# *TEMPLATE FOR ESTABLISHING RESEARCH ETHICS COMMITTEES IN THE CARIBBEAN*

- *A Recommendation by the Bioethics Society of the English-speaking Caribbean (BSEC)*

## Preamble

Health research in Caribbean countries is necessary for the improved health of citizens, but research involving human participants requires safeguarding the rights and welfare of the participants. The primary interest of researchers is the creation of scientific knowledge, which is generally not understood by the participants in research endeavours. In the research process, therefore, there are fundamental inequalities of knowledge and power, and research ethics committees have the mandate to ensure that all the ethical requirements for research with human participants are met by all researchers. However, some Caribbean countries do not as yet have established committees for the ethical review of research studies.

As a part of its mission to spread bioethics across the English-speaking Caribbean, BSEC hereby provides a template for establishing committees to review research protocols and provide the oversight of on-going research, which Caribbean countries may adapt to their particular needs.

## Composition of Research Ethics Committees - RECs

RECs across the Caribbean should ideally comprise 5 – 12 members. Committees fewer than 5 members may find it difficult to achieve the required three (3) categories of representation (mentioned below) at each meeting, while administration of those with more than 12 members might prove unwieldy.

Three (3) categories of persons should be represented on each committee:

1. Persons representing the lay public. (In the case of research involving human beings, such representatives should preferably be chosen from the community or group to be researched and should be present and voting at all committee meetings where decisions regarding the particular research protocol are to be taken).
2. Persons who have been trained in the scientific methodologies used in research.
3. Persons who have received some training in the ethical evaluation of research protocols.

The REC might also benefit from the inclusion of a statistician and a lawyer, but their inclusion is not imperative. While discussions may occur at any committee meeting, no decision regarding the merit of a particular research protocol should be taken unless at least one person from each of the three (3) categories in the composition of the REC is present, or, in absenture, such persons have formally submitted to the committee meeting their written response concerning the research proposal(s) to be assessed.

## Mandate and Terms of Reference for the Committee

The Chief Medical Officer (CMO) and the country's Ministry of Health are the custodies for the health and welfare of the inhabitants of their particular Caribbean country. Accordingly, CMOs and Ministries of Health should support the establishing and work of Research Ethics Committees within their countries to protect the welfare of their citizens. The work of the REC would be supported by each country's laws governing public health and safety.

However, for transparency and mitigating conflict of interest, the Chairman of the REC should be independent of the government or the institution in which the REC functions. Decision-making by the REC should be achieved ideally by consensus, as discussion and dialogue allow points of view and perspectives that might lead to a common understanding and agreement.

The needs of the particular country will determine the specific details regarding the REC's administration and its work.

## The Ethical Requirements for research with human participants

For a research programme involving human participants to be considered "ethical", it must meet all the following seven (7) requirements for research with human participants:

1. **Value.** The research project must be scientifically or socially valuable (e.g. improved health-related infrastructure, capacity-building). It could also lead to an increase in the body of knowledge available to policy makers, program managers, health practitioners, or the general public.
2. **Scientific validity.** The research must be conducted in a rigorous and valid scientific manner.
3. **Fair subject selection.** The participants in the research should be chosen only because of their relation to the subject being researched, and not because they are easily accessible.
4. **A favourable risk/benefit ratio.** A person's participation in research should be accompanied by a favourable balance of potential benefits and potential harm.
5. **Respect for persons.** This requires that a person's choice be respected, and that persons incapable of making their own choices be protected. It also includes respect for a person's right to withdraw from the research process, and confidentiality of personal information.
6. **Informed consent.** All the requirements for "informed consent" should be met.
7. **Independent review of the research.** All research should be subjected to review by a group of persons independent of the researchers, before the start of any research.

An eighth ($8^{th}$) requirement exists when the research involves international collaboration:

8. **Collaborative partnership.** Overseas and local collaborators share the responsibility for determining the health problem and value of the research to the local community, for respecting the community's values and traditions, and ensuring that the enrolled participants and the community receive fair benefits from the conduct of the research.

## Fundamental considerations necessary in research with human participants

A. ***The scientific design of the research.***

A clear scientific objective should be stated, the methodology should be valid and practically feasible, sufficient sample size (for adequate statistical power and representativeness) should exist to achieve the objective, a plausible plan for data analysis should exist, and the research process should be able to be implemented.

B. ***The care of participants.***
The welfare of participants should be carefully monitored throughout the period of their involvement in the research, and they should be provided appropriate treatment for any untoward event or severe adverse reactions resulting from the research.

C. ***The ethical and scientific standards and practices of the communities within which the proposed research will take place.***
Researchers should be fully aware of the foregoing.

D. ***The contribution that the research can make to health.***
While respecting the role of serendipity in research discoveries, the proposed research should be responsive to the health needs of the community within which it will occur, and should reflect the priorities of that community. Further, the principle of justice requires that any product developed as a result of the research in a particular community, should be made reasonably available to the inhabitants of that community *(ref. CIOMS).* In international research and/or research for financial gain, host communities should also ensure that they realise improvements in health-related infrastructure, proportional financial investments in the community's health, and/or capacity-building benefits from the research endeavour.

E. ***Avoidance of unethical conduct.***
Researchers should avoid all forms of unethical conduct in the proposing, performing, and reporting of the research.

F. ***Reporting of conflicts of interest.***
All potential conflicts of interest (e.g. personal, financial, career) should be reported on the submission of the research protocol.

G. ***Vulnerable populations.***
Special safeguards are necessary where research is proposed to involve vulnerable persons, including: children, prisoners, pregnant women, the foetus, persons living with HIV/AIDS, the mentally impaired, substance abusers, the elderly and terminally ill patients.

H. ***On-going monitoring of research.***
For proposed research involving *more-than-minimal risk* (see description of categories below), independent and on-going monitoring of the research project should be done by the research ethics committee. The principal investigator/researcher also has the obligation to provide monitoring information to the committee, particularly of any adverse events on a predetermined basis.

**Levels of risks:**

**Minimal risk:** The least possible risk. This risk describes procedures such as questioning, observing and measuring participants in an area or subject that is not controversial, provided that the procedures are carried out in a sensitive way, and that consent has been given. Other procedures with minimal risk include collecting a single urine sample, or using blood from a sample that has been taken as a part of treatment.

**Low risk:** This describes procedures that cause brief pain or tenderness, or small bruises and scars. Many children fear needles and so for them low rather than minimal risk are often incurred by procedures involving injections and venepuncture.

**High risk:** Procedures such as lung or liver biopsy, arterial puncture, and cardiac catheterization are not justified for research purposes alone. They should be carried out only when

research is combined with diagnosis and treatment intended to benefit the research participant concerned.

## Guidelines for the Content of Research Protocols

The following information should be included in research protocols:

1. **TITLE OF THE PROPOSED RESEARCH**
2. **DATE** (and Version – if there has been a previous submission)
3. **NAME AND ADDRESS (Postal and E-mail) OF ALL THE INVESTIGATORS, COLLABORATORS, AND/OR SUPERVISORS** (starting with the principal investigator). *Indicate which parts of the protocols each investigator will be responsible for, who will actually carry out any procedure on participants, and where appropriate, what training they have had.*
4. **SITE/S OF RESEARCH** (Attention should be paid to the facilities available for participants' comfort, and availability of emergency procedures in the event of an unanticipated occurrence).
5. **NUMBERS OF RESEARCH PARTICIPANTS TO BE ENROLLED**
6. **PROPOSED DURATION OF THE STUDY**
7. **A SUMMARY OF THE PROPOSED STUDY** – Not more than 250 words and should include:
   - ***I.*** *The hypothesis and scientific basis or justification for the study*
   - ***II.*** *The usefulness and significance of the study*
   - ***III.*** *An outline of the study design*
   - ***IV.*** *An indication of steps taken to ensure and maintain confidentiality*
   - ***V.*** *An assessment of the benefits (to participants and/or groups in the community or the entire community) and the risks*

8. **THE PROJECT PROPOSAL** – To include:
   A. An introduction and background information on the research topic
   B. A clear statement of the objectives of the research proposal
   C. The justification for the research *(This should include review of the current knowledge from the literature on the topic, with an explanation why this project is necessary, and how it will contribute to the overall knowledge in this area)*
   D. Materials and methods
   These include:
   - Details of procedures to be performed *(e.g. volume of blood, the frequency, timing, and possible site of the blood-taking; any drug administration, physiological measures, etc.)*
   - Which procedures may cause pain and/or discomfort for research participants
   - Choice of participants, inclusion/exclusion criteria, number of participants (and, where appropriate, a justification for that number), any controls, etc.
   - A statement that participants were selected only because of the specific problem under investigation, and not because of their easy availability, diminished autonomy, or any social bias.

   E. The name, address, telephone and fax numbers, as well as email address of a contact person
   F. A statement confirming that reasonable time will be given for the participant to consider his/her involvement
   G. Procedures for obtaining informed consent, including statements that the researcher/s will read the informed consent form to the participant or his/her legal guardian and will provide that person with a copy of the form, that questions from the person will be invited, and that all efforts will be made to ensure that s/he understands its content before the seeking of consent
   H. A copy of the informed consent form (see details below)
   I. Methods to protect the confidentiality of participants, and methods to ensure that a participant who opts out of a research endeavour is well protected as far as normal health care delivery is concerned

J. Methods for data collection and analysis
K. Assumptions made
L. Relevant references (i.e. literature citation)

9. **THE INFORMED CONSENT FORM** should include the following:
   a. Statements in language written for comprehension by the lay person outlining the purpose of the research, what will be done in the research study, and indicating that this has been explained orally and in writing to the participant (or the participant's parent or legal guardian – if a child) who understands what will be done. These must be countersigned by the participant or his/her legally authorized representative;
   b. Explicit statements about risk or discomfort to the participant, with an assessment of the degree of risk, and viable alternatives;
   c. A statement that the participant's involvement is voluntary, and that refusal to participate or (if after having agreed to participate) withdrawal from the study at any time will not affect the participant's access to or the type of care to which s/he is entitled;
   d. The name, address, telephone and fax numbers, as well as email address of a contact person for any queries;
   e. A statement confirming that reasonable time will be given for the participant to consider her/his involvement;
   f. Statements that the participant or her/his legal guardian has read the informed consent document, or that it has been read to her/him, and that s/he understands its contents; that a copy will be given to the participant; and that the signature of the participant or the legal guardian indicates that s/he has freely agreed to participate;
   g. The signature of a witness to the consent procedure who is **not** connected to the research undertaking

10. **DECLARATION OF CONFORMITY WITH GUIDELINES**
    A statement that all principles enunciated in the **Guidelines for the Conduct of Research involving Human Participants** by the Bioethics Society of the English-speaking Caribbean (BSEC) has been complied with (Guidelines available at the website: www.bioethicscaribe.org.jm)

*Guidelines adopted by: The Bioethics Society of the English-speaking Caribbean (BSEC)*
*20/6/07*

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