- People who are likely to benefit from research participation are not systematically excluded

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BACKGROUND TO CASE STUDIES

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Recognition of the need for and scope of research ethics at UG

- University of Ghana students and faculty are the key research stakeholders
- Our works are intended for dissemination, information, attention, and consumption of audiences beyond the researcher-scholar's proximal academic habitat.
- We understand that responsible, respectable, and successful engagement in research and scholarship in academia requires adherence to certain basic professional ethical principles to sustain the fidelity of academic work and the integrity of the researcher-scholar

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The University of Ghana Research Ethics Committees

- Mandate:
  - Review proposed research involving human and non-human participants conducted by students, faculty and staff of the University in order to ensure adherence to both local and international guidelines.
  - Ensure that the right, dignity, safety and general wellbeing of participants are protected
  - Adhere to the Standard Operating Procedures (www.cbasug.edu.gh/...).
  - Implement ethics policy (www.cbasug.edu.gh/...).

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3 CASE STUDIES

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Case 1: Teaching Material (Video) evaluation by "own class"

Teaching material used in two different campuses. "Researcher" teaches in "one" only of the two campus. Research design included researcher's campus and class

- A key requirement: The study should not involve participants who are particularly vulnerable or unable to give informed consent. (e.g. people under the age of 18, people with learning disabilities, **students you teach or assess**, etc.)
- Informed consent state clearly that participation is voluntary, without authority figures present, **protections in place to prevent retaliation**

- **Protections**
  - Don't include these own class students. The exclusion criteria should be explicit. No protection in place to prevent retaliation

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Case 2: ICT use and Children (<18yrs)

The study was designed to understand public use of ICT, particularly cell phones. Study included children, in which the researchers assumed has proliferated in recent times. No consent were specifically designed for children

- A key requirement: The study should not involve participants who are particularly vulnerable or unable to give informed consent. (e.g. people under the age of 18, people with learning disabilities, students you teach or assess, etc.)
- Exclusion criteria not properly thought through: impaired persons (Children) treated as Adults in the research on the assumption that ICT is proliferate

- **Protections**
  - Surrogate consent from parent or legal guardian and assent from child
  - Pay close attention to non-verbal behavioral cues indicating their wishes re: participation

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Case 3: Study involving use of patients' records from "Private Hospital"

The study involved using patient data from a private hospital over a period. ECBAS was concerned about whether the private hospital had ethical clearance to provide the details to the researcher. ECBAS needed to see proof of ethical clearance from "the private hospital" before ECBAS could grant ethical clearance

- **Need for multiple Ethical Clearance from different accredited sources (DO)**

- Protections
  - Keep institution from divulging identity of participants
  - Informed consent clearly should be in place
  - Recruitment procedures should not involve direct solicitation by persons in the private hospital

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Understanding the informed consent concept

- Informed consent is the process in which a researcher educates respondents about the risks, benefits, and alternatives of a given procedure or intervention

There are 4 principles of informed consent:

- The respondent must have the capacity (or ability) to make the decision.
- The researcher must disclose information on the instrument, test, or procedure in question, including the expected benefits and risks, and the likelihood (or probability) that the benefits and risks will occur.
- respondent must comprehend the relevant information.
- respondent must voluntarily grant consent, without coercion or duress.

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Re-Consent Process

- Consent is an ongoing process
- Re-assess vulnerability and take steps to protect subjects
- Re-assess capacity of participant to provide the requisite information

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Conclusion

- Research with vulnerable populations should be guided by the principles of justice, respect for persons, and beneficence
- Vulnerable participants should be included but given special/adequate protections
- Think carefully about the populations you plan to include in your research and take steps to ensure that their rights and welfare are protected

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THANK YOU

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