Ethics Policy on Research Involving Humans

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CONTEXT

The Institut de recherche Robert-Sauvé en santé et en sécurité du travail (IRSST) was created to contribute, through research, to the prevention of industrial accidents and occupational diseases and to the rehabilitation of affected workers. Its mandate is to ensure the development, use, and dissemination of the scientific knowledge required for this purpose. As both a research institute and a granting agency, the IRSST can count on teams of highly competent researchers[1] to help it carry out its mandate.

The research funded by the IRSST has particular characteristics that are taken into account in the Institute's Ethics Policy on Research Involving Humans. In general, the type of research involved is applied research, originating from requests from the working community and usually carried out in direct association with this community. To qualify for funding, the research must be recognized by the IRSST's Scientific Advisory Board (which consists of employer and union representatives, as well as members of the scientific and technical communities) as relevant, priority, and compliant with recognized research standards. This process offers certain guarantees regarding the relevance of undertaking the research and of its direct benefits for workers and employers.

Occupational health and safety research takes several forms, with some calling for human participation. Examples are interviews, surveys, observation of people or groups, consultation of personal information and documents from private archives, sample collection and laboratory tests, and prototype testing.

In all cases, respect for human dignity must be central to the investigators' concerns. A process of reflection to identify the ethical issues related to human participation is therefore required. This type of reflection is not simple; it requires the researchers involved to assess, in a reasonable manner, the negative consequences (however minor) that could be associated with human participation in the research, and to anticipate appropriate mechanisms for safeguarding the participants' well-being, health and safety.

The Ethics Policy on Research Involving Humans should be seen as a means adopted by the IRSST and its personnel for appropriately addressing the various dilemmas and concerns associated with research involving humans. The Institute's Research Ethics Committee (REC) supports this process; it must decide on the ethical validity of research projects involving humans carried out by IRSST researchers.

[1] In this document, the term researcher refers not only to scientific professionals active in research and research professionals, but also to technicians, research assistants and any other personnel involved in carrying out a research project.

This policy specifies the responsibilities and mechanisms associated with applying rules of ethical conduct to IRSST-funded research involving humans. It was developed in line with the research ethics practices and policies adopted by various universities and research centres in Canada. In general, research ethics policies and the related procedures represent minimal expectations with respect to research involving humans. They must be seen as an invitation to researchers to go even further to safeguard the best interests of any human participants in their research.

A FEW CORE PRINCIPLES[2]

In Canada, the philosophical articulation and development of rules and procedures regarding research involving humans have been re-examined and reformulated by the following three research councils: the 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). The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014* is the current Canadian standard on the ethics of research involving humans.

This policy statement establishes a unique ethics framework for all research involving humans (humanities and social sciences, natural sciences and engineering, medical research). It proposes guidelines common to all research disciplines.

Core Ethical Principles

The cornerstone of this policy statement is respect for human dignity, which means taking into account the intrinsic value of all human beings, as well as the respect and consideration they are due. This essential value is expressed in three core ethical principles: respect for persons, concern for welfare, and justice.

Respect for Persons

Participants in research are entitled to respect regarding the use made of their data and biological materials. Respect for persons is based on recognizing their autonomy, meaning their ability to choose to participate in research without interference. In real terms, respect for autonomy means requesting their free, informed, and ongoing consent. Potential participants should be sufficiently informed to thoroughly understand the aims of the research, but also its potential benefits and risks. Respect for persons therefore requires that researchers commit to accountability and transparency in the ethical conduct of their research. In particular, they have an obligation to identify all the factors and constraints of the research context. They must also seek to obtain the participation and consent of vulnerable persons where possible.

[2] Certain parts are based on the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2014)*.

Concern for Welfare
Privacy, control of information about a person, and use of a person's biological materials are part of his or her welfare in the same way as physical, economic, and social circumstances are. A person's welfare also encompasses the welfare of those who are important to him or her, and of the group or community to which he or she belongs.

This concern for welfare means that researchers should minimize the risks associated with the research. They should seek the best possible balance between the potential risks and benefits of the research, and avoid exposing participants to unnecessary risks. They should also provide participants with the most comprehensive information possible so that they themselves are able to assess the risks and benefits of the research project adequately.

Justice
The notion of justice involves the concepts of impartiality and fairness. For procedures to have integrity, it means that the research protocols are reviewed through the application of fair methods, standards, and rules, and that the ethics review process is applied in a truly independent manner. The principle of justice also implies the fair distribution of both the benefits and the burdens of the research. On the one hand, distributive justice means that no segment of the population should be subjected to a disproportionate share of the research burdens. On the other, it imposes on researchers the obligation to include, without discrimination, persons or groups that may derive benefits from the research. Particular attention should be paid to those who are in vulnerable circumstances or marginalized to ensure that they too benefit from fair and equitable treatment in research.

The IRSST adheres to these principles in a spirit of researcher accountability, and seeks to ensure that any research undertaken with its funding complies with high-level ethics standards. All research projects or activities that are submitted to the Institute and that involve human participation must therefore obtain an ethics certificate issued by a research ethics committee (REC) before work begins. The projects carried out by external researchers are submitted to the REC in their institution. Other research projects or activities requiring human participation must be submitted to the IRSST's REC.

These principles must guide researchers when they are writing research proposals, as well as the members of the REC when they are reviewing the ethical aspects of a research proposal.

OBJECTIVES

By adopting such a policy, the IRSST pursues the following objectives:

- to promote high ethical values in its research practices;
- to establish a reference framework regarding ethical conduct for research involving humans; and
- to specify the structure and mechanisms for applying rules of ethics.

APPLICABILITY

The Ethics Policy on Research Involving Humans applies to all research (activities or projects) funded by the IRSST or carried out by researchers associated with the Institute and requiring human participation. It also applies to the secondary use of information when data linkage is involved.

SHARING OF RESPONSIBILITIES

The IRSST is responsible for ensuring respect for human dignity in any research it funds. However, the Institute may have other reasons for refusing to allow certain research projects or activities to be carried out, even if it assesses their ethical aspects positively.

- **THE BOARD OF DIRECTORS**

The adoption of this policy and any potential amendments to it is the responsibility of the IRSST's Board of Directors. The Board is also responsible for appointing the members of the REC.

- **THE EXECUTIVE OFFICE**

The President-Chief Executive Officer is responsible for applying this policy. To do so, she has a duty to:

- ensure that the REC has sufficient financial leeway and administrative independence in the way it is organized to fulfil its obligations, and that its members are protected in the event of a civil suit.

- **THE DIRECTOR OF THE RESEARCH AND EXPERTISE DIVISION**

The Director of the Research and Expertise Division has a duty to:

- ensure, for research proposed by IRSST researchers, that the funding of any projects involving humans is conditional upon its acceptance by the IRSST's REC, and in the case of research proposed by external collaborators, that the funding of any such projects is conditional upon their acceptance by the REC of the managing institution;
- ensure, in the case of a research project carried out jointly with other research partners (universities, research centres, regional boards, etc.) that the project's funding is conditional upon the acceptance of the entire project by one of the RECs of the different institutions with which the researchers involved in the research are affiliated, and preferably that of the principal investigator;

- ensure, in the case of a research project being conducted in several institutions (so-called multi-centre research) and when these institutions have a REC, that payment of the project funding is conditional upon project acceptance by the respective RECs of these different institutions;
- ensure, when the external researchers do not have the necessary infrastructure for this purpose, that the proposals are submitted to the IRSST's REC;
- incorporate the ethical aspects of the file in the status reports for a project or activity that must produce a deliverable;
- send the research protocol or activity estimate to an appeals committee in the case of disagreement with a researcher following a review of the file by the IRSST's REC; and
- respect the REC's decisions.

- **IRSST RESEARCHERS (scientific professionals active in research and research professionals)**

IRSST researchers have a duty to:

- familiarize themselves with this policy;
- apply the ethics rules prescribed in this policy in all aspects of their research;
- obtain the requisite approvals from a REC before recruiting participants, collecting or officially accessing data on participants, or collecting human biological materials (the *Guide d'information pour l'obtention d'un certificat d'éthique* [Information guide for obtaining an ethics certificate] presents the documents and forms to be completed and sent to the REC so that it can carry out its mandate properly);
- comply with the terms and conditions described in their activity estimate or research protocol, and with any additional commitments conveyed to the REC;
- disclose any actual, potential, or perceived personal conflicts of interest, as well as any institutional conflicts of interest, that may influence the research results;
- document how the ethical obligations have been respected, in the status reports;
- inform the REC chair of *any significant changes in the protocol during the course of the research, and of any unforeseen events and incidental findings that may increase participants' risk level;* and
- produce a final report upon project completion (fill out the appropriate form).

It should be noted that the application of these rules does not exempt researchers from the obligation to comply with the relevant legislation and the rules of professional conduct issued by their associations or professional corporations.

- **RESEARCH COLLABORATORS**

a) When the funded research is carried out totally by external researchers (universities, research centres, consultants), the entire file is reviewed preferably according to the mechanisms

provided for at the principal investigator's institution. In such cases, the institution managing the research funds is responsible to the IRSST for ensuring that the research carried out by its researchers or graduate students is conducted according to the review and follow-up mechanisms established for this purpose; it is therefore responsible for issuing the requisite approvals, and as the case may be, for forwarding them to the IRSST.

- ♦ If the managing institution has reasonable doubts as to whether the research is ethical, it has the authority to suspend the work on the recommendation of the ethics committee, and must inform the IRSST thereof. In the case of multi-centre research, the managing institution must determine whether there is a need to obtain an ethics review in each of the centres and take the appropriate measures.

- ♦ If a collaborator does not have access to suitable mechanisms for having his or her project reviewed by a research ethics committee, the IRSST's REC is responsible for examining the ethical aspects of the proposal.

a) When researchers from universities, research centres, or other institutions partner with IRSST researchers to carry out projects requiring human participation, the proposal must be reviewed by the REC of the principal investigator's institution according to the ethics review rules prevailing in that institution.

THE IRSST'S ETHICS COMMITTEE ON RESEARCH INVOLVING HUMANS

- **CREATION OF THE COMMITTEE**

In order to apply research ethics rules, the IRSST creates a standing research ethics committee (REC). This committee is independent and multidisciplinary.

The REC has a twofold mandate. It must:

- ♦ evaluate the ethical validity of research projects requiring human participation that are carried out by IRSST researchers or by research collaborators with no access to a REC;
- ♦ support IRSST personnel (researchers, professionals, research assistants, technicians and managers) when they express concerns regarding ethics in research involving humans.

- **COMPOSITION OF THE REC AND APPOINTMENT OF MEMBERS**

All members of the Committee are appointed by the IRSST's Board of Directors for three-year renewable terms.

The REC must consist of at least five members representing the range of research fields covered by the proposals to be reviewed by the Committee, and having the necessary background and expertise to fulfil the functions. More than one member may be assigned to each function and substitutions are possible.

The composition of the Research Ethics Committee must be as follows:

- two members trained in research methods, fields, and disciplines;
- one member trained in ethics;
- one member versed in the relevant legislation (if applicable); and
- one member of the community who has no affiliations with the institution.

Administrative personnel assigned to ethics-related functions may sit on the REC as non-voting members.

- **RESPONSIBILITIES OF THE REC**

The Research Ethics Committee must operate in an impartial manner and listen without bias to all parties involved. It has the following responsibilities:

a) ethics review:

- examine all research projects or activities requiring human participation, in light of the core principles of the Institute's Ethics Policy on Research Involving Humans;
- request modifications to projects to bring them into compliance with research ethics; and
- issue the IRSST's ethics certificates.

b) follow-up of approved research protocols:

- ensure that the REC's recommendation is forwarded to the principal investigator;
- ensure that all the changes requested during the ethics reviews of the different research projects are complied with;
- re-assess the ethical content of projects when they are modified during execution or when unforeseeable events occur; and
- receive and study complaints relating to the ethical implications of research involving humans conducted by the IRSST (such complaints must be forwarded to the Committee chair, who will inform the Research Ethics Committee thereof and obtain its opinion).

c) continuous improvement process:

- propose means likely to promote compliance with the core ethical principles;
- plan for general meetings, periods of reflection, and training workshops for its members and for IRSST personnel;

- develop and update this policy and ensure that it is disseminated;
- keep informed about changing ideas and practices in matters pertaining to ethics in research involving humans; and
- receive all questions relating to this policy and the related rules, and ensure that they are forwarded to the REC.

d) accountability:

The REC is self-managed to ensure that it has the independence it needs to operate; nevertheless, it must:

- prepare and submit an annual report to the IRSST's Board of Directors (this report will summarize the manner in which the REC carried out its mandates and responsibilities. It will also describe the decisions rendered, and, as the case may be, any new ethical questions raised by these decisions).

THE IRSST'S REVIEW PROCESS FOR RESEARCH PROJECTS AND ACTIVITIES IS AS FOLLOWS:

1. The principal investigator sends the chair of the REC a complete file (the complete research protocol or activity estimate – including the components to be carried out by partners – and the related forms). In theory, the project must have undergone prior scientific peer review, in accordance with the usual procedures.

2. A quorum of three members with the desired expertise, relevant skills, and knowledge needed to review the ethics of the research is required for the committee to deliberate.

3. A member of the REC, involved as a researcher on a project or as a research field leader, may be heard by the REC, but must leave during deliberations on the project.

4. In order not to unduly delay the start of a research project or activity, the ethics review process is carried out with diligence.

   REC meetings are held, whenever possible, during the month following the transmittal. During these meetings, the REC examines the different research projects and activities submitted, in a plenary session.

5. The Committee's decisions, reached by consensus, may result in approval without modification, a conditional acceptance, or a substantiated refusal.

6. Ongoing research projects or activities must be the subject of continuous ethics monitoring that rigorously complies with the proportionate approach to ethics review.

The continuous monitoring approach is proposed by the principal investigator. It must include the obligation to report any unforeseen event and significant change in the research protocol to the Committee chair.

The Committee chair informs the REC members thereof, and they decide, in light of the information provided, on the relevance of reviewing the complete file, and, as the case may be, of allowing the work begun to continue.

At the end of the project or activity, a report on its ethical aspects must be submitted. In cases where a project spans several years, a report must be submitted at the end of each step defined by the Research and Expertise Division.

7. At any time during the research cycle, the principal investigator may ask to be heard by the REC. He or she must leave during the Committee's deliberations. The Committee may invite other members of the research team to attend a meeting before rendering its decision.

8. For certain specific cases, the Research Ethics Committee may use an accelerated process.

   These cases are related to either:

   a) the foreseeable degree of risk posed by the research to the participants. Where the risk is minimal, the Committee chair appoints two people from among the full-committee members to review the ethics of the research. This delegation has the expertise and knowledge needed to review the research; or

   b) the renewal of approval, minor modification of an already approved protocol, or any other reason considered valid by the Committee chair.

   The Committee transmits its answer in writing within 5 working days of this decision.

   In the case of a refusal or when modifications are required, the answer will explain the reasons for the REC's decision.

9. The project's principal investigator has the right to request a reconsideration of the Committee's decision concerning his or her project, and the Committee must accede to this request.

   When the researcher and the Committee cannot reach an agreement, the Committee's final decision may be appealed.

   The researcher must submit his or her appeal in writing to the Director of the IRSST's Research and Expertise Division within 15 working days of the Committee's refusal.

   The entire file is then forwarded to an appeals committee with expertise and knowledge comparable to that of the IRSST's REC. The substantiated opinion of this independent external committee is sent to the Institute's Research Ethics Committee, the Director of the Research and Expertise Division, and the principal investigator. If need be, steps are taken to comply with the appeals decision.