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RESOURCES FOR RESEARCHERS

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PART 1: CHIPER POLICIES

Standard Operating Procedures of CHIPER

<https://www.rithim.ca/chiper-policies-procedures>

PART 2: GENERAL RESOURCES REGARDING ETHICS, PRIVACY, AND RESEARCH INTEGRITY

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

- Research Requiring Research Ethics Board Review (Chapter 2)
- The Consent Process (Chapter 3)
- Conflicts of Interest (Chapter 7)
- Multi-Jurisdictional Research (Chapter 8)
- Research Involving the First Nations, Inuit and Métis Peoples of Canada (Chapter 9)
- Qualitative Research (Chapter 10)
- Clinical Trials (Chapter 11)
- Human Biological Materials including Materials Related to Human Reproduction (Chapter 12)
- Human Genetic Research (Chapter 13)

International Conference on Harmonisation: Guideline for Good Clinical Practice ICH E6 (R2) <https://ichgcp.net/>

CIHR Best Practices for Protecting Privacy in Health Research (September 2005)
<https://cihr-irsc.gc.ca/e/29072.html>

- Privacy Best Practices: 10 Elements
<https://cihr-irsc.gc.ca/e/29072.html#10Elements>

WHO Alliance for Health Policy and Systems Research with the Global Ethics Unit,
Ethical Considerations for Health Policy and Systems Research

<https://apps.who.int/iris/bitstream/handle/10665/330033/9789241516921-eng.pdf?ua=1>

Tri-Agency Framework: Responsible Conduct of Research

<https://rcr.ethics.gc.ca/eng/framework-cadre.html#a1>

**PART 3: GENERAL RESOURCES ON
COMMUNICATIONS**

The PRAS requires that the applicant provide a summary in “plain language.” In addition, communications with research participants should be in “plain language.” The following provide some tips on how to write using “plain language.”

Writing about Biomedical and Health Research in Plain English: A Guide for Authors

http://www.access2understanding.org/wp-content/uploads/2014/11/Access-to-Understanding-writing-guidance_v1.pdf

Writing the Lay Summary Basics (Queen’s University)

<https://cimvhr.ca/forum/resources/WritingTheLaySummaryBasics.pdf>

**PART 4: RESOURCES ON
KEY TOPICS IN HEALTH RESEARCH**

In this section, we have identified a number of resources that may be helpful to researchers. Included are resources derived from the academic literature as well as guidelines and toolkits developed by universities in Canada and beyond.

Managing Conflicts of Interest in Research

Good Practices in Handling Conflict of Interest (University of Sheffield)

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/conflicts-of-interest>

Conflict of Interest Identification Checklist (University of Melbourne)

https://staff.unimelb.edu.au/_data/assets/pdf_file/0012/1946577/COI-identification-checklist.pdf

Conflict of Interest Management Strategies (University of Melbourne)

https://staff.unimelb.edu.au/_data/assets/pdf_file/0011/1946576/COI-management-guide.pdf

Guidelines for Managing Real, Potential, and Perceived Conflicts of Interest (Ryerson University)

<https://www.ryerson.ca/content/dam/research/documents/ethics/guidelines-for-managing-real-potential-and-perceived-conflicts-of-interest.pdf>

Clinical Trials

Health Canada, Health Products and Food Branch Inspectorate's Good Clinical Practices

<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices.html>

Health Canada Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications

<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/clinical-trials/clinical-trial-sponsors-applications.html>

Health Canada Guidance Document for Clinical Trials for Natural Health Products
<https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/clinical-trials.html>

Health Canada Guidance Document: Part C, Division 5 of the Food and Drugs Regulations, “Drugs for Clinical Trials Involving Human Subject” (GUI-0100)
<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html>

Ethical Issues in Qualitative Research

D. Goodwin et al., “Ethical Issues in Qualitative Research.” *Qualitative Research in Health Care, Fourth Edition*. Edited by C. Pope and N. Mays. Jon Wiley & Sons, 2020.

<https://onlinelibrary.wiley.com/doi/abs/10.1002/9781119410867.ch3> (may be freely accessible through site licenses held by universities)

Orb et al., “Ethics in Qualitative Research.” *Journal of Nursing Scholarship* 33:1 (2000): 93-96.

<http://www.columbia.edu/~mvp19/RMC/M5/QualEthics.pdf>

Mitigating the Risks to Study Participants Completing Surveys

(Insert link to guidance document)

Community-Engaged Research

University of Manitoba’s Community Engagement Framework

https://www.umanitoba.ca/research/orec/media/Community_Engagement_Framework.pdf

Key Practices for Community Engagement in Research on Mental Health or Substance Abuse (from the Centre for Addiction and Mental Health)

<https://www.lgbtqhealth.ca/projects/docs/practicesforresearchonmhandsu.pdf>

K. Beier et al., “Taking Patient Involvement Seriously: A Critical Ethical Analysis of Participatory Approaches in Data-Intensive Medical Research.” *BMC Medical Informatics and Decision Making* 90:19, 2019.

<https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/s12911-019-0799-7>

Engagement Toolbox (Penn State University)

<https://aese.psu.edu/research/centers/cecd/engagement-toolbox>

The Canadian Public Health Association’s “Community Engagement in Public Health” Webinar Series

<https://www.cpha.ca/community-engagement-public-health>

Research Involving Indigenous Communities

Framework for Research Engagement with First Nations, Métis, and Inuit Peoples

https://umanitoba.ca/faculties/health_sciences/medicine/media/UofM_Framework_Report_web.pdf

Research with Vulnerable Populations

B.G. Gordon, “Vulnerability in Research: Basic Ethical Concepts and General Approach to Review.” *OCHSNER Journal* 20:1, 2020, 34-38

<http://www.ochsnerjournal.org/content/20/1/34>

A.Gonzalez-Duarte et al., “The Research Ethics Involving Vulnerable Groups.” *Rev Invest Clin* 71, 2019, 217-225

<https://www.medigraphic.com/pdfs/revinvcli/nn-2019/nn194a.pdf>

P. Shivayogi, “Vulnerable Population and Methods for Their Safeguard.” *Perspec Clin Res* 4:1, 2013, 53-57

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601707/>

Research in Children

Position Statement of the Canadian Paediatric Society on Ethical Issues in Health Research in Children (2018)

<https://www.cps.ca/en/documents/position/ethical-issues-in-health-research-in-children>

Reporting Child Abuse and Neglect: Your Responsibilities as a Researcher

Under Manitoba law, individuals (including researchers) are obligated to report real or suspected abuse of children to legal authorities. Failure to do so may result in fines or imprisonment. The factsheet summarizes essential information about reporting of child protection and child abuse, and provides links to Manitoba's handbook on this matter.

https://www.gov.mb.ca/fs/childcare/resources/pubs/ece_protocol_factsheet.pdf

Research into Rare Diseases

M. Coors et al., "Ethical Issues Related to clinical Research and Rare Diseases." *Transl Sci Rare Dis* 2: 3-4, 2017, 175-194.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5764070/>

M.T. Nguyen et al., "Model Consent Clauses for Rare Disease Research." *BMC Medical Ethics* 55:20, 2019.

<https://bmcomedethics.biomedcentral.com/articles/10.1186/s12910-019-0390-x>

Research During Public Health Emergencies

The Hastings Center

<https://www.thehastingscenter.org/research-ethics-resources-for-conducting-research-in-public-health-emergencies/>

Nuffield Council on Bioethics

<https://www.nuffieldbioethics.org/publications/research-in-global-health-emergencies>

Working with Data Repositories

Manitoba Population Research Data Repository Resources and Tools

http://umanitoba.ca/faculties/health_sciences/medicine/units/chs/departamental_units/mchp/resources/repository/resources_and_tools.html

CIHR Health Research Data: Resources (includes a number of data platforms that can be accessed by researchers)

<https://cihr-irsc.gc.ca/e/49941.html>

Data Management

Tri-Agency Statement of Principles on Digital Data Management

http://science.gc.ca/eic/site/063.nsf/eng/h_83F7624E.html?OpenDocument

Open Access

Tri-Agency Open Access Policy on Publications

http://science.gc.ca/eic/site/063.nsf/eng/h_F6765465.html?OpenDocument