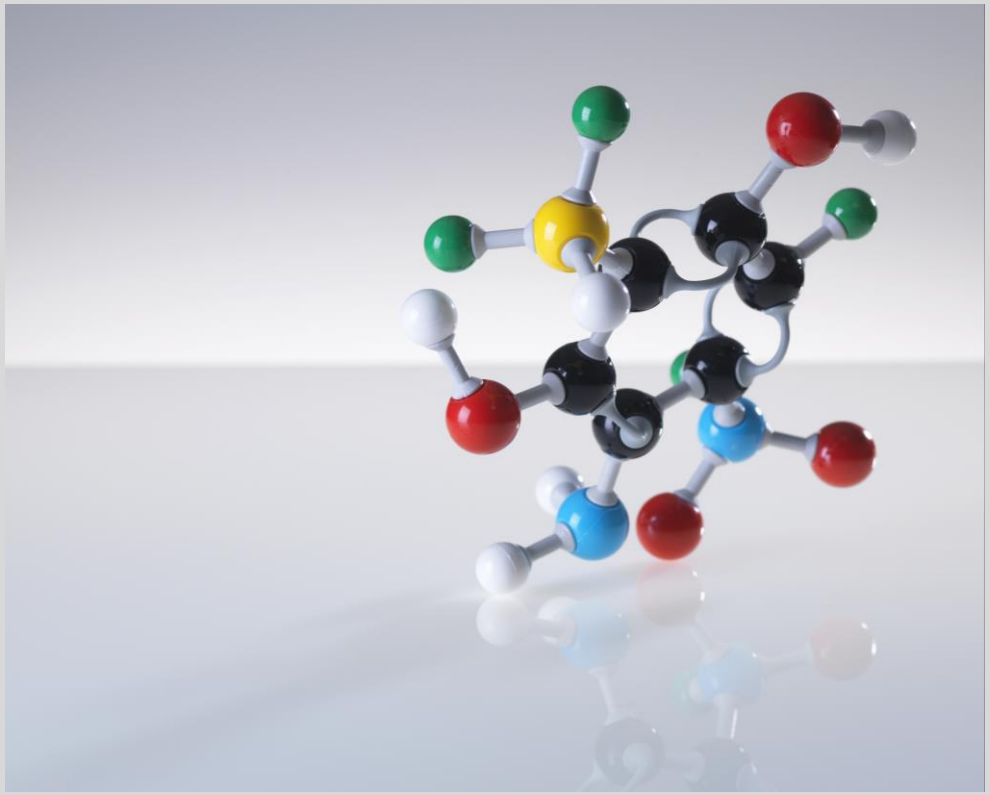
CONSENT

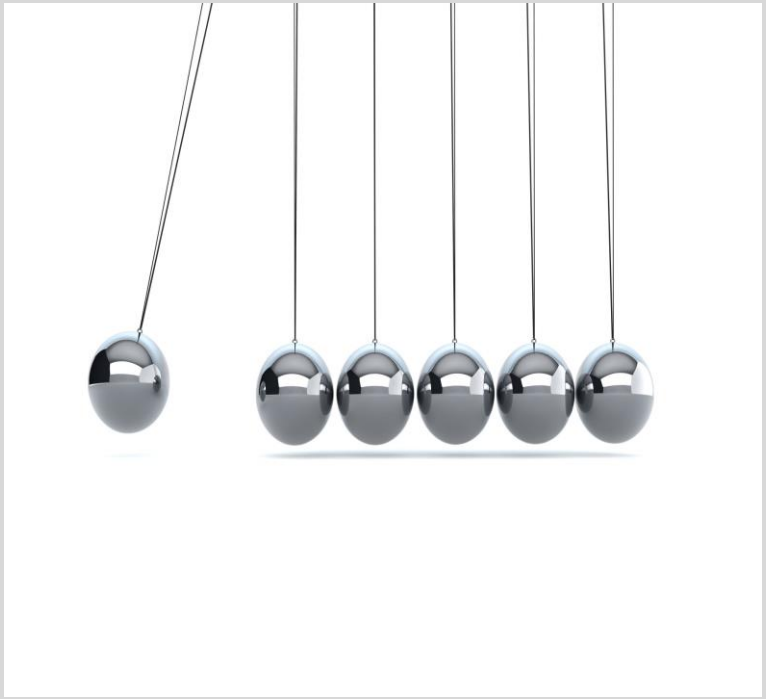
Ontario Cancer Research Ethics Board
RESEARCH ETHICS OFFICER
Alison van Nie

Central review board - OCREB

- Provincial/centre model – FB vs Delegated (one review)
- Review mandate: focus on multi-centre, high risk clinical oncology trials
- Multiple affiliated centres which delegate to OCREB
- Policies and procedures – compliant with all requirements
- Process for determining what requires review – i.e., requesting policies from affiliated institutions rather than a proposing a single OCREB policy for all



Ethical Principles of Consent



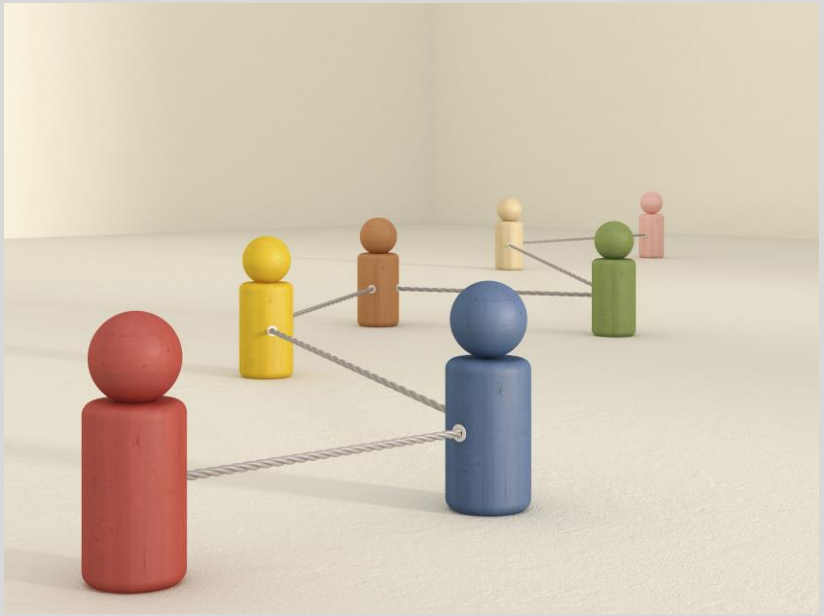
- The formal history of medical ethics is short.
- The discipline's foundation arose from the medical atrocities performed in the name of science by a group of Nazi doctors during World War II – of significance the lack of consent for the conduct of human subject research
- Consent is the foundational principle of research with humans
  - Equitable, knowledgeable, informed, voluntary, freely given without undue influence, coercion or prejudice
  - Not rushed, responsive to all questions, sensitive to the need to consult, relevant to the capacity of the person
  - Obtained prior to the conduct of any study procedures
  - Ongoing
  - Concern for welfare, engendering respect and representing justice
  - ensure compliance with TCPS2, Health Canada Division 5 (as applicable & ICH GCP), FDA & OHRP (as applicable)

ICH GCP E6(R3) draft

Freely given informed consent should be obtained and documented from every participant prior to clinical trial participation. For participants unable to provide informed consent, their legally authorized representative should provide consent prior to clinical trial participation.

The process and information provided should be designed to achieve the primary objective of enabling trial participants to make an informed decision on whether or not to participate in the trial. The informed consent process should take into consideration relevant aspects of the trial such as characteristics of the participants, the trial design, anticipated benefit and risk of medical intervention(s), setting and context in which the trial will be conducted (e.g., trials in emergency situations), and the potential use of technology to inform participants and obtain informed consent.

Remote/Virtual Consent



Apply the same principles

- Consider:
  - Access to potential participants
  - Email – consent for email/transfer of documents
  - Virtual via videoconference
  - Remote via phone/teleconference
  - Privacy/confidentiality requirements

- Obtaining consent:
  - Allow for time to consider, questions, provide ICF ahead of time
  - In-person meeting for introduction if feasible
  - Oral – witness for process of reading the consent to the patient - attestation
  - Signatures – a text or email of the signed/dated statement indicating voluntary acceptance of participation
  - Sent back securely or brought back in person
  - Signatures of study staff and copy to participant
  - Consent completed prior to the initiation of study procedures

Special Considerations for revising consent practices

- Evaluating the value in continuing enrolment
- Ensuring ethical criteria for consent are met
- Ensuring that participants are not disadvantaged if requests for interpretation or assistance with reading are required
- Collaborating with the sponsor, and the regulators
- Cooperating with institutional approaches and policies
- Expecting that the process may evolve/change
- Reducing the burden of associated changes for research staff

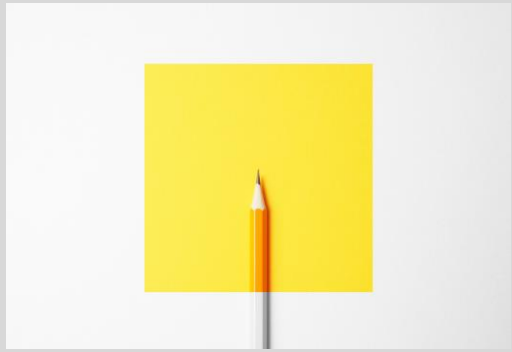
Pandemic-related research procedures

- Dealing with public emergencies – exposed/exacerbated practices
- Competing priorities, opportunities for change
- Reducing the burden for participants/centres/staff
- Planning for deviations
- Emphasizing flexibility
- Maintaining principles
- Responding to change
- Creating new policies
- Working within new regulations and guidance
- Evolving…..

Considerations

- the burden on resources due to the COVID-19 pandemic
- whether participants are at high risk of contracting the virus
- whether these changes still follow public health recommendations
- whether adding extra study sites and recruiting more participants should be halted or postponed
- when consent can't be obtained in person, sponsors should consider other methods, such as over the telephone, or Skype or video-teleconferencing.

Initial submissions



Initial submissions generally involve an in-person introduction to the study and in-person consent.

- *Is the study intervention significant from a clinical perspective requiring completion / continuation now? If not, is there consideration to suspend enrolment during the pandemic to ensure safety for the participants as well as for the staff or a rationale as to why enrollment should continue*
- *Ensure that the sponsor is aware and agrees to any remote consenting procedures and that all requirements for consent are met.*

Exception:

E.g., Verbal (telephone) Consent Process during COVID -19 Pandemic Situation

Potential study patients will be contacted via telephone and asked for their permission to continue the consent process via telephone.

If patient agrees, the research staff will explain the study and review all the aspects of the consent form via telephone with the patient – all questions will be answered. Once the patient provides oral consent it will be documented in the patient chart. The consent form will be e-mailed or mailed to the patient. Once the signed consent is obtained by the research staff, [mail/email] the participant will be registered to the study if all eligibility criteria are met. Study staff will sign the consent when it is returned to the centre and document the process. The participant also may sign the consent in-person at the centre. Consent will be obtained before any trial procedures are completed. A copy of the signed consent will be provided to the participant.

Example

The Research staff will review the study consent form with the participant in its entirety. Participants will have the opportunity to ask questions and will have their questions answered. Participants will be encouraged to discuss the consent/their decision with family and friends, etc. Research staff will telephone the patient to discuss their decision and to answer any questions. If the consent is signed remotely the document will be returned to the centre by mail or secure email, or the consent may be signed in person at the next in-person visit to the centre. The signed consent must be provided prior to implementing any study-related procedures.

As the current pandemic has highlighted the need to reduce visits within hospitals an **e-consent** will be implemented in instances where the participants do not provide consent during the in-person clinical visit. Electronic informed consent refers to using secure electronic systems and processes to convey information related to the study and to obtain and document informed consent. Once e-consent is received the research staff will contact the participant via telephone to confirm consent. Participants who provide consent at an in-person visit will provide their signature in person

Example

If the participant is unable to return to clinic to provide informed consent in person then the signature page of the informed consent may be faxed to the study coordinator. The fax number provided to the participant is an electronic fax number which is secure. The participant will return to the Centre as soon as possible to provide the original signed consent form. The study coordinator will document the entire consent process in their source document and sign the consent. The study participant will be given a copy of the signed consent form.

Ongoing submissions

Since this is a temporary measure in response to the pandemic, an amendment is not required; an explanation describing the plan to implement this remote/virtual consenting process is required to ensure that the required elements for consent are included in the process.

The following should be taken into consideration:

- How is the consent document provided to the participant and is the consent document reviewed with the participant prior to obtaining remote consent?
- Is the study intervention significant from a clinical perspective requiring completion / continuation now? If not, is there consideration to suspend enrolment during the pandemic to ensure safety for the participants as well as for the staff or a rationale as to why enrollment should continue
- If email communication with the participant is proposed as part of the procedure, consent for the use of email must be obtained and documented [follow institutional requirements]
- For centres with institutional policies regarding the use of email communication and virtual/remote consenting procedures, the policies should be submitted for pre approval
- Will a signature on the document be obtained and would a signed copy be provided to the participant? [this is a requirement] The process of obtaining the signature should be explained including the method for returning the document to the centre, providing the signature of the person obtaining consent/study staff, and providing a copy to the participant. [written signature on paper returned by mail, email or secure file transfer]
- When participants are enrolled using an alternative method to "in person" consenting (as noted in the initial application), the submission of a Centre Reportable event is required - as this is considered a deviation from the approved consenting process.

Re-imagining clinical trials

- Streamlining
- Engaging
- Satellites
- Distributive justice – expanded access to trials
- Using available technology wisely and effectively
- HC regulatory modernization

References

- Consultation: Health Canada's Clinical Trials Regulatory Modernization Initiative - Canada.ca
- Management of Clinical Trials during the COVID-19 pandemic: Notice to Clinical Trial Sponsors - Canada.ca
- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency Guidance for Industry, Investigators, and Institutional Review Boards January 27, 2021 https://www.fda.gov/media/136238/download