Ethics in Research: A Science Lifecycle Approach

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Introduction to the Workbook

It is often assumed that the ethical obligations of a researcher start and end with Research Ethics Board (REB) approval or after a research participant signs a carefully constructed informed consent form. However, the materials presented in this "Ethics in Research: A Science Lifecycle Approach" workbook introduce a more holistic approach to ethics. The workbook is not focused specifically on compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2),¹ which of course is essential for researchers at academic institutions in Canada. Instead, the purpose of the workbook is to foster awareness of the ethical issues that may emerge throughout the entire lifecycle of scientific knowledge from creation to translation. The materials are written for a graduate and post-graduate audience, which could include individuals representing a range of different professions (i.e., physicians, nurses) and professional levels (i.e., clinician-scientists, graduate students, research fellows, clinical fellows, etc.). Although written for this audience, it may also have a more broad interest.

The workbook begins by providing an overview of the four themes of the Canadian Institutes of Health Research (CIHR) funded health research including common ethical issues that may arise under each theme (Section 2). The following section presents the Knowledge-To-Action Ethics (KTA-E) Cycle, which is the conceptual framework for the entire document (Section 3). This cycle combines the KTA cycle (Graham et al, 2006.) with an ethical lens to address the complete lifecycle of knowledge creation and translation relevant to researchers and includes a wide variety of elements from data collection to sustaining knowledge use. All subsequent materials included in the workbook are informed by, and map onto, this conceptual framework.

Section 4 provides a series of scenarios built around the four themes of CIHR funded health research. There are four modules to represent each of these themes. All of the scenarios include a description of the case; a series of discussion questions; links to relevant ethics guidance documents; notes describing which aspects of the KTA-E cycle the scenario explores; links to relevant articles (where applicable); a scenario shift which provides additional facts to be considered and a guide to help lead discussion on the scenario. The scenarios and associated discussion questions should foster in-depth deliberation amongst users of this material and are designed to expose the ethical tradeoffs and complexities inherent in each case. The topics covered provide an overview of ethical issues that may occur under each theme but are not intended to be either true or exhaustive.

Some of the key points that could be raised in discussions about the scenario questions from Section 4 are highlighted after each scenario. This discussion guide should be viewed merely as a discussion-aiding tool that helps to identify only a few of the most important ethical aspects of the case. It should not be used to narrow discussions of the scenarios or to determine the correct answer to each scenario question. In most cases there is no single correct answer to the scenario questions. Instead responses are informed by a range of factors and may change depending on how circumstances are interpreted by the reader. Section 5 briefly describes some of the ethics resources mentioned throughout the workbook.

¹ For guidance on TCPS2 please review the CORE tutorial, webinars, and workshops provided at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/
The workbook should be used in a manner that best suits the user. In other words, it can be used in a group setting or by individuals as a self-study guide.

We consider this workbook to be an evolving document. We invite users to provide suggestions for improvement and expansion by building their own cases and then submitting them to the CIHR case study database for others to employ.

Dedicated email for feedback and new scenarios submission: ethicsedu@cihr-irsc.gc.ca. Updated versions of this document are downloadable at http://www.cihr-irsc.gc.ca.
The Four Themes of CIHR Funded Health Research

Research funded by CIHR is organized under the four themes\(^2\) shown below. This section provides a description of each theme as well as examples of common ethical issues that may arise under each theme. Research is not an activity that is isolated from society. A wide range of stakeholders influence the lifecycle of knowledge creation and application including funders, students, patients, industry, and policy-makers as illustrated in the examples below.

Theme 1: Biomedical Research: Biomedical research is research with the goal of understanding normal and abnormal human functioning, at the molecular, cellular, organ system and whole body levels, including development of tools and techniques to be applied for this purpose; developing new therapies or devices that improve health or the quality of life of individuals, up to the point where they are tested on human subjects. Biomedical research may also include studies on human subjects that do not have a diagnostic or therapeutic orientation.

- Common ethical considerations that researchers should be aware of under this theme include:
  - Access to, and the allocation of, scarce resources such as databanks or expensive equipment required to conduct research
  - Factors that may inappropriately influence the framing of research questions and the conduct of researchers such as personal gain and other conflicts of interest

Theme 2: Clinical Research: Clinical research is research with the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Clinical research usually encompasses research on, or for the treatment of, patients.

- Common ethical considerations that researchers should be aware of under this theme include:
  - The ways in which the funding source may influence the researcher and the research agenda
  - Equal access to research participation and the equitable distribution of research benefits to human participants

Theme 3: Health Services Research: Health services research includes research with the goal of improving the efficiency and effectiveness of health professionals and the health care system, through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and, ultimately, Canadians' health and well-being.

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- Common ethical considerations that researchers should be aware of under this theme include:
  - Complex ethical tradeoffs that must be considered when analyzing the economic efficiency of the health care system or particular services
  - Determining the best interests of diverse communities and the best way to serve the needs of these communities

**Theme 4: Social, Cultural, Environmental, and Population Health Research:**

*Population and public health research comprises research with the goal of improving the health of the Canadian population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.*

- Common ethical considerations that researchers should be aware of under this theme include:
  - Thinking through the special considerations or unique harms and benefits that may arise when conducting research with vulnerable groups
  - Weighing the best interests of groups or whole populations against the rights of individuals when conducting public health research
Integrating Ethics and the Knowledge-To-Action Cycle

This section presents the KTA–E cycle. As a conceptual framework, this cycle illustrates the iterative relationship between knowledge creation and knowledge translation and some of the potential ethical considerations at steps along the way. It builds on the work of Graham et al., 2006.³ The framework addresses the complete lifecycle of scientific knowledge relevant to researchers funded by CIHR and includes a wide variety of elements from data collection to sustaining knowledge use. All of the materials presented in this workbook are informed by, and map onto, this conceptual framework.

Defining terms

The Knowledge-to-Action process represents the process of knowledge creation and its translation into practice and policy. It is considered iterative, dynamic, and complex, both concerning knowledge creation and knowledge application (action cycle), with the boundaries between the creation and action components and their ideal phases being fluid and permeable. The action phases may occur sequentially or simultaneously and the knowledge phases may influence or be drawn upon during action phases. The cyclic nature of the process and the critical role of feedback loops are key concepts that underlie this conceptual model. While knowledge can be empirically derived (i.e., research based) the framework encompasses other forms of knowing such as contextual and experiential knowledge as well.

Within KTA, the Knowledge creation or the production of knowledge, is composed of three phases: knowledge inquiry (first-generation knowledge), knowledge synthesis (second-generation knowledge), and creation of knowledge tools and/or products (third-generation knowledge). As knowledge is filtered or distilled through each stage in the knowledge creation process, the resulting knowledge becomes more synthesized and potentially more useful to end users.

Knowledge translation is described by CIHR as a “dynamic and iterative process that includes synthesis, dissemination, exchange, and ethically-sound application of knowledge to improve the health of Canadians, provide more effective health services and products and strengthen the health care system.”⁴

Ethics has been described in many ways. Most approaches tend to contrast perceived opposites. For instance, a legalistic approach might contrast “right” and “wrong,” while an approach to ethics that is grounded in a religious perspective would highlight the contrast between what is considered “good” and what is seen as “bad.”


⁴ Canadian Institutes of Health Research website, section on knowledge translation: http://www.cihr-irsc.gc.ca/e/29418.html
In bioethics and research ethics review exercises, a ‘principled approach’ is most often used to invoke principles that are perhaps as close to universal as is possible, such as beneficence, non-maleficence and justice. This principled approach is invaluable to bioethicists and those conducting research ethics reviews, but it will not be deeply explored in the context of the present education package. Instead, the intent of this material is to help users develop an ‘ethics lens’ without resorting to any particular approach or training in philosophy.

Thus, for the purposes of this workbook, we will use a pragmatic approach to ethics that is primarily about developing the skills for a critical analysis of relations of power and context. This approach includes thinking critically about who has power and voice in a situation and who is (unintentionally?) silenced; who benefits and who does not, and in what contexts? This pragmatic approach to ethics asks analysts simply to consider each element in a given situation and note the potential consequences, rather than to apply any received ideas about good and bad, right or wrong. In other words, the goal of this approach is to develop the practical skills to recognize ethical issues and to decide on the most socially defensible course of action.

Taken together, these understandings of the processes comprising the KTA-cycle, together with a pragmatic approach to ethics, results in the CIHR KTA-Ethics cycle, which is a framework that encompasses the complete lifecycle of scientific knowledge.

**Explanation of the CIHR KTA-Ethics Cycle**

Figure 1 provides a visual overview of the complete conceptual framework starting with problem identification. The knowledge creation figure (Figure 2) covers topics such as, “knowledge inquiry, knowledge synthesis, and knowledge tools/products” (Graham et al., 2006). This phase in the lifecycle of scientific research begins with establishing partnerships and seeking funding and then moves on to the recruiting and data collection phases of research. Some of the ethical issues that can emerge from these topics are highlighted in the tables that accompany each figure. For example, when forming research questions, researchers should be aware of the ways in which contextual factors may influence their choices and how their decisions affect stakeholders, among other things. After data are analyzed, conclusions are drawn, and results are published, the cycle moves towards the knowledge translation of results, which may involve conducting additional research. As the situation warrants, the cycle may either continue with another iteration of knowledge creation, or move towards knowledge translation. The cycle is iterative and may move between knowledge creation and knowledge translation many times in a single inquiry.

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5 This pragmatic approach to ethics is inspired by the work of Ludwig Wittgenstein (http://www.galilean-library.org/manuscript.php?postid=43866 and http://www.iep.utm.edu/wittgens/#H3) and Michel Foucault.
Topics covered by the Knowledge Translation side of the cycle begin with the process of reviewing and adapting knowledge to a particular context and then selecting and applying that knowledge (Figure 3). Experience gathered through monitoring and evaluating knowledge allows the cycle to move towards next generation research and continued knowledge translation.

When used together, the figures in this section should help the user locate the entirety of their work within the lifecycle of scientific research, identify and think through some of the ethical issues particular to that phase of the cycle, consider how their work relates to earlier and later phases of the cycle, and identify what ethical issues they should anticipate both in the short and longer term.

**Diagrams of the CIHR Ethics Cycle**

This section provides illustrations of the KTA–E cycle. It is important to note that the explanations shown in the accompanying tables are provided for illustrative purposes only and are not intended to be exhaustive. Readers will notice that activities at stages 5, 6 and 7 of the knowledge creation side of the cycle are distinguished by their colour which is different from the rest. This distinction is deliberate and intended to show the activities such as collection of data, recruitment of participants, and REB submission that are typically associated with ethics in research only account for a small portion of the ethical issues inherent in the full lifecycle of science.
Figure 1. The Complete KTA-E Cycle

Table 1: Ethical considerations on entering the KTA-Ethics Cycle as shown above

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Some potential ethical considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Identify the (research or KT) problem.</td>
<td>- Influence of disciplinary and epistemological lens;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Influence of socio-political context;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Priority-setting process;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Agenda-setting process;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Stakeholder engagement;</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Power and voice: whose concerns are addressed; who is (unintentionally silenced)?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Social responsibility of research</td>
</tr>
</tbody>
</table>
Figure 2. The Knowledge Creation portion of the KTA-E Cycle
Table 2: Ethical considerations in KC activities illustrated above

<table>
<thead>
<tr>
<th>STEP</th>
<th>KC activities</th>
<th>Some Potential Ethical Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Establish partnerships</td>
<td>choice of collaborators; concern for equity; agency; influence; …</td>
</tr>
<tr>
<td>2</td>
<td>Form research question</td>
<td>Stakeholders involvement; influencing context; framing; theory used; …</td>
</tr>
<tr>
<td>3</td>
<td>Design project</td>
<td>resources/capacity available; theory used; methodology used (scientific validity); …</td>
</tr>
<tr>
<td>4</td>
<td>Seek funding</td>
<td>choice of funder; obligations to funder; public/private funding; …</td>
</tr>
<tr>
<td>5</td>
<td>REB submission</td>
<td>protection of participants; privacy; informed consent; data stewardship; Conflict of Interest (CoI); …</td>
</tr>
<tr>
<td>6</td>
<td>Recruit participants (if necessary)</td>
<td>protection of participants; privacy; informed consent; data stewardship; CoI; …</td>
</tr>
<tr>
<td>7</td>
<td>Collect data</td>
<td>protection of participants; privacy; informed consent; data stewardship; CoI; …</td>
</tr>
<tr>
<td>8</td>
<td>Analyse data</td>
<td>methodological choices; role of collaborators; …</td>
</tr>
<tr>
<td>9</td>
<td>Draw conclusions</td>
<td>implications for individuals; groups and populations; CoI; …</td>
</tr>
<tr>
<td>10</td>
<td>Publish results</td>
<td>Authorship; choice of publication venue; publication bias; negative results; …</td>
</tr>
<tr>
<td>11a</td>
<td>Towards KT of results</td>
<td>selection of evidence; …</td>
</tr>
<tr>
<td>11b</td>
<td>Further research</td>
<td>Responsible stewardship of funds; …</td>
</tr>
</tbody>
</table>
Figure 3. The Knowledge Translation Portion of the KTA-E Cycle

Knowledge Translation
(based on Graham et al., 2006)

1. Review and select knowledge
2. Adapt knowledge to context
3. Assess barriers to use
4. Apply knowledge (intervention)
5. Monitor knowledge use
6. Evaluate application of Knowledge (intervention)
7. Sustain knowledge use
8a. Toward next generation research (based on KT experience)
8b. Toward continued KT
Table 3: Ethical considerations in KT activities illustrated above

<table>
<thead>
<tr>
<th>STEP</th>
<th>KTA activity</th>
<th>Some Potential Ethical Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Review and select knowledge</td>
<td>KT theory; publication bias; data access; intellectual property; negative results; …</td>
</tr>
<tr>
<td>2</td>
<td>Adapt knowledge to context</td>
<td>Honouring local knowledge; voice; agency; …</td>
</tr>
<tr>
<td>3</td>
<td>Assess barriers to use</td>
<td>Concern for equity; access issues; …</td>
</tr>
<tr>
<td>4</td>
<td>Apply knowledge (intervention)</td>
<td>Resource allocation; equity; opportunity costs; intellectual property; …</td>
</tr>
<tr>
<td>5</td>
<td>Monitor knowledge use</td>
<td>Potential CoI; roles; responsibilities; …</td>
</tr>
<tr>
<td>6</td>
<td>Evaluate application of knowledge (intervention)</td>
<td>Criteria-setting; potential CoI; …</td>
</tr>
<tr>
<td>7</td>
<td>Sustain knowledge use</td>
<td>Sustainability concerns; capacity-building; robustness; opportunity costs; …</td>
</tr>
<tr>
<td>8a</td>
<td>Towards next generation research</td>
<td>Selection of evidence; responsible stewardship of funds; …</td>
</tr>
<tr>
<td>8b</td>
<td>Toward continued KT</td>
<td>Selection of evidence; responsible stewardship of funds; …</td>
</tr>
</tbody>
</table>
Hypothetical Scenarios

Introduction to Scenarios

The scenarios in this section are built around the four themes of CIHR health research: (1) Biomedical Research, (2) Clinical Research, (3) Health Services Research, and (4) Social, Cultural, Environmental and Population Health Research (explained in greater detail in Section 2). There are four modules to represent these themes, each of which contains at least three scenarios.

The hypothetical scenarios and associated discussion questions are intended to foster dialogue and debate amongst users. They are designed to expose the difficult ethical tradeoffs and complexities inherent to each case. All of the scenarios include a description of the case, a series of discussion questions, links to relevant ethics guidance documents, notes describing which aspects of the KTA–E cycle the scenario explores, and where applicable, links to relevant articles. A Discussion Guide follows each scenario.

It is important to note that there are no right or wrong answers to questions intended to explore ethics issues.

A Discussion Guide is offered at the end of each scenario. This guide is not exhaustive but highlights some of the key points that could be raised in discussions about the scenarios from Section 4. This guide should be viewed merely as a discussion aid to help identify some of the important ethical aspects in the case in order to prompt full exploration of the ethical issues at stake in each module.

The discussion guide should not be used to narrow discussions of the scenarios or to determine the correct answer to each scenario question. The issues it presents are not intended to be exhaustive; instead, the guide only serves to highlight some key points that if missed in the discussion would result in a serious gap. Users should refer to the KTA–E cycle to help locate these ethical issues within the lifecycle of scientific research and consider how these issues may influence other phases in the conceptual framework.
Biomedical Research

Biomedical research is research with the goal of understanding normal and abnormal human functioning, at the molecular, cellular, organ system and whole body levels, including development of tools and techniques to be applied for this purpose; developing new therapies or devices that improve health or the quality of life of individuals, up to the point where they are tested on human subjects. Biomedical research may also include studies on human subjects that do not have a diagnostic or therapeutic orientation.

Scenario #1: Publishing your Research

You are a PhD student in a lab conducting research on Parkinson’s disease. Your PhD work has produced an interesting finding and your supervisor is eager for you to publish it. You have drafted the manuscript and it is ready for submission to a leading journal in your area. However, you are not happy with one of the digital images that you are submitting with the paper. You are concerned that the results presented in the paper are difficult to observe in the image and discuss the issue with a postdoctoral fellow from your lab. She suggests that you use a photo manipulation software to adjust the background in the image to increase the contrast, which would make the differences easier to observe.

You want to make your lab look good and keep your supervisor happy. You are also aware that your doctoral funding is running out, and you are keen to finish and defend your manuscript-based thesis as soon as possible. You do not want your manuscript to be rejected or delayed because of this one image. Should you use a photo manipulation software to adjust the image?

Discussion questions
1. What are the ethical issues at stake in this case?
2. What are the potential long-term effects of postponing publication for you, for your lab, and for your field of research?
3. When does the beautification of data become falsifying data? Is beautifying data ever acceptable?

Scenario shift:
You decide to use a photographic manipulation software to adjust the image and submit it to the journal. Your supervisor informs you that she has just been asked to act as a peer reviewer on a manuscript that shows similar data and draws similar conclusions to your manuscript. Your supervisor says she can delay her peer review for as long as possible, and give very harsh comments and criticisms of the paper in order to delay its publication. This will give you a chance to get your paper published first and avoid being “scooped.”

Additional discussion questions:
4. What should you/your supervisor do in this situation? How does your decision affect other researchers?
5. What are some of the conflicts of interest that are at stake here? For you? For your supervisor?
Relevant ethics guidance documents:
- Committee on Publication Ethics (COPE): http://publicationethics.org/

Links to the Ethics Cycle conceptual framework:
- Through this scenario, participants can address issues under the following topics:
  - Publish results (authors listed on papers and agreeing to co-author a paper leads to important ethical consequences) (KC),
  - Review and select knowledge (publication bias is both a scientific and ethical issue) (KT),
  - Sustain knowledge use (lost opportunity costs associated with delaying the publication of important findings have ethical implications for the author as well as other researchers) (KT)

Link to real life case study:
- Image manipulation case studies on COPE: http://publicationethics.org/category/keywords/image-manipulation

Links to relevant articles:

Discussion Guide:
1. Ethical issues at stake include: conflict of interest and research integrity (including honesty, trustworthiness, respecting the research endeavor, fairness etc.).
2. Long-term effects of postponing publication include: ineffective use/ waste of resources, undermining the research endeavor, delaying research result translation, missed career opportunities, financial hardship.
3. Consider issues such as: whether modification omits an important factor/ finding; whether results would be interpreted differently with or without the change; whether modification leads the reader to a substantially different conclusion; accepted practices in your area of research (as defined by journals, professional bodies, etc.).
4. You and your supervisor should be aware of the repercussions of such actions on others (including other researchers, the scientific community, funders, and the general public). These repercussions may be detrimental and unfair.
5. Your supervisor should consider his roles as a peer reviewer and a supervisor/lab manager, and how these roles may result in conflicting interests. Other conflicts include the need/desire to publish prolifically versus research integrity/reporting of results in a timely fashion.

Scenario #2: Modifying Research Questions

You have just received funding from a stem cell research agency and CIHR to conduct induced pluripotent stem (iPS) cell research\(^6\) without the use of viruses. It is hoped that this research will eventually inform treatments that benefit patients undergoing transplants, among other things. You are aware that Company Science will be recruiting next fall and you would really like to work for them after you graduate. You know that they are interested in conducting transplantation research in a few select areas. These are important areas of research, but not the areas that you planned to address in your original research proposal approved by your supervisor and funders. If you add these questions to your original study, it will take longer to complete.

You are pretty sure that you could modify your original research questions or change a few of them altogether in order to address the company’s interests while still completing your research on time. A colleague tells you that it is common for students and postdocs to wander away from the questions and hypotheses in their original research proposals for a variety of reasons. What should you do?

Discussion questions:
1. Is it wrong to change your research proposal after it is approved by your supervisor? Under what circumstances would it be acceptable, if any?
2. Do you need to tell your supervisor about the reasons why you want to modify your research proposal? What if this case involved a PI on a project instead of a student? Would that make a difference? Who does a PI need to inform of modifications to a research proposal if anyone?
3. In addition to your other funding, what if Company Science had offered you a stipend to conduct transplantation research in their area of interest? What difference would this make to the case, if any?

Scenario shift:
You discuss changing your research proposal with your supervisor and she agrees for you to shift the focus of your research study. Your supervisor says that you do not need to discuss these changes with your funder as research proposals often change once put into practice. She explains that research results, design, methods, and populations may change without regard to what the granting agency agreed to fund.

Additional discussion questions:
4. Is it wrong to change your research proposal after it is approved by your funders?
5. How might your decision to change your research impact your funders? Other researchers? Future research studies?

\(^6\) Induced pluripotent stem (iPS) cell research involves engineering non pluripotent cells such as adult skin cells into a pluripotent state, thereby avoiding the use of embryos as a source of stem cells.
Relevant ethics guidance documents:

- The Stem Cell Ethics Education Website developed by Michael McDonald and his team at the University of British Columbia’s Centre for Applied Ethics. In particular, the section on conflict of interest: [http://www.stemcellethics.ca/themes/theme-9-commercialization/key-concepts-and-terms](http://www.stemcellethics.ca/themes/theme-9-commercialization/key-concepts-and-terms)
- CIHR Stem Cell Oversight Committee: [http://www.cihr-irsc.gc.ca/e/19312.html](http://www.cihr-irsc.gc.ca/e/19312.html)

Links to the Ethics Cycle conceptual framework:

- Through this scenario, participants can address issues under the following topics:
  - *Seek funding* (this case explores the ethical obligations that a researcher has to their funder concerning the knowledge they create) (KC),
  - *Form research question* (how researchers frame their questions impacts stakeholders of the research outcomes as well as other researchers) (KC),
  - *Toward next generation research* (the research conducted (or not conducted) today will inform future research efforts) (KT)

Discussion Guide:

1. Questions to be considered when determining the acceptability of modifying research direction include: whether the underlying scope of research remains the same; if the research still fulfills university requirements to obtain your degree; whether new research/novel findings suggest a new mode of inquiry is more appropriate/fruitful; if the supervisor can continue to provide adequate advice/input/supervision; supervisors’ (and/or committee members) perspective; and if your choices undermine other obligations (e.g., associated with other funding/awards).
2. Other interests, which may result in a conflict of interest, should be clearly outlined, discussed, and managed. Obligations to the supervisor, lab, funder, etc. must all be considered.
3. Financial (and other) conflicts of interest are relevant to this case. The potential result of these conflicts should be considered (e.g., behavioural change, allegiances, transparency, influence on result reporting, etc.).
4. Issues such as responsibilities to funders, research integrity, and scope of original project should be discussed. It is also important to consider how changes to a research proposal may impact stakeholders.
5. The broader effect of changing research direction should be explored. For example, funders may have specific reasons for supporting research in your specific area, and may have concurrently funded other researchers, whose proposals will now overlap, resulting in wastage of resources. It is also important to consider what would happen if all researchers ignored their original research proposals and research questions. If everyone funded to do research about X instead conducted research about Y. Consider the impact on current and future research projects.
Clinical Research

Clinical research is research with the goal of improving the diagnosis, and treatment (including rehabilitation and palliation), of disease and injury; improving the health and quality of life of individuals as they pass through normal life stages. Clinical research usually encompasses research on, or for the treatment of, patients.

Scenario #1: Who Decides?

Type 2 diabetes is becoming an issue of national importance for all Canadians. However, there are certain populations, such as Aboriginal peoples, who are at particularly high risk for this disease. Your research group is creating a new diagnostic test for patients with type 2 diabetes which identifies genes that may influence insulin function. Selecting and then carefully monitoring individuals who are at increased risk is an important method of achieving early diagnosis and improving the overall health of these patients.

You have been contacted by a local Aboriginal community who would like to develop a partnership with your research group in order to study and eventually improve the overall health of their community. You would like them to participate in your health research about type 2 diabetes, which significantly impacts their community. However, during an initial meeting with community elders, you discover that they are primarily interested in participating in research about a rare form of arthritis that has plagued their band for generations. What should you do? You want to treat the Aboriginal community members as partners in the research process and serve their stated needs as suggested in TCPS2. Yet, you are confident that conducting your health research about type 2 diabetes could lead to important discoveries that could benefit all Canadians in addition to this Aboriginal community.

Discussion questions:
1. What are some of the key ethical issues involved in this case?
2. Why should some communities be given special consideration in the design and conduct of health research?
3. What would be some of the potential outcomes if you decided to go ahead with the arthritis research study? Or only agreed to conduct your research about type 2 diabetes? Or decided not to conduct research with this community at all?
4. Would your decision change if this case involved a different community, such as a particular religious group? Or a different health topic, such as alcoholism?
5. How would your viewpoint differ if funding was already in place with this community to conduct your research about type 2 diabetes?
6. Would you feel differently if the community was primarily interested in looking at heart disease, as you could relate this to your diabetes research?

Scenario shift:
After discussing your concerns with the community elders, they inform you that they will agree to fund the arthritis research study. They suggest that you start with the arthritis research and then later, if funding levels permit and their community approves, you can move on to the type 2
diabetes research you originally wanted to conduct with the community. However, they are clear that they cannot guarantee any future funding for a variety of reasons.

**Additional discussion questions:**

7. How does the availability of funding for the arthritis research from the community change the ethical dimensions of this case?

8. What are some of the pros and cons of this funding arrangement? How does this arrangement differ from funding received from CIHR?

9. As a researcher, do your responsibilities change in this case? Who would you be responsible to if you agreed to conduct research funded by this community?

10. Who should set a research agenda? Who should pay for health research? Is it acceptable for a community to pay only for research that interests them?

**Relevant ethics guidance document:**

- Schnarch, Brian: Ownership, Control, Access, and Possession (OCAP) or Self-Determination Applied to Research

**Links to the Ethics Cycle conceptual framework:**

- Through this scenario, participants can address issues under the following topics:
  - *Forming research question* (how research questions are formed impacts stakeholders of research outcomes) (KC),
  - *Designing project* (choice of collaborators can impact the design of a research project as well available resources and methodologies used) (KC),
  - *Adapt knowledge to context* (research should give voice, power, and agency to research participants) (KT)

**Link to real life case study:**


**Discussion Guide:**

1. Key ethical issues to be considered include: conflicts of interest; resource allocation; utility and benefit; and responsibilities to funders, communities, research participants, and the Canadian public.

2. Issues such as: respecting different value/governing systems, historical, and other contextual factors; collaboration and trust in research; differing health needs; success and translation of research; etc., should be discussed.
3. There are many possible outcomes that can be discussed including: not fulfilling responsibilities to a funder; loss of trust; detrimental/beneficial implications for collaborative ongoing relationships; tradeoffs concerning meaningful research results that are beneficial to some versus meaningful research results which are beneficial to many; advocating the needs of an underserved community; etc.

4. Issues of stigma and discrimination of certain groups, and overall benefit, utility, effectiveness of the research, etc., should be discussed. Promoting the interests of the underserved communities could also be considered.

5. Responsibility and obligation to funders are important considerations here. Research integrity, resource allocation, and distribution of benefits are also relevant issues that should be discussed. What are some of the potential outcomes that stem from changing health topics when engaged in a funded research study?

6. The scope of the originally approved research/research funding plays a key role in choosing the appropriate course of action.

7. The availability of funding may result in a conflict of interest as the researcher may allow the interests/expectations of the funders to inappropriately shape the design and conduct of the research, for example. It also raises issues of fairness and responsibility (to researchers, funders, the community, and the broader Canadian public).

8. Issues to be considered include: fostering community consultation and collaboration in research; maintaining scientific rigor and appropriate use of methods; building and maintaining successful relationships. Research with an Aboriginal community (that is also funded by this community) will involve respecting the specific community values, desires, governance structure, and expectations, including adhering to the policy on research involving such groups (see TCPS2, Chapter 9).

9. Responsibilities change both because the community is the research funder (and therefore you are responsible to them as both funders and participants) and because of the special considerations involving research with Aboriginal communities outlined in TCPS2, Chapter 9.

10. Issues to be discussed include: the need for collaboration in establishing the goals, methods, etc., of the researcher; societal and community obligations to fund research; and wider social justice concerns.

**Scenario #2: Research with Children and Young Adults**

You are researching a new drug for the treatment of leukemia that avoids many of the common side effects of chemotherapy such as vomiting and nausea. It is just about ready for Phase III clinical trials. While the leukemia you are investigating primarily affects young children, you are considering doing the trial on young adults who usually experience a less severe form of the leukemia. Your decision is partly influenced by the fact that you have heard that to be considered ethical, research with young children involves many extra steps and delays. For example, your team would need to develop unique communication tools and recruitment strategies specifically designed for young children. Consequently, your team decides to test the drug in a young adult (mature minor) population to avoid these extra tasks.

**Discussion questions:**

1. Is this research scientifically valid? And if not, what are the ethical implications?
2. What are the costs of NOT doing research with younger children?
3. What are the costs of delaying your research? Who may suffer?
4. Would your opinion about this case change if the child subject group in question were healthy? What are some of the ethical issues associated with doing research with healthy children?

**Scenario shift:**
You commence your research with the young adult population. You are nearing the end of your recruitment period yet the preliminary results of the Phase III trial appear not to be statistically significant. You believe that this is because the inclusion population has a milder form of the leukemia and so the drug does not appear to be efficacious. You think that expanding the trial to include younger children with a more severe form of the leukemia may demonstrate a statistically significant benefit of the new drug.

**Additional discussion questions:**
5. Is it problematic to change methodology during a project to achieve statistical significance? What are some of the pros and cons?
6. When can an ‘adaptive design’ approach to research be justified, if ever?

**Relevant ethics guidance documents:**
- TCPS2 Chapter 4: B. Inappropriate Exclusion (section on Research Involving Children): http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/#toc04-1b
- University of Missouri-Kansas City School of Law: The Nuremberg Trials: The Doctors Trial: http://law2.umkc.edu/faculty/projects/ftrials/nuremb erg/nurembergdoctortrial.html

**Links to the Ethics Cycle conceptual framework:**
- Through this scenario, participants can address issues under the following topics:
  - **Toward continued KT** (how researchers allocate resources impacts future knowledge production and translation) (KT),

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7 Adaptive design can be described as “a study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from subjects in the study”. Mahajan, R. and Gupta, K. (2010). Adaptive design clinical trials: Methodology, challenges and prospect. Indian Journal of Pharmacology 42(4): 201–207: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2941608
Review and select knowledge (how researchers select knowledge can lead to biases and blind spots when results are translated) (KT),

Analyze data, recruit participants (subject selection impacts the methodological choices available to researchers and how results can then be analyzed) (KC)

Link to real life case study:

Discussion Guide:
1. Topics such as scientific background and rationale, justification, equipoise, research objectives, methodology and ability to meet research objectives and adequate statistical power should be discussed. Appropriate peer review may examine and highlight these factors. If research is not scientifically valid it cannot be considered ethical. ‘Bad’ science creates unnecessary risk, undermines the research endeavor and public trust, wastes resources etc.
2. The cost of not doing research with younger children leads to children being left as therapeutic orphans. In other words, although their exclusion protects them from the risks of medical research, they may also fail to benefit from this research.
3. Delaying research may result in prolonged and unnecessary suffering of those treated using traditional chemotherapy treatments (including death). Also, additional research dollars may not be used effectively/could have been allocated elsewhere.
4. Whether research is considered ethical or not relates to the balance of harms and potential benefits to research participants. When conducting research with children, the minimal risk threshold is applied unless the research is expected to be therapeutic. In this case, a minor increase over minimal risk may be allowed. Research with healthy children would never involve a therapeutic element (because they are not sick) so any minor increase over minimal risk would not usually be acceptable.
5. The argument against adaptive design include the potential to undermine the validity and integrity of the research and potentially misuse research money. Pros include using research funds more efficiently and producing research outcomes that may benefit stakeholders and the general public more quickly.
6. This flexible design can lead to some risks that must be considered, including timing issues (adaptations implemented too early) and insufficiently justified ad hoc changes (Mahajan and Gupta, 2010). It is important to consider how these potential risks may impact the safety of human participants and undercut the integrity/dependability of the research study.

Scenario #3: Testing a New Vaccine
Your research team has developed a vaccine for a communicable disease similar to H1N1 and it has undergone clinical trial testing and evaluation but only in healthy adult populations. You know that one of the groups most seriously impacted during the H1N1 outbreak was pregnant women. You would like to test your drug in pregnant women as soon as possible.

**Discussion questions:**
1. Is it fair to recruit pregnant women into this research study? Is it fair to exclude them?
   Are the risks to research participants, and potential risks to the fetus, worth the benefits to others that may emerge from this study?
2. What are the consequences of not doing this research with pregnant women?
3. Do citizens have a duty to participate in research that will potentially only benefit others?
   Under what circumstances, if any?
4. Considering unknown risks to the women and the fetus, how would you go about obtaining informed consent from women to participate in this research?

**Scenario shift:**
You received REB approval to test your vaccine in pregnant women but are having difficulty recruiting participants so your study has stalled. The elderly is another group with high morbidity and mortality from communicable diseases such as the flu and could also benefit from your new vaccine. You think you will have an easier time finding participants in this population because a friend of yours works as a nurse practitioner at a retirement home. She has agreed to help you recruit participants from her facility and explain the risks associated with research participation. For example, it is likely that because of their co-morbidities, the elderly may have a more severe reaction to the vaccine, and there is also greater potential for mortality related to receiving the vaccine.

**Additional discussion questions:**
5. How does this case differ from the one that includes pregnant women? Does the harm-benefit balance shift?
6. How would you go about obtaining informed consent for the elderly to participate in this research? What are the special considerations in obtaining consent from this group? Is it acceptable to recruit participants from a retirement home?

**Relevant ethics guidance documents:**
- TCPS2 Chapter 4: Articles 4.2 and 4.3 address research with women, including those who are pregnant: [http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-ep tc2/chapter4-chapitre4/#toc04-1b](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-ep tc2/chapter4-chapitre4/#toc04-1b)

**Links to the Ethics Cycle conceptual framework:**
- Through this scenario, participants can address issues under the following topics:
  - Assess barriers to use (results must be translated to groups equitably, all should have fair access) (KT),
Towards next generation research (the research conducted (or not conducted) today will inform future research efforts) (KT),

Towards continued KT (resources including knowledge must be fairly allocated) (KT),

Analyze data (recruit participants—the recruitment of participants impacts how data can be analyzed as well as applied) (KC),

Further research (how research is framed impacts future research that is built on current results) (KC),

Draw conclusions (researchers should be aware of how the conclusions of their studies impacts individuals and groups) (KC)

Discussion Guide:

1. Harms and benefits to research participants (including the ways in which the vaccine may be beneficial to fetal health) as well as harms and benefits to the broader community they represent (i.e., all pregnant women) should be discussed. Autonomy (respecting an individual’s right to choose) should also be taken into account.

2. Consequences include: not being exposed to the risks of the research; not gaining an understanding of the risks to developing fetuses; and not being able to benefit from research results (i.e., through a vaccine).

3. Consider issues of autonomy (including informed consent) versus social justice and responsibilities and duties we have as citizens. What are these duties? What would happen if everyone refused to participate in research?

4. Discuss components of the consent process such as: the meaning of free and informed consent; how to present possible risks and benefits; etc.

5. Risks of death/harms may differ. Broader justice/social implications and acceptable levels of risk to certain segments of the population may also be considered, including the potential for coercion among certain groups. For example, do potential participants really feel they can say ‘no’ to those who are providing their care? Are we taking advantage of a trusted relationship?

6. Consider the components of consent including whether it is free (e.g., not coerced) and informed (e.g., capacity issues and the use of substitute decision-makers). What makes a retirement home a “special case”? How is it different from recruiting elderly people from a mall or community center? How would you feel if this was your grandma’s nursing home?
Health Services Research

*Health services research includes research with the goal of improving the efficiency and effectiveness of health professionals and the health care system, through changes to practice and policy. Health services research is a multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviours affect access to health care, the quality and cost of health care, and, ultimately, Canadians' health and well-being.*

**Scenario #1: Research Choices**

You are a geriatric home health nurse interested in conducting research on barriers to medication and treatment plan adherence amongst the elderly. Through your practice you have noticed that some patients are very good at following their doctor’s advice and treatment plan, attending scheduled appointments and so on. However, other patients can be very frustrating; they do not take their medications, miss multiple appointments and do not follow guidelines on diet and exercise.

Your supervisor has asked you to design and implement a system to recognize patients who are ‘non-compliant’ and develop a way to ensure that they follow their treatment plan. There is a budget of $5,000 to conduct the research that will inform the design and implementation of this system. To date, you have developed a survey to be mailed to 8,000 seniors across Canada. You are excited about doing this as you should get a big ‘N’ and be able to publish the results in a good journal. However, a colleague is concerned that your survey is not being translated into other languages. She believes that cultural and linguistic issues may be at the heart of some ‘non-compliance’ behaviour. While you acknowledge that this might be possible, translating the survey into different languages would consume nearly your entire budget, and you would then have to conduct your survey with a much smaller (and less representative) sample. In addition, the translation process would take a few weeks, and you need to get the research completed quickly in order to apply for additional research funding in the next budget cycle.

**Discussion questions:**

1. What are the most important ethical issues involved in this case? How do these issues impact the research study you are conducting?
2. What do issues like sample size and who you sample have to do with ethics?
3. What is problematic about conducting research on only certain segments of the population?
4. Do researchers have an ethical obligation to make research inclusive? How would you balance this objective with the obligation of making research timely, efficient, and economically viable?
5. Does it make a difference if you do not anticipate any differences in results between different sociocultural groups?

**Scenario shift:**
You discuss your concerns about the cost and time associated with translation with your colleague. Although she has no data to back up her opinion, based on her extensive experience as a home health nurse, she believes that a large portion of those who are non-compliant are from a specific ethnic group who speak English as a second language. Your colleague is also from this ethnic group and speaks both English and X. She suggests that she could translate the survey into X quickly and at no cost so it could also be given to individuals from her ethnic group.

Additional discussion questions:
6. What are the benefits and drawbacks of having the translation done by this colleague?
7. Does translating the survey into another language make the research more ethical? Why or why not?
8. Should a researcher ever make assumptions about their research or assume a result? In what ways can this be helpful or harmful to the research endeavor? To the research subject?
9. Should the researcher consult with community members regarding the research? Why or why not? If so, who?

Relevant ethics guidance documents:
- Although this chapter is interested primarily in qualitative research, many elements also apply to other types of research. TCPS2 Chapter 10: Qualitative Research: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/

Links to the Ethics Cycle conceptual framework:
- Through this scenario, participants can address issues under the following topics:
  - Design project (choice of collaborators can impact how researchers design projects and may also impact how they access resources or human participants) (KC),
  - Analyze data (recruit participants-who is recruited into a study has a significant impact on the data collected, the methodologies used, and the results) (KC),
  - Draw conclusions (researchers should be aware of how the conclusions of their studies impacts individuals and groups) (KC),
  - Adapt knowledge to context (research should empower and give voice and agency to human participants) (KT),
  - Sustain knowledge use (researchers should seek to build capacity and consider lost opportunity costs associated with their studies) (KT),
  - Monitor knowledge use (researchers should be aware of conflicts of interest and responsibilities when monitoring knowledge use) (KT)
Links to real life case studies:
- Stahl, S.M., & Vasquez, L. (2004). Approaches to improving recruitment and retention of minority elders participating in research. *Journal of Aging and Health*, 16(5 suppl), 9S-17S.

Discussion Guide:
1. Ethical issues to be discussed include: social justice; fairness and equality in research participation; validity/utility of results; and research translation.
2. According to TCPS2, researchers do have an ethical obligation to make research fair and inclusive. For example, ethnic minorities, those who speak a different language, the elderly, children, prisoners, etc., should not be unjustifiably excluded from research participation as they may then also be excluded from enjoying the benefits of research results. However, resource constraints (including time, capacity of the research team, and money) also need to be taken into account and weighed in consideration of overall potential benefits and harms.
3. The evidence informing these expectations should be explored (e.g., existing data, observational perspectives, unjustified opinions). Potential outcomes of correct/incorrect expectations should also be considered (i.e., who will benefit from results, who will the results negatively impact).
4. Benefits include rapid turnaround and cost savings, while drawbacks include potential bias/inaccuracy in translation. Does access to quick and cheap translation justify going forward with this research?
5. Translation of the survey may make the research more ethical if it makes the research more inclusive/accessible and encourages participation from diverse groups. But, if your colleague’s assumptions turn out to be incorrect, was this a justified use of your time and the time of your participants? Consider issues like lost opportunity costs.
6. Assuming results may lead to issues such as premature conclusion-drawing, bias, etc. However, reflecting on what is already known and the expertise of the researcher (especially if it is objective) may be beneficial in that it makes the research endeavor more efficient.
7. Issues to consider in whether community consultation may be appropriate include: building community trust and support for the research (e.g., to improve recruitment rates or uptake of results); accessing local/community knowledge; methodological issues/constraints; sensitivity of research; potential impact of research findings; possibility of discrimination/stereotyping; and potential benefits and harms of not including/including the community.
Scenario #2: Reporting Research Results

You are a researcher funded through a public health research group and CIHR. Your research focuses on mental health services for adolescents, specifically in rural and remote communities. You have spent the past two years conducting a research project in collaboration with a small non-Aboriginal community in a southern region of Canada. The research was designed and conducted in a way that was consistent with community-based participatory research and as such, the community has been involved in every aspect of the research process, including identifying the research question, research methods, and analysis.

The research involved following adolescents who received two different types of intervention. The first group received face-to-face counseling on a weekly basis, a computer and internet to access an online support group and counseling program, and a stipend to attend a vocational training or educational program for one year. The second group received remote phone counseling once a week and monthly phone mentorship by a career counselor.

Your analysis of results suggests that there is no significant difference between those who received the more intensive counseling and services and those who received remote support. However, the community leaders are concerned that reporting these results will lead to budget cuts for health services in their community. They urge you not to report the results but instead request additional funds to examine the issue in more detail. They are convinced that further study will confirm that the more intensive program is actually more beneficial to adolescents over the long term.

Discussion questions:
1. What are the ethical issues at stake in this case?
2. As a researcher, what are your obligations to the community? Does the fact that this is a community-based participatory research project make a difference to your decision?
3. What are your obligations as a researcher? What role does research integrity play in this case (if at all)?
4. What are your obligations to the funders? And to Canadian society?
5. What decision would you make if you were unsure or unconvinced by the research findings?

Scenario shift
You receive a small amount of new funding to continue the study for three additional months and conduct supplementary telephone surveys regarding the effectiveness of the two interventions. At the end of the three months, you collect the survey responses and analyze the results. You are surprised to see that there now seems to be a marked difference in the effectiveness of the intervention between the two groups, with those who received the more intensive treatment appearing to do much better across all measures than those who received remote support. Given the results from the initial research, you are surprised by this finding, and are concerned that the research participants may have been ‘coached’ to provide certain answers to the surveys.
Additional discussion questions:
6. What should you do in this situation? What are your obligations as a researcher?
7. What are some of the possible consequences of doing nothing?

Relevant ethics guidance documents:

Links to the Ethics Cycle conceptual framework:
- Through this scenario, participants can address issues under the following topics:
  - Draw conclusions (how researchers draw conclusions has important impacts on individuals and groups) (KC),
  - Publish results (publishing negative results (or a null result) is important scientifically and ethically and has impacts on resource allocation, among other things) (KC),
  - Adapt knowledge to context (research should give voice and agency to as well as empower participants) (KT),
  - Toward continued KT (KT) (it is important to carefully justify the use of scarce resources used in research including funding opportunities),
  - Toward KT of results (selecting which evidence and results are disseminated has important ethical implications for participants and other researchers) (KC)

Link to relevant article:

Discussion Guide:
1. Ethical issues at stake include: respect for communities/groups; fair distribution and allocation of resources; and beneficence.
2. Obligations and responsibilities relate to issues of trust, respect, ongoing research/collaborations, etc. It is also important to weigh these obligations with obligations to your funder and obligations as a researcher to your field of study.
3. TCPS2 Guidelines for conducting research with First Nations, Inuit, and Métis Peoples of Canada (TCPS2, Chapter 9) may be considered. For example, it may be appropriate to consult the community to actively engage community members or representatives in all aspects of the research design and the translation of results including collaborating on the development of the research objectives and methodology, recruitment process, and so on.
4. Obligations to funders include: responsible, appropriate, and ethical use of funds; timely dissemination of findings and results; the commitment to produce high quality and accurate results; etc. Obligations to society and the Canadian taxpayer include responsible use of funds/resources and the timely dissemination of findings and results.

5. The implications of premature release of uncertain results versus delaying results due to genuine uncertainty should be discussed.

6. As a researcher your responsibilities include the creation of knowledge that is accurate, so concern for biased or spurious results should be addressed. If you suspect tampering or have evidence of tampering, these suspicions should be evaluated carefully and fully. However, it is important to avoid unjustified accusations that could lead to serious and negative long-term consequences for that community, erode trust, and permanently damage relationships among all involved parties.

7. The consequences of disseminating/publishing incorrect results should be discussed. Wasted or misdirected resources and other tradeoffs should also be considered. Inaction is not a morally neutral choice.

**Scenario #3: Surgical Robots**

You are a health economist collaborating with a health science research team at a Canadian university to study the uptake of their new technology. Your lab members have invented a new surgical robot with funding from CIHR. This new robot aids in prostate surgeries and leads to quicker surgeries, less blood loss, and faster recovery times for patients. It also lengthens the careers of surgeons because it is ergonomically designed. However, the robot is expensive to use because it involves additional training for the surgical team and special maintenance. At the current time it is only available to patients who wish to pay extra for this service. It will not be covered by provincial health insurance and is too expensive for most Canadians.

**Discussion questions:**

1. Is it fair to create health products using public funds that will not be available for all Canadians? Why or why not?
2. How might the benefits from this research benefit all Canadians?
3. Suppose that you were going to be interviewed by a reporter about this research. What would you tell her? How do you think citizens might react to the story she writes and should you care?
4. In what ways do CIHR investments into surgical robots impact the Canadian health care system? Other health technologies?
5. Do Canadian researchers have an ethical obligation to develop technologies or products that citizens in developing countries can afford? Or should they only be concerned with the health of Canadian citizens?

**Scenario shift**

A prominent hockey player recently underwent surgery using the robot and heralded the robotic surgery as being far superior to the usual form of surgery. As a result, there has been a huge increase in demand for prostate surgery via the robot, and several large medical centres have requested a robot for their surgical departments. Your team does not have the capacity to cope with the increased demand and you are considering starting a spin-off private company to produce the robots. However, to do this you would likely need to dedicate more than half your
time to the private company, and would also require the dedicated assistance of several research team members who were initially involved in developing the robot.

**Additional discussion questions:**

6. Is it acceptable for you to start the spin-off company and retain your position at the university? Why or why not? How might you manage any conflicts of interest (such as conflicts of commitment)?

7. Who stands to benefit from the spinoff company? Are there any trade offs?

8. What are your obligations to your university in this situation? Other researchers? Your department? Future patients? Your research team?

**Relevant ethics & legal guidance documents:**


**Links to the Ethics Cycle conceptual framework:**

- Through this scenario, participants can address issues under the following topics:
  - **Apply knowledge (intervention)** (fair allocation of resources is an important consideration when implementing interventions) (KT),
  - **Further research** (it is important for researchers to have sound ethical and scientific justifications for additional research) (KC),
  - **Toward next generation research** (experience gained through the knowledge translation process should be used to inform next generation research) (KT),
  - **Sustain knowledge use** (researchers should seek to build capacity and consider lost opportunity costs associated with their studies) (KT),
  - **Assess barriers to use** (it is important to address the accessibility of knowledge and ensure that knowledge and research outcomes are available equitably) (KT)

**Links to real life case studies:**


**Discussion Guide:**

1. Consider issues such as: fair and equitable use of resources; social justice considerations; and benefit-sharing.
2. This research may benefit Canadians in a number of ways including: moving science forward; leading to other discoveries that might help all Canadians; decreasing surgery wait times; and eventually providing surgery remotely to rural communities.

3. Consider the potential impacts of public exposure of your research and how it may make you feel. Would you feel uncomfortable in explaining/justifying any of your actions? If so, this may help you identify areas of ethical ambiguity or concern in your research that deserve further examination/thought. Researchers should care about public opinions regarding scientific research. CIHR funded research is conducted using public funds and is intended to benefit Canadian citizens.

4. CIHR investments into such technologies may impact the Canadian health care system in a number of ways such as: attracting top researchers, attracting pharmaceutical and device companies, stimulating economic growth, taking away from other areas of health research/technologies etc.

5. Reflect upon the social justice and resource allocation issues at play.

6. Discuss conflicts of interest (in terms of commitment/time and financial conflicts); how should it be approached/reported/discussed/acted upon? It is important to note that some conflicts of interest can be managed effectively and ethically if dealt with in an open, honest, and transparent manner.

7. Consider financial benefits (to you, your company, shareholders, etc.) and financial and other implications for your university (e.g., technology transfer agreements), other researchers/collaborators/students, and broader societal implications and benefits.

8. Financial, research outcome oriented, and social obligations should be discussed. Equity, benefit sharing, and legal issues should also be considered.
Social, Cultural, Environmental, and Population Health Research

Population and public health research comprises research with the goal of improving the health of the Canadian population, or of defined sub-populations, through a better understanding of the ways in which social, cultural, environmental, occupational and economic factors determine health status.

Scenario #1: Research using Social Media

You are part of a research team seeking to understand some of the social and cultural determinants that may be influencing the higher rates of suicide in teenagers who are openly identified as lesbian, gay, bisexual, or transgender (LGBT). Background research conducted by your team revealed that many LGBT youth discuss issues related to depression and suicide on online social networking sites. As part of your project, you would like to create an online social network page to attract LGBT youth. This page will invite them to raise and share their thoughts about important issues relevant to suicide and depression with other viewers. It will also provide contact information for those seeking professional help. Your team plans to review the page regularly and analyze the online conversations to determine common themes. You will also keep track of how popular the website is by counting visits and online contribution to discussions.

Discussion questions:
1. What are some of the potential outcomes for users of your website?
2. Is this type of research ethical? How can the researchers ensure that participants are fully aware of the risks and benefits of participation?
3. Would your opinions about this scenario change if it involved a different group of people (e.g., male athletes) or health topic (e.g., brain injury prevention in full contact sports) or recruited participants using other methods (e.g., telephone recruiters instead of social media)?

Scenario shift:
The initial phase of this research study has been successful and you better understand some of the causes of suicide and depression in teenagers who identify as LGBT. However, you would now like to explore the rates of depression and suicidal thoughts in teenagers from the general community and compare these to the findings from the LGBT study. You decide to develop a survey to post on your online page as well as other teen’s friendly sites. You are concerned that revealing the topic of the survey (depression and suicide) may bias your results as those who are depressed/suicidal may be more likely to answer it. Instead, you state that the survey is about a non-sensitive topic – opinions about local nightlife. The survey has some questions about nightclub events and alcohol consumption but also has lots of questions about suicide and depression.

Additional discussion questions:
4. Is it ethical to use deception in survey research? Why or why not? Would your views differ if this study involved face-to-face interviews or focus groups?
5. Would your opinions about using deception change if it involved a different group of people (e.g., male athletes) or health topic (e.g., brain injury prevention in full contact sports)?

6. What is the role of informed consent in this situation?

7. What are your ethical obligations to the teenagers who complete the survey? What about those whose survey results suggest they are very depressed and/or suicidal?

**Relevant ethics guidance documents:**

- TCPS2 Chapter 4: Article 4.7 discusses research with vulnerable groups:

**Links to the Ethics Cycle conceptual framework:**

- Through this scenario, participants can address issues such as:
  - *Design project* (methodologies that include deception raise important ethical issues that must be considered carefully before they are implemented) (KC),
  - *Monitor knowledge use* (researchers should be aware of their responsibilities associated with monitoring knowledge uptake and use) (KT),
  - *Analyze data* (collect data and recruit participants - how researchers recruit participants and collect data can impact the methodological choices available and how results can be analyzed) (KC),
  - *Draw conclusions* (researchers should be aware of how their conclusions impact individuals and groups) (KC)

**Links to relevant articles:**


**Discussion Guide:**
1. Potential positive outcomes include fostering dialogue and outreach and reducing isolation. Negative outcomes include the possibility of socially stigmatizing those who participate.

2. Research may be considered ethical if the potential benefits of research outweigh the potential harms. Harms and benefits of the research should be discussed including the potential loss of privacy, stigmatization, implications of results/findings, etc. If deemed necessary, researchers can use a variety of quantitative and qualitative methods to confirm that participants are aware of the harms and benefits of research participation including surveys, interviews, etc.

3. Consider how involving different groups changes the potential benefits/harms balance of the proposed research, including the vulnerability of the group in question. Think through the harms and benefits associated with different recruitment methods.

4. The ability to carry out the research without the use of deception should be discussed. According to TCPS2, deception may be justified if the research cannot be conducted without the use of deception, and if the benefits of the research outweigh potential harms. Deception disclosure is often required/warranted. Face-to-face interviews/focus groups may change the harms/benefit balance (e.g., while there may be some benefits to the face-to-face approach, risks to privacy and confidentiality may increase). Strict confidentiality cannot be maintained in a focus group setting because a researcher cannot control what participants say to others after they leave the room. They can request confidentiality, but cannot guarantee it. Informed consent should serve the role of respecting the autonomy of the research participant. Usually, this involves ensuring consent is fully informed (i.e., all risks are disclosed). However, consent cannot be fully informed when deception is required and only partial consent can be obtained. Disclosure of the deception after research data has been collected may be warranted and help address autonomy-related issues.

5. Consider how involving different groups changes the potential benefits/harms balance of the proposed research, including the vulnerability of the group in question.

6. Risks of the research should be considered. As a researcher conducting research according to TCPS2 guidelines, you must protect human participants, which may include providing psychological support/referral to those found to be ‘at risk.’

Scenario #2: Occupational Health

You recently joined a research team that conducts health risk assessments with seasonal workers on farms. An assessment conducted five years ago showed that a popular pesticide used by crop farmers should not significantly increase their cancer risk through either dermal or inhalation exposure to the chemical. However, follow-up research conducted this year reveals significantly higher rates of skin cancer in clusters of farm workers who use this pesticide.

You were asked to spearhead a social science research project to conduct telephone interviews with farm workers from this population to determine if they are in fact using the protective gear recommended by the producers of the pesticide (e.g., long sleeves, boots, gloves, masks). Most of those who are interviewed report that they are in fact using the protective gear and applying
the pesticide as directed. Your co-workers are satisfied that the higher rates of skin cancer in this cohort must be due to sun exposure in Canada or in their home countries and other hazards known to be associated with farming and not due to this particular pesticide. However, you would like to do follow-up research to conduct site visits to study the farmer workers’ actual behaviour in person but are unsure if you could or should justify using more funds for this research study. There have been massive cut backs in your organization and if you pursue additional funding for this research study, funds will have to be cut elsewhere. What should you do?

Discussion questions:
1. What are your responsibilities as a member of this research team?
2. Who are the stakeholders for this study?
3. What are some of the potential consequences of pursuing additional funding for this project?
4. What are some of the potential consequences of not pursuing additional funding for this project?

Scenario shift:
You decide to pursue additional funding to conduct surprise spot checks on randomly selected farm workers from your interview study. When they agreed to be interviewed, you told them that you may want to do some follow-up research with them but did not explicitly get permission from owners to visit their farms. Many of the farm owners and farm workers are annoyed by your impromptu visit but reluctantly allow you to review their pesticide protocols. During your visits, you determine that some of the farm workers have not been following all the manufacturer suggested procedures with the pesticide every time they use it. In addition, you find that many of the farm workers who have experienced higher rates of skin cancer are also using the same two or three other pesticides in addition to the one you are studying. This multiple exposure scenario may explain their higher skin cancer rates.

Additional discussion questions:
5. Was it wrong for you to conduct surprise site visits without informed consent from both the farm workers and the farm owners prior to the visit? What are some of the possible consequences of not acquiring informed consent prior to the visit?
6. What responsibilities do the farm owners have to the seasonal workers they employ? As a researcher conducting this study, do you have a duty to report exploitation of farm workers? Under what circumstances?
7. Suppose that the results of your site visits help to explain the increased skin cancer rates in these farm workers. Does this make the visits more acceptable? What if the results from the site visits do not help explain the increased cancer rates?

Relevant ethics guidance documents and selected readings:
Links to the Ethics Cycle conceptual framework:

- Through this scenario, participants can address issues under the following topics:
  - Analyze data (how researchers recruit participants and obtain informed consent significantly impacts their ability to access and then analyze data) (KC),
  - Adapt knowledge to context (research should empower participants) (KT)
  - Toward next generation research (activities conducted during the KT process can impact the ability of researchers to conduct future studies with the same participants) (KT)
  - Sustain knowledge use (KT) (it is important for researcher to build capacity through their research and consider the costs associated with lost opportunities),
  - Toward KT of results (resource allocation decisions and tradeoffs must be carefully analyzed throughout the knowledge translation process) (KC)
  - Selection of evidence (KC)

Discussion Guide:

1. Discuss responsibilities to: the funder; other research team members; your organization; research participants; current and future farm workers; and society (bear in mind societal costs such as health care for sick farm workers).
2. Stakeholders include: current and future farm workers using the pesticides and their families; farm owners; all Canadians who are potentially impacted through improper use of pesticides; pesticide manufacturers; etc.
3. Potential consequences include: confirming results (or proving otherwise); diverting funds from other research studies/projects/employees; and improving the lives of farm workers and their families.
4. Consequences of not pursuing further funding include producing incorrect or incomplete results that do not accurately capture the harms of pesticide use (including harms to current and future farm workers) as well as other social considerations impacting other stakeholders (such as Canadian Society, pesticide manufacturers, etc., as discussed above).
5. Consider whether the research could be conducted in any other way. What are the harms involved and how do they weigh against potential benefits? Consequences of not obtaining informed consent include: destroying trust; refusal of participants to take part in future research studies; and public backlash towards your organization.
6. Justice and fairness considerations such as vulnerability, coercion, autonomy, and rights should be discussed. Degree of risks associated with exploitation such as immediacy of risk, impact of exposure, knowledge of risk (by the farmers and farm workers) etc. should also be discussed.
7. Results of the research change the harm/benefit balance in considering the ethical permissibility of research. Discuss the difficulty of knowing this prior to obtaining results, and how this uncertainty may be addressed when considering whether research is permissible. Do the means justify the ends in this case?
Ethics Resources

This section includes a limited annotated bibliography of relevant ethics guidelines, policies, regulatory documents, and websites that users may find helpful. Items are presented in alphabetical order and include a brief description as well as a link to the resource where possible. Although not addressed here, researchers should also be aware of Codes of Ethics specific to their field of research or profession.

- **CIHR Best Practices for Protecting Privacy in Health Research, 2005**: These Privacy Best Practices are intended to provide guidance for the health research community in Canada on the application of fair information principles to research involving personal information, and to assist in the interpretation of the Tri-Council Policy Statement: Ethical Conduct for Research involving Humans (TCPS) by offering additional detail and practicality.

  Link: [http://www.cihr-irsc.gc.ca/e/29072.html](http://www.cihr-irsc.gc.ca/e/29072.html)

- **CIHR Open Access Policy**: This document outlines the Canadian Institutes of Health Research Policy on access to research outputs and data and aims to increase diffusion and availability of research results.

  Link: [http://cihr-irsc.gc.ca/e/32005.html](http://cihr-irsc.gc.ca/e/32005.html)

- **CIHR Updated Guidelines for Human Pluripotent Stem Cell Research**: This document, updated in 2010, outlines the CIHR guidelines for the use of pluripotent stem cells in research. It presents the guiding principles for such research, oversight for this research including the role of the Stem Cell Oversight Committee (SCOC), and specific research ethics issues that must be considered and addressed in planning and conducting research in this area.

  Link: [http://www.cihr-irsc.gc.ca/e/42071.html](http://www.cihr-irsc.gc.ca/e/42071.html)

- **Guidance for Industry: Health Canada Addendum to ICH® Guidance Document E11: Clinical Investigation of Medicinal Products in the Pediatric Population**: In recognition that the ICH guidance documents are not intended to be fully comprehensive, Health Canada developed an addendum to the ICH guidelines for research in pediatric populations. This document clarifies the Canadian regulatory considerations for clinical trials in the pediatric population, as well as providing further guidance on the ethical issues that may be encountered in such research.

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8 International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)
Health Canada/Public Health Agency of Canada REB: Researchers seeking to apply to this board for ethics review should familiarise themselves with the guidance documents available on their website. The website also provides links to important Canadian and international ethics resources.

ICH Harmonized Tripartite Guideline: Clinical Trials E7-E11: The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (known as ICH) provides guidance on the design, conduct, safety, and reporting of clinical trials. Their recommendations provide specific guidance on vulnerable populations in clinical trial research, such as the pediatric and geriatric populations.

International Compilation of Human Research Protection: This 2011 document provides a recent and comprehensive list of international human research protections. It was compiled by the U.S. Department of Health and Human Services, Office for Human Research Protections.

International Ethical Guidelines for Biomedical Research Involving Human Subjects: These 2002 guidelines were created by the Council for International Organizations of Medical Sciences (CIOMS), which is an international organization established by WHO and UNESCO. The document discusses a wide range of research ethics issues including research with vulnerable people and the harms and benefits of participating in research.

Ownership, Control, Access, and Possession (OCAP) or Self-Determination Applied to Research: A Critical Analysis of Contemporary First Nations Research and Some Options for First Nations Communities: This paper was first prepared for the First Nations Information Governance Committee (2004).

Public Health Ethics at the CDC: The Centers for Disease Control and Prevention (CDC) provides an overview of public health ethics issues and links to relevant resources on their website.
Science and Technology for Canadians. Access to Research Results: Guiding Principles: On this website the Government of Canada presents principles intended to make “research results as widely available and accessible as possible” including advancing knowledge, minimizing duplication, maximizing research benefits, and promoting accomplishments.

Three R’s Alternatives of Animal Research: The Canadian Council on Animal Care (CCAC) provides ethical guidance for research involving animal subjects including an explanation of how to employ the guiding principles of Replacement, Reduction, and Refinement.

Tri-Agency Framework: Responsible Conduct of Research: This 2011 document, created by Canada’s three federal research agencies - the Natural Sciences and Engineering Research Council of Canada (NSERC), the Canadian Institutes of Health Research (CIHR), and the Social Sciences and Humanities Research Council of Canada (SSHRC), outlines the various responsibilities of those involved in the research endeavour and ways to foster a “positive research environment.”

Tri Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2): This document is the joint research policy created by Canada’s three federal research agencies - the Natural Sciences and Engineering Research Council of Canada (NSERC), the Canadian Institutes of Health Research (CIHR), and the Social Sciences and Humanities Research Council of Canada (SSHRC). TCPS2 promotes the ethical conduct of research involving humans, and is used throughout Canada as a guide for University Research Ethics Boards and other institutions that receive funding from one of the three federal granting agencies.

Uniform Requirements for Manuscripts Submitted to Biomedical Journals: This website of the International Committee of Medical Journal Editors provides advice about various ethical issues associated with the conduct and reporting of research including conflicts of interest, and peer review.
- **U.S. Office for Human Research Protections (OHRP):** This office provides ethical guidance (including links to regulations and policies) for research with human subjects conducted in the United States.

  Link: [http://www.hhs.gov/ohrp/](http://www.hhs.gov/ohrp/)