GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department - SOP for Nipah Related Studies in Kerala for Studies involving Human Participants / Human Samples - Approved-Orders issued.

HEALTH & FAMILY WELFARE (F) DEPARTMENT

G.O.(Rt)No.3219/2023/H&FWD Dated,Thiruvananthapuram, 04-12-2023

Read: 1 Letter No. DHS/18606/2023-PH1 dated 13.10.2023 from the Director of Health Services, Thiruvananthapuram.

2 Letter No. ADMIN1/799/2023/SHSRC-K dated 26.10.2023 from the Executive Director, State Health Resource Centre- Kerala, Thiruvananthapuram

3 Email message dated 11.11.2023 from the Chairperson, State Medical Board (Nipah).

4 Letter No. K3-5838/2023/DME dated 13.11.2023 from the Director of Medical Education, Thiruvananthapuram.

ORDER

Nipah outbreak was reported in Kozhikode District in September, 2023 and received confirmation from ICMR-NIV Pune. Based on the online meeting chaired by Hon'ble Minister (H&WCD) on 20.09.2023, as per letter read as 1st paper above, the Director of Health Services has put forth a proposal stating the need for Standard Operating Procedure for Nipah research and suggesting a stakeholder mapping for Nipah related research.

2. Government have examined the matter in detail and are pleased to approve and issue the "*SOP for Nipah Related Studies in Kerala for Studies involving Human Participants / Human Samples*", as annexed to this order.

(By order of the Governor)
SUBHASH R
ADDITIONAL SECRETARY

To:
The State Mission Director -National Health Mission,
Thiruvananthapuram.
The Director of Health Services, Thiruvananthapuram.
The Director of Medical Education, Thiruvananthapuram.
The Chairperson, State Medical Board (Nipah).

All Principals, Government Medical Colleges.
All District Medical Officers (Health).
The Executive Director, SHSRC, Thiruvananthapuram.
Principal Accountant General (A&E/Audit) Kerala.
Information & Public Relations (Web & New Media) Department.
Stock File/ Office Copy to F2/341/2023-HEALTH.

Forwarded /By order

Signed by
Justin Joy J
Date: 04-12-2023 16:56:10
Section Officer

Annexure

SOP FOR NIPAH RELATED STUDIES IN KERALA FOR STUDIES INVOLVING HUMAN PARTICIPANTS / HUMAN SAMPLES

1. All research proposals related to Nipah Viral Disease, confined to geographical areas already identified with repeated outbreaks, whether proposed at the national or international level and by government or private entities, must be submitted for review before the officially recognized research and ethics committees. Specifically, these committees refer to the Institutional Research Committee and Institutional Ethics Committee of Government Medical College, Kozhikode. This requirement stands, even if the research proposal has already received ethical clearance from other institutions.
2. In all Nipah-related research projects to safeguard the confidentiality of patient-related data and uphold the interests of the State, it is mandated that each study includes at least one researcher affiliated with State government institutions as a co-investigator.
3. The research team should contain a Principal Investigator (PI) with Co-PIs or co- Investigators (Co-Is) as required for the proposal.
4. Either PI or Co-PI shall represent the Government of Kerala. They can be from the Health Services Dept., Medical Education Dept., National Health Mission or State Health Systems Resource Centre- Kerala (SHSRC-K). In Nipah-related research of the current or previous outbreaks and in future outbreaks from the same geographical areas the proposal should include investigator /investigators from the respective identified Districts already contributed or involved in the outbreak management from the Health Services Dept., and /or Medical Education Dept.as per the research requirements.
5. The PI (Principal Investigator) is responsible for assuming overall authority and accountability for the ethical conduct of research in accordance with the most updated guidelines issued by ICMR for biomedical research involving human participants (National Ethical Guidelines for Biomedical and Health Research involving Human Participants).
6. PI shall find the funding source or apply for research grants if it is required and responsible for conducting quality research.
7. A study in Nipah with a geographical setting of Kozhikode should have the

ethics committee clearance from the Government Medical College, Kozhikode so that the IEC can monitor the research as per the requirements.

8. All the research protocols shall be cleared by the Administrative Committee comprising the Principal Secretary of Health & Family Welfare Department, the Director of Health Services and the Director of Medical Education.
9. After obtaining the necessary IEC (institutional clearance as the case may be),IRC and institutional ethics committee clearance from the Government Medical College, Kozhikode as the case may be, all the research proposals with relevant IEC/IRC approvals shall be submitted to the Department of Health & Family Welfare directly to place before the Administrative Committee.
10. If any state-wide study is planned on topics related to Nipah Viral infection, the research proposals submitted by PIs under the Director of Medical Education shall be verified by the respective Human Ethics Committee; while the research proposals submitted by PIs under Director of Health Services shall be verified by Institutional Ethics Committee at SHSRC-K.
11. The research proposals submitted by PIs from non-governmental institutions and national-level institutes within or outside the State of Kerala shall obtain the respective HEC clearance and/or approval from SHSRC-K or State Board of Medical Research (SBMR) if the proposal is of State-wide research;
12. Considering the Nipah viral infection outbreak timelines and its public health importance, all proceedings at IRC and IEC should be conducted without delay.
13. The procedure for the collection of study data should be detailed in the study protocol, and the handling and storage of data shall be in compliance with the latest ICMR guidelines for biomedical research.
14. Nipah-related research, ***at the time of outbreaks or spillover*** (to focus resources on outbreak management), studies among survivors and close contacts (because of social issues, safety and privacy of people) and in research with the possibility of handling the live virus in humans or in the natural reservoirs (because of spillover threats) is of great public health priority and state concern.
    a. Studies requiring sample collection during viremia, need to use all the appropriate infection control practices and appropriate PPEs. These study subjects will be already admitted to an isolation facility and the

collection, packing and transportation should follow all protocols and precautions as per the guidelines already in place.

b. All healthcare workers involved in samples collection or study related activities should be adequately trained on the procedure before the delegation of duties. The usually recommended samples are; throat swab, Urine, Blood, and CSF.
c. The specimens to be collected and other requirements of the study proposal are to be detailed in the study protocol submitted.
d. All the samples should be collected adhering to the strict infection control practices, the team should have received adequate training and the packaging, labeling and transportation should be as per the existing State and National guidelines and protocols guidelines for the transportation of samples of blood and other biological samples especially in research related to pathogens like Nipah.

15. **Sero-surveillance Study**

a. Sero-surveillance protocols shall be drafted in collaboration with stakeholders like ICMR – NIV Pune and ICMR –NIE Chennai, Government Medical College, Kozhikode and the District public health team.
b. As the test kits are not currently commercially available and need support from NIV for the expertise and the resources (test kits), the Government shall do serosurveillance in collaboration with NIV and NIE for providing the test kits and technical support for conducting the study.
c. It should be an inter-institutional collaborative work as it was done in 2018 and should be completed within the time frames.
d. The DHS, DME and SHSRC-K will support the study as facilitators for the smooth conduct of the study.
e. The details of the study procedure should be mentioned in the proposal.
f. All study-related activities should be initiated only after obtaining the appropriate written informed consent. The subject (participant) information sheet and Informed Consent Form shall be drafted in the local language and submitted to the ethics committee.
g. All study-related approvals including the IRC and IEC approvals

should be obtained in a time-bound manner from Government Medical College, Kozhikode as it is of public health importance of the nature of outbreak emergencies.

h. For 'follow-up samples' after recovery/for serosurveillance study, the samples are to be collected from the nearest public health facility under the supervision of a Government medical officer. If there is a requirement for a sample collection from areas outside a Government facility like from the fields the proposal considering the convenience of study participants, it should be clearly drafted and the reason for the same should be properly mentioned. The District Surveillance Officer, Kozhikode should be responsible for organising the same.

16. Waste management collection, storage, and disposal requirements, and decontamination procedures should be mentioned during the submission of the proposal and adhered to strictly.
17. All activities related to the study must be reviewed and approved by the research and ethics committee, prior to the initiation of any study activities.
18. All study-specific procedures should be detailed in the study protocol. All study-specific procedures should be performed only after obtaining written informed consent and/or assent as required from the participants in the language the study participant understands.
19. Detailed descriptions of the tools, questionnaires and physical or biochemical parameters measuring instruments to be utilized should be clearly explained in the study design.
20. Any deviation from the actual proposed and approved study protocol should be informed timely to the concerned review board and ethics committees with reasons for the same.
21. For all study-related procedures, no cost shall be incurred from the participants for meeting the study procedures like diagnosis, investigations or treatment.
22. The PI shall submit timely progress and final reports as required to the Administrative committee & IEC as per the requirements if any.
23. Privacy and Confidentiality.
    a. The study should be initiated after the written informed consent and/or assent. All study-related activities should be done to ensure the privacy and safety of the participants, with minimum disturbance to the

participants' routine activities.

b. The appropriate travel reimbursements are to be done as per the approval from IEC as mentioned.
c. The samples collected should be used only for study-related activities where administrative sanction, IRC, and IEC approvals are obtained.

24. **Conflict of Interest:** The investigators should submit the disclosure of Conflict of interest with the proposal.
25. **Sponsorship/Grant/Funding:** Funding received or sought if any should be mentioned during the initial submission of the research proposal.
26. **Clinical trials related to Nipah:**
    a. Prior administrative sanction should be obtained and the protocol should be adhered to all the regulatory approvals and IRC and IEC approvals of the institution or within the geographical locality of the study (Government Medical College, Kozhikode in the present and previous outbreaks).
    b. All clinical trials should be scientifically and ethically sound. Clinical trials during an outbreak situation require pre-emptive preparedness and approvals.
    c. It could be in vaccine development, therapeutics, diagnostics, public health interventions, socio-behavioural interventions, or related areas.
    d. Voluntary written informed consent is mandatory before any study-related activity.
    e. The study subjects and investigators are to be protected through appropriate measures including insurance coverage as per the risk assessment.
27. A copy of the final study report should be submitted to the Principal Secretary, Health & Family Welfare Department, Government of Kerala for obtaining approval prior to publication, to be shared in the mail ID secy.hlth@kerala.gov.in.
28. Government shall give permission or a reply, in case no permission is granted, preferably within 3 days; but not more than 7 days on any ground.
29. The researchers should follow the guidance of the International Committee of Medical Journal Editors (ICMJE) on authorship and all other contributions are to be properly acknowledged in all publications.
