Proposal Class: Research Ethics

CSCI4148/CSCI6410/EPAH6410

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What are research ethics?

Research ethics are normative

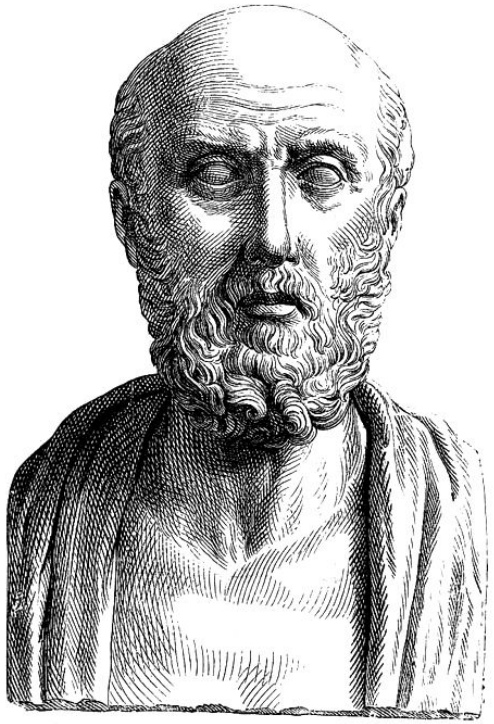
- Explicitly and implicitly codified values and norms in research that distinguish between acceptable and unacceptable behavior
- Contrast with theoretical/meta ethics
- Laws may also codify norms but ethical != legal

Research ethics blends theoretical frameworks

- Consequentialism
  - Bentham (Utilitarianism)
  - Based on outcomes
- Deontological ethics
  - Kant (categorical imperative)
  - Rawls (contractualism/veil of ignorance)
  - Duties and rights in research
- Virtue ethics
  - Aristotle, Aquinas
  - Related to character of researcher not necessarily actions (not really codified!)

Strongly established in medical/social science research

- “Hippocratic” Oath
  - “Do no harm”
  - But also no abortions or euthanasia (maybe) - medical paternalism
- Nuremberg Code (1947):
  - Trial of 23 Nazi physicians
  - Permissible Medical Experiments
  - Codified: consent, benefit, harm
- Helsinki Declaration (1964):
  - Research Ethics Committees (IRB/REB)
  - Concerns for individual outweigh concerns for society
  - Patient must benefit (or be healthy)
- Tri-Council Policy Statement 2 (2018):
  - Codification of principles for canadian research involving human subjects



https://en.wikipedia.org/wiki/File:Hippocrates.jpg

Short version:

- **Beneficence**
- **Nonmaleficence**
- **Autonomy**
- **Justice**

Not well established in data science

Many challenges:

- Specific consent difficult to impossible to obtain
- “Public data” and “minimal risk” research e.g., social media data/open deidentified data are historically exempted from REB
- Privacy/Anonymity issues
- Data Misuse (societal not individual benefit)
- Validity/Accuracy/Contextualisation (large datasets can be MORE vulnerable to biases)
- Personal/Group harm
  - Model reinforces biases in dataset
  - Subjectivity in model design
  - Model abuse/misuse

- Existing frameworks often unwieldy/inappropriate: lots of active ethical theory (e.g., duty of easy rescue, social contract)

Why are research ethics important?

Many egregious failures of research ethics

- 1933: Qu'Appelle SK TB Vaccine (600 indigenous children: ⅕ died due to conditions)
- 1946-1948 Guatemala Experiment (directly infected 1,300 people including prisoners, inmates, orphans, sex workers)
- 1942-1952: First Nationals Nutrition Studies (>1000 children in residential schools)
- 1957-1964 MK-ULTRA - Royal Victoria Hospital in Montreal (>300 patients ECT, Thorazine, Sensory deprivation attempts at brainwashing)
- 1932-1972 Tuskegee Syphilis Study (399 black men deliberately not treated for syphilis)

So, how do we do propose ethical research in health data science?

Start with big conceptual questions

- What potential good comes from this research cause?
- What potential harm?
- Can we do anything to mitigate the harm?
- Are there any alternatives to the same benefit?

Identify your conflicts of interest

A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain). Conflict-of-interest rules [...] regulate the disclosure and avoidance of these conditions.

— Dennis F. Thompson, *The New England Journal of Medicine*, 1993

- Requirement to declare COIs during knowledge translation

Evaluate your proposal on TCPS criteria:

1. Respect for autonomy
    a. Respect freedom of thoughts and action
    b. Take special measures to protect vulnerable individuals
2. Beneficence (non-maleficence)
    a. Minimize potential harms
    b. Maximise potential benefits
3. Justice
    a. Ensure fair spread of burdens/benefits (e.g., avoid exclusion of individuals solely on the basis of class, race, gender, disability, age (**TCPS-2**))
    b. Ensure those assuming burdens access benefits
4. Respect for community
    a. Engage community that is subject to the research in the research (patient-involved research)
    b. Open communication/knowledge translation
    c. Explicit requirement for research involving First Nations, Inuit, and Metis people (**TCPS-9**)

Consider consent

- Clinical standard: Informed voluntary opt-in to research (no coercion, care with vulnerable groups)
- How well can you inform someone else when doing inductive/prospective research?
- If the dataset had broad consent (e.g., “we can use data for research purposes”) is your research proposal in keeping with what participants might expect?
- If not, is it actually possible to get more specific consent?
- Can you reduce sensitivity of data to make broad consent more appropriate?

- Again: this is a **mess** in health data science

Ensure compliance with legal privacy requirements

- Privacy legislation
  - **Federal**: Personal Information Protection and Electronics Documents Act
  - **Provincial**:
    - Nova Scotia Personal Information International Disclosure Protect Act
    - Nova Scotia Personal Health Information Act
- Include considerations: data shouldn't leave Canada (thorny with cloud computing), consent is required for recruitment AND participation in research (although waiver of consent can be requested due to "impracticality").

General principles:

- Collect the minimum amount of data required
- Securely handle it/store it/share it with access logs

In pre-collected datasets this will have been considered but need to justify (and additional linkage/analyses may require reconsideration).

Procedural compliance

- REB application is still required (even if exempt) for any research involving humans
- Databases often have specific additional data access applications
- Will formalise the other components but are a **MINIMUM** requirement!