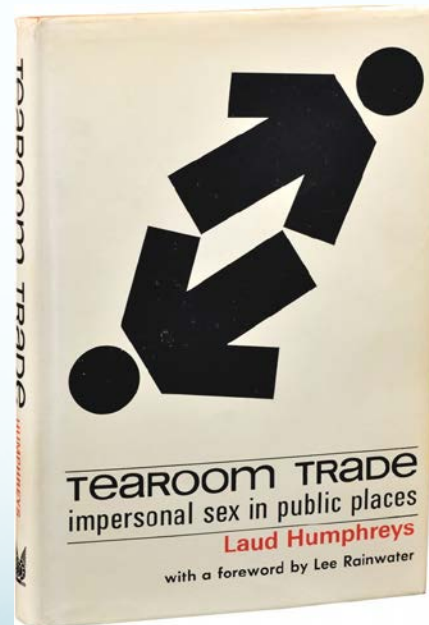
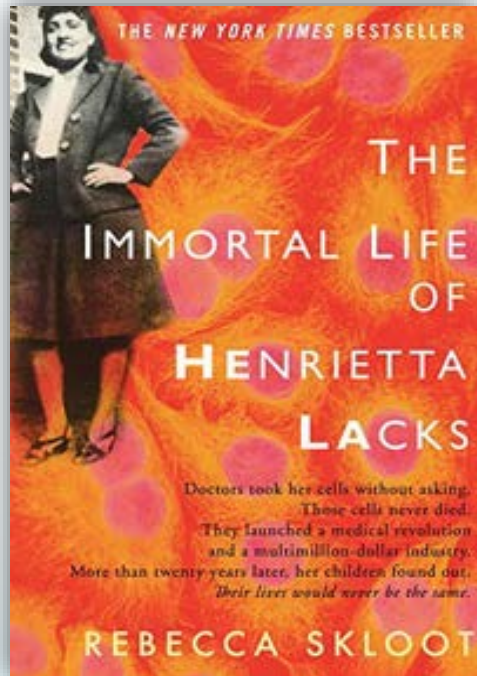


Research Ethics: A Brief Introduction

September 2018

Dina Shafey, Associate Director, ORE
dshafey@sfu.ca

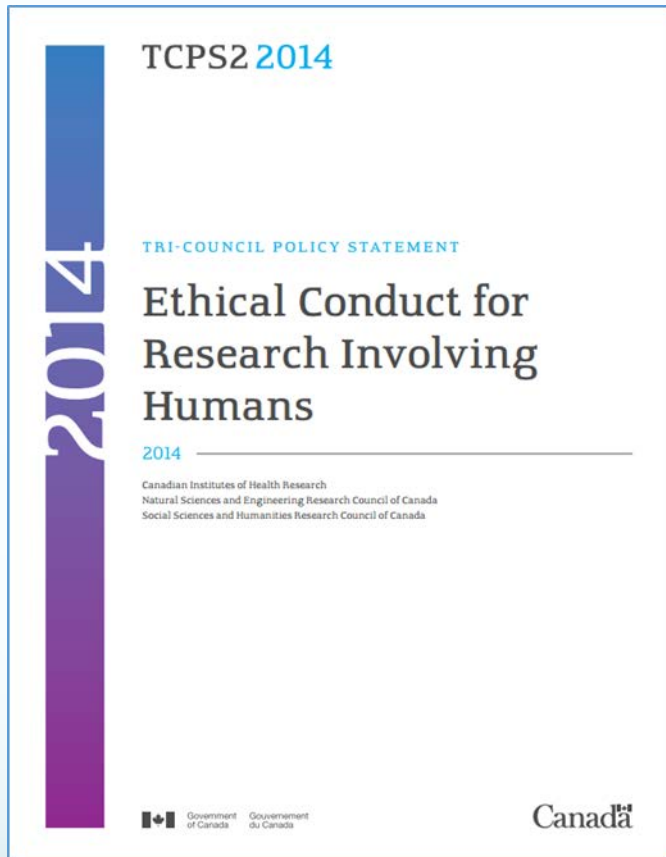
Why Does Research Ethics Matter?



Tuskegee syphilis
experiment 1932-1972

Objectives

- Apply the three core ethics principles to your own research studies
- Anticipate ethical issues in research
- Identify the risks of participating in research
- Identify the components of informed consent
- Know where to ask for help



- Tri Council Policy Statement: *Ethical Conduct for Research Involving Humans* (TCPS 2)
- Overarching Canadian policy framework for research involving human participants
- TCPS published in 1998
- Revised in 2010 and 2014 after extended periods of consultation with relevant stakeholders
- Clear efforts to make TCPS more relevant/applicable to social scientists

TCPS2- Key Principles

Respect for Persons



Centering on the Human Participant

- Who's Participating?
- Recruitment process
- The consent or assent relationship
- Methods employed
- Risk/benefit assessment
- Confidentiality and privacy protections



TCPS2- Key Principles

Respect for Persons



Principles of Consent

- Free
- Informed
- Ongoing

The Consent Process

- Consent is not a single act of someone agreeing to participate in a study. It is a process that begins with the recruitment and screening of participants and continues throughout their involvement in the research.
- Components of the Consent Process are:
 - Recruitment
 - Information
 - Documenting Consent
 - Debriefing (when required)

Keeping Consent Free

- When someone consents to be a participant in a study it is important that they have done so entirely of their own free will.
- Are there ways in which voluntariness can be compromised?
 - Incentives
 - Authority/Power Relationships
 - Undue Influence

Elements of Informed Consent

Consent form should be written in plain and simple language and provide an accurate description of:

- The research purpose and proposed use of data collected
- Foreseeable risks and potential benefits
- Extent of confidentiality promised
- Requirements of the study (e.g. duration, frequency, nature of tasks and/or measures)
- Withdrawal procedure
- Extent of incentives
- Data management (access and safeguards)
- Possible commercialization
- Disclose any conflicts of interest
- Plans for provision of new information
- Plans for dissemination of results
- Contact information of the researcher in charge of the study
- Contact information of the REB

Conflicts of Interest

Conflict of Interest or even the appearance of a conflict of interest can damage the trust relationships the research community depends on.

If you were a participant in a study comparing the user-friendliness of two different Apps and you heard later that the researcher had developed or invested money in one of them, would you trust the outcome of the study? Would you feel that you didn't have all the information to make an informed decision about participating?

Capacity to Consent

- Some research requires participants who may lack the necessary cognitive capacity to decide whether or not to participate in research.
- In research, capacity refers to the ability of prospective participants to:
 - appreciate the possible impact of foreseeable risks and potential benefits on their own well-being
 - understand how the conditions of the research may affect them (e.g. time required, difficulty of tasks)
 - evaluate whether participation in a particular research project may or may not be in their own best interest
 - when research involves those who are not capable of giving consent on their own behalf, researchers must seek the consent of an authorized third party

What scenarios/participant populations can you think of where capacity to consent may be an issue?

- children whose capacity is still developing
- Adults whose capacity is diminishing or fluctuating due to illness or injury
- Those whose capacity remains only partially developed

Assent & Dissent

- Even when an individual's authorized third party gives consent, it is important to involve the individual to the greatest extent possible.
- As prospective participants they may agree (assent) or not agree (dissent) with their authorized third party's decision to consent.

Secondary Use of Information

- Information that was collected for one purpose and is now being used to answer the current research question
- Examples of Secondary Use of Information
 - Data from a previous research study
 - Health data
 - Previous student work
 - Other Administrative data
- It matters if data is identifiable or de-identified.

TCPS2- Key Principles

Respect for Persons



Centering on the Human Participant

- Who's Participating?
- Recruitment process
- The consent or assent relationship
- Methods employed
- Risk/benefit assessment
- Confidentiality and privacy protections



Types of Risk

- Physical
- Psychological
- Economic
- Social
- Legal

Probability & Magnitude of Risk

- **PROBABILITY:** How likely is it that any participant will suffer any harm as a result of the study?
- **MAGNITUDE:** How severe could the harm be?

Minimal Risk Research

“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 the aspects of their everyday life that relate to the research.”

How To Apply The Principle of Concern for Welfare

- Consider potential impacts on participants' physical and mental health, on their social or economic circumstances, and on their privacy
- Consult any groups that may be affected by the research to assess the risk of negative impacts such as stigmatization and discrimination
- Eliminate and/or minimize risks
- Maximize benefits
- Provide accurate and accessible information

TCPS2- Key Principles

Respect for Persons



How To Apply The Principle of Justice

- In research design it is important to address the following issues:
 - Who are the participants? Why this group and not others?
 - Are any participant groups over- or under-represented because of their vulnerable circumstances?
 - Are there measures in place to treat people in vulnerable circumstances justly in the context of the research?
 - Is there an imbalance of power between participants and researchers?

Centering on the Human Participant

- Who's Participating?
- Recruitment process
- The consent or assent relationship
- Methods employed
- Risk/benefit assessment
- Confidentiality and privacy protections



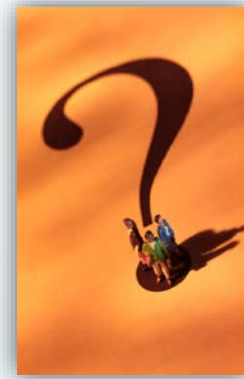
Confidentiality

Is the obligation of an individual or organization to

- safeguard entrusted information
- protect information from unauthorized access, use, disclosure, modification, loss or theft

Major Concepts: Confidentiality and Anonymity

- Directly Identifying Information
- Indirectly Identifying Information
- Coded Information
- Anonymized Information
- Anonymous Information



Videos, Photography and Audio Recordings

- Identifiable information
- Recommended to provide participants with a choice to be video recorded, photographed, audio recorded.
- Questions to consider:
 - Are these videos, photographs, audio recordings necessary for the research? Give option to choose.
 - What are the videos, photos, audio recordings going to be used for (analysis only, presentations, publications)?
 - Will images be blurred or voice distorted?

Dissemination

- Anonymize information as much as possible if you have not had participants consent to being directly identified.
- Indirectly identifying individuals should be avoided unless you have obtained prior permission to do so.
- Sharing individual anonymized data after study complete – disclosed in consent form
- Dissemination can be in made in many different formats (blogs, journal articles, presentations etc.) – what matters is if the information could identify your participants and what did they give consent to.

Data Storage/Access

- Data Management Plan
 - <http://www.lib.sfu.ca/help/publish/research-data-management/data-management-planning>
- Data Storage
 - SFU Vault - <https://www.sfu.ca/itservices/collaboration/sfu-vault.html>

New Ethics Application System

What's new and exciting?

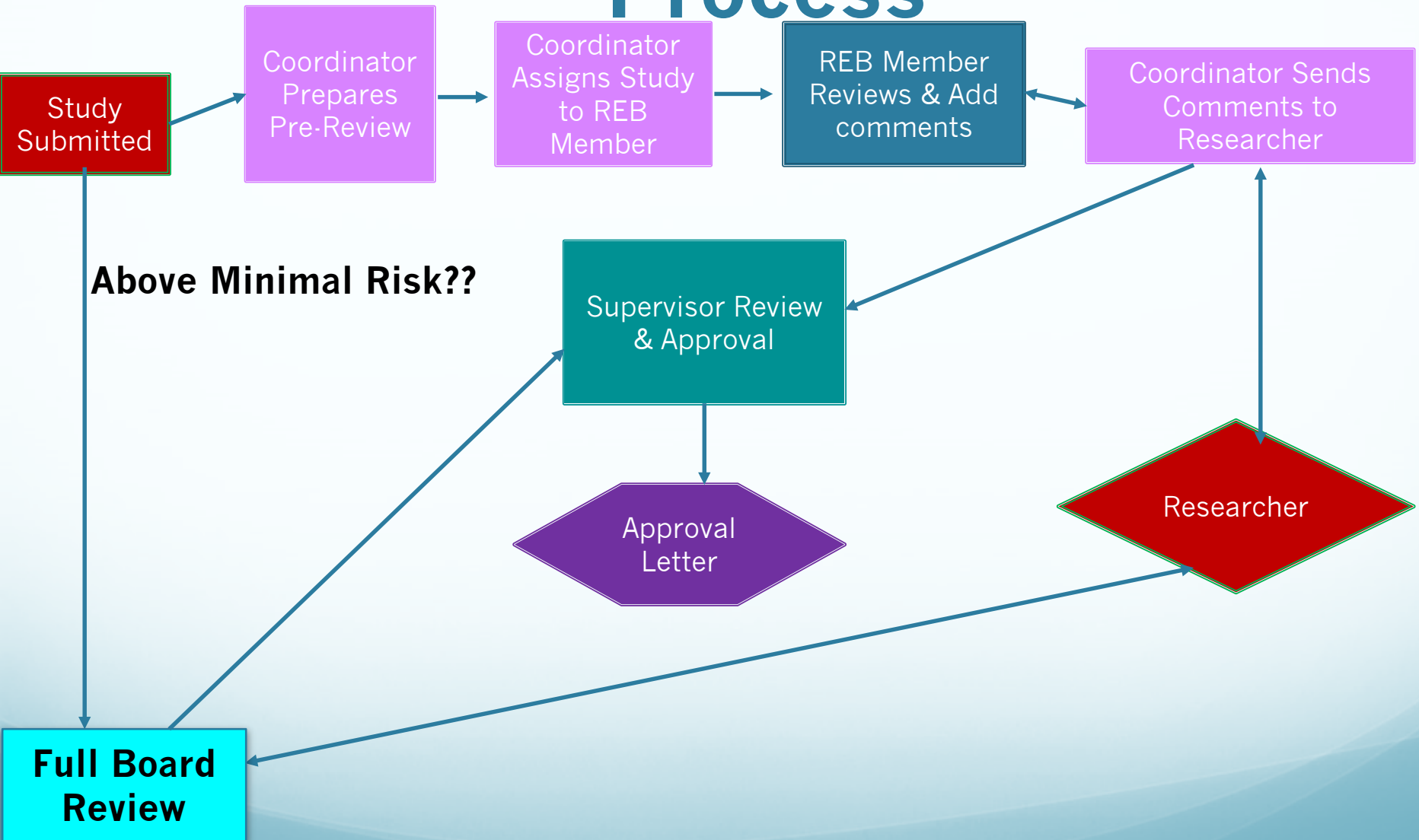
- Replace the current Ethics Database
- Improve self-service ability, such as tracking applications through workflows
- Improve reporting capabilities
- Single sign-on with your SFU Computing ID
- Dynamic forms that will focus on capturing appropriate information

When is it happening ?

- The first module, **Research Ethics**, will likely roll out late 2018/early 2019.

Review Process

Minimal Risk



HOME

CONTACT US

ABOUT ORE

DO I REQUIRE ETHICS APPROVAL?

MULTI-JURISDICTIONAL RESEARCH

ETHICS FORMS & TEMPLATES

POLICIES & GUIDELINES

RESEARCH ETHICS BOARD

REVIEW PROCESS

INITIAL & CONTINUING REVIEW

REGISTRATION TO ETHICS DATABASE

COURSE APPROVALS

EDUCATION AND TRAINING

FAQS



Human-Based Research

[LEARN MORE →](#)

ANNOUNCEMENTS

Funding Titles and ORE Application Titles

Grant proposals that have been peer-reviewed and funded by granting agencies [Read more](#)

Study Submission Deadlines for Full Board Applications

SFU Chosen as BCEHI Coordinator



The Michael Smith Foundation for Health Research (MSFHR) has awarded SFU the role of project coordination for the BC Ethics Harmonization Initiative for one year. [Read more](#)

[iBioCH Working Better Together](#)

ORE Links

Submission Deadlines

Application Login (Ethics Database)

Graduate Student Tutorial

VPR Links

Office of Research Services

Vice-President, Research



Tweets by [@SFUEthics](#)



SFU Research Ethics
[@SFUEthics](#)

Big News [@SFUEthics](#)! Stay tuned for more info...

What to Submit

- A detailed description of the study (Study Details, protocol, proposal, grant application, etc.)
- Consent documents
- Recruitment materials (posters, letters of introduction, email scripts, etc.)
- Any research instruments (questionnaires, interview questions, etc.)
- After you submit, you will not be able to go back to the Database to make changes! Send an email to dore@sfu.ca with the changes (e.g. documents attached) and ORE staff will attach to your application.

What the REB and ORE Look For

Participant Population

- Who? Where from? Vulnerability of participants

Consent process

- Is consent process plan appropriate for the participant population?

Adequacy of consent process

- Study procedures, voluntary participation, right to withdraw, risks, benefits, confidentiality, plan for incidental findings, if applicable

Risks to participants

- What risks does research expose participants to?

Confidentiality

- If/how confidentiality will be maintained?

General Advice

- **Consistency**
 - Make sure details provided are consistent throughout application: recruitment, procedures, consent & assent documents, advertisements, for example
- **Clarity**
 - Explain your procedures as clearly as possible: what you plan to do, how you plan to do it, to whom & how often
- **Detail**
 - Complete all sections of the application
 - Small details are important *but* balance between providing too much & too little

Research Exempt from REB Review

- **Article 2.2** Research that relies exclusively on publicly available information does not require REB review 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.
- **Article 2.3** REB review is not required for research involving the 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.

Research Exempt from REB Review

Article 2.4: REB review is not required for research that relies exclusively on 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.

Article 2.5 Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.

Harmonized Ethics Review - SFU

- Processes for the ethical review of multi-jurisdictional research at SFU are in place:
 1. Research Ethics BC PREP Platform
 2. Previously reviewed and approved, minimal risk research
- These processes take more time so be prepared!
- <https://bcahsn.ca/our-network/research-ethics-bc/>

Summary

- The 3 **core ethics** principles are the foundation for the ethical reasoning that guides interactions with participants in all research involving human participants.
- Researchers are obligated to provide as much information as individuals need to make a **fully informed choice** to consent or refuse to participate.
- **Context matters** when determining risk to participants and their vulnerability
- Be **transparent, clear** and **consistent** when describing your research, procedures and risk to the REB and to participants.

Need Help? Let us know!!!

Jeff Toward, Director, jtoward@sfu.ca, 778-782-6593

Dina Shafey, Associate Director, dshafey@sfu.ca, 778-782-9631

Sarah Bennett, Manager, sarah_bennett_2@sfu.ca 778-782-3447

Hanna Jones-Eriksson, Ethics Coordinator, hjoneser@sfu.ca, 778-782-6618

Alanna Dyck, Ethics Coordinator, alanna_dyck@sfu.ca 778-782-5719

Candase Jensen, Ethics Assistant, cspenst@sfu.ca, 778-782-5326

Check out our website – sfu.ca/ore