



CHAPTER 2

Research Ethics and Canadian Nursing: An Evolving Landscape¹

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“Research is a step into the unknown. Because it seeks to understand something not yet revealed, research often entails risks to participants and others. These risks can be trivial or profound, physical or psychological, individual or social. History offers unfortunate examples where research participants have been needlessly, and at times profoundly, harmed by research, sometimes even dying as a result. Ethical principles and guidelines play an important role in advancing the pursuit of knowledge while protecting and respecting research participants in order to try to prevent such occurrences.” (Canadian Institutes of Health Research et al., 2022, p. 5)

IT MAY BE SURPRISING TO SOME that the central ethical principles accepted in health care practice and health care research were developed in response to reports of “research” ethics abuses. As these research abuses came to light, physicians and philosophers in the United States issued the *Belmont Report* in 1978, which was then published in the Federal Register in 1979. The report identified three basic principles for research with people: respect for persons,

beneficence, and justice. These principles were enhanced, used in codes of ethics and other documents, and practiced in evaluating procedures in clinical settings and research environments. They continue to be key to ethical research today.

In this chapter, we will first discuss some of the major research ethics abuses in Europe, the United States and Canada. We pay special attention to those abuses that involved compliant nurses and also played a prominent role in subsequent measures adopted to eliminate or reduce harms in the name of research. We then turn to the development of codes of ethics and processes (in particular Research Ethics Boards, called REBS). We focus on Canadian provisions for guidance, including the development of the Tri-Agency funding body, the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2) guidelines for research, and an explanation of how REBS function. Throughout, the place of nurses in these developments will be examined.

In the latter part of this chapter we use Ethics in Practice case studies to explore the four main roles that advanced practice nurses have related to research ethics: in practice; as managers and leaders; as researchers and research coordinators; and as REB members. We close the chapter by offering areas for research ethics on the moral horizon and reminding nurses why vigilance and leadership must be ongoing when it comes to research ethics.

The Mid-Twentieth Century: A Dubious Era in Medical Research

We begin with a discussion of historical studies that sounded the alarm regarding scientists and health care practitioners who failed to honour the intrinsic value of human beings and respect for human dignity (Canadian Institutes of Health Research et al., 2022). Ours is not an exhaustive review of known atrocities, and certainly others remain untold.

Serious Research Abuses During World War II and in the United States

When the world became aware of the serious human rights abuses inflicted during World War II—including human experimentation—people were shaken. Two of the principal partners in the Axis alliance, Nazi Germany and Imperial Japan, conducted involuntary, inhumane experiments on prisoners of war and so-called “undesirables” and “enemies of the state” for reasons that included determining potential outcomes for their military (Emanuel et al., 2008; Harvard Law School Library, 2020; Tsuchiya, 2008; Weindling, 2008). For example, in one German experiment, researchers sought to determine how long a war pilot might live when shot down over the English Channel, based upon how long prisoners could survive in icy cold water. These trials eventually became known as the infamous “cold experiments in Dachau.” Dr. Josef Mengele and Dr. Sigmund Rascher were the German physicians viewed as responsible for this horrific research (Seideman, 1988). Investigators in similar projects studied the effect of exposing prisoners to exotic diseases and phosgene gas, a biological warfare agent, to determine how humans might respond, and then to develop remedies to protect future soldiers (Luna & Macklin, 2009). Scholars like Copeland (2021) and Shields and Benedict (2014)—and victims like Eva Mozes Kor (Mozes Kor & Wright, 1995), one of “Dr. Mengele’s Twins”—describe the roles that nurses and midwives willingly (and unwillingly) played in the Nazi medical experiments.

Despite the powerful condemnation of Nazi medicine and medical research at the Nuremberg trials (1946–47), experimentation on humans persisted and even increased after World War II in Western industrialized nations (Beecher, 1966; Mosby, 2013). Researchers typically enrolled healthy people from populations made vulnerable by their circumstances. Such circumstances included people from government institutions such as prisons, military camps, and homes for people with disabilities. In addition, investigators used medical students and family members (Lederer, 1995). Other experiments in the United States that caught the attention of the world include

1. the initial launch and subsequent continuation of the Tuskegee Syphilis Study (1932–1972),
2. the Willowbrook State School hepatitis studies (1950–1970),
3. the Salk polio vaccine testing at Polk State School and Watson’s Crippled Children’s Home (1950s), and
4. the harvesting and use of Henrietta Lacks’s unique “HeLa” cells (1951 to present).

Nurses had a role in all of these experiments. These nurses may have been somewhat aware that research activities were being conducted without the subjects’ full knowledge. For example, in 1932, the United States Public Health Service launched a study designed to determine the natural history of untreated syphilis in Black populations. Initially titled the “Tuskegee Study of Untreated Syphilis in the Negro Male,” what is now commonly referred to as the Tuskegee Syphilis Study began when there was no known treatment for syphilis. Researchers and support staff recruited 600 Black men from a poor community in Alabama (Dunn & Chadwick, 2004; Jones, 2008). The study was technically well designed, with a treatment group of men who had syphilis and a control group of men who did not have the disease. A local Black nurse named Eunice Rivers, who had trained at the Tuskegee Institute’s School of Nursing, was hired to be the on-site representative (Dunn & Chadwick, 2004). The start of study predated the discovery of penicillin; thus, since at the time there was no known treatment for syphilis, the men were all given only check-ups and aspirin by physicians and public health nurses. But when penicillin was discovered as a cure for syphilis in 1942, most subjects were actively denied penicillin, and the devastating effects of untreated syphilis continued to be observed. The study was only stopped in 1972 after an article in the *New York Times* (Heller, 1972) prompted widespread public outrage.

Nurses also took part in the Willowbrook State School experiment, conducted in New York between 1950 and 1970, which studied the effects of the hepatitis virus on children with developmental disabilities. After 1964, researchers deliberately infected children with hepatitis as a requirement of admission to the institution (Robinson & Unruh, 2008). Similarly, in the 1950s, Jonas Salk used children from the Polk State School and the Watson

Home for Crippled Children (in addition to himself and his family) as research subjects to study the effects of his polio vaccine (Juskewitch et al., 2010; Meldrum, 2008). Nurses participated in these studies too, or at least would have been involved in caring for the children and witnessing the effects of the trials.

Finally, we briefly outline the case of a Black woman named Henrietta Lacks, who became unwittingly famous for her rare and immortal “HeLa” cell line. In 1951, at 31 years of age, Lacks was diagnosed with aggressive cervical cancer which required regular gynecological check-ups (Skloot, 2010). Unbeknownst to Lacks, the visits were not just for her clinical care; they were also for research. The nurses involved in Lacks’s visits would have known that the “check-ups” she was required to attend were, in fact, to regularly obtain cells from her cervix, named after her as “HeLa” cells. Consent for the research purposes was not obtained, as was the norm at the time. “HeLa” cells have become a billion-dollar industry and are still widely used to study the effects of toxins, drugs, hormones, viruses, and gene mapping. Yet for many years, Lacks remained virtually unknown, and her family was impoverished; they could not afford health insurance (Skloot, 2010). In 2021, the estate of Henrietta Lacks sued a biotechnology company, accusing the company of continuing to profit from cells that physicians at Johns Hopkins Hospital took in 1951 without Lacks’s knowledge or consent (Associated Press, 2021).

Selected Serious Research Abuses in Canada

Canada’s history also includes ethically dubious medical research during the mid-twentieth century. Particularly egregious instances include

- nutritional studies in Indigenous communities and residential schools (1942–1952),
- lysergic acid diethylamide (LSD) studies at Allan Memorial Institute and Kingston Prison for Women (1950s),
- anaesthetic testing on a university student at the University of Saskatchewan (1961), and
- genetic testing on blood samples from members of the Nuu-chah-nulth First Nation (1982–2008).

Between 1942 and 1952, some of Canada's leading nutrition experts conducted nutritional studies in Indigenous communities and in the residential school system. In 2013, historian Ian Mosby exposed that one of the most ambitious studies, performed by Canada's Department of Indian Affairs, was conducted as the "James Bay Survey of the Attawapiskat and Rupert's House Cree First Nations." In these studies, researchers denied control and treatment groups of already malnourished children adequate nutrition. Nurses were instrumental in implementing the study procedures. To control as many factors as possible, these procedures continued, even though they were known to harm the children. For example, even previously available dental care was denied in some settings because the researchers wanted to observe the state of dental caries and gingivitis with malnutrition. Parents were not informed, nor were consents obtained. Even after children died, the experiments continued. MacDonald et al. (2014) titled their paper on the topic "Canada's shameful history of nutrition research." An interviewer from the Canadian Broadcasting Corporation's (CBC) *Unreserved* program spoke to Ian Mosby in April 2021 in the episode "The dark history of Canada's Food Guide: How experiments on Indigenous children shaped nutrition policy" (Tennant, 2021).

During the 1950s to the 1960s, experiments investigating the psychedelic drug LSD as a potential cure for mental illness were conducted in various locations across Canada. The most famous of these, Project MKULTRA, was led by Dr. Ewen Cameron, a prominent psychiatrist affiliated with the Allan Memorial Institute in Montreal, who had been called upon to assess the fitness of Nazi war criminals to stand trial at Nuremberg (Collins, 1997; Lemov, 2011). Cameron began to employ harmful techniques on his patients without their realization that they were being experimented on. The procedures included shock therapy, supplemented by large doses of LSD, and putting patients into insulin or drug-induced comas for weeks, during which they were subjected to taped messages for 16 hours per day. Cameron's patients suffered significant, ongoing harm as a result of these procedures. Some of these former patients successfully sued the United States Central Intelligence Agency, while other patients sued the Canadian government; both were funders of Cameron's projects. The CBC program

The Fifth Estate followed this story for many years (Cashore & Smart, 2017).

At the Kingston Prison for Women in the early 1960s, 23 inmates were involuntary research subjects in a study of the psychotherapeutic use of LSD. This practice was reported to Correctional Services Canada in 1965; the report, however, led to further investigations on the use of LSD and shock therapy (Gilmore et al., 1998).

In 1961, Walter Halushka, a 21-year-old student at the University of Saskatchewan, agreed to be a subject to test a new anaesthetic called Fluoromar at the University Hospital. Halushka was told that the test would last a couple of hours and that it was “perfectly safe.” In fact, the researchers had never administered the anesthetic before. Halushka and one witness signed a form titled “Consent for Tests on Volunteers” (Veatch, 1977). Normally, operating room nurses would review the consent form with a patient; there was no specific mention of such a process in the court testimony. The form Halushka signed was inadequate, given that the standard in 1961 required that research subjects understand the procedure and its risks. Unfortunately, none of the nurses questioned the two doctors or requested more information about the procedure (at the time, nurses questioning doctors was not the practice). Halushka appeared for the test, the anaesthetic was administered, and shortly thereafter he suffered a cardiac arrest. He was resuscitated, but remained unconscious for four days. Halushka was discharged from the hospital after 10 days, having been paid \$50 for the test. The procedure inflicted brain damage that prevented him from continuing his university studies.

In the landmark case of *Halushka v. University of Saskatchewan* (1965), Walter Halushka sued the hospital and the two physicians and was awarded \$22,500. Justice Hall ruled that

the consent given by a patient to a physician or surgeon, to be effective, must be an ‘informed’ consent freely given.... The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent.
(Veatch, 1977, pp. 291–293)

The examples of research ethics abuse described thus far are commonly cited as having established the standard for consent to research today.

Another well-known breach of research ethics in Canada occurred from 1982–1995. During those years, Nuu-chah-nulth First Nation provided a UBC researcher with blood samples for genetic testing to study the high incidence of rheumatic disease, an area of concern in their community. The study team included physicians and medical students as well as nurses. Years later, the community learned that the researcher had relocated to universities in two different countries and had taken the specimens with him. In fact, the researcher had gone on to conduct diverse research that was not part of the original consent, including biological anthropology research that the Indigenous community perceived as particularly harmful. In response, the Nuu-chah-nulth Tribal Council Research Ethics Committee (2008) developed research protocols that were responsive to the context of their unique communities. The remaining blood samples were eventually returned to British Columbia in 2004, and destroyed in 2008 (Arbour & Cook, 2006; Ha-Shilth-Sa, 2013; Wiwchar, 2004).

ETHICS IN REFLECTION 2-1

Acknowledging Past Wrongs

In most of the experiments described above, nurses would have been involved in the care of the patients. Nurses either accepted or ignored serious ethical dilemmas. We wonder why (particularly when children and adults who were already marginalized and in vulnerable circumstances were involved) nurses did not intervene or even report the wrongful practices underway. For example, I (Janet) lived in Montreal during part of the period that the LSD experiments were being conducted. A nurse colleague who worked at Allan Memorial witnessed and told me about Cameron's irregular practices, which seemed, to her, to be harmful. My colleague felt helpless and unable to even report the wrongs.

Looking back to this period, we must remember that the voices of nurses were rarely welcomed and nurses could be disciplined for daring to speak up or to even question a practice. We acknowledge that social, political, economic, and professional pressures have always existed and will continue to exist; these factors impact how nurses provide care (Copeland, 2021) and emphasize the importance of nursing leader-

ship. Although the authors of this chapter are confident that nurses today would see it as their role and moral duty to raise questions about their concerns involving research or practice, speaking up can still be challenging and can result in being isolated or harassed in the workplace.

Responses to Research Ethics Abuses

In response to ongoing revelations about ethics abuses in the name of research, in this section we review the key ways in which the Euro-Western world responded with codes of ethics, REBS, and ethics organizations. These structures were designed to meet three ethical objectives: promoting socially beneficial research, respecting the dignity and rights of research participants, and maintaining trust between the research community and society as a whole (McDonald, 2000).

Codes of Ethics

Before the 1950s, researchers engaged in human experimentation relied on informal guidelines or professional codes of ethics (Halpern, 2004). These ethical guidelines and codes were rooted in a worldview that reflected (and continues to reflect) the dominant traditions of Euro-Western moral philosophy, cultural and methodological perspectives, and political and social theory (Hayward et al., 2021, p. 403). Early work on such codes included the *Berlin Code*, prepared in 1900. The initial response by medical observers to World War II research abuses, particularly the Nazi Medical Experiments, was to establish some rules for research through the use of codes of ethics. The Nuremberg “Doctors’ Trial” in 1946–1947, the subsequent *Nuremberg Code* (1949), and the World Medical Association’s *Declaration of Helsinki* (1964) laid the fundamentals of biomedical ethics with regulations and requirements for ethical procedures. Thus, ethical standards of informed consent have been in place since World War II. Medical practitioners and researchers have used these codes as important guides for practice and research, yet as noted, at times they have been ignored.

The most influential of these documents was the *Belmont Report* (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979). The *Belmont Report*, seen as the cornerstone of modern health care ethics (including research), outlines a set of core ethical principles: respect for persons, beneficence, and justice. The principles were promoted in the release of the 1979 text titled *Principles of Biomedical Ethics*, by Tom L. Beauchamp and James F. Childress (2019). The wide use of these three to four principles (the Beauchamp and Childress text includes a fourth principle, nonmaleficence) advanced the moral theory that has become known as *principlism*.

Research Ethics Boards

Starting in the 1960s, government agencies in industrialized nations took on a greater role in funding medical research. A review process was set up as the main mechanism to provide ethical oversight of research involving humans in accordance with established standards and requirements. Referred to in Canada as Research Ethics Boards (REBs) (and elsewhere as Institutional Review Boards [IRBs], Research Ethics Committees [RECs], etc.), the main responsibility of REBs is to protect the rights and welfare of human research participants by ensuring that studies are conducted in a safe, ethical, and socially responsible way.

Typically, REBs are established by institutions such as universities, hospitals, and other health care facilities to review and approve applications related to research involving human participants. REBs have the power to propose changes, to refuse, and to stop experiments that fall short of ethical requirements. A secondary role for institutional REBs is to protect the interests of the institution and researchers (Stark, 2011). Independent REBs provide ethical review for researchers conducting research projects outside the auspices of an institution. The REB structure is a crucial mechanism to ensure research participant safety and successful research that benefits patients and their families, health care providers, and communities.

Ethics Organizations

Developments in research ethics during the 1960s and 1970s also prompted the founding of a number of ethics centres, including The Hastings Center near New York in 1969, The Kennedy Institute of Ethics at Georgetown University in Washington DC in 1971, and other centres in the US. In Canada, ethics centres and groupings formed in Montreal, Toronto, Halifax, Winnipeg, Edmonton, and Vancouver.

Research Ethics Structures and Guidance in Canada

In this section, we summarize Canada's unique system of research ethics. This includes the Tri-Agency research funding infrastructure: Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC). In addition, we review the Interagency Advisory Panel on Research Ethics; the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS 2), Canada's standard for ethical research; and the structure of REBS.

The Tri-Agency Funding Infrastructure

An ideal system of research ethics takes a holistic “lifecycle approach” that acknowledges the range of ethical issues that exist, or may develop, throughout the complete cycle of scientific knowledge—from creation to translation (Anderson et al., 2011). Over time, the Government of Canada streamlined the research funding process by creating three federal granting councils: CIHR, NSERC, and SSHRC. Collectively, these councils are referred to as the Tri-Agency. They are the major sources of research funding for Canadian post-secondary institutions:

- CIHR funds research primarily intended to improve or have an impact on health, produce more effective health services and products, and strengthen the Canadian health care system (founded in 2000);

- NSERC funds research primarily intended to advance knowledge in the natural sciences and engineering (founded in 1978); and
- SSHRC funds research intended to add to our understanding and knowledge of individuals, groups and societies (founded in 1977).

Nurses mainly apply for funding through CIHR or SSHRC.

To address the need for common research endeavors, in 2001 the Government of Canada also created the Interagency Advisory *Panel on Research Ethics* (PRE or the Panel) (Panel on Research Ethics, 2023a). This Panel was specifically developed to manage the ethics policy of the funding agencies and to steward the evolution and interpretation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), the joint research ethics policy statement of CIHR, NSERC, and SSHRC, first published in 1988. Institutions eligible to administer and receive Tri-Agency research funding must agree to adhere to the TCPS as a condition of funding.

Canada's Standard for Ethical Research: Tri-Council Policy Statement (TCPS 2)

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, commonly known as TCPS 2 (Canadian Institutes of Health Research et al., 2022), is the prevailing Canadian standard for ethical research involving humans. Respect for human dignity, the underlying value of the TCPS 2, is expressed through the following three core principles:

- *respect for persons*: recognizing “the intrinsic value of human beings and the respect and consideration that they are due. It incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired, or diminished autonomy” (Canadian Institutes of Health Research et al., 2022, p. 277).
- *concern for welfare*: requiring “researchers and REBS should aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any

foreseeable risks associated with the research” (Canadian Institutes of Health Research et al., 2022, p. 8).

- *justice*: referring “to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it” (Canadian Institutes of Health Research et al., 2022, p. 272).

Institutions and REBS across Canada have adopted the TCPS 2 even if they do not receive Tri-Agency funding. Those who devised the original TCPS in 1988, as well as ongoing additions to it (2010, 2014, 2018, 2022), fully recognize that the TCPS 2 works in conjunction with other sources of guidance for research ethics, including professional bodies such as the Canadian Nurses Association (CNA) and the Canadian Medical Association. For example, the CNA developed specific research ethics guidelines for nurse researchers in French and English (1994, 2002), where they emphasized the need for extra care and attention when health care professionals are involved with human research. Now, all these different professional organizations’ guidelines have become part of the Tri-Council governance. In addition, the CNA *Code of Ethics for Registered Nurses* (2017), articulates the following research-related responsibilities as a part of providing safe, compassionate, competent, and ethical care:

10. Nurses support, use and engage in research and other activities that promote safe, competent, compassionate and ethical care, and they use guidelines for ethical research that are in keeping with nursing values.
11. Nurses who are involved in research respect the well-being of persons receiving care above all other objectives, including the search for knowledge. They pay attention to the safety of persons receiving care and to *informed consent*, the risk-benefit balance, the privacy and

confidentiality of data and the monitoring of research. (p. 9, emphasis in original)

Relevant Ethical Guidelines, Policies and Legislation

In Canada, research is governed primarily by ethical guidelines which do not have the force of law; this is unlike the legislative approach taken by some other countries, such as the United States and France. Researchers should apply the guidelines of the TCPS 2 in conjunction with relevant and applicable ethical guidelines, policies, legislation, and regulation. For example, research participants' rights to privacy are legally protected by federal law (see *Personal Information Protection and Electronic Documents Act*, 2000) and provincial/territorial laws (see for example BC's *Personal Information Protection Act*, 2003). Thus, researchers have the obligation to safeguard any information collected in the context of their study, to know what legislation is applicable, and to comply with it. Legal requirements related to consent and the decision-making capacity of participants are established at the provincial/territorial level, such as BC's *Health Care (Consent) and Care Facility (Admission) Act* (1996). Another example applies to clinical trials research regulated under Health Canada's *Food and Drugs Act* (1985). In addition, depending on the type of research and the source of funding, Canadian researchers can be subject to international ethical guidance such as the *International Conference on Harmonisation Good Clinical Practice Guidelines* (ICH-GCP) (n.d.) and foreign oversight bodies such as the United States Food and Drug Administration.

TCPS 2: A Living Document

Another important feature of TCPS 2 is that the policy is positioned as a "living document" and continues to be revised as new challenges are placed before REBS, researchers, and our society. Processes are in place to engage with Canada's research community, to communicate interpretations of the TCPS 2, and to develop new guidance. For example, a very significant addition to the TCPS was realized in 2010 with a new chapter, "Research Involving the First Nations, Inuit and Métis Peoples of Canada" (Canadian Institutes of Health Research et al., 2022, pp. 146–182). This new Chapter 9

reflected a growing awareness about the need to conduct and review research involving Indigenous people more respectfully, and with understanding of a community's unique cultural traditions, customs, codes of practice, and worldview. Shawn Wilson (2008) describes research done “in a good way” as a sacred endeavour, grounded in respect and traditional wisdom, which leads to the support of community and creation of healing. The inclusion of Chapter 9 moves toward a “two-eyed seeing approach” (Bartlett et al., 2012; Bull, 2016) that incorporates both broad Indigenous principles (such as relational accountability, communality of knowledge, reciprocity, and benefit sharing [Kara, 2018; Wilson, 2008]) and core Western ethical principles (respect for persons, concern for welfare, and justice). In addition, TCPS 2's Chapter 9 is intended to work with Indigenous-led ethical processes and protocols such as the First Nations Principles of OCAP (ownership, control, access, and possession) (First Nations Information Governance Centre, n.d.). Researchers can use the OCAP framework for guidance on how First Nations data should be collected, protected, used, or shared in a way that is beneficial and respectful to Indigenous communities. The release of the Truth and Reconciliation Commission of Canada's final report (2015) reinforces the ongoing need for nurses to understand this new era of Indigenous research ethics.

Also in 2010, the term “participant” replaced “subject” in the TCPS to reflect an ideological departure from framing people as objects of study. In TCPS 2 (2022), participants in research are defined as “those individuals whose data, biological materials, or responses to interventions, stimuli, or questions by the researcher, are relevant to answering the research question(s)” (Article 2.1, p. 14). In 2018, new guidance included how to assess, manage, and review risks to communities, including situations where non-participants might be inadvertently exposed to a research intervention. TCPS 2 updates in 2022 include guidance on broad consent for the storage of data and human biological materials for future unspecified research, streamlining multi-jurisdictional research ethics review of minimal risk research, and research involving totipotent stem cells and human cell lines. The ongoing input of nurse researchers to the TCPS guidelines is essential in response to

societal, policy, and legislative changes, and related ethical challenges, and as new approaches of nursing inquiry are developed.

Research Ethics Education

The Panel organizes education in research ethics for the research community, such as the online tutorial *TCPS 2: CORE-2022 (Course on Research Ethics)* (Panel on Research Ethics, 2023b). The *CORE-2022* applies to all research involving human participants, regardless of discipline or methodology, with a focus on the Canadian context. Prior to research ethics approval, most REBS require that researchers who engage in research with human participants (and their personal information) complete this tutorial. Upon successful completion, learners can obtain a *CORE-2022* Certificate of Completion. We recommend that all readers who have not already done so take the time to explore this interesting four-hour course, available at no charge in English and French.

The Panel has also developed educational resources to assist people who are participating in research or are considering joining a study. These resources cover basic information about participation in research, specific information on topics such as privacy, risks and benefits, and consent, and how the ethics guidance in the *TCPS 2* aims to provide protection for research participants. We encourage all readers to find opportunities to participate in research studies to gain valuable experience about what it is like to be a study participant.

Canada's Research Ethics Boards

At the local level, the main body responsible for using the *TCPS 2* are researchers, and to oversee their steadfastness there are REBS. The *TCPS 2* sets out the following requirements for REB membership:

First, there must be at least five members, including both men and women, of whom at least

- a. two members have expertise in relevant research disciplines, fields, and methodologies covered by the REB;
- b. one member is knowledgeable in ethics;

- c. one member is knowledgeable in the relevant law. That member should not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research; and
- d. one community member has no affiliation with the institution. (Canadian Institutes of Health Research et al., 2022, Article 6.4, p. 97).

Additionally, Health Canada requires that “a majority of [REB members] are Canadian citizens or permanent residents” (Government of Canada, 1985, c.03.306). The majority of Canada's universities and health care delivery organizations (hospitals, health networks/authorities) have, or are affiliated with, local REBs. In some cases, researchers use a centralized REB (e.g., Ontario Cancer Research Ethics Board), a harmonized process (e.g., Research Ethics BC), an independent REB, or a single ethics process across research and practice activities inclusive of research, quality improvement (QI), program evaluation, etc. (e.g., Public Health Ontario). As noted above, REBs follow the guidelines of the TCPS 2, as well as other relevant ethical guidelines, policies, legislation, and regulation that apply depending on the research project. In addition, REBs and communities have collaborated to develop specific guidelines and enact their own processes for research ethical review that are sensitive to types of research or local communities. Examples of community-led ethical guidelines are increasingly available in relation to research involving Indigenous peoples (Hayward et al., 2021). Examples of such guidelines include the *National Inuit Strategy on Research* (Inuit Tapiriit Kanatami, 2018), as well as research involving communities marginalized by society, such as Vancouver's Downtown Eastside (Neufeld et al., 2019).

The Four Main Roles That Nurses Have Related to Research Ethics

The TCPS 2's core principles—respect for persons, concern for welfare, and justice—align well with the seven primary values in the *CNA Code of Ethics for Registered Nurses* (2017):

- providing safe, compassionate, competent and ethical care
- promoting health and well-being
- promoting and respecting informed decision-making
- honouring dignity
- maintaining privacy and confidentiality
- promoting justice
- being accountable (pp. 8–16)

Nurses are often at the point of care and are important advocates for patients and families, and so frequently find themselves at the front lines of health care research. Consequently, nurses across the profession need a good working knowledge of how ethical principles apply in the research context, how research ethics processes work, and how to identify and respond to ethical issues in research. In this section, we use Ethics in Practice case studies to explore the four main roles that nurses have related to research and some of the ethical issues that can arise: (1) as care providers (2) as managers and leaders (3) as researchers and research coordinators, and (4) as serving REB members. We give examples of how the core ethical principles and primary nursing values can be put into practice. Parts of this section were adapted from Chapter 14, written by Oberle & Storch (2013), in the second edition of *Toward a Moral Horizon: Nursing Ethics for Leadership and Practice* (Storch et al., 2013) and the CNA *Ethical Research Guidelines for Registered Nurses* (2002).

1. Nurses as Care Providers

Nurses working in organizations, and across all levels of practice, may be involved in a variety of activities, including research, quality improvement (QI), and program evaluation, to improve care and services (Faden et al., 2013). Nurses may be direct care providers for patients (clients, residents) and families, and may, at times, be research participants themselves, or researchers. The obligations of the nurse in these diverse roles may present ethical challenges. The practice/research distinction that began with the *Belmont Report* is founded on the belief that in clinical practice, patients' immediate interests are addressed because health care professionals are obligated to care for individual patients in a way that is personalized

to benefit each patient via standard care. On the other hand, in research activities, study participants are subjected to potential risks of harm for the benefit of future patients, the larger population, and/or to further the researchers' or institutions' goals. At times, the boundary between clinical care and clinical research is blurred, such as in cancer care (Kass et al., 2013). Likewise, boundaries between health care improvement/evaluation and research activities can also be unclear.

With regards to the harmony between research and practice, nurses require an understanding of such things as: what research is going on in their area; if patients (or their legal health care representatives) understand the nature of the studies they have voluntarily consented to participate in; if they (as nurses) are required to carry out research procedures; and how research project requirements fit into their other nursing responsibilities. If nurses find any elements of the research conducted in their workplaces troubling, these concerns should be voiced to researchers, nursing managers, or the REB. Each nurse is accountable for their own practice. This is not to suggest that it is easy—speaking up requires considerable moral courage and excellent communication skills.

ETHICS IN PRACTICE 2-1

Identifying Potential Harm for Research Participants

Jeremy is a clinical nurse specialist at a long-term care facility. He notices that Hao-Yu, one of the residents for whom he is caring, has become extremely disoriented over the past few days. Hao-Yu is usually a sound sleeper, but has been wandering at night. During the day, his appetite has diminished and he has lost interest in joining social activities. Jeremy checks Hao-Yu's chart and notices that he was enrolled in a clinical trial for an investigational diabetes drug. Hao-Yu began taking the study drug ten days ago. Jeremy has concerns that the research might be jeopardizing Hao-Yu's welfare. He makes a note in Hao-Yu's chart and decides to leave a voicemail for the research coordinator to determine if the study drug could be contributing to the changes in Hao-Yu's orientation (TCPS 2 guidance on *Safety Monitoring in Clinical Trials*). Jeremy also wonders if it would be a good idea to inform Hao-Yu's daughter-in-law, who is his health care representative, but he knows that she's busy with her job and young children (TCPS 2 guidance on the *Consent Process*). Before calling the family, Jeremy takes time to discuss Hao-Yu's situation with the nurse in charge.

REFLECTIVE QUESTIONS

1. *How is Jeremy in a position to protect his patients/residents from harm and to promote their well-being when they are involved in research studies?*
2. *How can Jeremy ensure that his patients/residents (and possibly their families) understand the nature of the study they are enrolled in, and that their consent is fully informed, voluntary, and ongoing? What organizational support does Jeremy need to do this?*

ETHICS IN PRACTICE 2-2

Applying an Ethical Approach to All Learning Activities

As the nurse practitioner (NP), manager, and nurse leader of a busy urban emergency department (ED), one of Chris' roles is overseeing and providing operational approval for all learning projects. Projects deemed to constitute "research" also require research ethics approval. A group of staff from another department approach Chris because they want to implement an intervention to help ED staff better manage aggressive behaviour in patients brought to hospital by police or ambulance. To help the team determine if the project is research or QI and to answer their question if consent is required from staff and/or patients, Chris directs the team to the *ARECCI Screening Tool* (Alberta Innovates, 2017) to learn: (a) the level of risk of their project (b) the types of ethical risks and concerns and (c) the appropriate type of ethics review (REB or internal organizational review). The team completes the ethical screening and prepares to submit their project to the REB. The project lead schedules a meeting with Chris to discuss the study protocol, which involves researchers shadowing patients to observe what happens when things go wrong in the ED. Chris suggests that having researchers shadow patients who are already in vulnerable circumstances could interfere with the important trust-building needed to ensure the highest quality of care. The team appreciates this input and revises their study protocol to incorporate a trauma-informed practice lens and to shadow clerical, medical, and nursing staff instead of patients.

REFLECTIVE QUESTIONS

1. *How can Chris ensure that newer perspectives that are implemented in practice, such as a trauma-informed practice lens, are also integrated into research protocols and REB processes to review research?*
2. *For learning projects that do not require REB approval, such as QI and program evaluations, how can Chris ensure that these projects are conducted in an ethical manner?*

2. Nurses as Managers and Leaders

Nurses may be managers and leaders in organizations where there is an ongoing range of learning activities including research, QI, and program evaluation to improve care and services. Frontline nurse managers and leaders are responsible for assessing and managing nursing workload and quality of care, ensuring a positive work environment, fostering a moral climate, and managing unit budgets.

Research activities can have an impact on all of these areas, and in many institutions, operational approval by nurse managers or leaders is required before a researcher is permitted to bring a study into the organization. Before providing that signature, the manager has a responsibility to become familiar with the protocol, ask any questions that arise, and await satisfactory answers provided by the researcher. If there is no operational approval requirement for research within an institution, managers should be prepared to seek a change in organizational policy. Part of that policy should include an outline of responsibilities of nurse managers and staff nurses in regard to research activities; statements about workload and funding issues; and requirements for nursing support, including education. Organizations should not be silent on such matters, as failure to address such issues can place patients, their families, and nurses at unnecessary risk and cause undue stress.

3. Nurses as Researchers and Research Coordinators

Advanced Practice Nurses (APNs) may be principal investigators or co-investigators in their own studies, and nurses at all levels of practice may work as research assistants or research coordinators for other health care research studies. REBS generally provide research teams with comprehensive procedural guidance and direction on determining, first of all, if a research project requires REB review (TCPS 2 guidance on *Scope of Research Ethics Review*). Such guidance is helpful to research teams preparing a submission to the REB. The research protocol, the document that describes the overall planning of a study, is a critical component of an REB application. Research protocols generally include a comprehensive description of each of the following elements:

- background and rationale
- objectives
- methods
- recruitment of human participants
- informed consent/assent
- potential harms and benefits to participants, families, and communities
- privacy and confidentiality
- knowledge translation and dissemination plan
- budget, potential biases and limitations
- other considerations where relevant (e.g., multijurisdictional research; sex and gender)

Appendix 2-1 summarizes the key considerations when writing research proposals. Individual REBS typically provide guidance on what information should be covered in each section of a research protocol. For example, Health Canada's REB (Health Canada, 2022) provides a helpful summary of key considerations. We advise applicants preparing an REB submission to follow the directions carefully to ensure their research protocols provide sufficient ethical and methodological detail so that the REB can assess the proposal. The protocol must be written in order that each REB

member (even those members who are not experts in the field of the research) will be able to understand the research.

A complete research submission includes related documents such as questionnaires, interview scripts, recruitment materials, and consent and assent forms. Informed consent for research also involves processes that need to be established for the research to begin. Key areas to be included in an informed consent discussion include: (a) protection of confidentiality (b) knowledge of the processes involved (c) understanding about any discomforts and inconveniences, foreseeable risks and costs, and (d) any benefits and compensation provided (Kluge, 2013). Some REBs provide checklist tools to help identify required regulations, guidelines, and policies to ensure all applicable elements are present in the study documents. At times, the REB requests that the researcher (or principal investigator) present to the REB or answer questions. A research project cannot begin until the REB has given full unconditional approval. However, in some areas of research, and particularly the qualitative paradigm, the process of gaining entry (the ethical and academic processes the researcher undertakes to access and engage with research participants and the broader professional and institutional community) can blur the lines of when research data is collected. The TCPS 2 chapter on *Qualitative Research* is helpful in this regard.

Once a research project is approved and underway, reflexivity is an integral part of the process of rigorous inquiry that involves researchers being able to be critically reflective of the research process they are engaged in. As noted by Australian ethicists Marilys Guillemin and Lynn Gillam (2004),

Being reflexive about research practice means a number of things: first, an acknowledgment of micro-ethics, that is, of the ethical dimensions of ordinary, everyday research practice; second, sensitivity to what we call the “ethically important moments” in research practice, in all their particularities; and third, having or being able to develop a means of addressing and responding to ethical concerns if and when they arise in the research (which might well

ETHICS IN PRACTICE 2-3*Balancing Conflicting Ethical Duties*

Binder is an NP and researcher who is studying the experience of new mothers who are breastfeeding. She visits research participants in their homes, observes how the infants latch, and helps the mothers learn how to use a breastfeeding pump. Due to the COVID-19 pandemic, postpartum NPs and public health nurses are engaged in contact tracing and vaccine clinics. During a study visit, Binder assists Sara with breastfeeding as they chat about latching technique. Suddenly, Sara begins to sob and confides that her partner is abusing her six-year old son. Binder is surprised, but quickly shifts into counsellor mode, comforts the baby, and listens. Binder is aware that this is an “ethically important moment” because Sara was told that her information would be kept confidential in the study, yet provincial legislation requires mandatory reporting of child abuse. Nothing in the consent form addressed a situation such as this. Binder considers her conflicting ethical duties: to keep Sara’s disclosure in confidence or to report the abuse for fear that Sara’s son is at risk of harm (TCPS 2 guidance on the *Ethical Duty of Confidentiality*). Before she leaves Sara’s home, Binder and Sara talk about a safety plan for her and children. Binder immediately seeks guidance from her colleagues, her professional regulatory body, and the REB to find ways to report the abuse in a way that is sensitive to the interpersonal and ethical aspects of the research relationship.

REFLECTIVE QUESTIONS

1. *Besides the obvious ethical issue about whether Binder is ethically required to breach Sara’s confidentiality, what immediate ethical concerns was Binder faced with involving if and how to respond to what Sara told her?*
2. *How might the practice of reflexivity help Binder to process and learn from Sara’s surprising disclosure?*

include a way of preempting potential ethical problems before they take hold). (p. 276)

4. Nurses as REB Members

Finally, APNs may be members of REBS. Serving on an REB is an important role for advanced practice nurses to consider, both to learn more about the work of assessing research in line with the TCPS 2 and to add safeguards of local significance. Both authors of this chapter have served on REBS and consulted with REBS. We have found REB service to be a good way to learn and keep abreast of the TCPS 2 guidelines while also developing knowledge in new areas of practice and research. Because APNs serving on an REB have a breadth of experience in nursing practice, they are normally the first to pick up on research measures that would be difficult or contraindicated for patients/families or other potential participants (such as staff). Nurses are also often more sensitive to the patient and family experience of the research.

Research involving humans can be ethically justified only when the research is scientifically sound, the potential benefit significantly outweighs the potential for harm, there is an adequate process for informed consent (assent where applicable), and there is justice or fairness in the selection of participants. For example, Health Canada's REB (2022) provides a useful summary of key considerations when reviewing research proposals to assess whether a proposal meets the ethical requirements for research involving humans, including

- methodology (e.g., if the study is likely to produce valid results)
- selection and recruitment (e.g., based on sex, gender, age, ethnicity, and language)
- informed consent process (e.g., voluntariness, capacity, and comprehension)
- potential harms and benefits, and how these are distributed
- privacy and confidentiality (e.g., highly sensitive information, identifying information, biological samples), and
- any real, apparent, or potential conflicts of interest that may affect how the research is conducted

An ill-designed study is a waste of resources (time, funding dollars, personnel) and possibly participants' goodwill—and is therefore

unethical. Appendix 2-1 summarizes the key considerations when reviewing research proposals.

ETHICS IN PRACTICE 2-4

Advancing Nursing Inquiry

Danielle, a nurse educator in a community hospital, is an advocate of interprofessional research in the hospital. She conducts her own research and has mentored research teams, most of which include graduate nursing students and patient representatives. Danielle has been asked to serve as a member of a nearby university's **REB**, which to date has mostly reviewed clinical trials. At one of the first **REB** meetings she attends, Danielle observes the members having difficulty reviewing a study using interpretive description, a qualitative methodology developed in the nursing profession by Sally Thorne from the **UBC** School of Nursing. In particular, the **REB** members seem puzzled with the vague description of sample size in the protocol. Danielle realizes that her **REB** colleagues lack familiarity with nursing research methodologies. She then proceeds to appraise the study application on the basis of her knowledge about how emergent research works in the field and ethical concerns that could arise, based on the **TCPS 2** chapter on *Qualitative Research*. The **REB** Chair expresses their gratitude to Danielle, and requests that she provide an education session on nursing inquiry to all **REB** members.

REFLECTIVE QUESTIONS

1. *In what ways did Danielle, as a nurse educator and advanced practice nurse leader, contribute constructively to the **REB**'s discussion and promote working as an effective team?*
2. *As an **REB** member, what should Danielle do if she is assigned to present a research protocol, but lacks confidence about her knowledge? For example, if she is unfamiliar with the small community that is the study population of interest, or if she is unsure about the requirements of the research methodology?*

Research Ethics on the Moral Horizon: Vigilance Must Be Ongoing

In this chapter, we have reviewed key events in the recent era of Euro-Western research ethics. We have outlined respect for persons, concern for welfare, and justice, as the core principles of the **TCPS 2**. We have discussed the role and function of research ethics boards in Canada and provided examples of how the **TCPS 2**,

Canada's standard for ethical research, works in conjunction with other codes, legislation, and guidelines. In addition, we have identified four key roles for advanced practice nurses in promoting ethical research and provided examples of ethical issues that can arise in each of these areas.

Nurses must be vigilant when it comes to research ethics. Unfortunately, despite more than half a century's evolution of bioethics and research ethics oversight, it is clear that health care ethics-related transgressions are not a thing of the past. At this time, we have noted three violations of health care ethics and human rights recently reported:

- Lipphardt et al. (2021) identified concerns with how researchers analyzed the genetic data of marginalized populations via public DNA databases, focusing on implications for Roma people.
- Taylor (2021) raised issues about an experimental COVID-19 “cure” tested in Brazil in 2021.
- In April 2022, Health Canada announced a review of all trials involving methylenedioxymethamphetamine (MDMA, also known as “ecstasy”) to ensure patient safety and compliance with regulations (Lindsay, 2022).

As information is uncovered—and as societal attitudes, norms and ethical awareness evolve—new accounts of abuse of research participants and scientific misconduct (such as data falsification, data fabrication, or plagiarism [Marcus & Oransky, n.d.]) continue to be revealed (Emanuel et al., 2008; Pimple, 2017; Resnick, 2018). For these reasons, we urge nurses to advocate for the appropriate representation of, and collaboration with, diverse and historically underserved populations in research, and to consider the perspectives of research participants. In this chapter, we have underscored the active and critical roles that those in the nursing profession—and particularly advanced practice nurses—play in protecting the rights and welfare of patients and research participants while advancing the pursuit of knowledge.

QUESTIONS FOR REFLECTION

1. *What kinds of guidelines are in place in your workplace to guide nurses' involvement in research?*
2. *Why might there be gaps between what you think nurses ought to do in research-related situations, what nurses believe they ought to do, and what nurses actually do?*
3. *What kinds of research-related issues have you encountered in your practice, and what action have you taken?*
4. *What kinds of opportunities do advanced practice nurse leaders have to promote ethical research in ways that:*
 - *uphold the primary values in the nursing profession?*
 - *increase collaboration with diverse and historically underserved populations?*
 - *better align with diverse community values/needs and broader societal goals, such as Indigenous reconciliation and social justice?*

Endnote

- 1 In this chapter, we draw on content from: Oberle, K., & Storch, J. L. (2013). Research ethics in nursing. In J. L. Storch, P. Rodney, & R. Starzomski (Eds.), *Toward a moral horizon: Nursing ethics for leadership and practice* (2nd ed., pp. 282–301). Pearson.

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APPENDIX 2-1

Key Considerations for Writing and Reviewing Research Proposals

TOPIC	RELEVANT QUESTIONS
Background and Rationale	
To ensure that the study is important, merits participants' time, and generates important knowledge.	<ul style="list-style-type: none"> • Is there evidence that the study is necessary and important? • Is there evidence that the right questions are being asked? • Is there evidence that the approach used is appropriate?
Study Objectives	
To ensure that the study is feasible and reasonable.	<ul style="list-style-type: none"> • Are the objectives of the study reasonable and manageable given previous work in the area? • What are the expected outcomes and knowledge of the study?
Methods	
To ensure that the study is scientifically sound and results are likely to be valid and meritorious.	<ul style="list-style-type: none"> • Do the research methods seem appropriate to the question? • Is the study likely to produce valid results? • What, where, how, on whom, and when will the study take place? • What types of biological samples will be collected, and will genetic testing be conducted? • How will samples/data be used and analyzed?
Sample and Recruitment of Human Participants	
To ensure that there is justice or fairness in selection of participants, and participants are recruited appropriately.	<ul style="list-style-type: none"> • Is the sample appropriately delineated? • Are appropriate inclusion criteria present? • Is any population excluded inappropriately (e.g., based on sex, gender, age, ethnicity, language)? • Are people in the sample vulnerable in any way? • What has been done to protect potential participants from harms? From feeling coerced? • Is there evidence of undue inducement to accept more than minimal risk? • What recruitment strategies and materials are to be used?

TOPIC	RELEVANT QUESTIONS
Informed Consent/Assent	
To ensure that there is an adequate process for informed consent (assent where applicable), and that consent/assent is free, informed and ongoing.	<ul style="list-style-type: none"> • Is there evidence that elements of informed consent /assent (voluntariness, capacity, and comprehension) will be present? • Are alternatives to participation outlined (for therapeutic studies)? • Are consent and assent documents written in plain language? • Are the required elements of consent (as outlined by TCPS 2 and institutional policy) present? • Will consent be oral or written? • Is there a justified request for authorized representatives if appropriate? • Is there a justified request for waiver of consent if appropriate?
Potential Harms and Benefits	
To ensure that the potential benefit significantly outweighs the potential for harm, and that harms and benefits are considered in terms of participants, their families, and communities.	<ul style="list-style-type: none"> • Are potential (known and reasonably anticipated) harms and discomforts adequately described? • Are possible benefits described appropriately (in other words, not overstated)? • Have appropriate measures being taken to maximize benefit and minimize harm? • What happens if participants become injured or get sick as a result of being in this study? • Have any rights to legal recourse been waived?
Privacy and Confidentiality	
To ensure that participants' privacy and confidentiality will be protected.	<ul style="list-style-type: none"> • What types of personal information about participants will be collected (e.g., highly sensitive information, identifying information, biological samples)? • What personal information about participants will be disclosed, to whom (e.g., study sponsor, Health Canada, REB), and why? • How will personal information be protected (e.g., coded), how long will information be kept, and how/where will it be stored? • What happens to information/samples if participants wish to withdraw their consent?
Knowledge Translation and Dissemination	
To ensure that the results of the research will be shared.	<ul style="list-style-type: none"> • Will participants and their communities receive and benefit from the results of the research?

TOPIC	RELEVANT QUESTIONS
<p>Budget</p> <p>To ensure that there is adequate funding to conduct the research and potential biases and limitations are identified.</p>	<ul style="list-style-type: none"> • Is the budget appropriate? Are expenses of the study clearly laid out? • Are expenses to be assumed by appropriate bodies? For example, who pays for extra diagnostic tests? • Are participants to be compensated for out-of-pocket expenses? • Is there evidence that the investigator might benefit inappropriately (i.e., is there a suggestion that the researcher is being paid to recruit participants, and could this then lead to inappropriate recruitment?) • Are there any real, apparent or potential conflicts of interest that may affect how the research is conducted?
<p>Other Considerations</p>	<p>For some research studies, other areas may need to be addressed, such as:</p> <ul style="list-style-type: none"> • Multicentre or multijurisdictional research • Sex and gender • Official languages • Indigenous research • Community engagement • Legislation and regulations

Note. Appendix 2-1 is largely adapted from *Research ethics and nursing*, by K. Oberle and J. L. Storch (2013, Table 14-1, p. 287), in J. L. Storch, P. Rodney, & R. Starzomski (Eds.), *Toward a moral horizon: Nursing ethics for leadership and practice* (2nd ed., pp. 282–301). © 2013 by Pearson Canada. Additional information from *Research Protocol Instructions* by Health Canada's Research Ethics Board (Health Canada, 2022). © 2021 by Health Canada.