

Experimental Design and Research Ethics (REB CORE)

6 Oct 2011
BUSI275
Dr. Sean Ho

- **HW4** due 10pm
- Work on **REB** forms

Experimental Process

- Research question (RQ): topic of interest
- Population of interest and unit of observation
 - Per person? Per store? Per year?
- How to collect data: survey? Observer?
 - Sampling: how to recruit participants?
 - Survey questions
- Pre-test survey on a small set
 - Refine survey as needed
- Collect full dataset (required sample size?)
- Analyse: understand the structure in the data
- Interpret and present results

Research ethics



National Council on Ethics
in Human Research

Conseil national d'éthique
en recherche chez l'humain

- Three core principles:
 - Respect for Persons
 - Concern for Welfare
 - Justice
- Affects:
 - How we recruit participants
 - Disclosure of purpose and risks/benefits
 - Voluntary, informed, ongoing consent
 - Privacy + confidentiality, handling of data
 - Conflicts of interest

Ethical abuses in research

- Tuskegee syphilis study (1932-72)
 - Observe **natural** progression
 - **400** poor, black, men w/syphilis
 - **Not told** they had it or **treated**
 - “Health checkups” actually **placebo**
 - Not given **penicillin** even after it was proved effective in 1940s
- Baylor “Texas Vampires” (1998)
 - 70 relatives in **NL** with Wolff-Parkinson-White
 - Rushed, pressured **consent** process
 - No follow-up, **disclosure** of results



What requires REB approval?

- What is **research**?
 - “An undertaking intended to **extend knowledge** through a disciplined **inquiry** or systematic **investigation**.”
- Not research: **Quality Assurance**
 - Assessing or improving **performance**: job satisfaction, safety compliance, etc.
 - **Mandated** by the job or training
- Not research: **Creative Practise**
 - **Critique** of art, analysis of **creative process**,...
 - Work involving **human subjects** (e.g., focus group) **does** count as research

What is exempt from REB?

- Existing data in **public domain**
 - e.g., **StatCan, Forbes, CBC**
 - **Steward** of the data grants legal access
 - ◆ Check terms and conditions / license
 - No reasonable **expectation** of privacy
- Studies **internal** to an organization
 - QA, **performance** review, assessment
 - e.g., does age of company-provided **computer** correlate with employee **satisfaction**?
 - If internal data is later used for **broader research**, that would require REB approval

What is exempt from REB?

- **Observation** in public places
 - Mall, sports arena, public bus, etc.
 - No reasonable **expectation** of privacy
 - No staged **intervention** or direct **interaction**
 - No personally **identifiable** info in results
- **Secondary** use of **anonymised** data
 - Originally gathered for non-research use
 - ◆ Patient or school records, online polls
 - No way to **identify** individuals from data

Example: REB exempt?

- A team of **political scientists** have observed that the difference between the **exit polls** (how people said they voted) and the **official vote** count (how the vote turned out) during a recent election was far **greater** than would normally be considered statistically possible.
- They have collected **exit polling data** from a large representative sample of voting locations across the country and have **interviewed electoral staff** from these stations. The interview transcripts show a pattern of **irregularities** in the **collection** of voting results from the computers and the treatment of **ballot boxes** holding paper voting slips.
- The report of their findings promises to be very **critical** of electoral policy and of the current **administration** of the country.

Voting study example

- **Answer:** No, most likely not REB exempt
- **Exit poll** data and actual **vote counts** are okay:
 - **Secondary** use of **anonymous** data
- **Interviews** with electoral staff count as **research** involving human subjects
 - Need **informed consent** from interviewees
 - Disclose **risks & benefits**
 - Allow **anonymity**

Principles: Respect

- **Autonomy**
 - Voluntary participation
 - Opportunity to ask questions
 - Ability to opt-out at any time
- **Informed consent**
- **Honesty** (any deception requires debriefing)
- **Privacy & confidentiality**
 - Securing personally identifiable data
- **Fair recruitment** (no unneeded selection bias)
- **Follow up** (what did we do with their data?)

Principles: Concern for Welfare

- Risks vs. benefits
 - Informed consent
 - Risks include social stigmatization, impact on employment, right to privacy
 - Benefits do not mean cash compensation, but greater understanding of themselves or some issue, or treatment, aid, etc.
- Will our research benefit anyone, or is it purely for the sake of knowledge?
- Vulnerable populations
 - Children, seniors, mentally ill, poor, ...
- View them as people, not just data

Principles: Justice

- Inclusion / exclusion:
 - What are our **criteria** for participants?
 - Are we unfairly **discriminating** against anyone in the **way** we recruit participants?
 - Are we **excluding** anyone who could **benefit** from the study?
- Any **materials** presented to the participants:
 - **Posters** / flyers, **emails**, wording of questionnaire, **consent** form
 - If the **participant** sees it, the **REB** needs to see it!

Example: what are the risks?

- A sociological researcher wants to use a **snowball** sampling technique to interview workers in a telephone **call centre** about their **working conditions**.
- This technique involves asking current **participants** in the study (recruited from advertisements) to identify **others** who may be interested in doing the study.
- It is well known that the **employer** is **resistant** to all outsiders who may alter the call centre's practices.

Obtaining consent

- Must be **voluntary**:
 - No coercion, **pressure**, undue incentive
 - No **penalty** for opting out
- Must be **informed**:
 - Disclose **purpose, risks, benefits**
 - Give **contact** info and opportunity for **Q&A**
 - Participant must have **capacity** to consent
- Must be **ongoing**:
 - If **new info** arises that may impact whether the individual wishes to continue, you must **inform** them and **ask** whether they wish to continue
- Consent may be **withdrawn** at any time

REB criteria

- Inclusion / exclusion criteria
- Risks & Benefits
- Privacy & Confidentiality
 - Data Management
- Recruitment (Sampling) Procedures
- Consent Procedures
 - Withdrawal of consent / participation
- Materials: flyers, scripts, surveys
- Dissemination / publication of results

For more details

- Handy links, templates from NS Ag Coll
 - Colin Robson's research links
- The full rules are in the TCPS-2:
 - Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans
- TCPS-2 CORE: Course on Research Ethics
 - HTML and Flash-based, go at your own pace
 - Anyone can register (use your @mytwu.ca)
 - Cool case studies, and quizzes to test self
 - PDF certificate upon completion
- If the REB rejects your application, you may be required to complete the CORE tutorial

TODO

- HW4 (ch5-6): due tonight at 10pm
- HW5 (ch7-8): due Thu 13 Oct at 10pm
- REB form due Tue 18 Oct 10pm
 - If approval by TWU's REB is required, also submit printed signed copy to me
 - You are encouraged to submit early to allow time for processing by TWU's REB (3-4 weeks)