RIVERS STATE HEALTH RESEARCH ETHICS COMMITTEE

RESPONSIBILTY

The Rivers State Health Research Ethics Committee (RS HREC) is accredited by the National Health Research Ethics Committee (NHREC) with the responsibility of ensuring that all health research and clinical trials carried out in the State are conducted following appropriate ethical standards and good clinical practices.

COMPOSITION OF RS HREC MEMBERS

The Rivers state HRE committee is made up of technical and non-technical drawn from the lay public for representatives.

BASIC REQUIREMENTS FOR OBTAINING ETHICAL APPROVAL FROM THE RS HREC

For every piece of research, the (primary or otherwise) researcher is required to apply formally to the Chairman RS HREC through the Permanent Secretary, Rivers State Ministry of Health attaching two copies of the research protocol in spiral bound form including the titlepage aims, methodology, informed consent document, data collection tool and interview guide where appropriate. Applications may be submitted as prescribed to the office of the Permanent Secretary, Rivers State Ministry of Health physically at Room 5, 2nd Floor, Block A State Secretariat Complex, Port Harcourt or electronically via contact@riversstatemoh.gov.ng.

Researchers from outside the State may be required to have Rivers based co-researchers, supervisors or co-supervisors.

Request for access to information/data for health research should be accompanied by copy of ethical approval for same piece of research.

DURATION FOR PROCESSING OF SUBMITTED PROTOCOL

1. Protocols for expedited review/approval (4 - 6 weeks)
2. Protocols for Exempted approval (1 – 2 weeks)
3. Clinical trials protocols for Full Committee review (6 – 8 weeks)

GUIDELINES FOR SUBMISSION AND PROCESSING OF NEW APPLICATIONS TO RIVERS STATE HEALTH RESEARCH ETHICS COMMITTEE.

1. Applications for review by the RS HREC can be submitted on any week day from 8:30am to 4:00pm to the RS HREC office, Room 5, 2nd Floor, Block A, State Secretariat Complex, Port Harcourt, Rivers State, Nigeria.

2. Applications should contain the following:

   a. Cover letter (addressed to the Permanent Secretary, Rivers State Ministry of Health). The cover letter for applicants such as undergraduate students and postgraduate students must be directed through the relevant Head of Department (or Head of Unit) and must be countersigned by a competent supervisor.

b. Brief double spaced (font size minimum 12) summary of the research protocol (in lay terminology).

c. Research protocol (2 hard copies, spiral bound and one soft copy in pdf format) including the informed consent document compliant with the recommended format.

3. Research protocols emanating from researchers where departments or examining bodies specify a format for research protocols (e.g. the West African Postgraduate Medical College, National Postgraduate Medical College, etc) the RS HREC accepts protocol formatted according to the specifications of the relevant body, with the provision that the format contains the relevant information.

4. Guidance in the preparation of the informed consent document can be obtained from the RS HREC office in the form of a prototype document adapted from the NHREC prototype.

5 The Secretariat will check all applications for completeness prior to accepting the application. Incomplete applications will be rejected by the Secretariat.

6 Acknowledgement of receipt will be made by issuance of an acknowledgement or by email notification from the secretariat. Documentation of receipt of application will be made in the RSHREC records.

7 All complete applications received will be evaluated by the Chair and Secretary to determine the type of review to be assigned (exempt review, expedited review or full review) within 5 working days of receipt of a complete application.

8 The precise status of a protocol regarding assignment of review will be made by the Chair in line with guidelines specified by the NHREC. Researchers CANNOT independently determine that their study is exempt from ethical review.

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In the case of exempt protocols, a letter of exemption will be issued by the Chair, and the decision will be communicated to the Committee at the next scheduled meeting for ratification.

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In the case of expedited reviews, the RS HREC adopts a method of assigning such reviews to expert reviewers from the research community...

Ethical issues requiring clarification may necessitate a request to the researcher for in-person clarification of pending issues. Provisional approval may then be issued to the researcher (signed by the Chair) where there are no ethical issues...

All decisions are reviewed at the next scheduled meeting of the RSHREC and either ratified or subjected to modification. A final decision is communicated to the researcher clearly stating the date of final decision, duration of approval, and other relevant information as recommended by the NHREC.

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Researchers applying for full review will be required to attend the HREC meeting. Such applications will then be reviewed by members of HREC (together with additional experts as circumstance demand)...

Decisions emanating from such review will be communicated to the researchers in writing including, where relevant, a time frame for addressing any pending issues.

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In reviewing applications, due consideration will be given to the science of research as it impacts on ethics, in addition to other conventionally assessed ethical issues. All reviewers will be provided with a guidance document to use as protocol...

The guidance document is included in the appendix to this SOP, is publicly available to researchers and reviewers, and can be obtained from the RS HREC

13 Requests for modification or clarification will be communicated to researchers in writing. Researchers will be requested to address all such issues within 6 weeks. If no response is received within 8 weeks, the protocol will be dismissed. The researcher may re-apply thereafter.

14 Review of protocols will be in accordance with guidelines stipulated in the National Code of Health Research Ethics (NCHRE) and the CIOMS/WHO guidelines.

15 The final decision regarding a protocol will be based on the unanimous decision of all present at the index HREC meeting...

Where there is dissent regarding a decision by any member present, further guidance may be sought by inviting external experts and/or seeking further clarification from the researchers or two thirds majority decision (including that of a relevant expert and non - scientific lay member).

16 The RS HREC endeavors to complete all reviews between 8 - 12 weeks