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Ethics in Research: a science lifecycle approach

Revised 2018

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Canada

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Updated versions of this document are downloadable at http://www.cihr-irsc.gc.ca/e/48832.html

Contents

Section 1: 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 has signed a carefully-constructed informed consent form. However, the materials presented in this "*Ethics in Research: A Science Lifecycle Approach*" Workbook (the Workbook) introduce a more holistic approach to ethics. This Workbook is not focused specifically on compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* 2nd Edition (TCPS 2-2014)[1] or the *Tri-Agency Framework: Responsible Conduct of Research* (2016)[2] which of course are 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 primarily intended for a graduate and post-graduate audience, which could include individuals representing a range of different professions (e.g., physicians, nurses) and professional levels (e.g., clinician-scientists, graduate students, research fellows, clinical fellows, etc.). Although written for these audiences, this document may also be of interest to others, in particular, REB administrators and their staff, government and university employees, and students in health- and law-related disciplines.

This Workbook begins by providing an overview of the Canadian Institutes of Health Research (CIHR) four themes of health research (described below), including common ethical issues that may arise generically or individually under each theme complemented by multi-theme and multidisciplinary activities (Section 2). The subsequent section (Section 3) presents the Knowledge-To-Action Ethics (KTA-E) Cycle, which is the conceptual framework for the entire document. This cycle, supported by CIHR, captures the essence of KTA activities of health research, and combines the KTA cycle (Graham et al, 2006)[3] with an ethical lens to address the complete lifecycle of knowledge creation and translation relevant to researchers. It 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 (Hypothetical Scenarios) provides a series of scenarios (case studies). Some of these case studies are based on each of the four CIHR themes while others are multi-themed or intended for non-health researchers. All of the scenarios include a description of the situation; 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 trade-offs and complexities inherent in each case. The topics covered provide an overview of ethical issues that may occur under each theme but are neither exhaustive nor real cases.

[1] For guidance on TCPS 2 please review the CORE tutorial and webinars provided at http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/

[2] http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/

[3] http://www.cihr-irsc.gc.ca/e/40618.html retrieved in June 2017

Some of the key points that could be raised in discussions are highlighted after each scenario in Section 4. This discussion guide should be viewed as a heuristic tool that helps the user identify some 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.

The Workbook can be used in a group setting or by individuals as a self-study guide.

This is 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.

Dedicated email for feedback and suggestions for new scenarios submission: ethics.education@cihr-irsc.gc.ca

Updated versions of this document are downloadable at http://www.cihr-irsc.gc.ca/e/48832.html

Section 2: Ethical Considerations About Health Research

The Four Themes of CIHR Funded Health Research

Research funded by CIHR is organized under four themes[4]: Biomedical; Clinical; Health Services; and Social, Cultural, Environmental, and Population Health Research. This section provides a description of each theme as well as examples of common ethical issues that may arise under each theme. The examples given below are not exclusive to any particular theme, nor is the list of examples exhaustive.

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, an ethical analysis should encompass the interests and participation of society as a whole in the research endeavour.

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 participants that do not have a diagnostic or therapeutic orientation.

[4] See CIHR Grants and Awards Guide, Section 1-A5, Themes http://www.cihr-irsc.gc.ca/e/22630.html. Retrieved in November 20, 2017.

- Some common ethical considerations that users of this Workbook should be aware of under this theme relate to:
    - 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;
    - Factors influencing the reporting of research findings.

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.

- Some common ethical considerations that users of this Workbook should be aware of under this theme are:
    - The ways in which the funding source may influence the researcher, the research agenda and the interpretations of the results of the research;
    - Appropriate research design and modeling particularly when non-human participants are going to be used;
    - 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.

- Some common ethical considerations that users of this Workbook should be aware of under this theme involve:
    - Assessing complex ethical trade-offs when analyzing the economic efficiency of the health care system or other 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.

- Some common ethical considerations that users of this Workbook should be aware of under this theme involve:
    - Reflecting on the unique harms and benefits that may arise when conducting research with groups in situation of vulnerability;
    - Weighing the best interests of groups or populations against the rights of individuals when conducting public health research.

Multi-thematic and Multidisciplinary Knowledge Creation to Action Activities

While classifying CIHR-funded research under four pillars serves a number of organizational purposes – as with any classification, the method is somewhat artificial. Health research has led the way in multidisciplinary approaches but the reality is that nearly all publicly-funded scientific endeavours today are multidisciplinary. The reasons for this are because publicly-funded research is problem-driven, and the nature of science itself has changed with the move from positivist linear explanations to complex systems-based research and explanatory models. The multidisciplinary approach (with relative definitions of the term) is no longer just optional. It is de rigueur. Also, the agents creating knowledge are not always conventionally described as researchers. Students and public servants, for example, frequently conduct KTA activities that should be evaluated through an ethical lens.

Additional ethical considerations that could be common to all research include:

- The frame of the project, constituted by:
    - the research agenda and who shapes it;
    - the presumed standards of acceptable evidence prompting to action;
    - the intended consequences of the research (impact), and
    - the unintended consequences of the research (repercussions)
- Unforeseen biases;
- Real or perceived conflicts of interest;
- Appropriate design and conduct of the research activity;
- Appropriateness and integrity of the knowledge translation-related activities.

Section 3: 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.[5] 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.

[5] Graham, I., Logan, J., Harrison, M., Straus, S., Tetroe, J., Caswell, W., & Robinson, N. (2006). Lost in knowledge translation: Time for a map? *The Journal of Continuing Education in the Health Professions*. Vol. 26(1), 13–24. Retrieved fromhttps://www.ncbi.nlm.nih.gov/pubmed/16557505/in December 9, 2016.

Defining terms

The Knowledge-to-Action (KTA) process represents the process of knowledge creation and its translation into practice and policy. It is considered iterative, dynamic, and complex, concerning both knowledge creation and knowledge application, 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.

Within KTA, 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 formally defined by the Canadian Institutes of Health Research as a dynamic and iterative process that includes the synthesis, dissemination, exchange and ethically sound application of knowledge to improve health, provide more effective health services and products, and strengthen the health care system. This definition has been adapted by others, including Health Canada and the United States National Center for Dissemination of Disability Research and the World Health Organization (WHO).[6]

Ethics, as a critical field of inquiry, 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 or moral-based perspective would highlight the contrast between what is considered "good" and what is seen as "bad."

In bioethics and research ethics review processes, a 'principled approach' is most often used to invoke values that are perhaps as close to universal as is possible, such as beneficence, non-maleficence, autonomy and justice[7] in the United States or its Canadian equivalent: respect for persons, concern for welfare, and justice.[8] This principled approach is invaluable to bioethicists and those conducting research ethics review and oversight, particularly when human participants are involved.

[6] Canadian Institutes of Health Research: Knowledge Translation in Health Care: Moving from Evidence to Practice: http://www.cihr-irsc.gc.ca/e/29418.html retrieved in December 9, 2016

[7] https://www.ncbi.nlm.nih.gov/pubmed/10655857 retrieved in September 2016

[8] *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (*2014), Article 1.1 http://www.pre.ethics.gc.ca/pdf/eng/tcps2-2014/TCPS_2_FINAL_Web.pdf retrieved in September 19, 2016

The intent of this material is to help users develop an 'ethics lens' without resorting to any particular approach or requiring training in philosophy. The direct application of right/wrong or good/bad dyads in the KTA activities does not help in the identification of the ethical issues, and the principled approach leading to compliance. Another approach is therefore needed. 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 to power and context includes thinking critically about who has power and voice in a specific situation, and who is intentionally or unintentionally silenced; who benefits and who does not; what the consequences of the acts are and in what contexts they occur. Other important ethical aspects are those related to consensual participation in research; responsible use of nature; human and financial resources; respect for human and non-human participants; respect for society; social responsibility of research and researchers; and the importance of creating knowledge as a fundamental aspect of human nature.

This pragmatic approach to ethics asks users of this Workbook 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.

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 the next generation of research and continued knowledge translation.

When taken 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.

Figure 1. The Complete KTA-E Cycle

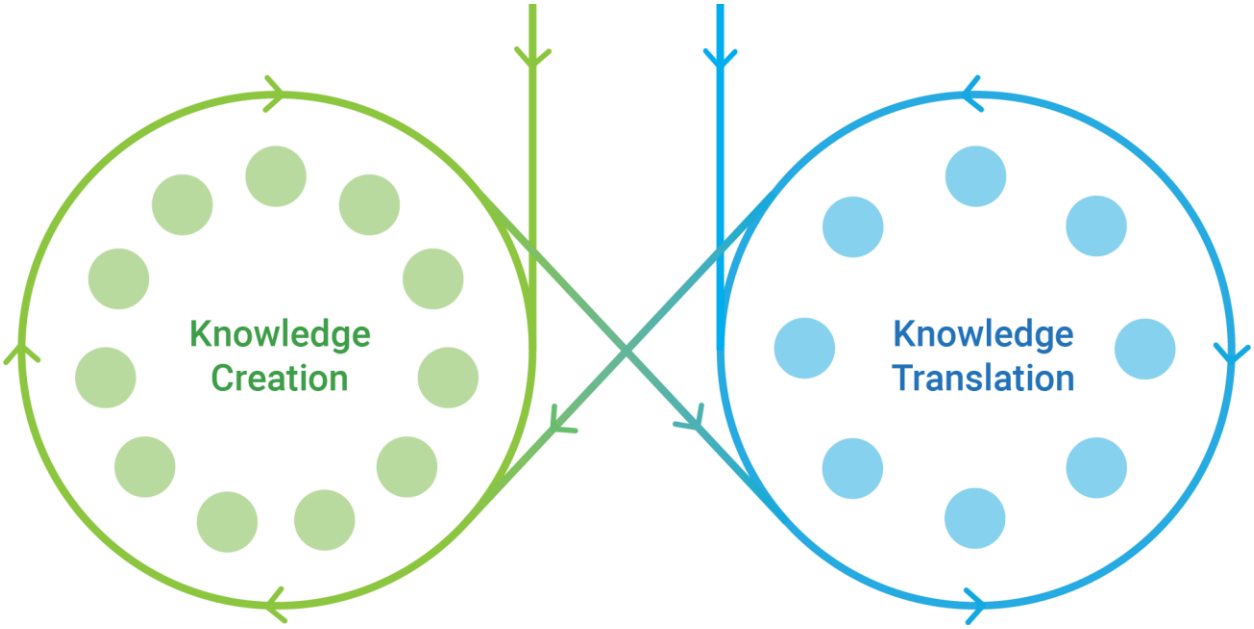

Table 1: Ethics Lens on entering the Knowledge to Action Cycle		
Activity	Ethics Lens	
	Identify the Knowledge Creation opportunity or problem	Problem Identification e.g. • How do we know what we know? • What are the socio-political and economical contexts of knowledge? • What are the concerns? • How did the process of agenda-setting evolve? • What powers and voices are represented? • Is the social responsibility of research considered?

Figure 2. The Knowledge Creation portion of the KTA-E Cycle

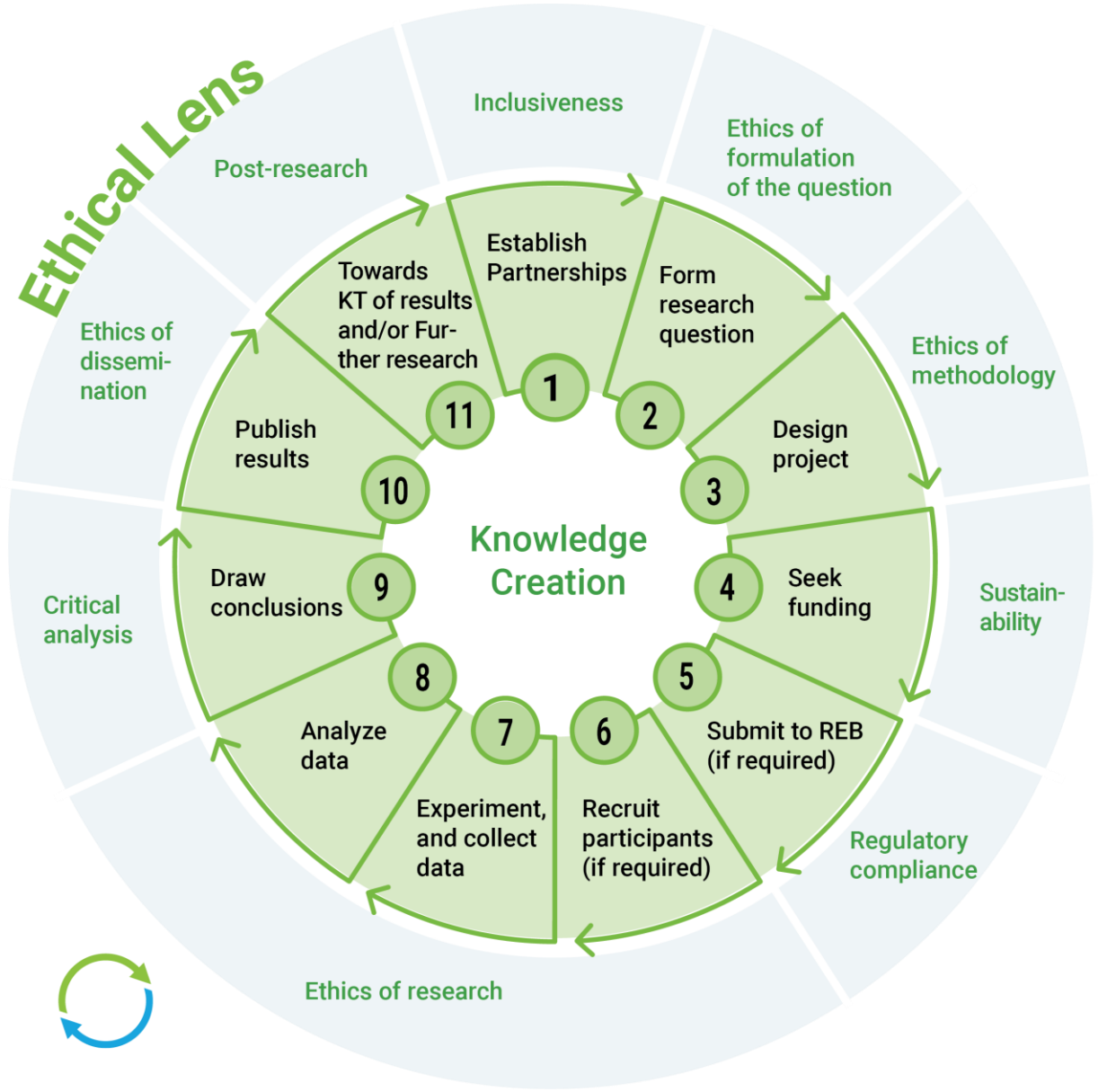

Table 2: Ethics lens in Knowledge Creation activities illustrated above		
	Knowledge Creation activities	Ethics Lens
1	Establish Partnerships	Inclusiveness e.g. • Choice of agents • Concern for equity • Right to opinion • Agency issues • Influence and coercion • Who is present and who is absent
2	Form research question	Ethics of formulation of the question

Table 2: Ethics lens in Knowledge Creation activities illustrated above		
	Knowledge Creation activities	Ethics Lens
		e.g. • Stakeholder involvement • Influence of context • Theoretical framework • Articulation
3	Design project	Ethics of methodology e.g. • Resources and/or capacity available • Research framework • Methodological and scientific validity • Adequacy of the research model
4	Seek funding	Sustainability e.g. • Choice of funders and/or partners • Obligations to funders • Social obligations towards partners
5	Submit to REB (if required)	Regulatory compliance e.g. • Protection of human and non-human participants (risks and benefits) • Adequacy of the informed consent process • Privacy issues • Data stewardship
6	Recruit participants (if required)	Ethics of research e.g. • Fair selection of participants • Adequate sex and gender representation • Bio-safety and bio-security safeguards • Research integrity issues • Ethical issues related to data analysis • Reproducibility • Post-research debrief of participants
7	Experiment, and collect data	
8	Analyze data	
9	Draw conclusions	Critical analysis e.g. • Personal biases • Implications for individuals, groups and populations • Issues related to conflict of interest • The "inferential gap" between what is observed and the conclusions drawn for action: o How to judge the sufficiency of evidence to prompt action? o Who judges? By what

Table 2: Ethics lens in Knowledge Creation activities illustrated above		
	Knowledge Creation activities	Ethics Lens
		standards? o How to protect from bias?
10	Publish results	Ethics of dissemination e.g. • Issues related to authorship • Choice of publication venue (provisional and final; formal and informal) • Publication bias • Publication of negative results
11	Towards KT (knowledge translation) of results and/or Further research	Post-research e.g. • Implications and consequences of knowledge • Potential utilization

Figure 3. The Knowledge Translation Portion of the KTA- E Cycle

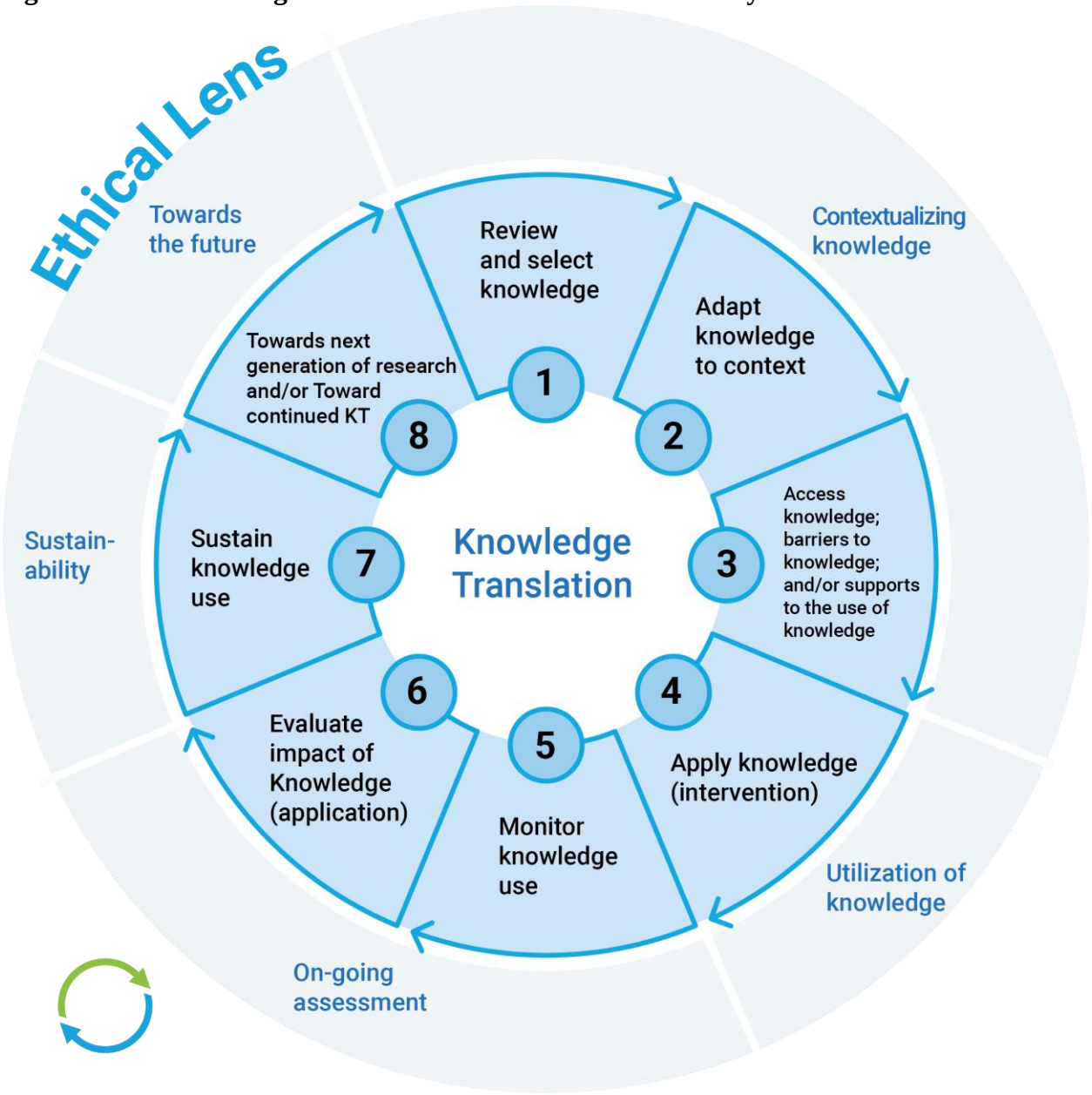

Table 3: Ethics lens in Knowledge to Action activities illustrated above		
	Knowledge to Action activities	Ethics Lens
1	Review and select knowledge	Contextualizing knowledge e.g. • Selection bias • Access to publications • Intellectual property • Interpretation of results • Concern for equity • Honouring local knowledge
2	Adapt knowledge to context	
3	Access knowledge; barriers to knowledge; and/or supports to the use of knowledge	

Table 3: Ethics lens in Knowledge to Action activities illustrated above		
	Knowledge to Action activities	Ethics Lens
		• Agency issues
4	Apply knowledge (intervention)	Utilization of knowledge e.g. • Resource allocation • Issues of equity
5	Monitor knowledge use	On-going assessment e.g. • Criteria setting • Roles and responsibilities • Reflection on knowledge: social, cultural, economic, economic implications of knowledge use
6	Evaluate impact of Knowledge (application)	
7	Sustain knowledge use	Sustainability e.g. • Sustainability concerns • Capacity building • Robustness of knowledge and of the system of knowledge creation • Opportunity costs
8a and 8b	Towards next generation of research and/or Toward continued KT (knowledge translation)	Towards the future e.g. • Selection of evidence • Responsible stewardship of funds • Responsible conduct of research

Section 4: Hypothetical 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. In addition to the themes, multi-thematic and multidisciplinary KTA activities as explained in greater detail in Section 2 are explored. There are five modules to represent these themes.

The hypothetical scenarios and associated discussion questions are intended to foster dialogue and debate amongst users. They are designed to expose the difficult ethical trade-offs 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 the lifecycle of scientific research and consider how these issues may influence other phases in the conceptual framework.

NOTE: Section 4, containing the scenarios will be published in April 2018.

Section 5: Ethics Resources

This section includes a limited 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[9]. Although not addressed here, researchers should also be aware of Codes of Ethics specific to their field of research or profession.

- **Guidance for Industry: Health Canada Addendum to International Conference on Harmonisation 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.

  Link: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/clini/e11_addendum-eng.php

- **Health Canada/Public Health Agency of Canada Research Ethics Board (REB):**
  This REB reviews all research involving human participants that is:
  - Carried out by Health Canada or the Agency (intra-mural);
  - Performed by Health Canada or the Agency in collaboration with external researchers;
  - Carried out on Health Canada or the Agency premises;
  - Conducted under contract to Health Canada or the Agency; and/or
  - Funded by Health Canada or the Agency through grants and contributions to external researchers.

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.

Link: http://www.hc-sc.gc.ca/sr-sr/advice-avis/reb-cer/index-eng.php

- **International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (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.

  Link: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html

- **International Compilation of Human Research Standards:** This 2017 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. The document is updated frequently;— the link below corresponds to the 2017 edition.

[9] Hyperlinks were last retrieved in 19 September 2017.

Link: https://www.hhs.gov/ohrp/sites/default/files/international-compilation-of-human-research-standards-2017.pdf

- **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.

  Link: http://www.recerca.uab.es/ceeah/docs/CIOMS.pdf

- **Laboratory Biosafety and Biosecurity: Principles of Laboratory Biosafety e-Learning Course**: This modular course has been developed by the Public Health Agency of Canada and the Canadian Food Inspection Agency to help strengthen biosafety and biosecurity principles.

  Link: https://training-formation.phac-aspc.gc.ca/course/index.php?categoryid=2&lang=en

- **Nuremberg Code:** This code provides directives for human experimentation.

  Link: https://archive.hhs.gov/ohrp/references/nurcode.htm

- **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).

  Link: http://www.naho.ca/journal/2004/01/09/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/

- **Public Health Agency of Canada (PHAC): Core Competencies for Public Health in Canada:** Core competencies are the essential knowledge, skills and attitudes necessary for the practice of public health. They transcend the boundaries of specific disciplines and are independent of program and topic. They provide the building blocks for effective public health practice, and the use of an overall public health approach. Generic core competencies provide a baseline for what is required to fulfill public health system core functions. These include population health assessment, surveillance, disease and injury prevention, health promotion and health protection.

  Link: http://www.phac-aspc.gc.ca/php-psp/ccph-cesp/pdfs/cc-manual-eng090407.pdf

- **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.

  Link: http://www.science.gc.ca/eic/site/063.nsf/eng/h_9990CB6B.html

- **The Belmont Report:** The Belmont Report is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.

  Link: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

- **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.

  Link: http://3rs.ccac.ca/en/about

- **Tri-Agency Statement of Principles on Digital Data Management:** In 2016, the Tri-Agencies adopted a Statement of Principles on Digital Data Management as an important step towards strengthening research data management in Canada. The Statement outlines the agencies' overarching expectations for research data management and the roles of researchers, research institutions, research communities, and research funders in supporting data management.

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

- **Tri-Agency Framework: Responsible Conduct of Research:** This 2016 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."

  Link: http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/

- **Tri-Agency Open Access Policy on Publications:** This document outlines the 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

- **Tri Council Policy Statement: Ethical Conduct for Research Involving Humans 2nd Edition (TCPS 2):** 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). TCPS 2 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.

  Link: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/introduction/

- **Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (ICMJE Recommendations).:** This website of the International Committee of Medical Journal Editors (ICMJE) provides advice about various ethical issues associated with the conduct and reporting of research including conflicts of interest, and peer review.

Link: http://www.icmje.org/about-icmje/faqs/icmje-recommendations/

- **World Medical Association Declaration Of Helsinki – Ethical Principles For Medical Research Involving Human Subjects**: The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

  Link: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.