

**MINISTRY OF HEALTH, JAMAICA
GUIDELINES FOR THE CONDUCT OF RESEARCH
ON HUMAN SUBJECTS**

INTRODUCTION

Researchers (academics, scientists, students) have the responsibility to adhere to the highest ethical and scientific standards in formulating, conducting and presenting research. Researchers/investigators have the responsibility to:

- Ensure that the welfare of human subjects participating in research is safeguarded.

- Respect **all** ethical principles in research, including:
 - a. The research participants' rights to privacy and confidentiality of research and information
 - b. The right of subjects to information on experimental procedures
 - c. Participants' psychological well-being
 - d. Respect for participants' social stability

**PROCEDURES FOR GOOD ETHICAL PRACTICE IN
RESEARCH WITH HUMAN SUBJECTS**

1. Research protocols (proposals) should
 - i. Explicitly state all potential benefits (direct or indirect) and all possible risks or advantages to the participants in the study;
 - ii. provide the exact description of the nature of participation to be given to the participants in the study;
 - iii. Indicate when it will be communicated orally and in writing

The information should include:

- The objectives and **purposes** of the study
- Any **experimental** procedures
- Any known short or long term **risks**
- Possible **discomforts**
- Expected **benefits** of the procedures used
- **Duration** of the studies
- **Alternative** methods for treatment (if the study is a clinical trial)
- **Suspension** of the study if there is a finding of significant negative effects or if there is sufficient positive effects that continuing with the study cannot be justified
- Freedom of participants to withdraw from the study if desired

2. Researchers/Investigators should:
 - i. Indicate any special incentive or treatment that subjects will receive through their participation in the study and why. If there is any type of remuneration, they should specify the amount, method of delivery, time and reason why payment is required.
 - ii. Indicate how the information obtained from participants in the study would be kept confidential
 - iii. List any drugs, vaccines, diagnostics, procedures, instruments or other devices to be used, and state whether they are approved/not approved, new or currently being used in Jamaica.
 - iv. Provide a brief synopsis of how the findings of the research would be reported and delivered to the participants in the study and other interested parties, including the Ministry of Health.
 - v. Indicate and justify any inclusion of children, the elderly, and the physically challenged or pregnant women in the research.
 - vi. Justify any non-inclusion of women (of any age), ethnic group, racial group or other social category from the study group.
 - vii. When necessary, indicate how the appropriate gender balance would be assured in the study groups. They should indicate, when appropriate, how gender inequities, and discrimination and disadvantages can affect a person's involvement in the research.

INFORMED CONSENT

Before informed consent may be obtained, the investigator or persons designated by the investigator should provide the participant or that person's legally authorized representative ample time and opportunity to inquire about details of the research and to decide whether or not to participate in the research.

If a participant or his/her legally authorized representative is unable to read, a witness not connected to the research protocol should be present during the entire informed consent discussion. This witness should also sign and personally date the consent form, thereby attesting that:

- a. The information contained was accurately explained to the research subject
- b. The subject or his/her legally authorized representative understood the information
- c. The consent was freely given

- d. The written informed consent form should be signed and dated by the participant, and by the person who conducted the informed consent discussion.
- e. No investigator may involve human beings as subjects in research unless he/she has obtained the legal and ethical informed consent of the subject(s), or the subject's legally authorized representative.
- f. An investigator shall seek such consent in ways that minimize the possibility of coercion or undue influence for the subject to participate in the research.
- g. The right of the research subject to safeguard his or her integrity must always be respected.

The following shall be provided to each prospective participant in research:

- 1. A statement in lay language that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed and the identification of any procedures that are experimental;
- 2. Any random assignment of participants to trial arms of the research;
- 3. A description of any reasonably foreseeable risks or discomforts to the participant;
- 4. A description of any benefits to the participants and to others, which may reasonably be expected from the research. When there is no anticipated direct benefit to the participant, the participants should so be informed.
- 5. A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the participant;
- 6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- 7. For research involving more than minimal risk, an explanation as to whether any compensation and medical treatment are available if any injury occurs, and if so, what they consist of and where further information may be obtained;
- 8. Any pro-rated payment to be made to the subject for participating in the research;
- 9. The anticipated expenses, if any, to the subject for participating in the research;
- 10. The approximate number of participants expected to be involved in the trial;
- 11. Any foreseeable circumstances under which the subject's participation in the research may be terminated;

12. A statement that the subject, or the subject's legally authorized representative, will be informed in a timely manner of any new information that may be relevant to the subject's willingness to continue participating in the research;
13. An explanation of whom to contact for answers to pertinent questions about the research-related injury to the participants;
14. A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the subject may discontinue participating at any time without penalty or loss of benefits to which she/he is otherwise entitled.

None of the oral or written information concerning the research, including the informed consent form, should contain any language that causes the participant or his/her legally authorized representative to waive or to appear to waive any legal rights, or that releases or appears to release the investigator, the institution, the sponsor, or their agents from liability for negligence.

CONFIDENTIALITY

Confidentiality imposes the duty on researchers/ investigators effectively securing any access to participants' personal information. Records that may identify participants must be kept safe and confidential, and should not be made publicly available unless so required by local laws or regulations. Confidential information must not be released without the participants' consent.

RESEARCH ON MEDICAL RECORDS

Research to be done on medical records will require the approval of the Chief Executive Officer, or Senior Medical Officer for the institution, or Medical Officer of Health for the parish. Research to be done on medical records where the information to be accessed will identify persons, will also require the **informed consent** of the individual patient (see Policy Manual on **the Release of Client Information**). Any research by students should be supervised by an appropriately trained person duly recognized by the Medical Officer of Health for the parish, the Regional Technical Director, or the Chief Medical Officer or his/ her designate. Students should be taught to research with due regard for ethical guidelines.

CATEGORIES OF RESEARCH PROTOCOLS

1. Observation studies or systematic collection of clinical data where **NO** additional procedure is to be performed on the subject of the research, and where appropriate protections are instituted to safeguard the identity of the subjects.
2. Studies with **MINIMAL** risk that may lead to information that is beneficial in the management or treatment of the **INDIVIDUAL** research participant.
3. Studies with **MINIMAL** risk where the objective is an increase in knowledge **WITHOUT** there being any benefit to the participating subject.
4. Studies with **MORE** than minimal risk, but where there may be an immediate and personal benefit for the **INDIVIDUAL** participant.
5. Studies with **MORE** than minimal risk where the results will **NOT** benefit the individual patient or subject.

REVIEW OF RESEARCH PROTOCOLS

- i. Review of research protocols judged to be Category 1 may be expedited by the local Medical Officer of Health for the parish and a report of the study outcome sent to the Chief Medical Officer, Ministry of Health.
- ii. Studies falling under Categories 2-5 should be submitted to the Ministry of Health for evaluation.
- iii. Where the ethical or scientific merit of proposed research is adjudged to be dubious, the Medical Officer of the health may also refer the protocols to the Ministry of Health for evaluation.
- iv. The local Institutional Ethics Panel should review and approve all research protocols prior to commencement of the research.
- v. Research protocols being submitted to the Ministry of Health's Ethics and Medico-legal Affairs Panel should include a copy of the approval obtained from the local Committee if available at the time of submission.
- vi. Research protocols submitted to the Ministry of Health's Ethics and Medico-legal Affairs Panel should allow a **lead time of four to six weeks** for approval.
- vii. All submissions should be electronic, accompanied by one hard/paper copy.
- viii. Where the study occurs over an extended period, periodic study updates at six-month intervals and a summary of the findings should be submitted to the Chairman of the Ministry of Health's Ethics and Medico-legal Affairs Panel.

OVERSIGHT OF RESEARCH

The principal researcher/investigator should inform the Medical Officer of Health if any:

- untoward occurrence is observed;
- procedures deviate from that which was originally approved;
- alteration of the protocol is desired;
- Principal researcher/investigator, for any reason, longer has full day-to-day control of the research procedure.

The Medical Officer of Health will keep a file of all research protocols submitted for approval, with a copy of those being forwarded to the Ministry of Health. This file shall be open to inspection by members of the public.

Any person who feels that a research project is unethical, has the duty to present his/her concerns to the Medical Officer of Health, the Regional Technical Director, or the chief Medical Officer in writing. The Regional Technical Director or the Chief Medical Officer or his/her designate will then receive the ethical aspects of research, investigate the concern, then take whatever action deemed appropriate.

GUIDELINES FOR PREPARING RESEARCH PROTOCOLS

Research protocols should be submitted to the Medical Officer or Health in the parish where the proposed research is to be conducted, for evaluation of the ethical and scientific merits. Where the site of the proposed research includes a hospital, the Senior Medical Officer of the facility should also receive a copy of the research protocol, and his/her approval to conduct the study should be obtained. The following information will be required for the consideration of research proposals.

1. **TITLE OF THE PROPOSED RESEARCH**
2. **DATE** (and version – if there has been a previous submission)
3. **NAME AND ADDRESS 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 participants, and if appropriate, what training they have had.
4. **SITE (S) OF RESEACH** (Attention should be paid to the facilities available for participants' comfort, and availability of emergency procedures in the event of an unanticipated occurrence).
5. **NUMBER OF SUBJECTS TO BE ENROLLED**
6. **PROPOSED DURATION OF 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 assessment of the benefits (to participants and/or groups in the community or the entire community) and the risks
 - IV. An outline of the study design
 - V. An indication of steps taken to ensure and maintain confidentiality
8. **THE PROJECT PROPOSAL** – To include:
 - An introduction and background information on the research topic
 - A clear statement of the objectives of the research proposal
 - The justification for the research (This should include review of the current knowledge from the literature on the topic, with an explanation of why this

project is necessary, and how it will contribute to the overall knowledge in this area)

- Materials and methods

These include:

Details of procedures to be performed (e.g. the volume of blood the frequency, timing, and possible site of the blood – taking; any drug administration, physiological measures, etc.)

Choice of subjects, inclusion/exclusion criteria, number of subjects (and, where appropriate, a justification for that number) any controls, etc.

- Procedures to be performed on human subjects. This should indicate:
 1. Which procedures are new, i.e. experiment, and which are routine procedures that would have been done on the participants, even if they were not involved in the study.
 2. Which procedures may cause pain and/or discomfort for research participants
- Procedures for obtaining informed consent should include:
 - i. Methods to protect the confidentiality of the subjects, and methods to ensure that a subject who opts out of the study is well protected as far as normal health care delivery is concerned
 - ii. Details of data collection and analysis
 - iii. The citing of relevant references (i.e. literature etc.)
- A copy of any questionnaires to be administered
- A table of contents with all pages numbered

All abbreviations should be explained

9. **FAIR SELECTION OF SUBJECTS**

A statement affirming that subjects were selected only because of the specific problem under investigation, and not because of their easy availability, diminished autonomy, or due to social bias.

Researchers/investigators should be cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women,

mentally and physically challenged persons, or economically or educationally disadvantaged persons.

10. **COPY OF THE INFORMED CONSENT FORM**

This must include:

- Statements outlining in lay language the purpose of the research, what will be done in the 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 participant or his/her legally authorized representative;
- Explicit statement about any risk or discomfort to the participant, with an assessment of the degree of risk, and viable alternatives;
- A statement that the subject's participation is voluntary, and that refusal to participate, or (if after having agreed to participate) withdrawal from the study at any time not affect the participant's access to care or affect the type of care to which she/he is entitled;
- The name, address, telephone and fax numbers, and e-mail address, if any, of a contact person;
- A statement confirming that time was given for the participant to consider his/her involvement;
- Statement that the participant or his/her legal guardian has read the informed consent form or that it has been read to him/her. And that she/he understands its content; that a copy will be given to the participant; and that the signature of the participant or the legal guardian indicated that she/he has freely agreed to participate;
- The consent procedure should bear the signature of a witness who is **not** connected to the research protocol

11. **DECLARATION OF CONFORMITY WITH GUIDELINES**

A statement that all principles enunciated in Ministry of Health's **Guidelines for the Conduct of Research on Human Subjects** has been complied with.

Guidelines adopted by: The Advisory Panel on Ethics & Medico-Legal Affairs
Ministry of Health, Jamaica

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