Human Research Ethics

COMPSCI 345

Not in textbook

Human research ethics

- So, we want to 'experiment' on humans to assess usability
  - Unfortunately (from the perspective of convenience), experimenting on humans is a very formally constrained undertaking, with a Code and associated procedures
    - At least in the University and Medical (e.g., hospital) environments of the West, where the code is just about uniform
    - In the corporate environment, I guess anything is OK as long as you don't get sued – many of the same principles are still helpful from that perspective

Nuremberg Code

- In 1947, the judgment by the war crimes tribunal at Nuremberg laid down 10 standards to which physicians must conform when carrying out experiments on human subjects
    - See http://www.cirp.org/library/ethics/nuremberg/
  - This Code now underlies all university and medical human research ethics approval procedures
- 1. The voluntary consent of the human subject is absolutely essential… The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment.
  - *This has lots of implications for what we do in front of the main part of an experiment*

Nuremberg Code (contd)

- 2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature
  - *This is somewhat problematic for doing studies just for the sake of research training*
- 4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury
- 6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment
  - *So it can be risky and painful as long as it's worth it*

Nuremberg Code (contd.)

- 9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible
  - *And this is usually softened to be whenever they wish and with absolutely no penalty (e.g., bias in their subsequent treatment as an employee, patient or student)*

HREC approval

- What's needed?
  - Fill out the forms (see http://www.health.auckland.ac.nz/research/ethics/human/uni/)
  - Your response is reviewed by a University of Auckland Human Participants Ethics Committee (UAHSEC) that may approve, or tell you why not (often they have a few questions which are easily answered)
    - UAHSEC is staffed by a variety of disciplines, a lawyer, a 'moral philosopher', etc. (see http://www.auckland.ac.nz/uoa/about/uoa/committees/council/ethics/tor.cfm)
  - Particulars of the pro forma
    - Consent Form
    - Project Information Sheet
    - Motivation
    - Description of the protocol
    - Lots of other stuff

Major ethics approval issues

- Informed Consent and Project Information
  - That Nuremberg Code principle #1 (and also #9) leads to a specific format for these two forms
  - Project Information sheet explains what you're doing, identifies the researchers, and names HREC (independent) contacts
  - Consent Form is like a contract that says they understand what they're in for (explicitly agreeing to any audio or video taping and use of direct quotations), can stop at any time without penalty, etc.
    - Signed by investigator and participant (hence investigator is attesting that participant understands)
  - These forms (as a contract) must be perfect in terms of grammar and overall clarity of expression

Ethics approval issues (contd.)

- Motivation
  - Need to justify that the experiment is not arbitrary
    - Usually a literature review and a defensible statistical method to address well-defined hypotheses
- Protocol
  - HREC wants to know just what you're going to *do* to the participants
    - Each and every step
    - How long will it take?
    - Copies of all questionnaires (phrasing of questions must be perfect)
    - Good description of the software (and esp. of any unusual hardware)

Other ethics stuff

- Safety
  - Is it safe? (to degree of 'everyday life')
  - What will you do if participant has a problem?
- Recruiting and coercion
  - How will participants be sought?
    - Putting up posters (sending emails, etc.)? Do you have approval?
  - Will the population feel pressured to participate (or think they should bias their responses)?
    - E.g., if they are employed by the investigator
- Intellectual Property (IP) and data storage
  - Who owns the data?
  - Where will it be kept? (expectation of keeping for 7+ years in case of data fraud challenge)
  - Need to be clear on management of confidentiality and anonymity (these are not the same thing!)

UAHSEC timing

- At UA the committee meets once a month
  - If your timing is poor, might take 7 weeks to get the protocol seen (then some time for a response, which asks questions to be taken up at next meeting…)
    - Meeting schedule at http://www.auckland.ac.nz/uoa/about/uoa/committees/council/ethics/schedule.cfm
  - For an honours dissertation, UAHSEC approval must be integral to project plan (i.e., gotten into early) or you'll run out of time
- Must have *final* approval or you're not covered by Uni's insurance
  - Technically, your thesis can't be marked (or the degree awarded) without approval
  - *Of course this is only for thesis work that involves human subjects*