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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 and use of scientific knowledge required for this purpose and to disseminate it. To carry out its mandate, the IRSST can count on teams of competent researchers, both as a research institute and as a granting agency.

The research funded by the IRSST has characteristics that must be considered in developing and implementing ethics policies for research involving humans. In general, it is applied research, originating from requests from the working community, and carried out most of the time in direct association with this community. To be carried out, it must be recognized as relevant, a priority, and complying with the recognized research standard by the IRSST's Scientific Advisory Board, consisting of employer and union representatives, as well as members of the scientific and technical communities. This process offers certain guarantees regarding the relevance of the research and direct impacts for workers.

Occupational health and safety research takes several forms, with some calling for human participation, as for example, interviews, surveys, the observation of people or groups, consultation of personal information and documents from private archives, the collection of samples and laboratory tests, and the testing of prototypes.

In all cases, respect for the people participating in the research work must be central to the investigators' concerns. To achieve this, reflection to identify the ethical issues related to human participation is required. This type of evaluation is not simple; it requires that the researcher assess in a reasonable way the negative consequences, even minor ones, that could be associated with human participation in the research, and anticipate the appropriate mechanisms for protecting their well-being, health and safety.

The Ethics Policy for Research Involving Humans is a means adopted by the IRSST and its personnel for appropriately addressing the different dilemmas or concerns associated with research involving humans. The IRSST's Research Ethics Committee (REC) supports this process; it must decide on the ethical validity of research projects involving humans carried out by IRSST researchers¹.

This policy specifies the responsibilities and mechanisms for applying rules of ethics to IRSST-funded research involving humans. Its development was in keeping with the research ethics practices and policies adopted by different universities and research centres in Canada. In general, research ethics policies as well as the resulting procedures represent minimal

¹ In this document, the term researcher means both a scientific professional active in research and a research professional.



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expectations for research involving humans. They must be seen as an invitation to researchers to go even farther in their procedures.

A FEW GUIDING PRINCIPLES

In Canada, leadership relating to philosophical reflection and to the development of rules and procedures regarding research involving humans was taken on by the three research councils, namely the Medical Research Council of Canada (MRC), 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* is the current Canadian standard on the ethics of research involving humans.

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

This statement is based on eight guiding ethical principles that reflect the values of the entire research community. These guiding principles are presented in the box².

Guiding ethical principles

The approach taken in this framework is to guide and evoke thoughtful actions based on principles. The principles that follow are based on the guidelines of the Councils over the last decades, on more recent statements by other Canadian agencies, and on statements from the international community. The principles have been widely adopted by diverse research disciplines. As such, they express common standards, values and aspirations of the research community.

Respect for Human Dignity: The cardinal principle of modern research ethics, as discussed above, is respect for human dignity. This principle aspires to protecting the multiple and interdependent interests of the person -- from bodily to psychological to cultural integrity. This principle forms the basis of the ethical obligations in research that are listed below.

In certain situations, conflicts may arise from application of these principles in isolation from one other. Researchers and REBs must carefully weigh all the principles and circumstances involved to reach a reasoned and defensible conclusion.

² Taken textually from the Tri-Council Policy Statement (Statement, p. i.5, i.6 and i.7).



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Respect for Free and Informed Consent: Individuals are generally presumed to have the capacity and right to make free and informed decisions. Respect for persons thus means respecting the exercise of individual consent. In practical terms within the ethics review process, the principle of respect for persons translates into the dialogue, process, rights, duties and requirements for free and informed consent by the research subject.

Respect for Vulnerable Persons: Respect for human dignity entails high ethical obligations towards vulnerable persons -- to those whose diminished competence and/or decision-making capacity make them vulnerable. Children, institutionalized persons or others who are vulnerable are entitled, on grounds of human dignity, caring, solidarity and fairness, to special protection against abuse, exploitation or discrimination. Ethical obligations to vulnerable individuals in the research enterprise will often translate into special procedures to protect their interests.

Respect for Privacy and Confidentiality: Respect for human dignity also implies the principles of respect for privacy and confidentiality. In many cultures, privacy and confidentiality are considered fundamental to human dignity. Thus, standards of privacy and confidentiality protect the access, control and dissemination of personal information. In doing so, such standards help to protect mental or psychological integrity. They are thus consonant with values underlying privacy, confidentiality and anonymity respected.

Respect for Justice and Inclusiveness: Justice connotes fairness and equity. Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also concerns the distribution of benefits and burdens of research. On the one hand, distributive justice means that no segment of the population should be unfairly burdened with the harms of research. It thus imposes particular obligations toward individuals who are vulnerable and unable to protect their own interests in order to ensure that they are not exploited for the advancement of knowledge. History has many chapters of such exploitation. On the other hand, distributive justice also imposes duties neither to neglect nor discriminate against individuals and groups who may benefit from advances in research.

Balancing Harms and Benefits: The analysis, balance and distribution of harms and benefits are critical to the ethics of human research. Modern research ethics, for instance, require a favourable harms-benefit balance -- that is, that the foreseeable harms should not outweigh anticipated benefits. Harms-benefits analysis thus affects the welfare and rights of research subjects, the informed assumption of harms and benefits, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that attend proposed research. These realities and the principle of respect for human dignity



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impose ethical obligations on the prerequisites, scientific validity, design and conduct of research. These concerns are particularly evident in biomedical and health research; in research they need to be tempered in areas such as political science, economics or modern history (including biographies), areas in which research may ethically result in the harming of the reputations of organizations or individuals in public life.

Minimizing Harm: A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and societally important aims that cannot be realized without the participation of human subjects. In addition, it should be kept in mind that the principle of minimizing harm requires that the research involve the smallest number of human subjects and the smallest number of tests on these subjects that will ensure scientifically valid data.

Maximizing Benefit: Another principle related to the harms and benefits of research is beneficence. The principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in professions such as social work, education, health care and applied psychology. As noted earlier, human research is intended to produce benefits for subjects themselves, for other individuals or society as a whole, or for the advancement of knowledge. In most research, the primary benefits produced are for society and for the advancement of knowledge.

The IRSST adheres to these principles with the idea of making researchers responsible, and wants to ensure that research undertaken with its funding meets high level ethics standards. Thus, all the research projects or activities that are submitted to it and that involve human participation must receive an ethics certificate issued by a research ethics committee before being begun. The projects carried out by academics are submitted to the REC in their institution. Other research requiring human participation must be submitted to the IRSST's REC.

These principles must guide researchers in writing research projects as well as the members of the ethics committee during their evaluation of the ethical aspects of a research proposal.



OBJECTIVES

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

- ◆ promotes high ethical values in its research practices;
- ◆ establishes a reference framework in ethics for research involving humans;
- ◆ specifies the structure and mechanisms for applying rules of ethics.

APPLICABILITY

The ethics policy for research involving humans relates to all research (activity or project) funded by the IRSST or carried out by researchers associated with the IRSST requiring human participation.

SHARING OF RESPONSIBILITIES

The IRSST has the responsibility of ensuring that the fundamental rights of humans are respected in the research that it finances. However, the IRSST may have other reasons for refusing that certain research be carried out even if a project is evaluated positively for its ethical aspects.

● THE BOARD OF DIRECTORS

The adoption of this policy and any amendments that could be made to it is the responsibility of the IRSST's Board of Directors. The appointment of REC members is also its responsibility.

● THE EXECUTIVE

The President-Chief Executive Officer is responsible for the application of this policy. In doing so, she must:

- ◆ ensure that the REC has, within its organization, sufficient financial margin of maneuver and administrative independence to fulfil its obligations, and that its members are protected in the event of a disagreement.

● THE DIRECTOR OF THE RESEARCH AND EXPERTISE DIVISION

The Director of the Research and Expertise Division must:

- ◆ ensure, for research proposed by IRSST researchers, that the funding of any research project involving humans be conditional on its acceptance by the IRSST's REC, and in the case of research proposed by external collaborators, that the funding of research



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projects involving humans be conditional on its 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 be conditional on the acceptance of the entire project by one of the RECs of the different institutions to which the researchers involved in the research belong, and preferably that of the principal researcher;
- ◆ ensure, in the case of a research project being conducted in several institutions (so-called multicentre research) and when these institutions have an REC, that the funding of the project be conditional on acceptance by the respective RECs of these different institutions;
- ◆ ensure, when the external researchers do not have the necessary infrastructure for this, that the proposals be submitted to the IRSST's REC;
- ◆ define, if applicable, in the framework of certain files seen by the IRSST's REC, the steps in the project or the activity that must be the subject of a deliverable accompanying a report on the ethical aspects of the file;
- ◆ send the protocol or the activity specifications to an appeal committee in the case of disagreement with a researcher following a reevaluation of the file by the IRSST's REC;
- ◆ respect the REC's decisions.

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

IRSST researchers have the responsibility of:

- ◆ becoming familiar with this policy;
- ◆ applying the ethics rules prescribed in this policy in all aspects of their research;
- ◆ obtaining the required approvals from an REC before undertaking their research (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 properly carry out its mandate);
- ◆ informing the chair of the REC of any significant changes in the protocol as the research is being carried out.

It should be noted that the application of these rules does not release the researchers from the obligation of complying with the rules of professional conduct issued by their professional associations or corporations.



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- **RESEARCH COLLABORATORS**

- a) When the funded research is carried out totally by outside researchers (universities, research centres, consultants), the entire file is evaluated preferably according to the mechanisms of the principal researcher's institution. In such a case, the institution managing the research funds is responsible to the IRSST for ensuring that the research conducted by its researchers or graduate students is carried out according to the examination and follow-up mechanisms provided for this purpose; it is therefore responsible for issuing the required approvals, and if need be, for forwarding them to the IRSST.
 - ◆ If the managing institution has reasonable doubt as to whether the research is ethical, it has the authority to suspend the work on recommendation of the ethics committee and must inform the IRSST about this. In the case of multicentre research, the managing institution must determine whether there is a need to obtain an ethics evaluation in each of the centres and take the appropriate steps.
 - ◆ If a collaborator does not have suitable mechanisms for having his project evaluated by a research ethics committee, the IRSST's committee is responsible for examining the ethical aspects of the proposal.
- b) When researchers from universities, research centres or other institutions are associated with IRSST researchers in carrying out projects requiring human participation, the proposal must preferably be evaluated by the REC of the principal researcher according to the ethics evaluation rules prevailing in the institution to which he belongs.



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THE IRSST'S ETHICS COMMITTEE FOR RESEARCH INVOLVING HUMANS (REC)

• CREATION OF THE COMMITTEE

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

The REC's mandate is two-fold:

- ◆ It must evaluate the ethical validity of research projects requiring human participation carried out by IRSST researchers or by research collaborators without access to an REC;
- ◆ It must support the IRSST's personnel (researchers, professionals, research assistants, technicians and managers) when they express concerns about the ethics of research involving humans.

• COMPOSITION OF THE REC AND APPOINTMENT OF MEMBERS

All the members of the committee are appointed by the IRSST's Board of Directors for three-year renewable mandates. To ensure continuity of the committee, members are renewed by rotation.

The composition of the ethics committee is the following:

- ◆ two IRSST scientific professionals active in research or research professionals, with one acting as chair, and two scientists chosen from among our collaborators are selected so that all disciplines are covered; one community representative without IRSST affiliation, one person trained in ethics, as well as one person specialized in law.
- ◆ Two members, one trained in ethics and the other in law, will furthermore be designated as substitutes. The committee can also include any person likely to enlighten it on a specific file, or ask for the opinion of outside experts (scientific experts, etc.).

• THE REC'S RESPONSIBILITIES

The research ethics committee must operate in an impartial way and listen without bias to all the players. It has the following responsibilities:

a) Ethics evaluation:

- ◆ examine all research projects or activities requiring human participation;
- ◆ ask for modifications to the project to make it comply with research ethics;
- ◆ issue the IRSST's ethics certificates;



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b) Follow-up of approved research protocols:

- ◆ ensure that the REC's recommendation is forwarded to the project officer;
- ◆ ensure that the means established during the ethics evaluation of the different research projects are complied with;
- ◆ reevaluate the ethical content of the projects when they are modified during execution;
- ◆ receive and study complaints relating to the ethical issues of research involving humans carried out at the IRSST (such complaints must be forwarded to the chair of the committee who will inform the research ethics committee and obtain its opinion);

c) Continuing improvement process:

- ◆ propose means likely to promote compliance with the guiding 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;
- ◆ remain informed about the evolution of ideas and practices in the ethics of research involving humans;
- ◆ receive all the questions relating to this policy and the related rules as well as ensure that they are forwarded to the REC;

d) REC management:

To ensure the independence necessary for its operation, the REC is self-managed; nevertheless it must:

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



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THE RESEARCH PROTOCOL EXAMINATION PROCESS AT THE IRSST IS THE FOLLOWING:

1. The researcher in charge sends the CER chair a complete file (the complete research protocol or the activity specifications – including the components carried out by partners – and the related forms). The project must have received prior scientific evaluation by peers, according to the usual procedures.
2. A member of the REC, involved as a researcher on a project or as person in charge of a field, may be heard by the REC but must leave when the deliberations on the project take place.
3. So as not to unduly delay the start of a research project or activity, the ethics examination is done with diligence.

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

4. The committee's decisions, arrived at by consensus, may result in approval without modification, a conditional acceptance, or a reasoned refusal.
5. A quorum of 4 members, including the people specialized in ethics and law or their substitutes, is necessary for the committee to deliberate.
6. Ongoing research must be the subject of continuous ethics follow-up whose rigour must comply with the proportionate approach to ethics evaluation.

The continuous monitoring method is proposed by the person in charge of the project. It must include the obligation of reporting to the committee chair any significant change in the research protocol.

At the next meeting, the committee chair informs the REC members about it, and they decide, in light of the information provided, on the relevance of reviewing the complete file, and if need be, on continuing the work.

At the end of the project or activity, a report on the project's ethical aspects must be submitted. In the case where the project continues over several years, a report must be submitted at the end of each step defined by the Research and Expertise Division.

7. Throughout the research cycle, the person in charge of the project may ask to be heard by the REC. He must leave during the committee's deliberations. The committee can invite other members of the research team to attend a meeting before it renders its decision.



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8. For certain specific aspects, the ethics committee can use an accelerated process.

These cases are related either to the renewal of an approval, the minor modification of an already approved protocol, or any other reason considered valid by the committee's chair.

The approval of each protocol subjected to the accelerated process must, however, be confirmed during a regular meeting of the research ethics committee.

9. In all cases, regardless of the process used, the researcher in charge will be informed of the committee's decision by telephone, immediately after the meeting.

The committee's answer is forwarded in writing (5 working days) after this decision.

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

10. The researcher in charge of the project has the right to request a reevaluation of the committee's decision concerning his project and the committee must comply with this request.

When the researcher and the committee cannot agree, the committee's decision may be appealed.

The researcher must submit his appeal in writing to the IRSST's Director of the Research and Expertise Division within 15 working days following the committee's written response.

The entire file is then forwarded to an appeal committee. The justified opinion of this independent committee outside the IRSST is sent to the IRSST's ethics committee, to the Director of the Research and Expertise Division, as well as to the researcher in charge of the research. If need be, steps are taken to comply with the appeal decision.