Belmont Report Overview

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Why Are We Here

- **To provide a framework that will guide the resolution of ethical problems arising from ICT network research that involves communications data from human subjects.**

- **To be considered:**

  (1) boundaries between ICT network research and accepted and routine practice of network operations management,

  (2) role of risk-benefit criteria in determining appropriateness of research involving human subjects,

  (3) appropriate guidelines for selection of human subjects for participation in such research and the data involved,

  (4) nature and definition of informed consent in network measurement and experimental research settings.

Tackling What Belmont Addressed:

- **I. Ethical Principles and Guidelines for Research Involving Human Subjects**
- **II. Boundaries Between Practice and Research**
- **III. Basic Ethical Principles** **IV. Applications**

  1. Respect for Persons 1. Informed Consent

  2. Beneficence 2. Risk-Benefit Assessment

  3. Justice 3. Selection of Subjects

I. Ethical Principles and Guidelines for Research Involving Human Subjects

- **Belmont Procedural Background:**
  - Authority: National Research Act 1974 created the Nat'l Commission for the Protection of Human Subjects of Biomedical & Behavioral Research
- **Mandate**: 1. identify basic ethical principles that should underlie such research involving human subjects 2. Develop guidelines to assure compliance with principles
- **Design considerations:**
  - (i) boundaries between biomed and behavioral research and accepted and routine practice of medicine
  - (ii) role of risk-benefit criteria in determining appropriateness of human subjects research
  - (iii) guidelines for human subjects selection for the research
  - (iv) nature and definition of informed consent in various research settings
- **Period of Performance**: 4 days discussion, monthly deliberations for > 4 yrs
- What it **did not** recommend: specific admin action by HEW
- What it **did** recommend: that it be adopted in its entirety as statement of Dept policy

I. Ethical Principles and Guidelines for Research Involving Human Subjects

- Belmont Drivers:
  - Nuremburg Code- developed post WWII during Nuremburg War Crime Trials; standards for judging doctors and scientists who had experimented on and reportedly abused concentration camp prisoners; basis for later codes assuring ethics in HSR (Helsinki Declaration 1964, US HEW Guidelines 1971 codified 45 CFR 46)
  - What are the codes: rules to guide investigators/reviewers; do not address complex situations and can be difficult to interpret or apply

- Role of principles: prescriptive basis for formulating, interpreting, critiquing the rules; purpose to provide framework to guide resolution of ethical problems.

II. Boundaries Between Practice and Research

- important to distinguish between
- challenging because blur and are not carefully defined
- “practice”= interventions designed solely to enhance well-being of individual and have reasonable expectation of success; e.g., diagnosis, preventative treatment, therapy
- “research”= activity designed to test hypothesis, contribute to generalizable knowledge; a new or untested procedure is not necessarily a qualifier
- general rule= if there’s an element of research, it should undergo HSR

III. Basic Ethical Principles

- = general judgments that justify ethical prescriptions and evaluations of research

  1. Respect for Persons

  - persons should be treated as autonomous →consider their choice and opinions, provide adequate notice and allow voluntariness, do not obstruct their actions unless clearly detrimental to others
  - persons with diminished autonomy deserve protection → this will vary with situation, should be periodically re-evaluated
  - may require balancing

- 2. Beneficence
  - Obligatory

  (1) do not harm (according to best judgment)

  (2) maximize possible benefits and minimize possible harms (applies to particular project and enterprise of science in general)

  - can be ambiguous (e.g., research involving childhood disease- more than minimal risk to research subjects, individual subjects not direct beneficiaries)

III. Basic Ethical Principles

- **3. Justice**
  - equal distribution of benefits and burdens of research
  - who is equal and unequal
  - what justifies departure/exception
  - common formulas:

    (a) to each person an equal share

    (b) to each person according to need

    (c) to each person according to effort

    (d) to each person according to societal contribution

    (e) to each person according to merit

  - infamous e.g. → 19th C. burden on poor ward patients and benefits of improved medical care to private patients; 1940's Tuskegee syphilis study use poor, rural black men to study

IV. Applications

- **1. Informed Consent (~Respect for Persons)**

(Step 1) Information

- research procedure, purposes, risks and benefits, alternatives, statement offering subject to ask questions and withdraw, how are subjects selected, who is responsible for research
- "reasonable volunteer" standard: disclose the info necessary to allow person to decide whether they wish to participate (kitchen sink not necessary)
- consideration: impair research validity may justify incomplete disclosure only if : (a) truly necessary to accomplish research goals (b) no undisclosed risks that are > minimal (c) adequate plan for debriefing subject, when appropriate, and disseminating results to
- distinguish destroy/invalidate research v. inconvenience

(Step 2) Comprehension = manner and context info conveyed

- consideration: incompetents (young, aged, mental, infirm); 3rd party proxy

(Step 3) Voluntariness: freedom from coercion and undue influence

IV. Applications

- **2. Assessment of Risk - Benefits (~ Beneficence)**
  - **investigator = whether research is properly designed**
  - **review committee = method to assess whether risks are justified**

  - **benefit= something of positive value related to health/welfare**
  - **risk= harm (psychological, physical, legal, social, economic)**

  - **scope: subject, subject family, society**
  - **? subject risk < subject benefit + societal benefit**

IV. Applications

- **2. Assessment of Risk - Benefits (~ Beneficence)**
  - **systematic assessment called for: (unlikely to quantify)**

    (a) how valid is presupposition

    (b) is the method of ascertaining risks explicit

    (c) is estimate of harm or benefit reasonable (known facts, studies)

    (d) considerations:

brutal treatment never justified; only necessary risks to achieve objective; if significant risk of serious impairment, must demand justification; if vulnerable populations are involved, should demonstrate appropriateness; must thoroughly document risks & benefits in informed consent process

IV. Applications

- **3. Selection of Subjects (~ Justice)**
  - 2 levels: social and individual
  - injustice arises from social, racial, sexual and cultural biases institutionalized in society
  - e.g, racial minorities, poor, infirmed, ill

Our challenge… should we choose to accept it:

- Modernize Belmont to our ICT society
- Interpret and Apply these principles and guidelines to Network Measurement & Security research
- Use-case driven