

NAVIGATING THE RESEARCH ETHICS PROCESS

RESEARCH ETHICS BOARD REVIEW, CONTEXT & PROCESS REFRESHER

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INTRODUCTION TO RESEARCH ETHICS (HUMAN RESEARCH)

Broad Themes

- Research Ethics History and Context**
- Research Guidelines, Regulations and Policies**
- Research Ethics Board Review Process and Tips**





WHY RESEARCH ETHICS BOARD REVIEW?

- Nuremberg Doctor's Trial
- Nuremberg Code (1947-48)
- Declaration of Helinski (World Medical Association, 1964)

NORTH AMERICAN STANDARDS

Tuskagee Study of Untreated Syphilis

- . 1932 standard treatments for syphilis toxic and dangerous (i.e., Salvarsan, mercurial ointments and bismuth)
- . aim of study to see if it would be better not to treat patients for syphilis but rather develop treatments for each stage of disease
- . Doctors recruited 399 African-American men thought to have syphilis and also 201 healthy African-American men as a control group
- . Patients did not give informed consent and in fact were not told what disease they had—instead they were told they had “bad blood”
- Even after the discovery of Penicillin as a treatment for Syphilis in the 1940 the study continued until a whistleblower leaked the story to the press and the story hit the media in 1972



Heinrietta Lacks (cancer patient at John Hopkin's University Hospital (1951)

Cancerous cell samples taken without consent for research use
 HeLa cell line created that is still being used in cancer research to this day
 The University has profited from the unauthorized use of Mrs. Lack's biological sample

Research with Indigenous Populations and tissue and genetic biobanks

Havasupai in Arizona and Nu-chah-nulth First Nations in B.C

Havasupai invited researchers from Arizona State University to study the high rate of diabetes in their people, the researchers used the samples to study tribal schizophrenia, population genetics and migration patterns.

The Nu-chah-nulth asked a University of British Columbia researcher to study a genetic basis of arthritis and related diseases, the researcher shared the samples for research on HIV/AIDS, population genetics and evolutionary history.



RESIDENTIAL SCHOOL NUTRITION EXPERIMENTS (1942-1952)

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Standard Prison Experiments (1971)/ Case of David Reimer (1967)



ETHICS CONTEXT

Ethical conduct of research is essential to good study design

Can determine whether scientific journals will publish research

A Condition of the University of Regina holding Tri-Council Funding (CIHR, NSERC and SSHRC) is that researchers conduct research in an ethical manner and other funding sources also have requirements for ethical research conduct.



ETHICS GUIDELINES THAT RESEARCH ETHICS BOARDS FOLLOW IN CANADA

Research Ethics Board's in Canada follow the **Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2022)**

Respect for persons

Individual autonomy, Informed consent, Voluntary participation, Privacy and confidentiality

Concern for Welfare

Physical, mental and spiritual well being
Physical, Social and Economic well being
Quality of a person's experiences

Justice

Fairness and Equity
Selection of study participants
Inclusiveness



The following require ethics review and approval by an REB before the research commences:

- (a) research involving living human participants;
- (b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells (applicable to materials derived from living and deceased individuals);
- c) Research utilizing retrospective or prospective personal health data;



TCPS 2 2022 DEFINITION OF RESEARCH

Research is defined by TCPS 2 as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Program evaluation, quality improvement, or quality assurance initiatives, *when used exclusively for assessment, management, or improvement purposes* are exempt from REB review.

Important to note that Course Based Research Activities are considered research that require review, under U of R Research Policies these can be reviewed by an approved department ethics committee.



Research Not Requiring Ethics Review

- **publicly available** through a mechanism set out by legislation or regulation and that is protected by law; or
- in the **public domain** and the individuals to whom the information refers have no reasonable expectation of privacy
- research involving **observation** of people in public places and does not involve any intervention staged by the researcher, those being observed have no reasonable expectation of privacy and that any dissemination of research results does not allow identification of specific individuals
- **creative practice activities**, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.



MINIMAL RISK AND ABOVE MINIMUM RISK RESEARCH

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.

TCPS 2 does not contain a clear definition of the category of Above Minimal Risk, however, from the definition of minimal risk we can say that above minimal risk studies would entail that the probability and magnitude of possible harms implied by the participation in the research is greater than those encountered by participants in those aspects of their daily lives that relate to the research.



ETHICS BOARD AND PROPORTIONATE REVIEWS

BENEFACTENCE/NON-MALEFICENCE: MINIMIZE HARM/MAXIMIZE BENEFIT

ASSESSMENT AND BALANCE OF REAL/POTENTIAL RISKS/HARMS/BENEFITS



WHICH APPLICATION SHOULD YOU CHOOSE?

There are 4 different types of ethics applications

- ❖ **Standard Application Form (Faculty or Student version/Behavioural and Biomedical applications)**

-recruitment, consent form and process, data security

- ❖ **Secondary Use of Data Form**

-if you have identifiers than the research is not anonymous

- ❖ **Course Based Research Form**

-use our templates for surveys etc. and make sure student's understand ethical requirements of privacy and confidentiality

- ❖ **Approved by Another Institution Form**

Make sure you submit all relevant documents from the REB of record



THE REVIEW PROCESS

Minimal Risk Study or Above Minimal Risk Study?

Minimal Risk studies will undergo a delegated review process and a Notice of Ethical Review (NER) requesting revisions will be issued or an approval letter will be sent to researchers.

Minimal risk studies can be submitted to the REB at any time, there are no deadlines for submission.

Above Minimal Risk Studies are reviewed at monthly board meetings



THE RESEARCH ETHICS BOARD MEMBERSHIP

2 Chairs and a Vice Chair

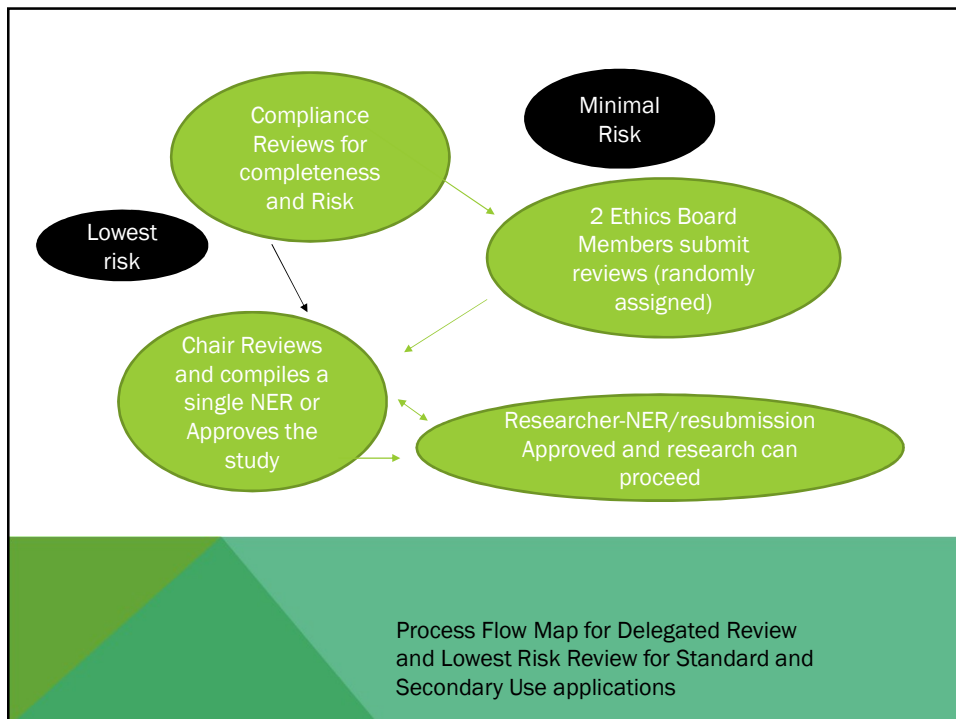
Voluntary Membership

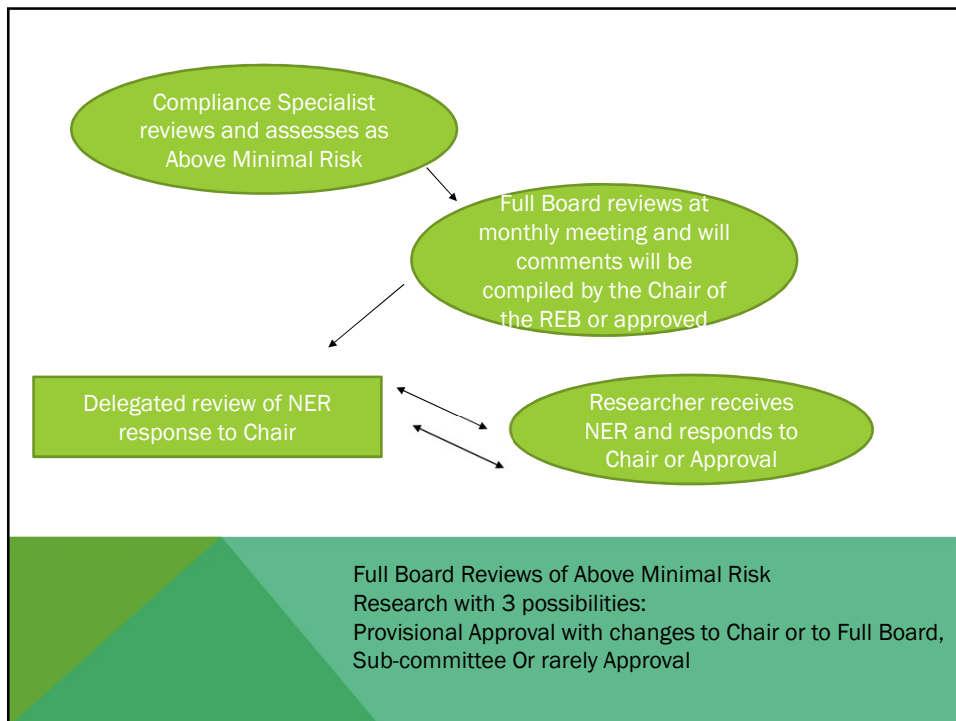
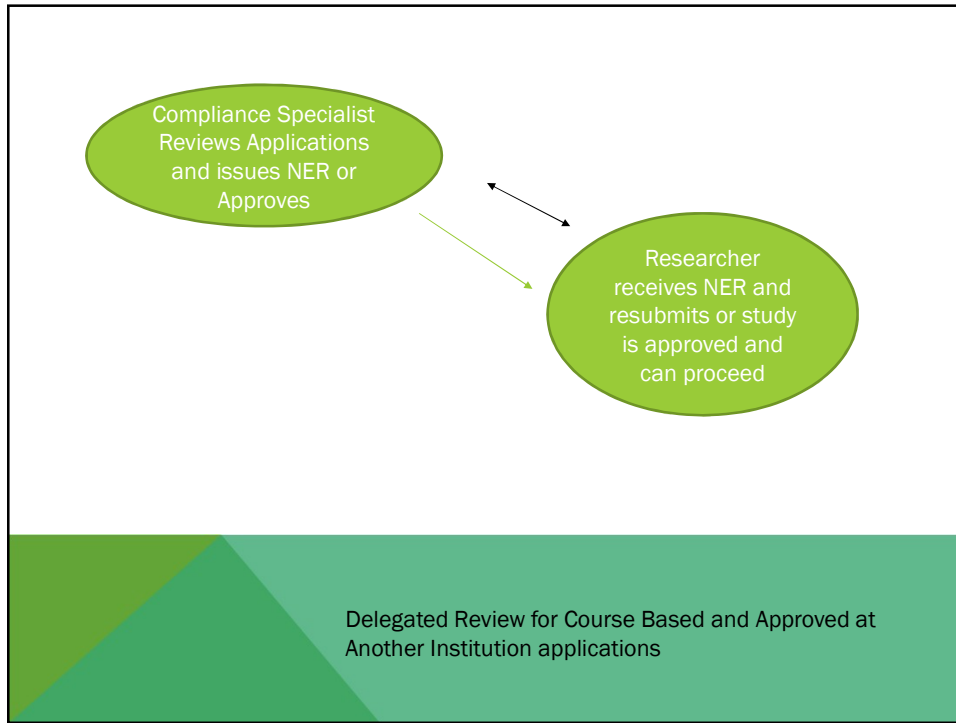
Faculty from various departments and Staff

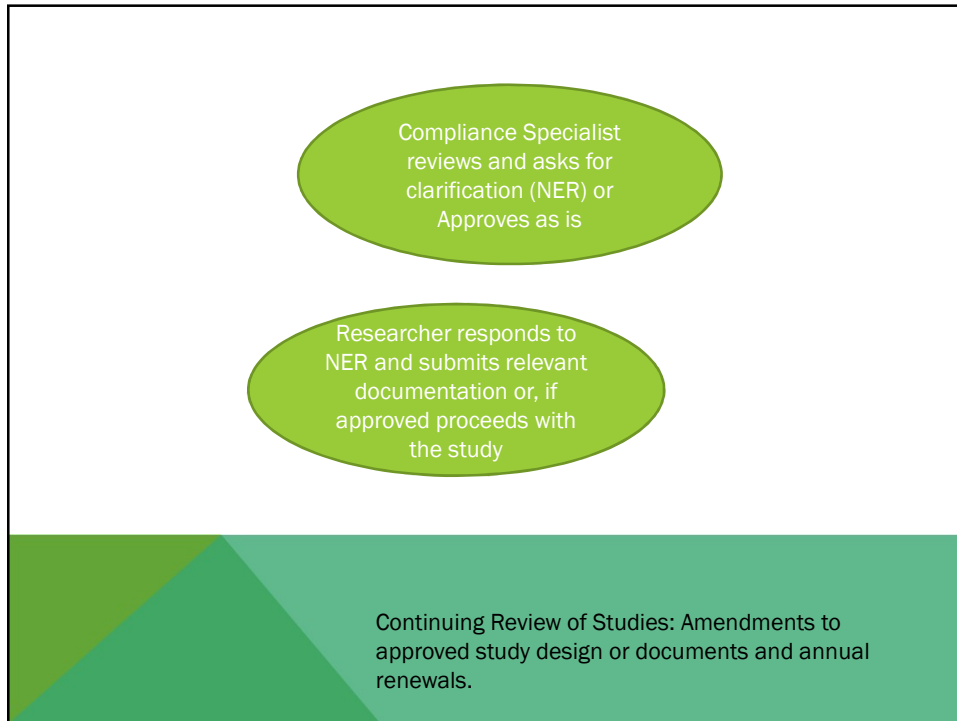
Subject Matter Experts

Community Members (including expertise in law
and medical research)

Students







RESEARCH SHOULD HAVE POTENTIAL FOR ACADEMIC/SCIENTIFIC MERIT

Question of sufficient value
Conducted as per REB-approved protocol
Findings disseminated accurately and in timely way
Public trust is critical:
Trust in the Institution
Trust in the Investigator
Trust in the research process



The University of Regina logo is located in the bottom right corner of the slide. It consists of a shield-shaped crest with a crown on top, containing a cross and other heraldic symbols. To the right of the crest, the text "University of Regina" is written in a serif font, with "University" on the top line and "of Regina" on the bottom line.

INFORMED CONSENT TCPS 2 2022 ARTICLE 3.2

Obtained BEFORE research begins.

Maintained throughout

Consent ≠ contract as the participant is not obligated to stay in the study or comply by signing the consent form, however, the researcher does have a responsibility to the participant and society through the consent form to have provided full disclosure of all study procedures and risks



INFORMED AND VOLUNTARY CONSENT

Relevant language-technical terminology should be explained in lay terms.

Appropriate reading level-we usually suggest a grade 6-8 reading level.

Culturally Appropriate-consideration to the values and customs of others.

Recruitment must not be coercive and without undue influence.

Adequate time to consider participation.



"The biggest risk in this study is just reading the consent form!"

WHAT IS FREE AND INFORMED CONSENT?

Informed: it is the responsibility of the researchers to make sure that participants are provided with all information relevant to their continuing willingness to consent to participate in the research—thus the notion of ongoing consent—any changes or new knowledge must be shared with participants

Voluntary: if, for any reason, participants reconsider their decision to be part of the research it is their ongoing right to withdraw without any sort of penalty—a participant does not need to provide any reasons for withdrawing from a study and should be able to ask that their data and human biological materials also be removed from the study.

Meaningful: any change in cognitive status or ability to provide informed and voluntary consent must negate the consent status of that participant

RISK ASSESSMENT SHOULD INCLUDE THE VULNERABILITY OF PARTICIPANT POOL FOR THE STUDY AND CAPACITY TO CONSENT OR ASSENT

Marginalized Groups or Populations: Women, BIPOC populations that have traditionally been either under represented in research or been used for ill designed and ethically problematic research

Women

Black, Indigenous or People of Color

2SLGBTQ+

Those that are mentally or physically Challenged or Divergent

Economically disenfranchised

Children

The Elderly

Students, when the researcher is in a position of power

RELEVANT ETHICS CONSIDERATIONS

Behavioural Research

Key things to keep in mind:

Recruitment method-how are participants determined for your project-what is rationale for inclusion criteria? Submit all recruitment material.

The Consent Process must be thorough.

Implied Consent Form Template for anonymous surveys

Behavioural Consent Form Template for studies that include participant contact of any kind, including in person or telephone or ZOOM interviews or focus groups.

Depending on whether directly identifying information is being collected or if there is direct participant contact you may require a master list, a master list links a participant identifier (name, contact information, etc.) to a study code (e.g. 111).

Data Collection tools should only contain a study code, no direct participant information.

Requires TCPS 2 tutorial certification (<https://tcps2core.ca/welcome>)

BEHAVIOURAL CONSENT FORM TEMPLATES

anonymous surveys

Use the implied consent form template

Assure that researchers do not have access to participant identifiers

Have an Admin person from various departments/institutions distribute recruitment emails using bcc line for potential participants email addresses

Interview/Focus group consent form template

If either telephone or ZOOM consent will be used we require a consent form script and a consent log to document the verbal consent.

Prior to initiating the study interventions consent needs to be documented.

PROTECTION OF PRIVACY AND CONFIDENTIALITY IN RESEARCH

Privacy and confidentiality are recognized as fundamental human rights

Providing consent allows investigators to use data about participants for defined purposes, with limits on how data is collected, analyzed, disseminated, and stored and by whom (i.e. research team members) or if you are hiring a service that information needs to be shared with REB.

Breaches could lead to harm in the form of:

- Criminal charges
- Loss of family or friends
- Embarrassment
- Discrimination
- Loss of insurance coverage
- Loss of employment

PRIVACY LAW AND DATA SECURITY

- (1) The Privacy Act – Limits the collection, use, and disclosure of personal information for federal government departments and agencies
- (2) The Personal Information Protection and Electronic Documents Act (PIPEDA) – Sets out rules for how private sector organizations may collect, use or disclose personal information
- (3) The Local Authority Freedom of Information and Protection of Privacy Act (Applies to all Employees of Provincial Institutions or Affiliated Institutions)
- (4) Saskatchewan Health Information Protection Act (HIPA) – Has specific provisions relating to use and disclosure for research

DO'S AND DON'TS OF DATA SECURITY AND STORAGE

Do

Use portable USB devices for data collection or better use FILR to store data or University drives

password protect USB Data files

Make sure that identifying information (consent forms or your master list) and your data set are kept separate from one another

Please note for student projects the supervisor is responsible for retaining all study documentation securely for the life cycle of the study

Do Not

Save files on your personal laptop without password protecting the files

Use your own personal USB device

Leave data where someone else could find it

Send data to/from emails without adequate protection

DO'S

Keep the data for a minimum of 5 plus to 25 years following completion of study (P.I.s Only!)

Delete files when no longer required (Students)

Permanently delete data from devices when no longer required using trusted deletion software

DON'T'S

Assume that because the data are coded or not on sensitive topic, that you don't have to comply with all of the data security requirements

Discuss the data with anyone not on the study team

Keep data or the master list unsecured in your home or office

TCPS 2 ARTICLE 5.3

Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

Factors relevant to the REB's assessment of the adequacy of the researchers' proposed measures for safeguarding information include:

- a) the type of information to be collected;
- b) the purpose for which the information will be used, and the purpose of any secondary use of identifiable information;
- c) limits on the use, disclosure and retention of the information;
- d) risks to participants should the security of the data be breached, including risks of re-identification of individuals;

e) appropriate security safeguards for the full life cycle of information;

f) any recording of observations(e.g., photographs, videos, sound recordings) in the research that may allow identification of particular participants;

g) any anticipated uses of personal information from the research; and

h) any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records.

TCPS 2 Article 3.2 (i-l)

- **an indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants;** a description of how confidentiality will be protected (Article 5.2);
- **a description of the anticipated uses of data;** and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made;
- **information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;**
- a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm;
- and in clinical trials, information on stopping rules and when researchers may remove participants from trial.

Put yourself in the
participant's shoes
How would you want
to be treated?
What would give you
confidence in a
research team?



CONVERIS APPLICATION COMMON ERRORS

To move applications forward you must click on “save and close” at bottom right of screen and in pop up move to the next appropriate level of review

Student Projects: Students cannot move the application to REB review, the Supervisor is to provide guidance at each stage and review submissions at each stage and then move it forward to ethics review

SUPERVISORS SHOULD BE LISTED AS PI’S WITH STUDENTS GOING FORWARD PLEASE

There is limited space in each section of the application to add text, submit addendums providing details

Use our templates and read our guidance documents and the Converis Researcher Manual and Quick Sheet with screen shots to take you through the application process (<https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/ethicsforms.html>)

Research Policy, ZOOM guidance and Finance Requirements for Cash and Cash Equivalents: <https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/policies.html>

Questions?

Contact:

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Research.ethics@uregina.ca

306-337-3130/639-590-3221

Website: <https://www.uregina.ca/research/for-faculty-staff/ethics-compliance/human/ethicsforms.html>