A primer on an Ethics committee’s role and responsibilities ...........................................2
  What is an ethics committee ................................................................................................2
  What is in a Research Proposal .........................................................................................2
Rights of Participants ........................................................................................................3
  Relationship with the participants ..................................................................................3
  Informed consent .............................................................................................................4
Role of an ethics committee ...............................................................................................6
Basic Definitions ................................................................................................................6
Questions to consider during review of protocols .............................................................7
  Informed consent: ............................................................................................................7
  Monitoring and observation: ..........................................................................................7
  Privacy and confidentiality: ............................................................................................8
Risk-benefit analysis: .........................................................................................................8
Selection of participants: ...................................................................................................8
Recruitment and Incentives: ...............................................................................................8
Categories of Approval ......................................................................................................8
Links ..................................................................................................................................10
A primer on an Ethics committee’s role and responsibilities

What is an ethics committee

An ethics committee makes moral judgments on behalf of people they represent or have an interest in protecting as some ethical imperative.

Ethics involve moral judgments, which consist of approving or disapproving of an action in such a way that we state our (dis)approval. Ethics is about judging research as good or bad. Judgments are based on the standard a culture uses for approving or disapproving an action.

Ethics is a systematic, reflective consideration of our moral beliefs & practices. In other words, it is a conscious stepping back and reflecting on morality. It is a “systematic” reflection because it is a discipline that uses special methods and approaches to examine moral situations. It is a “reflection” because it consciously calls into question assumptions about existing components of morality – habits, customs, traditions, beliefs, etc.

Research ethics are considered macro-ethical: and consider how one group of persons such as members of a community collectively treats other communities and individuals such as members of the group itself and non-members. Research ethics are also considered Normative as they provide prescriptive actions or guides based upon principles; these principles are used to resolve moral dilemmas.

Current normative ethical practices are based upon foundational ideas that are used as tools to allow for decisions to be made on research proposals. These foundational ideas include:

1. The Use of 5 principles to guide ethical decisions
   1.1. Non-malfeasance and benevolence – first do no harm, second prevent harm, third remove harm, and finally research must be beneficial, this component of ethics is a cost/risk/benefit analysis
   1.2. Autonomy – to allow the person to determine their own course in life (applies to informed consent, to be addressed later; includes the idea that research must respect and protect the rights and dignity of participants)
   1.3. Justice – must consider the social environment and the possible burdens and benefits to society
   1.4. Confidentiality – must provide an environment that will protect and ensure the anonymity of people.
   1.5. Fidelity and veracity – being faithful to these principles, what a reasonable person would do. Respect, competency, commitment to ethics, follow laws, honor whatever is agreed, etc.
   Veracity; veracity means that you will tell the truth and includes honesty. These values must be adopted by the research and the ethics committee.

What is in a Research Proposal

Research proposals must contain specific elements to be considered ethical research, these principles include;

(i) Essentiality; researchers must demonstrate that they considered existing literature/knowledge and its relevance, and alternatives to the subject/issue under study.
(ii) Maximization of public interest and of social justice: research should be done in an effort to benefit all society, guided by social justice and public interest.

(iii) Research projects must be committed and demonstrate the ability and commitment to complete the project. Researchers must demonstrate how there is the appropriate expertise, knowledge, ability and skill to complete the research.

(iv) Research must respect, protect the autonomy, rights and dignity of participants. Participants must volunteer and be informed of what they are volunteering for and their rights in regards to their participation.

(v) Participants identity must remain private, anonymous and in confidence. All information on participants must meet these guidelines.

(vi) All risks must be identified by the researchers; all research poses a risk to society and individual, researchers must demonstrate how they will mitigate these risks and what will happen if a risk is incurred, i.e. providing counseling.

(vii) Participants should be reimbursed for their time, people involved in research, participants, research assistants, and researchers, and community partners should be acknowledged participants should not be exposed to undue risk.

(viii) As research is a social activity researchers must demonstrate how they will make their findings available to the public, especially the participants and community partners.

(ix) Researchers must be accountable and transparent both in financial accounting and maintaining records and material related to the administration of the research project.

(x) Researchers are primarily responsible to meet ethical guidelines, the institutions that are affiliated to the research project are responsible to oversee that all ethical guidelines are met

**Rights of Participants**

**Relationship with the participants**

Participants should be seen as indispensable and worthy partners in research. Researchers should recognize and ensure that respect, protection and promotion of the rights of participants are made intrinsic to every stage and level of research undertaken by them.

Research undertaken should not adversely affect the physical, social and/or psychological well being of the participants. The risks and benefits of the research to the prospective participants must be fully considered; research that could lead to unnecessary physical harm or mental distress should not be undertaken. Researchers should make adequate provision for the comfort of the participants as well as for protection against all possible and potential risks.

The criteria for selecting research participants should be fair. The easy accessibility of the participants alone does not constitute a fair criterion for their inclusion in research as that will make them bear an unfair share of the direct burden of participation. At the same time, it should be borne in mind that no particular group or groups should be unfairly excluded from research, as that could well exclude them from the social understanding of their situation, and can also unfairly exclude them from direct, indirect or potential benefits of research.

The relevant social, cultural and historical background of the participants should be taken into consideration and given appropriate importance in the planning and conduct of research. Researchers should not impede the autonomy of participants by resorting to coercion, promise of unrealistic benefits or inducement. Participants and communities should not be exploited and the time taken for data collection from these sources should not be inordinately long.
Participants are autonomous agents and must have the right to choose whether or not to be part of the research. They also have the right to change their decision or withdraw the informed consent given earlier, at any stage of the research without assigning any reason.

**Informed consent**

Voluntary and informed participation of individuals or communities is necessary for research. Their participation should be based on informed consent; the greater the risk to participants, the greater is the need for it. Informed consent is essential to protect the participants, not the researchers and institutions. Consent for participation in research is voluntary and informed only if it is given without any direct/indirect coercion and inducement, and is based on adequate briefing given to the participants about the details of the project. The briefing should be given both verbally and in writing in a manner and language that the participants know and understand. Researchers have a duty to ensure that the participants comprehend the information given. The verbal and written briefing of the participants, in the manner and language they understand, should include the following details:

(i) **Purpose of research**: The goal and objective of research should be presented in plain language.

(ii) **Identity of the researchers**: Name and address of researcher(s), the institution(s) and the main person of the ethics committee/ethical review board or any such ethics group of the institution.

(iii) **Identity of others associated with the research**: Name(s) and address of chief consultant(s), funder(s) or sponsor(s), etc., if any.

(iv) **Why selected**: Reasons or method for selecting the particular locality, community and/or any other setting; and individual(s) or group(s) within that, for participation in the study.

(v) **Harms and benefits**: The possible, anticipated and potential benefits and/or harms (direct/indirect, immediate/long term) of research and their participation.

(vi) **Privacy, anonymity and confidentiality**: Information on the extent of privacy, anonymity and confidentiality that will be provided to participant(s). This must include, at least, the firm commitment that privacy, anonymity and confidentiality of data identifying participants will be strictly maintained. In case the data identifying participants is to be shared with or made available to individuals/organizations not in the research team, information about them (their names, addresses etc.) should be provided.

(vii) **Future use of information**: The future possible use of the information and data obtained, including use as a database, archival research or recordings for educational purposes, as well as possible use in unanticipated circumstances, like its use as secondary data should be made known to participants. Such use should be only of anonymous or abstracted information and data, and should in no way conflict with or violate the maintenance of privacy, anonymity and confidentiality of information identifying participants.

(viii) **Right not to participate and withdraw**: Participants should also be informed about their right to decline participation outright, or to withdraw consent given at any stage of the research, without undesirable consequences, penalty and so on. The participants should be informed that they are free to object to and refuse to allow the use of data gathering devices, such as camera, tape recorder, etc.

(ix) **Right to get help**: The researcher should try and get all the possible help that the participants might require. The researcher also has a responsibility to help the participant(s) in cases of adverse consequence or retaliation against the participant(s) by any agency due to their participation in the research. Information, which may contribute to the improvement of quality of life of the participants, should be passed on to concerned person(s), official(s) or the agencies.

If the data collection from the participant(s) is done in more than one sitting or contact and there is a long time period between the sittings/contacts, informed consent should be sought each time. In some cases, revealing the identity of the group of participants, groups, village(s), neighborhood(s), etc, in the report could have an adverse effect on members/residents there. Sometimes the researchers are not able to anticipate the possibility of adverse effect at the time of conducting research and
publishing reports. Researchers should take care that the study communities and/or localities are not identified or made identifiable in the report unless there are strong reasons for doing so. If the researcher(s) and institution intend to identify them in the report, participants’ informed consent allowing such disclosure should be obtained.

*Non-disclosure of all information:* In some specific situations and research issues, it is not practically possible to carry out research if all the details of the study are revealed to participants. This may be due to genuine difficulties in accessing participants, possibility of affecting change in behavior or responses, etc., when the details are revealed. Thus, it is not possible to obtain the informed consent in the same way as described above. In such cases, the following should be done:
(i) A detailed justification for not revealing all necessary information must be provided in the research proposal and methodology and should be subject to peer and ethical reviews. Only on approval in peer review, should such research be undertaken.
(ii) The participants’ right to privacy, anonymity and confidentiality gains additional importance in such cases as they do not know fully the real purpose or objective for which they provide information.
(iii) Even if through a peer review process it is accepted that some of the information about the study need not be revealed, participants must be provided the rest of the information. Under no circumstance should the researchers withhold the information regarding risks, discomfort, unpleasant emotional experiences, or any such aspect that would be a major factor in taking the decision to participate.
(iv) As far as possible, debriefing should be done with the participants after completion of the research, giving reasons for not providing full information. As a part of the debriefing process, it might often be necessary to provide services such as counseling and referral.

*Consent where gatekeepers are involved:* In some situations there may be a need to obtain permission of the ‘gatekeeper’ to access the participants for research. The following care must be taken in such situation:

Gatekeepers are those who control researchers’ access to participants. They could be persons in-charge of research setting, a community leader whose advise or instruction the participants follow, or any other without whose consent the researchers are unable to obtain access to participants. Such as child abuse. Peer review is indispensable and the protection of children especially from the immediate consequences of research gains prime importance.

(i) Permission obtained from the gatekeeper must not be substituted for the need to take separate and full informed consent of the participants. The rights of participants in such situation are the same as in all other cases and need determined protection.
(ii) For obtaining permission of the gatekeeper, no pre-condition demanding sharing of information or data obtained should be accepted.
(iii) In the process of research or data collection, adequate care should be taken to ensure that the relationship between the gatekeeper and the participants is not jeopardized.
(iv) Greater care should also be exercised in protecting participants and their interest while publishing and disseminating results of research.

Informed consent in the case of research with children (below the age of 18 years) should be sought from the parents/guardians as well as the children themselves. Where the parents/guardians consent to participate, and the children have declined, the rights of the children should be respected. The consent from parents/guardians should be waived only in special cases

*Privacy, anonymity and confidentiality*
Anonymity and confidentiality are the inherent rights of all participants. The right whether to remain anonymous or to be identified lies with the participant. It becomes all the more important in research
projects dealing with stigmatized, sensitive or personal issues and information. Possibility of the breach of confidentiality and anonymity should be anticipated, addressed and explained to the participants. Appropriate methods should be devised to ensure privacy at the time of data collection. These methods are also essential to ensure the validity of data.

The obligation to maintain privacy, anonymity and confidentiality extends to the entire research team, other researchers in the institution, the administrative staff, and all those (from or outside the institution) not directly associated with the research who may possibly have access to the information. While deciding on what information should be regarded as private or confidential, the perspective of the participant(s) on the matter should also be given adequate importance. Researchers should maintain appropriate anonymity and confidentiality of information in creating, storing, accessing, transferring and disposing of records under their control, whether these are written, automated or in any other medium.

**Role of an ethics committee**

Research proposals must be cleared by the ethics committee and must provide initial review of the project to ensure that ethical guidelines are met, provide advice on project. Scientific evaluation should be completed before ethical evaluation.

Adequacy of documentation for ensuring privacy, confidentiality and justice issues

The ethical review should be done through formal meetings and should not resort to decisions through circulation of proposals.

- Evaluate annual progress of ongoing projects, assess final reports of all research activities
- Decision making by building broad consensus
- Members must voluntarily withdraw during conflict of interest
- Ethics committees can reverse its decision on a research project after receiving information that will adversely affect risk -benefit ratio.

The ethics committee should be cognizant of:

- Any amendment to the protocol from the originally approved protocol with proper justification.
- Serious and unexpected adverse events and remedial steps taken to tackle them.
- Any new information that may influence conduct of the study.
- Meetings must be minuted and approved and signed by chair and kept confidential.

**Basic Definitions**

- **Research**: systematic investigation designed to develop or contribute to generalized knowledge
- **Human subject** (participant): living individual with whom a researcher obtains data.
- **Informed consent**: the process during which individuals are educated about the nature of research and make a knowledgeable and voluntary decision regarding participation.
- **Benefit**: a valued or desired outcome.
- **Minimal Risk**: when the probability and magnitude of anticipated harm or discomfort is not greater than that ordinarily encountered in daily life/during routine physical or psychological exams/tests.
- **Privacy**: the extent to which an individual has control over the timing, extent and circumstances under which they interact with others (pertains to methods used to collect information).
- **Confidentiality**: the way in which information that is disclosed in a relationship of trust is treated – the understanding that this information will not be divulged to others in ways that are contrary to the agreement at the time of disclosure (pertains to how collected information is treated/shared).
- **Monitoring**: On-going collection and analysis of data to ensure that the research design and protection of participants is sufficient.
- **Review**: Oversight of research by ethics committee on a periodic (at least an annual) basis.
- **Morality**: Morality refers to the first-order beliefs and practices about good and evil by means of which we guide our behavior. Morality is made up of a lot of values and duties based on beliefs that people take for granted most of the time. Values describe certain qualities that constitute “a good life”. Duties describe actions in response to claims that are either self-imposed or imposed by others. Personal morality is made up of values and duties adopted by individual as relevant. Large component of personal morality represents a common denominator of shared belief about values and duties called societal morality. Morals are culturally, ethnically, class or geographically generated. Morality of a strata/group of society is group morality.

<table>
<thead>
<tr>
<th>Ethical principle as described in</th>
<th>Belmont Report</th>
<th>Meaning Aspects for IRB review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respect for individual autonomy</td>
<td>Protection of individuals with reduced autonomy</td>
<td>Beneficence &amp; non-malfeasance Maximize benefits &amp; minimize harms Risk/benefit analysis</td>
</tr>
<tr>
<td>Informed consent</td>
<td>Protect confidentiality</td>
<td>Justice Equitable distribution of research burdens &amp; benefits</td>
</tr>
<tr>
<td>Scientific merit</td>
<td>Justice Equitable distribution of research burdens</td>
<td>Justice Equitable distribution of research burdens &amp; benefits</td>
</tr>
</tbody>
</table>

**Questions to consider during review of protocols**

**Informed consent:**
- Does the study involve a vulnerable population?
- Are the risks and anticipated benefits clearly explained?
- Is the language and presentation of information appropriate for the study population? Is translation from English required?
- Can individuals make decisions about consent under the described conditions?
- Who will ascertain consent? Is the presence of a third party necessary?
- Should consent be ascertained periodically over the course of the study?
- Should the IRB monitor the information provided to potential participants to determine its sufficiency? Who will facilitate this?
- Is a waiver of consent requirements justified? Does the study pose a greater than minimal risk? Will additional information be provided at completion? “The IRB may waive the regulatory requirement for written documentation of consent in cases where: (1) the principal risks are those associated with a breach of confidentiality concerning the subject’s participation in the research (e.g., studies on sensitive topics such as drug abuse or sexual deviance); and (2) the consent document is the only record linking the subject with the research

**Monitoring and observation:**
- How will data be recorded and maintained?
Will researchers be monitoring the research? Is their plan adequate? Is the principal investigator full time on the project (or is there an appropriate individual for oversight)?
Is there a mechanism for researchers to update the IRB in the event of unexpected developments?

**Privacy and confidentiality:**
- Would the research be considered an intrusion and would individuals be offended? Are there ways to reduce this? Does the aim of the study justify this intrusion?
- Will sensitive information (e.g., information regarding alcohol or drug use, illegal conduct; or issue that could lead to social stigmatization) be collected?
- Are there sufficient provisions for protection of confidentiality? Who will have access to data?
- Are researcher’s statements to participants regarding confidentiality sufficient?

**Risk-benefit analysis:**
- Are risks and anticipated benefits accurately identified, evaluated, and described?
- Are risks greater than minimal risk?
- Has attention been paid to minimizing risk and maximizing likelihood of benefits?
- Are there adequate provisions for monitoring risks and benefits? Is a data safety monitoring committee required?

**Selection of participants:**
- Do participants belong to group that is most likely to benefit from the research?
- Is participant selection justified?
- Will the research pose an unfair burden for potential participants?
- Are there procedures to minimize the pressures on potential participants?

**Recruitment and Incentives:**
- Will informed consent be possible given the recruitment strategies employed?
- Are incentives required – given the demands of participation and the study population?
- Are incentives offered reasonable? Will they pose an undue influence for participation?

**Categories of Approval**
Ethics Review would have ONE of the TWO following outcomes:

(A) The investigators can begin the study without submitting additional information to the ethics committee.
(B) The investigators may not begin the study until additional information is provided. Based on the discussion during the review process, one of the following five categories of approval is applied to each application:

In the case of (B), ONE of the following FIVE categories are applied (including denial):

(a) Study can begin and approval letter is issued:
1. Straight Approval Or Approval With Comment:
   1.1. Granted when the Committee has no questions about the application.
   1.2. The members may, however, make comments about this approval or recommendations for future submissions. Such comments will be included in the approval letter itself.
2. Conditional Approval:
2.1. Granted when the Committee approves an application with conditions and the members recommend, but do not require, a response to those conditions.

2.2. Such conditions usually involve changes in the consent form; however, the members are willing to allow the study to be conducted even if no changes are made.

2.3. Conditional approval can also be given, for example, if an investigator is asked to submit a finalized version of a questionnaire or letters of support from others including institution’s departments cooperating in the research.

2.4. Conditional approval may not be given if government/legal requirements are not met.

2.5. Conditions will be explained in the approval letter. Once the investigator responds to the conditions, a letter is sent out that indicates the conditions have been removed; however, no new approval letter is generated.

2.6. Study cannot begin until committee’s concerns or required changes are communicated in writing, the investigators respond to the concerns or requested changes, and the response is approved.

3. Contingent Approval:

3.1. The Committee approves the study in principle.

3.2. However, the members require a written response from the investigator regarding particular items of concern. The members may ask the investigator to: (a) clarify a point, (b) provide further information, (c) make revisions in, for example, the protocol, recruitment, and/or consent form.

3.3. Normally, only Chairperson reviews the response from investigator. The Chair has the option of sending the response to the Full Committee or a Subcommittee. At this stage as far as possible, no new or additional issues should be raised unless (a) it is found that some aspects of government/legal requirements were overlooked during the Committee review and/or (b) in the opinion of the Chair, the new or additional issue is of high importance and was inadvertently overlooked during the Committee review.

3.4. No approval number is given until the questions and/or concerns of the Committee have been satisfactorily addressed and approved by the Chair.

4. Returned For Additional Information:

4.1. Committee is not prepared to approve the study without additional information and review.

4.2. Requested when serious concerns are raised about the risk/benefit ratio or other issues of participants’ protection and the members agree that additional information, justification, or changes are needed before approval can be reconsidered.

4.3. The Committee members have explicitly asked that the study be returned to them for additional review.

4.4. The investigator must respond to this request in writing and then the Full Committee or the Subcommittee reviews this response depending on the decision of the members or Chair.

4.5. If the revised proposal meets the requirements, it is granted contingent, conditional, or straight approval at the time of the second review. However, the study may be returned again if the members request it.

5. Denial Of Approval:

5.1. Committee disapproves the study in principle.

5.2. Denied approval because members’ concerns for the protection of the participants have not been satisfactorily addressed even after the revision.

5.3. Before the proposal/project is denied approval, the Committee must invite the investigator to present his/her views/justification and the same are discussed by the members of the Committee with the investigators and among themselves.
Not for circulation, confidential

**Links**

http://www.pre.ethics.gc.ca/english/tutorial/
http://www.heretohelp.bc.ca/publications/aboriginal-people/alt/2
http://www.who.int/eth/Ethics_basic_concepts_ENG.pdf
http://epi.berkeley.edu/ERB%20Resource.pdf