



NEBRA
Analyze of the survey

**Annex 11 : Ghana – Navrongo
Health Research Center IRB : SOP**

**FINAL REPORT
JULY 2006**

→ ESPACE ÉTHIQUE
ASSISTANCE PUBLIQUE - HÔPITAUX DE PARIS

**UNIVERSITÉ
PARIS-SUD 11**
DÉPARTEMENT DE RECHERCHE EN ÉTHIQUE

REVISED STANDARD OPERATING PROCEDURES FOR NHRC IRB

1. Mission Statement

The Navrongo Health Research Centre (NHRC) as an important unit within the Ministry of Health has the responsibility of contributing to the improvement of the health status of all people in Ghana and the northern sector in particular through appropriate research activities.

As an independent representative body set up to review, evaluate and decide on the ethical merits of the NHRC research protocols, the IRB is committed to ensuring and guaranteeing the rights, dignity, safety and protection of all individuals and communities who participate in NHRC research activities.

The NHRC IRB is responsible for reviewing various field and clinical trials involving the use of human beings, ranging from local data-gathering protocols to clinical practices outlined in the Declaration of Helsinki, ICH Good Clinical Practices, Belmont Report, and any other applicable regulations and guidelines.

2. Terms of Reference

The NHRC IRB shall operate within the following terms and references:

- I. The NHRC IRB shall review health research protocols submitted to it within a reasonable time and document its views in writing to the applicant(s), clearly identifying the study, the documents reviewed and the dates for the following:
 - Approval for commencement of the study
 - Modifications required prior to its approval
 - Disapproval
 - Termination/suspension of any prior approval
- II. The NHRC IRB shall work to safeguard the dignity, rights, safety and wellbeing of all study subjects and communities. Special attention shall be paid to studies that may include vulnerable subjects.
- III. The NHRC IRB may request the investigator (s) to enlighten them on any aspect of the study but the investigator shall not participate in the deliberations of the IRB or in the voting of the IRB on any issue.
- IV. The NHRC IRB shall obtain the following documents from investigators:
 - Summary of Protocol
 - Study protocol (s) and/or amendment(s)
 - Written informed consent forms and consent form updates that the investigator proposes for the use of the study
 - Subject recruitment procedures
 - Written information to be provided to subjects
 - Available safety information
 - Information about benefit available to subjects
- V. The NHRC IRB shall consider the suitability of the investigator (s) for the proposed study by considering relevant qualification, training and experience, as documented by current curriculum vitae and/or by any other relevant documentation.
- VI. The IRB may request more information than is given it when in the judgment of the IRB, the additional information would assist them in taking a decision on the protocol or provide protection of the rights, safety and/or well-being of the subjects.
- VII. The IRB shall review both the amount and type of benefit to subjects to ensure that neither presents problems of coercion or undue influence on the study subjects.
- VIII. The NHRC IRB shall concern itself strictly on the scientific and ethical merits of submitted protocols for approval; executing the tasks free from bias or influence AND NOT INVOLVING ITSELF IN THE DAY TO DAY ADMINISTRATION, POLICY AND OTHER ISSUES OF NHRC.
- IX. To assist investigators in the submission process, the following items will be made available to them by the IRB Administration:

Institutional Materials

- IRB standard operating procedures
- Meeting schedule
- IRB membership list
- Protocol submission form
- Sample Consent form and consent form checklist
- Sample progress report

Other Materials

- Federal Policy for the protection of Human Subjects “Common rule Policy”
- Code of federal regulations: 45 CFR Part 46 DHHS, NIH
- The Belmont Report
- CIOMS guidelines
- The Declaration of Helsinki
- Other reading materials on human subject protection.

3. MEMBERSHIP

3.1 COMPOSITION

The IRB shall compose of representatives of the following bodies, subject to periodic review:

- Regional Directorate of Health Services
- The Head of NHRC
- Health Group-NHRC
- Population group- NHRC
- Kassena-Nankana District Administration
- KNDK Health Committee
- Kassena-Nankana Traditional Council
- Academia-UDS Navrongo Campus
- NCWD UER Branch

As mandated by federal regulations, at least one member of the NHRC IRB shall be a clinical scientist, one a non-scientist and one a community representative.

3.2 Terms/Conditions of Appointment

- I. The IRB shall consist of a reasonable number of members who collectively have the qualification and experience to review and evaluate the science, medical aspect and ethics of research protocols.
 - II. The Head of the Navrongo Health Research Centre shall be a non-voting member of the IRB.
 - III. Each membership contributing body shall use methods suitable to it to nominate or replace member(s). Rotatory membership replacement shall be encouraged in order to ensure continuity of work.
 - IV. Efforts shall be made to ensure gender equity.
 - V. Any member who has any vested interest in a proposal submitted to the Board for review other the terms and reference of the Board shall make known to the Chair and shall not participate in the deliberations on the protocol.
 - VI. Members shall be willing to publicize their identity, name, profession and affiliation to the NHRC IRB.
 - VII. Members shall be willing to sign and abide by the confidential agreement regarding meeting deliberations, applications, protocol submissions, information on research participants and related matters which they have had the privilege to have as a result of being members of the IRB.
- VIII. The NHRC shall request for a replacement of any member under the following circumstances.
- Protracted illness of a member, which does not permit him/her to participate in the deliberations of the IRB.
 - Persistent absenteeism of a member without reasonable cause

- Voluntary withdrawal by a member.

4.0: ADMINISTRATION AND FUNCTIONS

4.1 Offices and Secretariat

The officers of the IRB shall comprise of the following:

1. Chair
2. Vice-Chair
3. Administrator

This body shall have a permanent secretariat at NHRC manned by the IRB administrator and assistants. The NHRC shall provide the necessary funding for the operations of the IRB.

4.2 Responsibilities of Chair

The Chair shall be a respected person in the community, who has the qualifications of a scientist member of the NHRC IRB, is concerned about human rights and ethical issues and is well-informed in regulations relevant to the use of human subjects in research. The Chair shall be appointed for a four-year term, renewable for a second consecutive four-term. S/he shall perform the following duties:

- I. Conduct IRB meetings in accordance with all regulations
- II. Prepare and provide a statement of assurance when required by the regulations guiding the establishment of the IRB
- III. Facilitate the provision of training and educational programs to new IRB members, continuing IRB members and the greater science community of the NHRC. The training shall include programs about the basic principles of human subject protection, current literature, regulations and guidelines affecting the IRB and NHRC.
- IV. Review and accept revisions that were made per committee recommendation pending protocol approval.
- V. Determine submissions that are exempt from review, and notify the IRB and the submitting investigator of such exemptions
- VI. Perform expedited review of research that meets the expedited review criteria.
- VII. Assign responsibilities and duties to the Vice Chair and any other member in his or her absence.
- VIII. Assign responsibilities to other members of the Board.
- IX. Supervise the Administrator and ensure s/he is performing her task dutifully.

4.3 Responsibilities of Vice Chair

- I. These shall be the same as Chair in the latter's absence
- II. Any assigned responsibilities by the Chair or the IRB.

4.4 Responsibility of the Head of NHRC

- I. He shall prepare and provide a statement of assurance when required by the regulations guiding the establishment of the IRB.
- II. He shall ensure the provision of the necessary logistic and financial support for the smooth operations of the IRB.
- III. As a non-voting member, the Head of NHRC shall take part in all discussions of the Board but shall not be allowed to vote on decisions made by the Board.
- IV. If he has an interest in a particular protocol, he shall not take part in the reviewing process of that protocol.

4.5 Responsibilities of Member of the IRB

- I. Review protocols to safeguard the rights and well-being of study participants
- II. Support the executive in the discharge of their duties when called upon.
- III. Undertake duties assigned to them by the Chair or Vice-Chair
- IV. Shall endeavor to study documents submitted to them before meetings
- V. Attend meetings regularly and participate actively during deliberations.

4.6 Responsibilities of Administrator

- I. The Administrator shall be responsible for the oversight of IRB documents, records and archives.
- II. Perform a pre-review of each submission of the IRB to ensure adherence to administrative submission requirements.
- III. Undertake all administrative procedures in providing training and educational programs to new IRB members, continuing IRB members, and the greater science community of NHRC. The training shall include programs about the basic principles of human subject protection, current literature and regulations and guidelines affecting the IRB and NHRC.
- IV. Support the Chair in preparing and providing a statement of assurance when required by the regulations guiding the establishment of the IRB.
- V. Design and disseminate templates for IRB submission documents, including research protocols, informed consent materials, agreements and periodic and final reports.
- VI. Design and maintain a system for collecting and filing all IRB documents, including meeting minutes, member qualifications, protocol submission versions, deviations from approved protocols, and periodic and final reports.
- VII. Assist the institution to recruit new IRB members
- VIII. Prepare and submit annual IRB operational budget and plan to the NHRC management with consultation with the Chair.
- IX. Accept, verify, duplicate and distribute all submitted items to the appropriate members for IRB review. Ensure that all required materials for a submission are present and complete.
- X. Create and distribute meeting agendas, and arrange meeting logistics.
- XI. Attend IRB meetings, take minutes during the meetings, and verify and distribute minutes in a timely manner.
- XII. Correspond with all submitting researchers at all times throughout the submission and review process, while remaining independent of the researcher's protocol operations. Advise submitting investigators on preparing and submitting protocols for review according to SOPs.
- XIII. Properly distribute and keep files of all correspondence
- XIV. Assist the Chair to conduct IRB meetings. Continually study and update staff about IRB operational regulations.
- XV. Be available for and attend any outside investigations or audits of the Board. Comply with requests during an investigation or audit.

XVI. 5. MEETINGS

XVII.

XVIII. 5.1 IRB Meeting Schedule and Distribution of Agenda

XIX.

XX. Except for unavoidable circumstances, the NHRC IRB shall meet once a month, on every second Saturday of the month at 10am prompt in the NHRC conference room, provided materials have been submitted for review. In such a case, the IRB Chair shall provide an alternate meeting time and date.

XXI. The Chair shall lead the meeting. In the absence of the Chair, the Vice-Chair shall lead the meeting.

XXII. The IRB Administrator shall notify all IRB members of an upcoming meeting at least one week in advance by at least one of the following means: electronic mail, fax or carrier mail/messenger delivery. The notification will include a meeting agenda, which shall outline all protocol and related research submissions for consideration in the meeting, and shall include all related materials, including copies of protocols, informed consent materials, continuing and final reviews, safety reports, etc. In the case where the Administrator is unsuccessful in routing the materials to the IRB members, the Administrator shall at the least notify the member(s) of the occurrence of the meeting, and shall arrange for alternative means of material distribution. Whenever possible, the IRB Administrator shall distribute the materials electronically.

XXIII. The IRB Administrator shall notify all IRB members of any changes in meeting time, date or agenda as soon as discovered.

XXIV. The IRB Administrator shall keep an archive of all copies of meeting agenda and all other documents.

5.2 Meeting Procedure

- I. **The IRB Chair or Vice shall call the meeting to order only when a quorum of members are present. For a quorum, a majority of IRB membership must be present, including at least one member whose primary concerns is in non-scientific areas. If the protocol under review involves a target group of women, there must be a female member of the Board present to form a quorum. If a quorum is not formed, the meeting will be rescheduled.**

- II. The IRB Chair or Vice shall follow the agenda for the progress of the meeting. The Chair may also choose to deviate from the agenda based on personal judgement. The meeting shall most likely follow the following order:
 - Acceptance of the previous meeting's minutes
 - Matters Arising out of minutes
 - New business
 - Action items (voting on protocols, acceptance of serious adverse events, periodic and annual reports, and final reports)
 - Other matters
- III. If the meeting is to review a new submitted protocol, the principal investigator of that protocol must be present to answer questions that will be raised by the board.
- IV. At the end of the meeting, the IRB Administrator shall retrieve and destroy all documents (protocols, consent forms and other documents related to a particular project) which have been discussed and completed by the IRB.

5.3 Meeting Minutes

- I. During IRB meetings, all deliberations shall be recorded in written meeting minutes or recorded electronically. The minutes shall include a list of attendees, actions taken by the IRB, the vote on those actions, including the number of members voting for, against and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of issues and their resolution. The IRB Administrator shall also include a summary of each considered protocol in the minutes.
- II. The IRB Administrator shall send a draft copy of the minutes to all IRB members either electronically or by fax or mail. The Administrator will send the draft no later than with the copy of the next meeting's agenda.
- III. All IRB members shall review the minutes for accuracy and completeness. They may make recommendations to the minutes by communicating with the IRB Administrator, or at the next IRB meeting.
- IV. The Chair or Vice-Chair shall review the minutes for accuracy and completeness and will sign the minutes. The Director of NHRC may be given a copy of the final version of the minutes.
- V. The IRB Administrator shall archive the official minutes with the meeting's agenda and all relevant attachments.

6. NEW PROTOCOL REVIEW

6.1 New Protocol Submission

- I. The Principal Investigator of a protocol is responsible for following protocol submission procedures as outlined in this SOP.
- II. The IRB Administrator is responsible for receiving and processing new protocol submissions, and for ensuring that all elements required for consideration are present.
- III. The submitting Investigator will submit a research protocol with the following required documents:
 - Covering letter from the Head of NHRC
 - Summary of the protocol
 - A full protocol prereviewed by a scientific committee with the comments.
 - Enrolment forms
 - Questionnaires
 - Consent forms
 - Curriculum Vitae of investigators
- IV. Investigators must submit all documents at least one month prior to the commencement of the research study.
- V. The IRB Chair is responsible for determining whether a submitted protocol qualifies for expedited review.
- VI. Depending on the decision of the Chair on a particular protocol, primary reviewers would be appointed to review the protocol.

6.2 Participation of Protocol Investigator in IRB Meetings and Voting Procedure

- I. The IRB Administrator will notify all Principal Investigators of the meeting scheduled to consider their submissions at least two weeks before the meeting date. The Administrator will also notify all PIs about their protocol's place in the agenda. An Associate Investigator may attend on the Principal Investigator's behalf if necessary.
- II. The Principal Investigator may be invited into the meeting room during consideration of his or her protocol.
- III. The Principal Investigator may be invited to make a 15-20-minute presentation on the protocol under consideration. After the presentation, the PI shall remain in the meeting to answer any questions, concerns and suggestions from members.
- IV. After the question and answer period, the Principal Investigator and any other attendees with a potential conflict of interest with the protocol or institution submitting shall leave the meeting during the voting period.
- V. Each IRB member shall vote for, against a protocol or abstain. An absentee member is allowed to send in his/her comments but cannot vote.
- VI. In order for a protocol to be approved, it shall receive the approval of a majority of those members present at the meeting. The IRB may also decide to postpone decisions on a protocol if more information or consideration is required.
- VII. If the IRB decides to disapprove a research proposal, the IRB shall include in its written notification to the investigator a statement of the reasons for its decision, and will give the investigator an opportunity to respond in person or in writing.

- VIII. After the committee has voted on a protocol, the committee may invite the Principal Investigator back into the meeting room for immediate notification of the voting results. The IRB may also decide to contact the PI by other means to communicate the results after the meeting.

7. EXPEDITED REVIEW

An expedited review shall be conducted by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB in accordance with the requirements.

The following categories shall be qualified for an expedited review:

Research activities that present no more than minimal risk to human subjects.

Minor changes in previously approved research during the period for which approval is authorized.

In an expedited review, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure.

The administrator shall inform all members about the outcome of an expedited review as soon as practicable.

8. CONTINUING REVIEW

- I. The IRB Chair and IRB members are responsible for determining whether the research is reviewed annually, or more frequently appropriate to the degree of risk.
- II. The IRB is also responsible for determining whether an independent data and safety monitoring board is required.
- III. The investigator of the research is responsible for keeping the IRB informed of significant findings that affect the risk/benefit ratio and thus the need for more frequent review. The investigator is also responsible for following the continuing review procedures and deadlines as outlined in this SOP.

8.1 Determination of Frequency of Continuing Review

- I. At a research activity's initial review, the IRB will determine:
 - How often it will re-evaluate the research project. All research will be reviewed at intervals appropriate to the degree of risk, but not less than once per year but at least once before the end of the data collection stage.
 - The factors to be considered in setting the frequency of review should include the nature of the study, the degree of risk involved, and the vulnerability of the study subject population.
 - **Whether these studies need verification from sources other than the investigator that no material changes in the research have occurred.**
- II. The investigator will utilize the continuing review form to complete the annual review report. The report will include all required elements, including the following:

- Number and demographics of participants enrolled
 - Changes in principal and/or associate investigator(s)
 - A summary description of subject experiences
 - Any serious adverse events experienced
 - Numbers of and reasons for withdrawals from the research
 - The research results obtained thus far
 - A current risk-benefit assessment based on study results
 - And any new information since the IRB's last review.
- III. If the investigator cannot provide any of the required information, s/he will provide justification for the delay in the report, and a timetable for provision of the information. The investigator will also submit a copy of the consent documents and procedures currently in use.
- IV. The investigator will submit one hard copy of the continuing review report, with original signature. The investigator is also encouraged to submit an electronic copy of the review report via e-mail or disc.
- V. Upon receipt of the continuing review report, the IRB Administrator will conduct a pre-committee review to ensure all the required elements are present. The IRB Administrator will work with the submitting investigator to ensure all elements are present before distribution of meeting items. The IRB Administrator will place the continuing review report on the next meeting's agenda.
- VI. The IRB Chair may elect to invite an independent or alternate reviewer to the meeting.
- VII. IRB members will consider and vote upon all continuing review reports in full meeting utilizing the protocol voting procedure. The risk/benefit ration may change over time. The criteria the IRB uses to approve or disapprove continuation of research are the same as the criteria for approval of an initial research project.
- VIII. The IRB will review the consent process and documents to determine whether they are still accurate and complete, whether new information that may have been obtained during the course of the study needs to be added, and whether the documents being used by the clinical investigator have current IRB approval.
- IX. After reassessment, the IRB may require that the research be modified or halted. The IRB may also impose special precautions or relax special requirements it had previously imposed on the research protocol. They will also determine whether there are any important new findings that might affect the willingness of participants to continue participating in the research. If so, they will require the Investigator notify the participants of these findings.
- X. The IRB Administrator will archive continuing review reports and supporting materials with the relevant meeting minutes.

8.2 Timing of Continuing Review

- I. If the IRB has not reviewed and approved a research study by the study's current expiration date, IRB approval has expired and research activities should stop. No new subjects may be enrolled in the study. However, if the investigator is actively pursuing renewal with the IRB and the IRB believes that an over-riding safety concern or ethical issue is not involved, the IRB may permit the study to continue for the brief time required to complete the review process.

- II. If the investigator cannot provide any of the required information, the investigator will provide justification for the delay in the report, and a timetable for provision of the information. The investigator will also submit a copy of the consent documents and procedures currently in use.

8.3 Use of Data and Safety Monitoring Board (DSMB)

- I. **In larger studies or trials, the IRB may also require a DSMB be formed to keep the IRB up-to-date of the balance between risks and benefits.**
- II. The primary responsibility of a DSMB is to safeguard human subjects by analysing accumulating data relevant to the risks and benefits on a regular basis. Especially in long-term trials, the DSMB reviews data periodically to assess effectiveness and toxicity, and to decide if and when the data are sufficiently favourable to one treatment that the study should be discontinued. The DSMB must also decide whether adverse effects are serious enough to warrant termination of the study.

9. Archiving of SOPs

The purpose of this Standard Operating Procedure is to outline the process for authoring, reviewing, archiving and amending Standard Operating Procedures (SOPs) for the Navrongo Health Research Centre Institutional Review Board.

9.1 Procedure

The Procedure's section will be written in immediate future tense using active verbs. It will be written so that a reader unfamiliar with the procedure would be able to duplicate the procedure accurately in proper time sequence by following the document.

9.2 Distribution and Archiving

- I. The IRB Administrator will distribute the SOP to all IRB members, archive the electronic copy and the paper original, and update the indexed list of SOPs.
- II. All requests for extra copies may be made to and fulfilled by the IRB Administrator.

9.3 SOP Revision

If the Board wishes to revise or update an SOP, it will request an electronic copy of the document from the IRB Administrator, or may request minor changes be made directly by the IRB Administrator.

9.4 Annual Review

- I. The SOP will be evaluated for accuracy and timeliness in an annual review. The IRB Administrator will alert the Board of an annual review requirement.

- II. The Board, IRB Administrator or an assigned reviewer will ensure that the SOP reflects the most current outline of procedures.
- III. If the document does not need revision, the author will return the document to the IRB Administrator for recording and filing.

References

45 Code of Federal Regulations 46.115 IRB Records, .108.b IRB Functions and Operations.

The Belmont report

CIOMS guidelines

US Code of Federal Regulations: 21CFR56.115 IRB Records