Beyond seeking informed consent: Upholding ethical values within the research proposal

by Virginia Lee

Congratulations! After weeks of conceptualizing, writing and revising, you have finally arrived at the final version of a research proposal. So, what’s next? Before implementing the study, all research involving human subjects is required to undergo a formal process to seek research ethics approval from a Research Ethics Board (REB) in Canada. Seeking research ethics approval goes far beyond submitting a well-written informed consent form. The purpose of this article is to describe the ethical values that underlie many aspects of the research proposal that would be subject to review by the research ethics board committee members. An investigator needs to take these values into consideration when planning the research study and preparing the ethics board application.

WHAT IS A RESEARCH ETHICS BOARD?

Research Ethics Boards (REBs) are local regulatory structures that exist for the purpose of reviewing, authorizing, amending, or terminating research. REBs are typically independent committees composed of individuals who volunteer their expertise and time and have no conflict of interest with the research study under review. The committee may include representatives from medicine, nursing, pharmacology as well as lawyers, bioethicists, and the community. The committee’s mandate is to ensure that the proposed research abides by the established ethical principles set out by the Tri-Council Policy Statement (TCPS) on the Ethical Conduct for Research Involving Humans (CIHR, NSERC, SSHRC, 2014). The TCPS was first established in 1998 by three federal research granting agencies, the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, to govern the safety, well-being and respectful treatment of human participants involved in a study for research purposes.

WHAT IS THE PURPOSE OF SEEKING RESEARCH ETHICS APPROVAL?

Obtaining clinical research ethics approval prior to beginning a study provides assurance that the proposed research was reviewed to ensure 1) the study has the potential to contribute scientific, clinical, or socially valuable knowledge, 2) the rights and welfare of study participants are protected, and 3) the risks inherent in the research study can be reasonably justified relative to the potential benefit gained from the study.

DOES THE PROPOSED RESEARCH HAVE THE POTENTIAL FOR SCIENTIFIC AND SOCIAL VALUE?

The potential to generate new knowledge, advance understanding or make a scientific, social, or clinical contribution is part of what makes clinical research ethical (Emanuel, Wendler, & Grady, 2000). Although the purpose of the review is not to assess the science of the research per se, it is important that the research rationale, questions, methods and procedures are clearly described to convince the REB members that the science will be conducted properly for the proposed work. The purpose of the background and literature review within the context of an ethical review is to emphasize the significance of the study to justify exposing volunteers to inconveniences or potential risks in the study, and to justify the use of scarce resources for research purposes. Clinical intervention studies would be expected to include information to justify the use of a placebo in lieu of the standard treatment, or to demonstrate clinical equipoise (that is, the absence of consensus in the current state of evidence or uncertainty about the clinical effectiveness of the experimental interventions) (Emanuel, Wendler, & Grady, 2000).

Enrolling participants in poorly designed research that will produce uninterpretable or biased results is considered unethical. The study findings are only as good as the methods used to produce them. Only methodologically rigorous studies can generate meaningful, reliable and valid results which can then be interpreted with reasonable confidence. The most appropriate design and tools should be used to answer the research question. Thus, in your ethics application, it is useful to include data collection methods that can provide for psychometrically valid and reliable measures in the case of quantitative studies or sample interview questions in the case of qualitative studies. Similarly, a data analysis plan that is absent or incomplete might lead to uninterpretable, weak, or meaningless results and constitute a waste of time and resources.
ARE THE RIGHTS AND WELFARE OF RESEARCH PARTICIPANTS PROTECTED?

Study participants are essentially volunteers who are asked to agree to comply with a defined set of procedures within a specific time frame. Decisions about patient eligibility, inclusion and exclusion criteria must be based on a scientific rationale and be guided by the principles of respect for fairness, justice and inclusiveness as well as the principle of free and informed consent. How a patient is deemed eligible, and when and where a patient is approached during recruitment, must take into consideration whether there may be unintentional bias or coercion involved. Researchers may not approach patients directly because they do not have authorization to delve into patient clinical records for the purpose of patient recruitment. For this reason, it is recommended that a member of the treating team who is unrelated to the study, and regularly has access to the targeted patient population be the first to approach a patient and ask permission for a researcher to contact them. Timing is another factor to consider during patient recruitment. Are patients more vulnerable when distressed or in crisis? Was there sufficient time given to the patient to ask questions and to allow the patient to accept or decline participation? Might some patients be in a privileged position to enter the study by virtue of the time or day of recruitment? One notion that must surpass all is that the patient’s welfare comes first before the needs of the study.

The project purpose and the project procedures must be presented to the potential participant in a way that is understandable, clear and in an environment that facilitates freedom of choice. Employ the use of translators if necessary, or access to a family member or caregiver who can translate. Patients should be aware of their right to withdraw at any time from the research study without being subject to any form of discrimination, loss of rights, or opportunities to which they would otherwise be entitled. Know that a onetime consent is not a blank consent for the remainder of the study. Reviewing the patient’s interest to remain in the study is warranted.

Coercion occurs when one party is in a position of trust in relation to another, and may exercise influence over the other. For example, it may be difficult for patients to decline or make a decision consistent with their own values if the person seeking consent is a professor seeking consent from a student enrolled in his class, a nurse manager seeking consent from a staff nurse on her unit, or a nurse or physician seeking consent from a patient under his/ her care. Thus, it is important that the person presenting the study and seeking informed consent not be perceived as a person in a position of influence or authority over the potential participant.

Coercion may also take the form of inducements (e.g., money, free medication) that may influence the participant to decide or act a certain way or accept the risk that they would otherwise not accept. Compensation to reimburse meals missed, travel or parking costs are not usually considered inducements for patient participation if these are commensurate with the costs or inconveniences experienced by the participant.

The informed consent form (ICF) is a document written in plain language to ensure the potential participant has the necessary information about the research study to make an informed decision to accept or decline participation in the study. Using jargon or providing partial, incomplete information is misleading and compromises the consent process. The ICF should follow health literacy guidelines referring to scientific terms with an explanation in parentheses, and include sufficient information to permit an informed decision to participate or decline entry into the study. You may need to assess the level of literacy of your informed consent using specific software that can indicate the grade level. The participant, the principal investigator, and sometimes a witness, dates and signs the ICF to indicate that the researcher has communicated all necessary information to the participant, that the participant has read the information and has had enough time to ask questions. A signed copy of the ICF needs to be provided to the participant.

ARE THE POTENTIAL SCIENTIFIC BENEFITS PROPORTIONATE TO THE RISKS INVOLVED?

All clinical research inherently entails uncertainty about the degree of risk and benefit. The principle of beneficence and non-maleficence and respect for patients’ dignity, privacy and confidentiality are important here. It is the researcher’s responsibility to protect participants from harm or abuse, and to ensure that participants are not unnecessarily exposed to undue risk or burden. When the risks to the participants are more than minimal, the scientific importance of the research must be carefully reassessed. Participants require transparency in the study procedures (i.e., number of clinic visits; the frequency, duration, and number of tests and procedures that the patient is asked to complete beyond what is standard of care) to be able to carefully weigh the potential risks involved against the potential benefits, which should never be overstated. Whenever possible, it is recommended to streamline data collection, clinical tests or procedures necessary for research purposes within routine clinical processes of care to reduce the burden placed on patients. As an example, schedule research interviews on days for the next follow up visit when the patient will be in clinic anyway. All known and potential for unknown risks (physical, psychological, informational) should be described completely, including the incidence of their occurrence and the plan as to how risks will be mitigated or managed should these arise.

In summary, submitting your research proposal for REB Review need not be a daunting or complicated task. REBs exist to facilitate research, not impede it. Inquiring at your local REB about the availability of templates for ICF, checklists to ensure all aspects are attended to, the criteria to warrant expedited review, and the timeline...
of when the REB members meet to review protocols is a worthwhile step. Although we may be eager to launch into the action phase of our research, the a priori work involved to safeguard our patients’ rights, welfare and safety is imperative, particularly given the constantly evolving contexts in which research is conducted. Navigating the research ethics process is a welcome opportunity to learn and ensure an added layer of protection for our potential research participants who are essentially partnering with researchers to advance knowledge.

REFERENCES