NAVIGATING THE RESEARCH ETHICS PROCESS

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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

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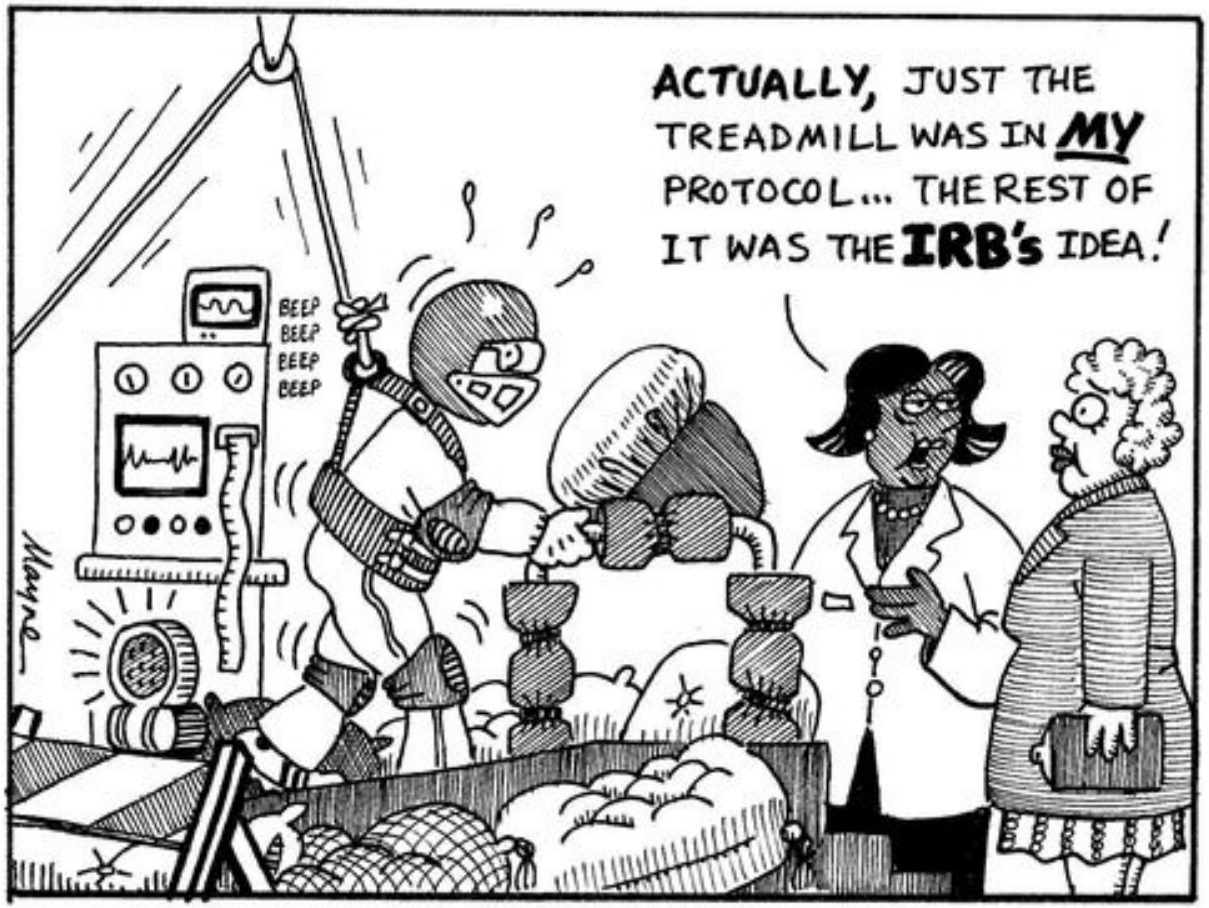

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WHY RESEARCH ETHICS BOARD REVIEW?

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

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 Nuu-chah-nulth First Nations in B.C

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

The Nuu-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)

The Department of Indian Affairs in partnership with a well known Pediatric researcher from The Hospital for Sick Children in Toronto carried out clinical trials on First Nations and Metis children in Residential Schools.

There was no consent and parents were not told the children were in experiments.

In these experiments, control and treatment groups of malnourished children were denied adequate nutrition.

In one study, children were given a flour mix containing added thiamine, riboflavin, niacin and bone meal.

Rather than improving nutrition, the children became more anemic, likely contributing to more deaths and certainly impacting development.

ETHICS CONTEXT

Ethical conduct of research is essential to good study design

Can determine whether academic/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.

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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

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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.

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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.

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;

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

BENEFICENCE/NON-MALEFICENCE: MINIMIZE HARM/MAXIMIZE BENEFIT

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

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WHICH APPLICATION SHOULD YOU CHOOSE?

There are 4 different types of ethics applications

- Standard Application Form (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

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THE REVIEW PROCESS

Are all required documents submitted?

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

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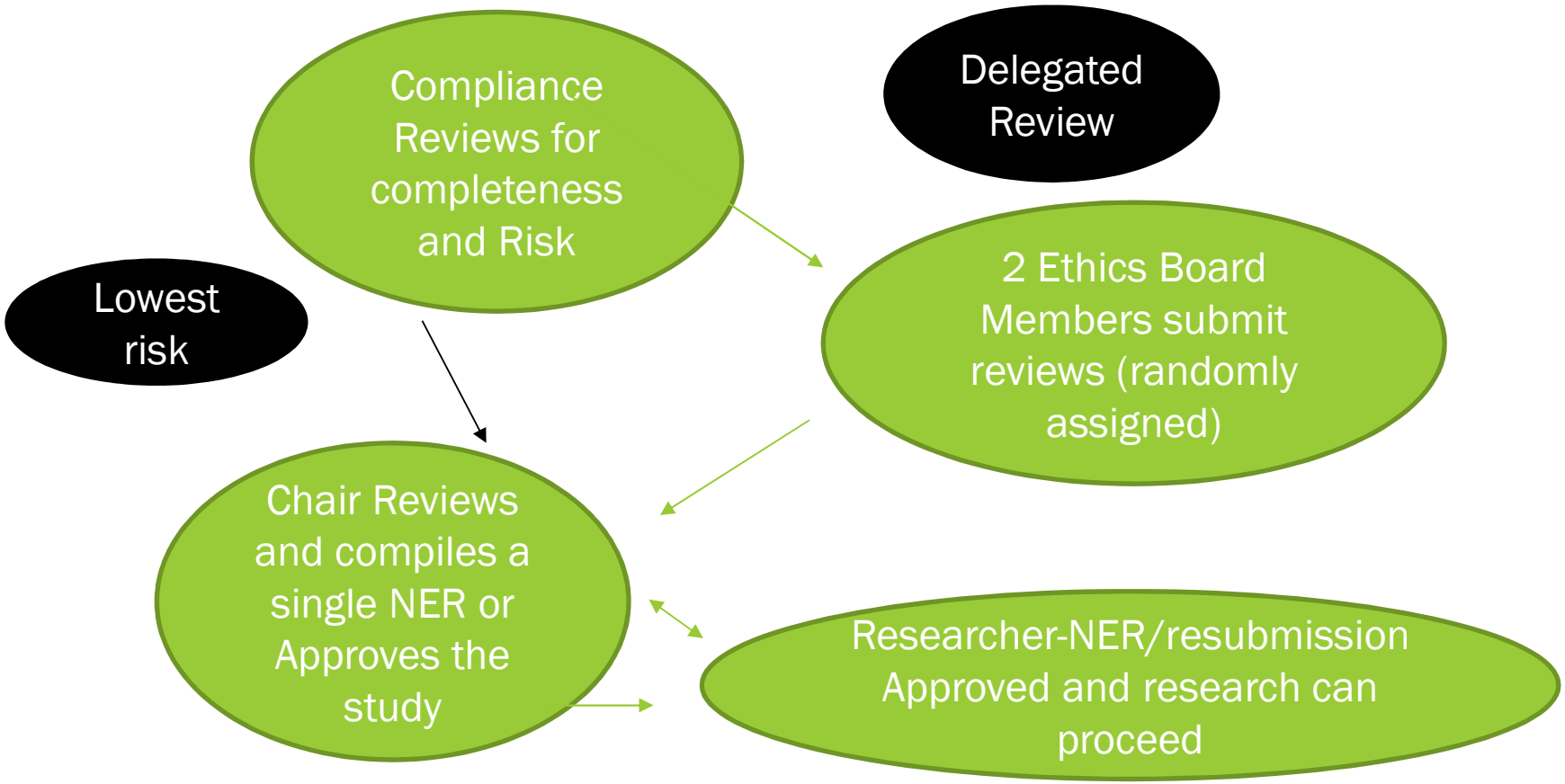
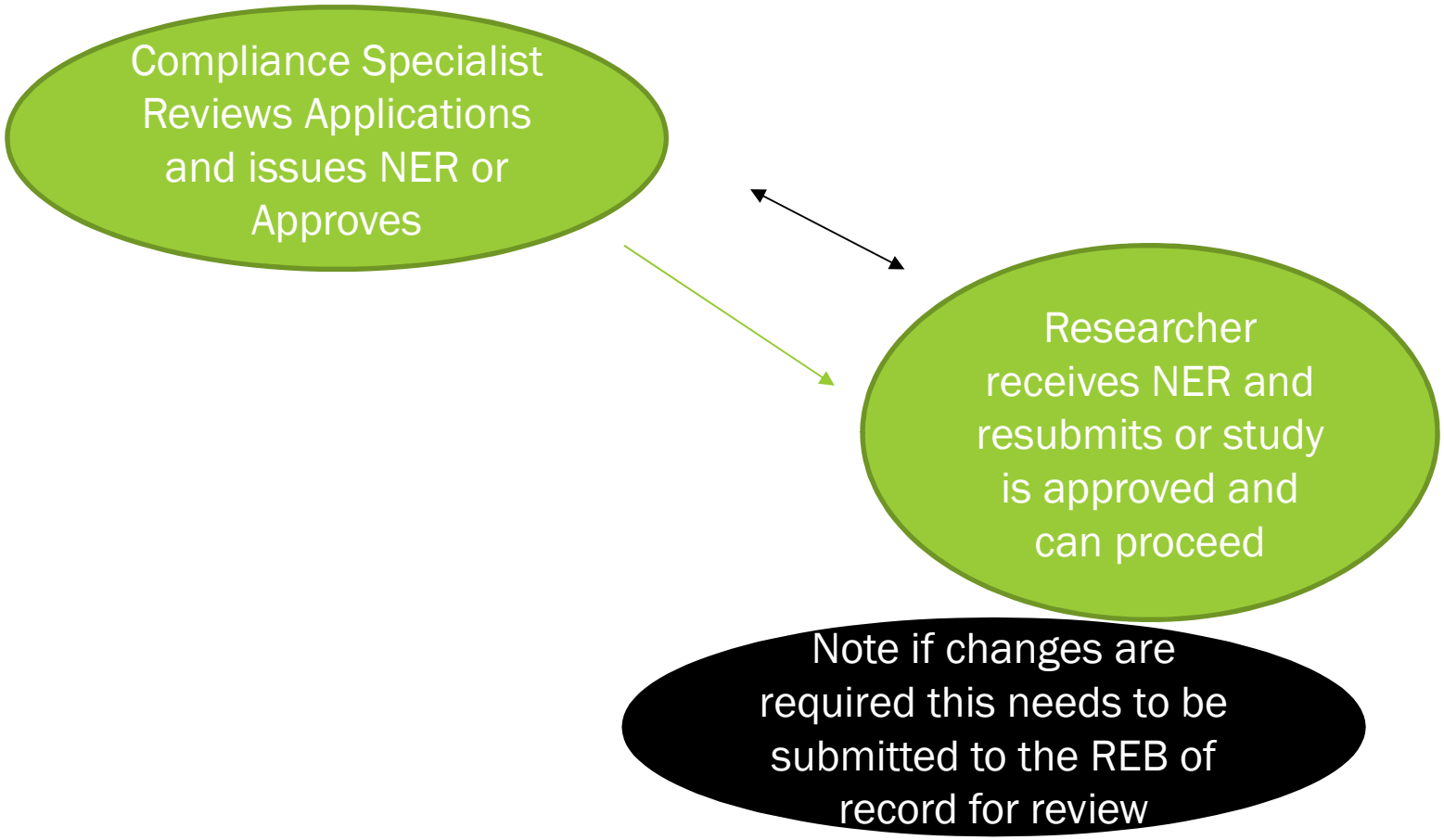
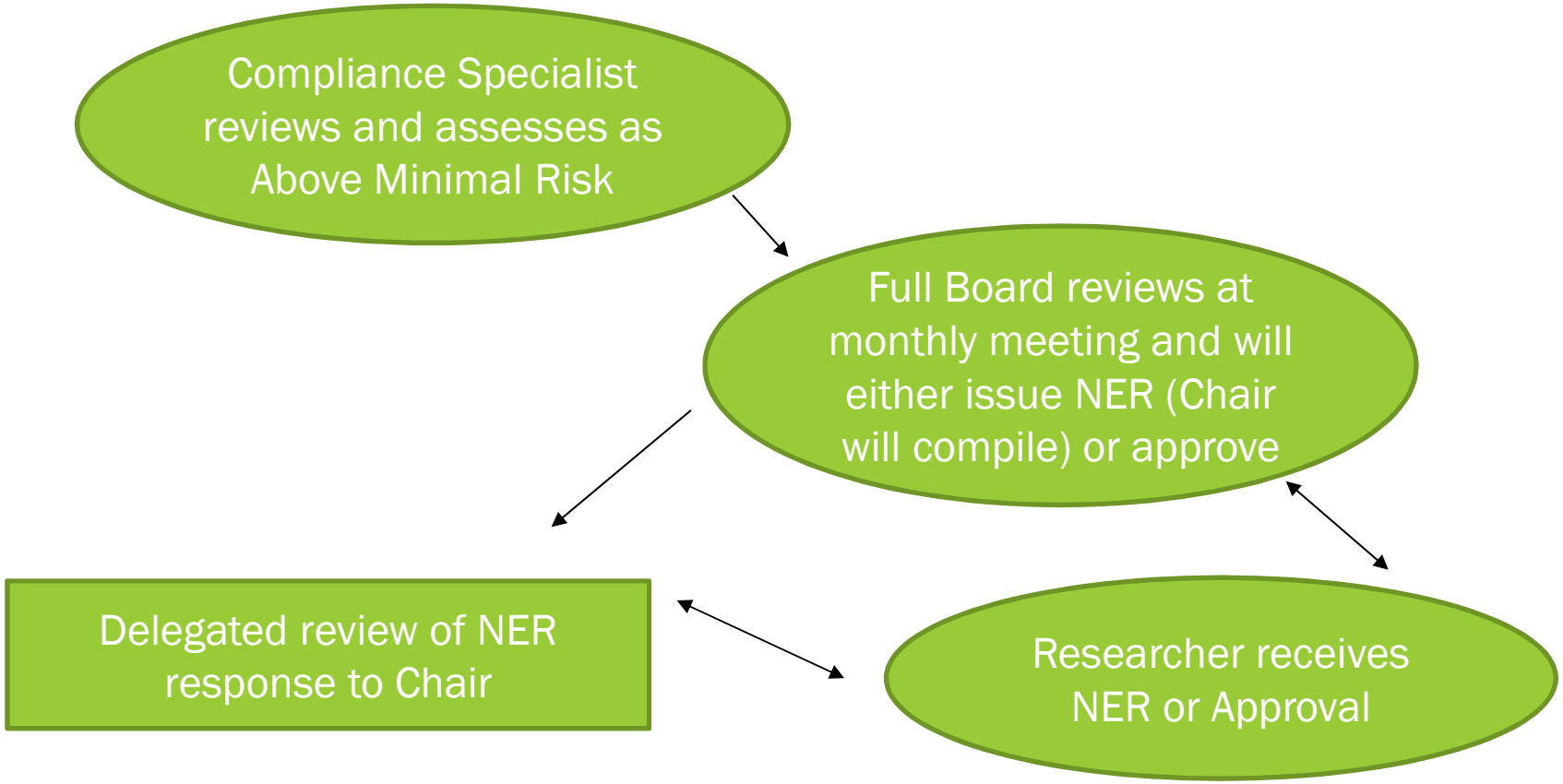


Process Flow Map for Delegated Review and Lowest Risk Review for Standard and Secondary Use applications



Delegated Review for Course Based and Approved at Another Institution applications



Full Board Reviews of Above Minimal Risk
Research with 3 possibilities:
Provisional Approval with changes to Chair or to Full Board
Or rarely Approval

Continuing Review of Studies: Amendments to approved study design or documents (changes to approved study must be submitted for review) and annual renewals.

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

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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

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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!"*

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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(i.e. study procedures, risks, time required, data security precautions)—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

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
Those that are mentally or physically Challenged or Disabled
Economically disenfranchised
Children
The Elderly
Students, when the researcher is in a position of power
Those traditionally excluded from research such as LGBTQIAS+

CAPACITY

Ability of participants to understand relevant information presented about a research project and to appreciate the potential consequences of their decision to participate or not participate

Affected by:

The complexity of the choice being made

The circumstances surrounding the decision

The point in time at which consent is sought

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 most be thorough and debriefing process outlined.

Will you be sharing transcripts or transcripts summary (see our templates on this).

Implied Consent Form Template for anonymous surveys, U of R recommends using Qualtrics

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

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), a template is available.

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

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

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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.

Include a shortened form of consent to share with participants if multiple study procedures are entailed to assure continued consent.

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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, and the security precautions as well as the data that the company collects clearly stated in the application form.

Breaches could lead to harm in the form of:

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

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PRIVACY LAW AND DATA SECURITY

Two federal privacy regulations and two provincial privacy regulations:

(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). Applies to students, faculty and staff at the U of R, Schoolboard employees, government employees and those affiliated with the government

(4) Saskatchewan Health Information Protection Act (HIPA) – Has specific provisions relating to use and disclosure of personal health information for research

For Clinical Trials

Health Canada Regulated Trials require a No Objection Letter

Must be registered with clinicaltrials.gov and the Compliance Specialists can assist with this process

U of R has a Health Canada Cannabis Research Licence
Compliance Specialist can assist with this process

International Council on Harmonization Good Clinical Practice Guidelines to be followed (GCP)

U of R Research Policies

https://www.uregina.ca/research/policies-forms-top/research-policies.html

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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;

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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.

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

Do

Use portable USB devices for data collection or better use U of R file storing sources such as FILR to store data or University drives (password protected documents and research documents should have restricted access)

password Computer and USB Data files

Make sure that identifying information (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 (password protect files and send password in separate email)

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DO'S

- Keep the data for a minimum of 5 plus to 25 years following completion of study (P.I.s Only!)
- If the study data will be kept indefinitely and may be used for further research specify in consent forms and REB applications
- 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

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Keep all data confidential, take extra precautions to guard against potential breaches of security

Be mindful that accessing data as part of your position role is very different from accessing that same data for research purposes, this carries added responsibility and repercussions if there are data breaches

Put yourself in the participant's shoes

How would you want to be treated?

What would give you confidence in a research team?

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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

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Office of Research Partnerships & Innovation
Office of Research Services

Questions & Answers

REB Review - Context & Process Refresher | February 10, 2023 at 1:00 p.m.

Presenter: Rashmi Pandya

Question #1:

Thank you for offering this presentation! I am a new faculty at UR and have a number of active research projects that have been previously approved by my previous university. What is involved and where do I start to get approved for these projects in place at UR?

Answer #1:

First step would be to let your prior institution know you will be moving your research projects to the U of R as you are now affiliated with the U of R. We will accept the initial approval and subsequent amendment approval documents and do our review on the basis of those. If you can fill in the Approved at Another Institution application form and make sure you submit all the most recent documents as well as the original REB approval please. If you are transferring funds as well, please email me and I can introduce you to the correct person in the Grants division of the Department.

Question #2:

How much time does it take in general, to get ethics approval for a master's thesis considering current trends?

Answer #2:

Currently we are at about 6 weeks but we are catching up on a backlog and the hope is we can shorten this to 5 weeks maximum. Our intake volume may affect these timelines. Please note that that timeline is for initial review, the quality of the application will determine how much revision will be required on the application. I would recommend perhaps running a draft proposal by Research Compliance for your first application so that we can work with you to assure a speedy review. Also please note simple survey projects have a much faster review timeline than more complicated studies that involve more participant interaction (i.e. interventions, interviews, focus groups etc.).

Questions & Answers

Question #3:

I am doing a grounded theory study and my interview questions will evolve with the study. Do I need to submit an amendment for each time I add/change/revise a research question?

Answer #3:

Yes, the REB does require all changes to the originally approved Protocol (application and study documents) be submitted for review. The Compliance Specialist reviews those in a delegated review, unless changes impact risk factor for participants, the turnaround for delegated reviews is usually about 2 weeks but can be shorter for minor changes. However, some projects that have participant partners (i.e. participatory research) often do not have details of the actual study intervention, as the planning stage is part of the project, in these cases please reach out to me and we can assess whether an amendment is necessary at each stage of that process.