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Ethics Framework

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Section A

Background and Introduction of Framework, Part 1

Background

- Development of framework
- Purpose of framework

Background: Principles

- Introduction to ethical principles (*Belmont*)
 - Beneficence
 - Justice
 - Respect for persons
 - AMENDMENT: Integrity/responsibility

Background: Review of Guidance

- Review of contemporary guidance documents
 - Council for International Organizations of Medical Sciences (CIOMS), (2002)
 - ▶ *International Ethical Guidelines for Research Involving Human Subjects*
 - Indian Council on Medical Research (2006)
 - ▶ *Ethical Guidelines for Biomedical Research on Human Participants*

Background Review

- Review of contemporary guidance documents
 - Emanuel, Wendler, and Grady. (2000, May 24-31). What makes clinical research ethical? *JAMA*, 283, 20, 2701-2711.
 - Emanuel, Wendler, Killen, and Grady. (2004, March 1). What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J Infect Dis*, 189, 5, 930-937.

Background: Purpose

- Purpose of framework
 - Promote systematic approach to case analysis

Framework

Framework for Analyzing a Case

This framework is meant to provide the user with a systematic approach to case analysis. While the framework presents a series of directions/questions in a specific order, the process of analysis may lead the user to re-visit prior directions/questions. The principles/requirements listed under item C are meant to remind the user of the range of issues that may be relevant to the analysis. Few cases will raise all of the principles/requirements listed. Not all directions/questions will be relevant in the analysis of every case. The final product of analysis ought to be a recommendation for action(s). Justifications for the recommendation(s) will be drawn from what is learned by the user during the process of analysis.

A. Review the facts of the case.

B. Identify the potential moral concerns, or challenges raised by this case.

C. Which ethical principles/requirements are associated with each moral concern, challenge raised?

1. Beneficence¹

- a. Scientific validity^{2,3}
- b. Social value²/Essentiality⁴
- c. Precaution and risk minimization^{3,4}
- d. Favorable risk-benefit ratio^{2,3}
- e. Dissemination of results⁴
- f. Local capacity building³

2. Justice¹

- a. Fair selection of study population^{2,3}
 - Protection of rights and welfare of vulnerable subjects³
- b. Non-exploitation^{2,3,4}
 - Fair benefits⁵
- c. Relevance to the community from which study sample to be drawn³

¹ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. The Belmont Report. Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Found at <http://www.hhs.gov/ohrp/human-subjects/guidance/belmont.html>.

² Emanuel EJ, Wendler D and Grady C. 2000. What makes clinical research ethical? *JAMA* 283: 2701-11.

³ CIOMS. Ethics and Research on Human Subjects. 2006. International Guidelines. Geneva, Switzerland, 2002.

⁴ Indian Council on Medical Research. Ethical Guidelines for Biomedical Research on Human Participants Guidelines

⁵ Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries. Ethics: fair benefits for research in developing countries. *Science* 298:2133-4.

3. Respect for Persons/Study Communities^{1,2}

- a. Informed consent^{2,3,4}
 - Voluntariness⁴
- b. Community/engagement agreement^{2,4}
- c. Privacy and confidentiality^{3,4}
- d. Compensation for research related injury³
- e. Post trial access to beneficial interventions

4. Integrity/Responsibility⁴

- a. Professional Competence⁴
 - Data management⁴
- b. Collaborative and non-exploitative partnership among investigators⁵
- c. Negotiated and equitable ownership of research findings
- d. Accountability and transparency³
 - Independent ongoing review^{3,4}
- e. Regulatory compliance⁴

D. Consider which, if any, of the ethical principles/requirements are in tension or in conflict with each other.

E. What are the key facts relevant to the ethical principles/requirements identified in the case?

1. Are there facts missing that would assist in the case analysis?
 - a. If yes, what assumptions will you make in order to proceed?
2. Are there contextual issues relevant to the case analysis?

F. If yes, are these contextual issues relevant to the ethical analysis of this case? What options (or alternatives) are *possible* for how to proceed?

1. Which options are there? Which of these options are the most realistic in this context?
2. What are the pros and cons of adopting each option?
3. What concerns remain regarding the most realistic options?
4. Can any additional actions be taken to further minimize these concerns?
5. How would each of the options address the moral concerns, tensions identified?

G. Which option would you *recommend* (or what is your assessment of what happened)?

1. Provide the ethical reasoning behind (or ethical justification for) your choice.

⁶ Emanuel EJ, Wendler D, Killen J and Grady C. 2004. What makes clinical research in developing countries ethical? The benchmarks of ethical research. *JID* 189: 930-7.

Framework: Basics

- Process of analysis may lead user to revisit prior directions/questions
- Not all directions/questions will be relevant in the analysis of every case
- Final product of analysis
 - Recommendation for action
 - Justification for recommendation drawn from what is learned in process of analysis

Framework: Facts

- Review the facts of the case

Framework: Concerns/Challenges

- Identify the potential moral concerns or challenges raised by the case

Framework: Principles/Requirements

- Which ethical principles/requirements are associated with each concern, challenge raised?
 - Principles/requirements meant to remind user of range of issues that might be relevant
 - Few cases will raise all principles/requirements listed

Framework: Principles/Requirements

- Beneficence
 - Scientific validity
 - Social value/essentiality
 - Precaution and risk minimization
 - Favorable risk-benefit ratio
 - Dissemination of results
 - Local capacity building

Framework: Principles/Requirements

- Justice
 - Fair selection of study population
 - ▶ Protection of rights and welfare of vulnerable subjects
 - Non-exploitation
 - ▶ Fair benefits
 - Relevance to the community from which study sample to be drawn

Framework: Principles/Requirements

- Respect for persons/study communities
 - Informed consent
 - ▶ Voluntariness
 - Community/engagement agreement
 - Privacy and confidentiality
 - Compensation for research-related injury
 - Post-trial access to beneficial interventions

Framework: Principles/Requirements

- Integrity/responsibility
 - Professional competence
 - ▶ Data management
 - Collaborative and non-exploitative partnership among investigators
 - Negotiated and equitable ownership of research findings
 - Accountability and transparency
 - ▶ Independent ongoing review
 - Regulatory compliance