Sending an application for review at BCIT's REB

What is research ethics?

- For our purposes, it's "...the analysis of ethical issues that are raised when people are involved as participants in research." (source)
- The aim is to protect human participants ("**Concern for Welfare**" in TCPS2)
- Ensure that research is conducted in a way that serves interests of individuals, groups and/or society as a whole ("**Justice**" in TCPS2)
- Examine specific research activities and projects for their ethical soundness (e.g., consent, risk, confidentiality) ("**Respect for Persons**" in TCPS2)
- Depends on social, political, and cultural contexts – See definitions PDF
- To see examples of unethical human experiments see and the next slide

Unethical human experiments (source)

Also see this research ethics timeline

- Mustard Gas Tested on American Military
- Radioactive Materials in Pregnant Women
- Unit 731
- Nazi Human Experimentation
- Human Experimentation in North Korea
- Human Experimentation in the Soviet Union
- Infected Mosquitos in Towns
- Milgram Experiment
- Tuskegee Syphilis Study
- Syphilis Experiment in Guatemala
- Stanford Prison Experiment
- Effect of Radiation on Testicles
- Sexual Reassignment
- Medical Experiments on Prison Inmates
- The Aversion Project
- Experiments on Newborns
- Project MKUltra
- The Monster Experiment
- Study of Humans Accidentally Exposed to Fallout Radiation
- Operation Midnight Climax
- Hepatitis in Mentally Ill Children
- Project Artichoke
- Electroshock Therapy on Children
- Dr. William Beaumont (Dr. William Beaumont)
- Emma Eckstein
- Stateville Penitentiary Malaria Study (Stateville Penitentiary Malaria Study: Primaquine)
- Project QKHILLTOP
- Henrietta Lacks (Henrietta Lacks)
- Prison Inmates as Test Subjects
- The Tearoom Sex Study

Who writes the rules in Canada?

- The interagency **Panel on Research Ethics** (PRE) responsible for revising rules through consultation in Canada
- Develops and implements the TCPS2

- Tri-Council Policy Statement (three government agencies funding research):
- CIHR - Canadian Institute of Health Research
- NSERC – National Sciences and Engineering Research Council
- SSHRC – Social Sciences and Humanities Research Council

- TCPS2 - December 2010, 2014, 2018

Overlapping levels of guidelines, policies, and legislation
Depending on where you work and what type of human research you do

- Tri-Council Memorandum of Understanding for maintaining eligibility for funding (NSERC, SSHRC, CIHR)
- Institutional Policies and Procedures
  - Colleges/Universities
    - BCIT Policy 6500 - Research Ethics for Human Participants (how TCPS2 applies to BCIT – "All research associated with BCIT that involves living human participants and/or human biological materials requires review")
    - BCIT Policy 6600 - Integrity in Research (applies to funded research activities only)
  - Hospitals, Health regions, CIHR Guidelines for Health Research with Aboriginal Peoples
  - ICH Good Clinical Practice Guideline, Provincial Health Information Protection Acts and Privacy Acts (FIPPA/PIPA)
  - Health Canada, CGSB - National Standard of Canada for Research Ethics Boards Reviewing Biomedical Clinical Trials
  - USA Office for Human Research Protection (OHRP), USA FDA, USA Code of Federal Regulations (many Parts/Sub-parts)

Education on rules provided in Canada by

- Panel on Research Ethics (PRE): Course on Research Ethics (CORE)
- Canadian Association of Research Ethics Boards (CAREB)

What is an REB?

- Research Ethics Board - required at each institution that receives federal research funding
- Independent board that reports to the "highest governing body." (Board of Governors at BCIT)
- Group of volunteers or appointees who review human research at each institution
- Members represent different areas of expertise
  - The REB shall consist of at least five members, including both men and women, of whom:
    - (a) at least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
    - (b) at least one member is knowledgeable in ethics;
    - (c) at least one member is knowledgeable in the relevant law (but that member should not be the institution’s legal counsel or risk manager).
    - (d) at least one community member who has no affiliation with the institution.
  - BCIT has 10-15 members representing different schools and areas of research.

What kind of research is exempt from review?

- **Publicly available information** when: the information is **legally accessible** to the public and appropriately protected by law; **or** the information is publicly accessible and there is **no reasonable expectation of privacy** (see here).
- **Observation of people in public places** where: it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; individuals or groups targeted for observation have no reasonable expectation of privacy; and any dissemination of research results does not allow identification of specific individuals (see here).
- **Secondary use of anonymous information**, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information (see here).
- **Quality assurance and quality improvement studies**, program evaluation activities and performance reviews, or testing within normal education requirements (see here).
    - See Dalhousie REB guidelines for differentiating among research, program evaluation and quality improvement (FAQ #5).

What kind of research is covered by the REB?

- Whether or not the research is funded by BCIT or Tri-Council Agencies…
- *Any* research “under its auspices” involving living human participants or involving human biological materials (from living and deceased individuals) if:
    - (a) any of the researchers are associated with BCIT,
    - (b) any of the participants are associated with BCIT,
    - (c) any BCIT resources are used in the study.
- Research is defined as "An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation."
- Samples or data collected from an identifiable person (*includes objects and devices a person uses or touches when they are identifiable*).
- Data collected from exempt curriculum development, program evaluation, or quality studies **if used to answer a research question** or **published in a journal that requires documentation of ethics approval**. Called secondary use

How will I apply?

- Visit the BCIT REB website to read the FAQ and find the forms and instructions/guidelines
- Email the REB Chair if your research involves other institutions--we may be able to "harmonize" your review with the other institutions so you only fill out one application on UBC RISe (see FAQ #7).
- Applications are reviewed as either delegated ("minimal-risk“) or full-board ("above minimal-risk“) studies, so ask the Chair or administrator how and when to apply, based on risk level.
- Minimal risk: “Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.”

How will I apply?

- *Step 1:* Complete the TCPS2 CORE tutorial and save a copy of the certificate if you don't have a certificate. Email the copy with your application. The tutorial can be found here

- Step 2: You probably want to take our free online Research Ethics Approval course:
  - Students will find the course in their My Courses listing in the Learning Hub.
  - Employees will find the course in their My Courses listing in the Employee Learning Centre.

- *Step 3:* Download the application form (PDF) and fill out each section - Most of what's in the application should be summarized somewhere in the consent form, except written for the participant (*you/your*)

How will I apply?

- *Step 4:* Write the attachments including the consent form and invitation letter. Name the attachments to make them easy to recognize and if possible include the suggested attachment letter given in the application (e.g., “Appendix F” for surveys and data forms).
- Research plan
- Consent form
- Recruiting materials (e.g., invitation letter, poster, text for posting to social media*) *Templates can be found on REB websites (such as here). See application guidelines for others*
- Study materials (e.g., printout of online survey, interview questions, data collection forms, videos)
- TCPS2 CORE certificate

- *Step 5:* You’ll generally email the completed application and all attachments directly to the REB chair. If you are a student, your program may have different requirements, and you may have a pre-review before you can submit to the REB. Ask your instructor

Common mistakes

- **Age of consent for research**
- *Please don't exclude those under 19. Most minors can consent (to minimal-risk) but added parental consent is often required in schools.* See BCIT guidelines for section 24

- **Recruitment**
- *Please don't recruit friends, family, and classmates. Recruitment of friends, family, and classmates may not represent a good population sample (quality of study) and represents a form of coercion.* Broad public postings preferred. See BCIT guidelines for section 18.6

- **Feedback for participants**
- Please provide some optional feedback for participants such as having them ask to receive a summary or invitation to a presentation.

Common mistakes

- **Surveys**
- *No questions should be required (have asterisks)*
- *Warning needed if personal information is stored outside Canada (e.g.,* SurveyMonkey free *account or Google forms)*
- *Turn off IP tracking*
- *Include full consent form at the top of the survey, ending with "Having read the above, I understand that by clicking the "Yes" button below and completing the questionnaire I agree to take part in this study."*
- See BCIT guidelines for section 21.3
- and UBC Online Survey Guidance Notes for more information

Common mistakes

- **Remuneration**
- *Prize draws are regulated games, so please follow the rules.* Prize draw summary
- *Remuneration should also be equitable and not cause undue inducement. Ask yourself if participant will view payment as "nice to have" or "need to have"*
- See BCIT guidelines for section 19.8 and University of Toronto guidelines for a more complete discussion.

See UBC guidelines for the legal background.

- **Anonymous vs confidential**
- Only a survey where you **don't collect any identifiable information** is anonymous, so please don't promise "anonymity" for any other type of study. Other research is confidential (you pledge to not disclose their identity).

- **Demographics**
- *Collect minimum necessary and be inclusive of sex/gender/orientation/race (provide "other" option and allow skipping questions)*
- See BCIT guidelines for section 19.6 and this on sex and gender

Common mistakes

- **Conflict of interest/sponsorship**
- *Need to declare financial interest of sponsor, Principle Investigator, and co-investigators/family.*
- See BCIT guidelines for sections 12 and 23

- **Student research**
- *Student research is still research, especially when presented outside classroom (see this)*

- **Review harmonization**
- *Faculty/staff who are collaborating with others need to submit an application to BCIT as well but can forward a joint ethics application if outside BC. In BC joint applications are submitted through UBC RISe platform.* See FAQ #7

- **Critical research**
- *If an organization hasn't agreed to participate in a study, participants need to know about the potential impact on the organization*
- See BCIT guidelines for section 19.6 and this

- **Academic freedom**
- *Faculty and outside investigators are free to study what they choose without interference (academic freedom).*
- *See BCIT policy 5701*

What if I'm collaborating with researchers at another university or health authority?

- If in BC, ethics between institutions is harmonized, with applications going through UBC's RISe application (module called PREP for Provincial Research Ethics Platform (also see REBC).
- If outside BC (or partner institution in BC hasn't joined PREP) then contact both REBs and ask them if they can coordinate the review.
- Submit one application to one board, receive one set of provisos (comments), make one set of revisions.

What if I'm doing survey research?

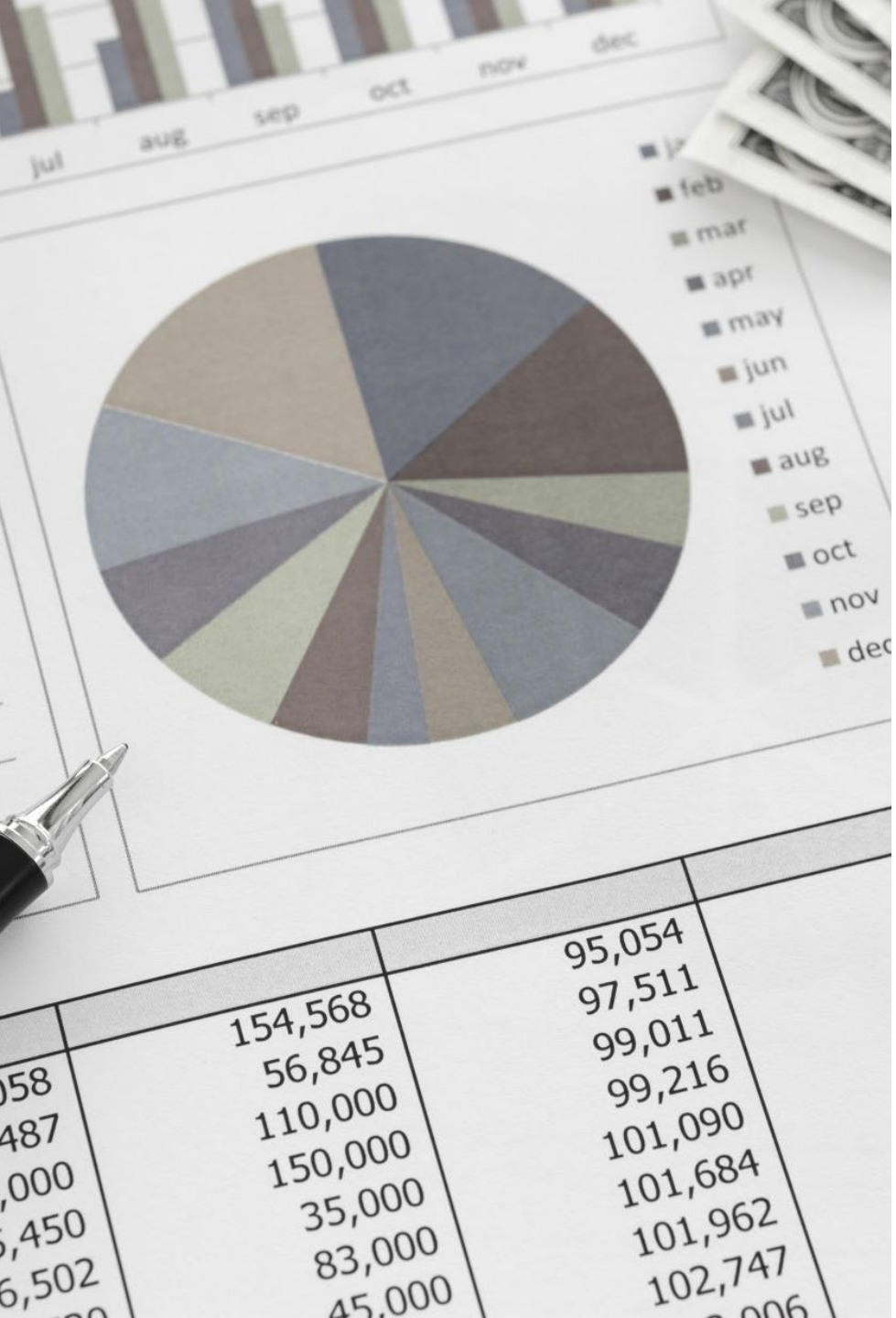
- Collect data from as wide a group of participants as possible. Participants should be assured that their time is going into a valid and valuable study.
- Avoid recruiting classmates, friends, and family (e.g., through personal social media) because they may feel obligated to participate (i.e., friendly coercion)
- BC privacy rules are meant to prevent personal information from leaving Canada without consent.
- For example, US Patriot Act could be used to access survey data stored on US servers (e.g., Google, Survey Monkey).
- Surveys that collect personal information (anything that can identify someone such as name, email, phone, ID number, etc.) should use servers in Canada.

What if I'm doing survey research?

- BCIT has some SurveyMonkey licences set aside for student projects or you can use another Canadian survey company (e.g., this or this)
- **BDC has a list of providers** with a column for hosts with Canadian servers: If you don't collect personal information (i.e., completely anonymous) then you can use any free survey program/website.
- Like any form of research, surveys should be well-designed, without bias (e.g., race, gender, age), and not place participants at undue risk.
- If personal information will be stored outside Canada, participants must be informed and asked for consent (see this)

What if I’m doing survey research?

- BCIT has survey guidelines to help you:
- If you do a prize draw:
  - Laws in Canada govern them as "lotteries," so you have to follow rules (see 6.5.2 here and this)
  - REB will look at whether prize amount is excessive (coercive), risks privacy, or is unfair to a particular group of participants.
  - Most prize draws exclude members and family of the organization doing the draw because it goes against the spirit (ethics) of the incentive for the general public to participate. In the case of funds from BCIT (BC government), compare this to a spending ethics scandal that has been in headlines: here
  - CRA tax law plays a role when only employees participate (taxable benefit)
  - *See BCIT guidelines - 19.8*
  - Include full consent form at the top of the survey, ending with “Having read the above, I understand that by clicking the “Yes” button below and completing the questionnaire I agree to take part in this study.”



What happens after I apply?

- Reviewed for risk (see below) and completeness, usually within 3-5 days.
- Assigned a study number (e.g., 2019-01) and reviewed over 10 business days by members of the board (**if minimal-risk**). If additional expertise is required, reviewed by outside consultants/REBs.
- Send you a list of suggested revisions (provisos).
- You return the list of changes and revised documents.
- Letter of approval by email with the approval date and instructions for post-approval activities (certificate of approval from the administrator at a later date).
- Approved for one year from the approval date

Post-approval

- Renewal or to make changes (e.g., recruitment documents, study design, forms, co-investigators), file an amendment form (Post-Approval Form and instructions here)
- Apply for continuation or amendments within the year, or you will need to reapply.
- Complete an Unanticipated Problems/Adverse Event report using the Post-Approval Form if any problems/adverse events.
- Complete an End-of-Study report using the using the Post-Approval Form when all data collected.

What might make a study "above-minimal-risk" and require full-board review (at REB meeting)?

- Risks of research include **physical** risk (harm through bodily contact or administration of any substance, device or other intervention), **psychological or emotional** harm (harm due to feeling embarrassed, uncomfortable, anxious or upset), **social** risk (harm due to loss of status, privacy, or reputation, and includes legal, financial or employment risk).
- Vulnerability factors such as participant capacity (mental, emotional, cognitive), age, wellness or health status, institutionalization, power relationships, gender and gender identity, setting and recruitment, dependency.
- Common examples of above-minimal-risk studies include:
  - Moderate to serious physical, emotional, psychological, legal, social, or economic risk to participants.
  - Disadvantage due to experimental design (e.g., randomization in an intervention study).
  - Sensitive questions or invasive procedures.
  - Vulnerable populations where participants' capacity to consent may be affected (e.g., infants and young children, individuals with cognitive or intellectual disabilities).
  - Possibility of coercion (e.g., studies involving "captive" groups such as employees, students, members of the military, prisoners).
  - Partial disclosure or deception (e.g., some information which may affect participants' decision to participate is withheld at time of initial consent).