

# Navigating Ethics for Research Studies

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Innovation & Development Commons Brown Bag Lunch  
March 30, 2017



# UNBC-Northern Health Partnership



2016

UNBC



173

43

H: 21

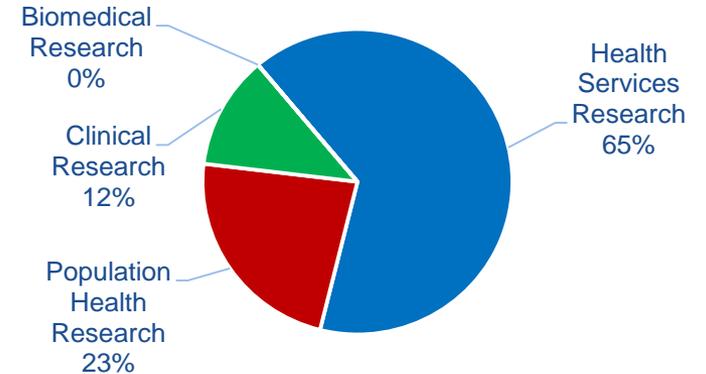
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12% - Health funder

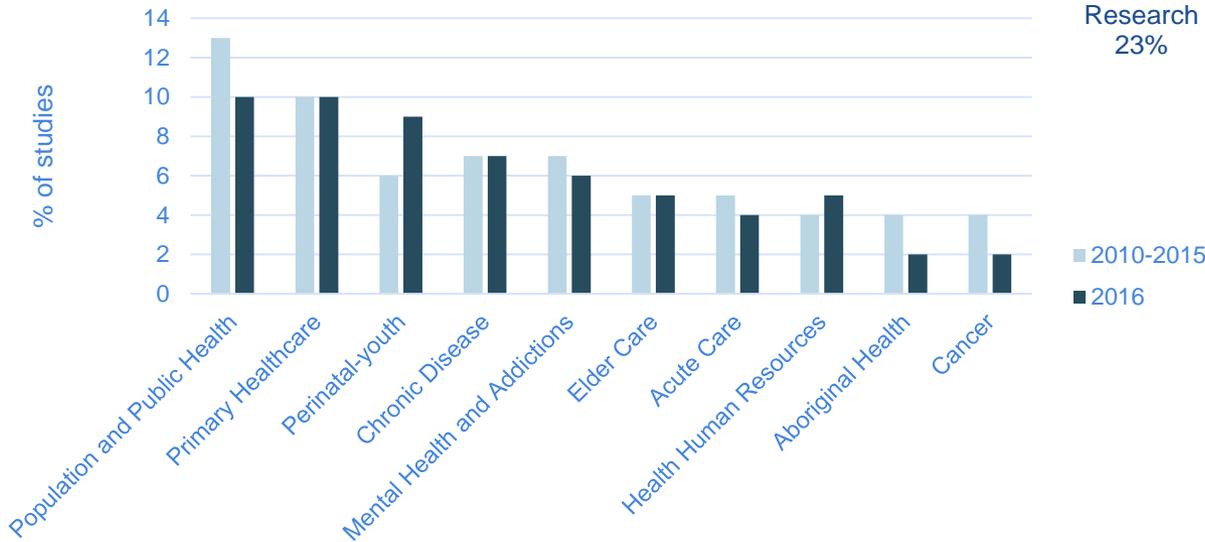
UNBC PI/Co-I - 33%

# Research in Northern BC

Research by CIHR Theme, 2016



Top 10 Categories of Research Reviewed



# Research in Northern BC – 2016 Examples

- Determining the Prevalence of Problematic Substance Use in Pregnancy: A Retrospective Chart Review and Situational Analysis (Dr. S. Mitchell, UBC Obstetrics & Gynaecology)
- Developing a Support Framework for Rural Health Care. What Rural Physicians Think (D. Snadden, UBC Family Practice Medicine)
- Gap Analysis of Outpatient Parenteral Antimicrobial Therapy Services in Northern Health (B. Barr, UBC Pharmacy)
- Pursuing Integration: Case Studies of Organizational Transformation (Dr. P. Kumar, UNBC Mathematics)
- Putting the POWERPLAY advantage to work. The development and optimization of a workspace mental wellness module for men in northern and rural locations (Dr. C. Seaton, UNBC Psychology)
- The NORTH Clinic Experience: Patient experiences of participating in a novel and non-traditional cardiac rehabilitation program (D. Banner-Lukaris, UNBC Nursing)

# Overview – Research Ethics Presentation



# Research Ethics at UNBC

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## **WHY:** Federal, Provincial and University Levels

The people of Canada through Acts of Parliament wish to promote research that is conducted according to the highest ethical standards

### Value of respect for human dignity

- Respect for Persons
- Concern for Welfare
- Justice

Ethical Conduct for Research Involving Humans

TCPS2 2014

- Review
- 7. Conflicts of Interest
- 8. Multi-Jurisdictional Research

- [Acknowledgements](#)
- [Introduction](#)

## TCPS 2 (2014) - Table of Contents

### TCPS 2: CORE Welcome

- [More Information<sup>1</sup>](#)
- [Rollover Glossary<sup>2</sup>](#)
- [External Link<sup>3</sup>](#)
- [Internal Link<sup>4</sup>](#)

### TCPS 2: CORE

Government of Canada / Gouvernement du Canada **Canada**

**Panel on Research Ethics**  
www.pre.ethics.gc.ca

Français Home Contact Us Help Search canada.gc.ca



**LOGIN TO CORE / CREATE ACCOUNT**

Best viewed at a screen resolution of 1280 x 720 pixels.

The online tutorial the *Tri-Council* modules focus on methodology.

The purpose of secondarily, for

If this is your first on navigating the program

- [CORE User](#)
- [FAQ](#)
- [Acknowledgements](#)
- [Terms of Use](#)

- PRE**
  - Terms of Reference
  - Members
  - Organizational Structure
- The Policy (TCPS)**
  - TCPS 2
    - Introduction
    - 1. Ethics Framework
    - 2. Scope and Approach
    - 3. The Consent Process
    - 4. Fairness and Equity in Research Participation
    - 5. Privacy and Confidentiality
    - 6. Governance of Research Ethics Review
    - 7. Conflicts of Interest

### TCPS 2 (2014)— the latest edition of *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*

**Notice: TCPS 2 (2014) has replaced TCPS 2 (2010) as the official human research ethics policy of the Agencies.**

[TCPS 2 \(2014\) - Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans](#) (PDF 609KB)

#### TCPS 2 (2014) Companion Document

The following PDF document offers details on the changes made to TCPS 2 in the 2014 version:

[Highlights of Changes \(2014\)](#) (PDF 36KB)

#### TCPS 2 (2014) - Table of Contents

- [A. Establishment of Research Ethics Boards](#)
- [B. Procedures for Research Ethics Board Review](#)
- [C. Reconsideration and Appeals](#)
- [D. Research Ethics Review during Publicly Declared Emergencies](#)

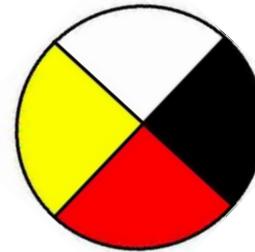
• [Chapter 7](#)

# Your Research

Idea



Place



Research Ethics



Operational Approvals



# HOW: Finding UNBC Research Ethics Forms and Resources

Funding Opportunities

EXTERNAL FUNDING OPPORTUNITIES

Research Page Research Ethics Guidelines

- Grant and Contract form (pdf)



ROMEIO Online Applications >



Follow UNBC Research

Tweets by UNBCResearch

RESEARCH ETHICS & SAFETY: HUMAN SUBJECTS

UNBC Research Ethics

- REB Renewal and/or Amendment Application >
- BCEHI Coversheet for Harmonized Research Ethics Review >
- Research Risk Assessment Guidelines (pdf)
- Information Letter / Consent Form Guidelines >
- Information Letter / Consent Form Template >
- Information Letter / Consent Form Checklist >
- Sample Confidentiality and Non-Disclosure Agreement >

NH Operational Approval process >

News Events Dates & Deadlines

Surveys

Research shows tobacco use causes high death rates for alcohol!

Using Fluid Surveys >

# UNBC Forms, Resources & Links

## RESEARCH ETHICS & SAFETY: HUMAN SUBJECTS

### UNBC Research Ethics

• [REF In Principle Review/Release of Funds Application](#)

• [RCGEH Governance for Harmonized Research Ethics Review](#)

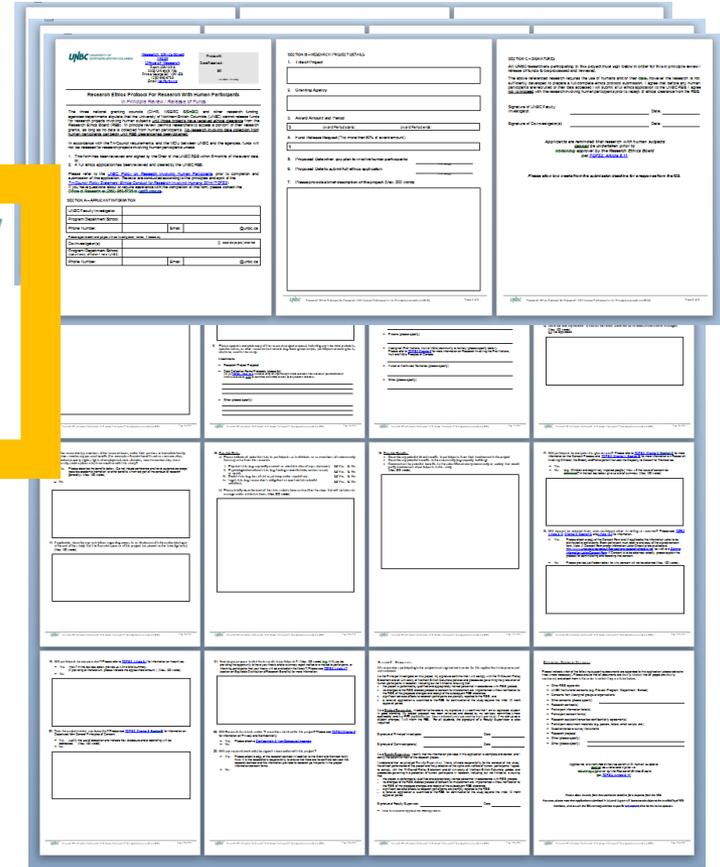
- Research Risk Assessment Guidelines
- Information Letter / Consent Form Guidelines
- Information Letter / Consent Form Template
- Information Letter / Consent Form Checklist

### Northern Health Authority

• [NH Application for Operational Approval](#)

[NH OPERATIONAL APPROVAL PROCESS](#)

[USING FLUID SURVEYS](#)



# When is Northern Health involved?

Home Our Services Your Health Careers About Us News & Events Contact Us Professionals Blog



## NH Research Review Committee



Your Health > Research > NH Research Review Committee

Search... GO

Aboriginal Health

Advance Care Planning

Community Care Licensing

End-of-Life Care / Hospice Palliative Care

Environmental Health

Health Alerts

Health Topics

Healthy Living & Communities

### NH Research Review Committee

Research at Northern Health requires two approvals to proceed:

- Research Ethics Approval
- Northern Health Operational Approval

Research ethics and operational approvals can be pursued simultaneously. Once the conditions for research ethics and operational approval are met, a letter of approval from the Research Review Committee will be emailed to the Principal Investigator and the Northern Health managers who provided operational approval for the research.

#### About the Research Review Committee

All research conducted within or for Northern Health (NH) must be reviewed and approved by the Northern Health Research Review Committee (RRC). The RRC is mandated by NH policy to approve, reject, propose modifications to or terminate any proposed or ongoing research involving humans that is conducted: in NH facilities/programs; by NH staff or physicians; or with NH staff, physicians and/or patients.

### Dates

#### 2016 Research Review Committee

Appls. Deadline	Meeting Date
Jan 13, 2017	Jan 26, 2017
Feb 10, 2017	Feb 23, 2017
Mar 7, 2017	Mar 23, 2017
Apr 10, 2017	Apr 27, 2017
May 8, 2017	May 25, 2017
Jun 9, 2017	Jun 22, 2017

\*Applications submitted by the deadline will be reviewed within 2 weeks.

# Operational Approval

- Operational Approval Guidelines
- Operational Approval Form
- Medical data and charts

## Northern Health Operational Approval for Research

Northern Health supports partnership and participation in research activities, for innovation and research-based practice. We use knowledge generated from research to improve the quality of care we deliver, and as a vehicle to create change in our region and encourage excellence in research.

All research conducted within, or for Northern Health (NH) must be approved by the Research Review Committee (RRC). The RRC is also directed to consider the impact on the NH organization. As such, the researcher must obtain operational approval as part of the Research Approval to the RRC. This ensures that there is knowledge about and acceptance of research happening in the region, as well as acceptance of risk and acknowledgement of the impact on NH facilities.

for:  UHNBC  Regional/multi-site (privileges in NH facilities)

NH facility:

### How do I obtain Operational Approval?

Signature pages can also be faxed to 250-566-2676 Attn: Research Review Committee.

Refer to the *Northern Health Operational Approval for Research Projects Information Sheet* for information on who can grant operational approval and the roles and responsibilities of the Researcher and the Northern Health Approval Manager.

Title of Project



# Operational Approval Managers

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As the person responsible for Department Authorization, my signature confirms that:

- I am the appropriate person to provide operational approval on behalf of Northern Health for this research.
- Resources (e.g. human or financial resources, space) required to conduct the research can be provided and the activities can be executed while service delivery is maintained. Cost recovery agreements have been negotiated with the researcher if required.
- I will communicate to the appropriate people in the organization that the research is happening and is supported by Northern Health, and how the organization is supporting this research
- I will support knowledge translation (i.e., bringing the research to practice and decision-making)

# I've filled in the forms... then what?

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Submit your Application to UNBC REB for processing.

## Minimal Risk:

- Rolling electronic submission of signed application to [reb@unbc.ca](mailto:reb@unbc.ca)
- Allow two weeks for a response from the REB

## Above Minimal Risk:

- Submission deadlines posted on website along with meeting dates, 8 copies of all documents to be delivered to the Office of Research Room 2018.

**Joint Research Project Involving Northern Health...**

# If Joint Research Involving UNBC & NH

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Complete UNBC REB Application



Complete NH application for Operational Approval

➔ Submit UNBC REB New application to UNBC REB

➔ Submit both to:

[researchcommittee@northernhealth.ca](mailto:researchcommittee@northernhealth.ca)

UNBC REB response time is dependent on the Level of Risk for the Application.

If revisions are needed, approval will be possible once they are completed.

# HARMONIZATION

## Multiple Jurisdictions Involved

Define the Roles of Research Team Members,  
AND Team Members Institution for ethics review

Complete Cover Sheet for Harmonized Research



BC **Ethics Harmonization** Initiative

HOME ABOUT NEWS RESOURCES CONTACT

Search ...

### Resources

BCEHI is pleased to offer a range of materials to support researchers, research ethics administrators, and reviewers in understanding and implementing harmonized approaches to ethics review.

In this section, the following resources are available:

#### Ethics review resources

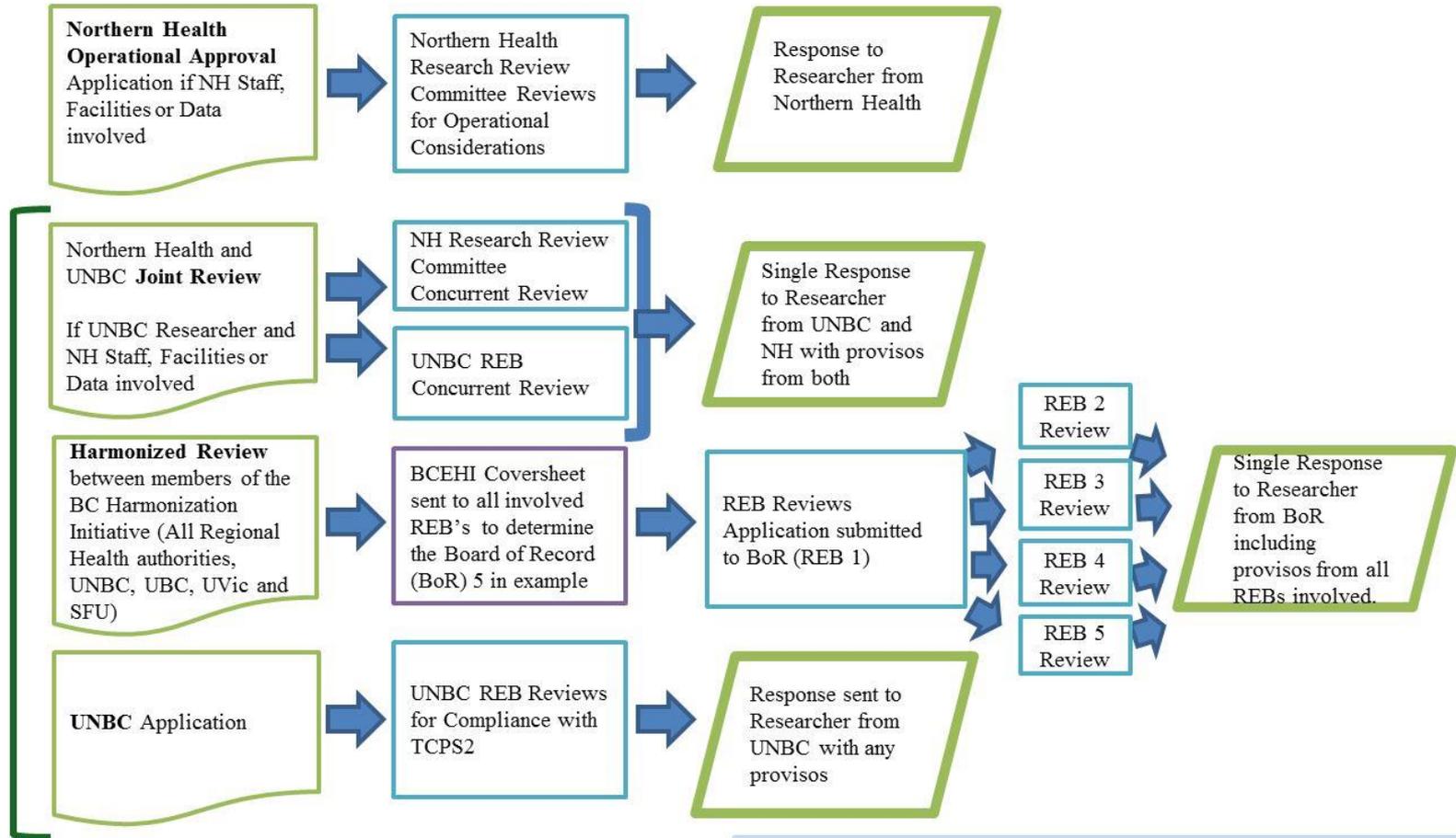
- [Determining if a study is minimal risk – common criteria guideline](#)
- [Cover sheet for harmonized research ethics review](#)

### Latest News

Above Minimal Risk harmonized ethics review pilot launched June 1, 2015

Harmonized process replaces joint UVic/VIHA research ethics review process May 28, 2015

# Joint, Harmonized or Single Research Ethics Reviews:



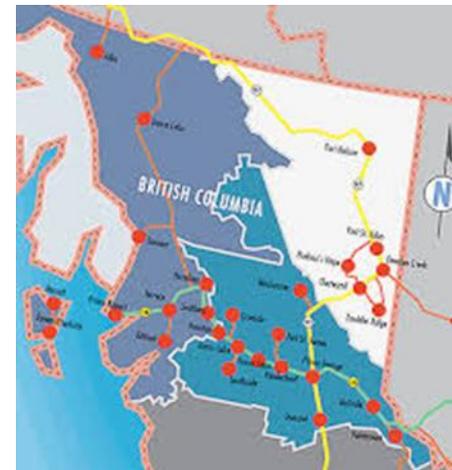
# NMP Faculty, Clinical Students & Residents

UBC Research Ethics Boards

Guidance Notes on the Streamlined process for:

UBC Family Practice Residents, UBC Dietetic Interns, UBC Pharmacy Residents,  
and UBC Summer Medical Students Research Projects.

<https://ethics.research.ubc.ca/behavioural-research-ethics/breb-guidance-notes>



# Amendments, Renewals & Board of Record

For all Studies:

Changes to The Study



Amendment

➔ If involving NH, researcher sends once approved Study approval coming to end date

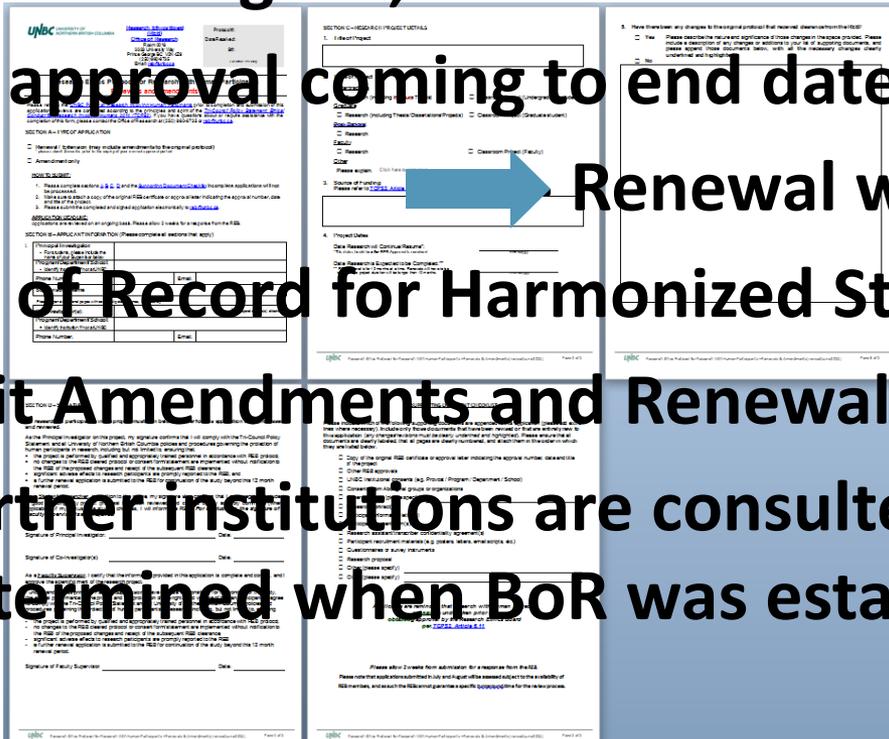


Renewal

➔ Renewal with Amendments Board of Record for Harmonized Studies:

Submit Amendments and Renewals through the BoR

- partner institutions are consulted or notified as determined when BoR was established





# Contact

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**Northern Health:**

e-mail: [ResearchCommittee@northernhealth.ca](mailto:ResearchCommittee@northernhealth.ca)

**Webpage:**

[https://northernhealth.ca/YourHealth/Research/  
NHResearchReviewCommittee.aspx](https://northernhealth.ca/YourHealth/Research/NHResearchReviewCommittee.aspx)

**UNBC Research Ethics Board:**

E-mail: [reb@unbc.ca](mailto:reb@unbc.ca)

**Webpage:**

[http://www.unbc.ca/research/research-ehitics-  
safety-human-subjects](http://www.unbc.ca/research/research-ehitics-safety-human-subjects)