



Institut National de Santé Publique, d'Épidémiologie Clinique et de Toxicologie
National Institute of Public Health, Clinical Epidemiology, and Toxicology

RESEARCH ETHICS COMMITTEE POLICY

AUGUST 2021

Research Ethics Committee Policy

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1. Background and Mission

The Research Ethics Committee (REC) at INSPECT-LB will implement ethical principles through advice on ethical issues, approval of proposals, and follow-up on research progression.

The main ethical principles are respect for persons, beneficence, justice, integrity, informed consent, confidentiality and data protection, and disclosure of any conflict of interest.

Research Ethics Approval Form, Informed Consent, Conflict of Interest, and other helpful documents are available to download from: <https://inspect-lb.org/research-templates/>

2. Definitions

2.1. Community-Based Research

Community-based research describes research that takes place in or involves a community.

2.2. Informed Consent

Informed consent is the process of telling potential research participants or their legally authorized representatives about the core elements of a research study and what their participation will involve. This process is one of the central components of the ethical conduct of research with human subjects. In research involving body sample collection or interventional procedures, a written informed consent document containing the required information and the presentation of that information to prospective participants are mandatory.

2.3. Conflict of Interest (COI)

A conflict of interest exists when professional judgment concerning a primary interest (such as the validity of research) may be influenced by a secondary interest (such as financial gain or personal competition). This form requires investigators to disclose three types of information:

- Associations with commercial entities that provided support for the work reported in the submitted protocol;
- Associations with commercial entities that could be viewed as having an interest in the general area of the submitted protocol; and
- Non-financial associations that may be relevant or seen as relevant to the submitted protocol.

2.4. Minimum Risk

Minimum risk means that harm risks anticipated in the proposed research are not higher than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3. Duties and Responsibilities

The duties and responsibilities of the REC are to:

1. Assign a REC number (yearREC-3-digit number-INSPECT-mm-dd*, e.g., 2021REC-001-INSPECT-09-04) and review the proposed research studies. **month and day of the first submission.*
2. Advise and formulate recommendations regarding the policies and procedures of research conductance, including insurance coverage for participants in interventional research.
3. Secure high ethical standards throughout studies, including:
 - a. Protection of human subjects and animals in research.
 - b. Safety of personnel engaged in research.
 - c. Security and privacy of all collected data.

4. Prerogatives

The REC has the prerogative to:

1. Approve a new research project*.
2. Put on hold for pending complementary documents or missing information. Tabled decisions do not imply provisional acceptance or rejection at this stage. Information or documents not submitted within a month will lead to the rejection of the application.
3. Reject with an explanation.
4. Discontinue ongoing research in case of a breach of ethical principles.

***Approved projects should be cited as follows:**

The Research Ethics Committee at INSPECT-LB approved the study protocol (20XXREC-XXX-INSPECT-mm-dd) as this work has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

5. Procedures

5.1. Chair and Members

1. The REC consists of five members from INSPECT-LB of different educational backgrounds, elected for a 3-year term.
2. The five elected members will vote for one of them to chair the committee for a one-year term.
3. The Chair calls for routine meetings, signs approved research projects, and disseminates final decisions to researchers.
4. All members should show commitment to all meetings and related activities.
5. The REC may opt to invite guests to specific meetings for further guidance and recommendations when deemed necessary.

5.2. Election of the Chair and Members

a. Election of the Chair and members of the first REC

1. INSPECT-LB Director calls for elections by e-mail to all INSPECT-LB members one month prior to the date of the elections.
2. Members willing to run for the elections should reply by e-mail within the deadline.
3. Eligible members should have at least five years of experience in research. Ethics diploma/certificate is a plus.
4. The electorate is made up of all INSPECT-LB members.
5. A simple majority of the voting members (50+1) will constitute the quorum. Excused members should be considered absent in the quorum count.
6. Members who obtain the highest number of votes will be elected for a three-year term.
7. In case of a tie, the vote of the INSPECT-LB Director counts twice.
8. The elected committee will vote for the Chair among its members.
9. The REC will designate one of its members as a rapporteur, responsible for administrative tasks.
10. Two of the members will resign after a two-year term, and elections will be held to elect two new members.

b. Election of the Chair and members after the first term

1. The REC Chair calls for elections by e-mail to all INSPECT-LB members one month prior to the date of the elections.
2. Members willing to run for the next elections should reply by e-mail within the deadline.
3. Eligible members should have at least five years of experience in research. Holding ethics diploma/certificate is a plus.
4. The electorate is made up of all INSPECT-LB members.
5. A simple majority of the voting members (50+1) will constitute the quorum.
6. Members who obtain the highest number of votes will be elected for a three-year term.
7. In case of a tie, the vote of the Chair counts twice.
8. The REC will designate one of its members as a rapporteur, responsible for administrative tasks.
9. Election of the Chair within the same term: all elected members have the right to run for the Chair position. Only current members will vote.
10. Election of the Chair for a new term: the new committee will elect the new Chair from the candidates running for this position.

5.3. Resignation of the Chair or Members

1. The Chair or any member willing to resign should inform the INSPECT-LB Director and REC of their decision at least one month ahead.
2. When the Chair resigns, a new Chair will be elected from the current committee members for the remaining term.
3. When a member resigns, the Chair will coordinate with all members to appoint a new member who will serve for the remaining term.
4. In case three or more members resign, then the current committee term will end, and new elections will be held as per 5.2.b. If all the candidates running for the new committee have never served on the REC, then the elections will be held as per 5.2.a.

5.4. Absence

1. Members absent for more than 30% of the time (within one calendar year) should be replaced by electing a new member after the Chair issues a written document.
2. A member who misses three consecutive meetings shall be considered duly resigned and will be replaced automatically by electing a new member after the Chair issues a written document.
3. The newly elected member will serve for the remaining term.

5.5. Meetings and Follow-Up

1. The REC will meet when needed.
2. Decisions will be taken by circulating e-mails to vote on projects approval.
3. Members should give their feedback within a week of receiving the e-mail.
4. In case a member does not answer within the deadline, implied consent is considered after one reminder.

5.6. Annual Report

The REC summarizes all the activities on a yearly basis and disseminates the report to INSPECT-LB members through the Director.