Clinical trials
Consent

Medical research must follow the rules of ethics. Participants in clinical trials must therefore be treated in the most ethical and responsible way possible.

For a research project to be ethical, the first step is to ensure that candidates give their **free and informed consent.**

Free means the consent is given voluntarily, under no constraint or pressure. No one is forced to participate in a clinical trial. Every person must have all the time they need to reflect on the decision they will take.

Informed means the research team must be sure that:

The candidates have received information that specifies:

- The goal of the clinical trial
- The name of the researchers leading the trial
- Who is paying the costs of the study (institutions, individuals, sponsors, etc.)
- The expected duration of their participation
- The nature of their participation (blood tests, urine tests, etc.)
- Participants' other responsibilities
- The potential advantages of participating in the clinical trial
- All the risks associated with participating in the trial that can reasonably be foreseen
- The fact that no candidate is obliged to participate and that they can withdraw consent at any time, without prejudice
- The fact that the results of the clinical trial could be used commercially
- How the clinical trial data will be shared and the possibility, if any, that participants' identities might be known

- The name and contact information for a resource person which can be contacted by participants
- The steps taken to protect the confidentiality of participants and their personal information
- The reimbursement of expenses and any other payments that could be made to participants
- The fact that consent does not mean waiving legal recourse if the participant is harmed because of the clinical trial

The candidates understand all the information provided

The language used to explain the clinical trial must be clear. Candidates must be able to ask all the questions they want. Before taking a decision, they must also have all the time they feel is necessary to reflect on the information received and discuss it with other people.

Candidates should be entirely comfortable with the way they take their decision. Clearly understanding all the information received and having the time to reflect on it allows candidates to take the best possible decisions.

The research team must ensure that the consent is **is valid for the entire time of the clinical trial.** This means that if the protocol, risks, or advantages change during the trial, the participants must be informed.

Any participant can withdraw consent at any time during a clinical trial without having to provide any explanation or justification. In such a case, the participant can request the removal of all their personal information or of all biological samples they provided for the purposes of the clinical trial.

The consent must be in writing. Usually, the candidate signs a form to this effect, in the presence of a witness. Written consent is required by Québec law (Québec Civil Code) and by the Code of ethics of physicians of Québec.

The **Quebec Cancer Consortium** for Novel Therapeutics and Biomarkers (QCC) is a **collaborative network** of four hospitals, with their respective research centres, and two university-based cancer research centres. **Its goals are to standardize and harmonize practices** in clinical and translational **research**, to **improve cancer treatment** by accelerating advances in precision medicine and immuno-oncology, and to **engage with cancer patients to develop educational material and raise awareness** of clinical trials of precision medicine and immunotherapies.

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