## Annexure 2. Research Proposal Contents

The protocol should include the following:

1. The face page carrying the title of the proposal with signatures of the investigators;
2. Brief summary/ lay summary;
3. Background with rationale of why a human study is needed to answer the research question;
4. Justification of inclusion/exclusion of vulnerable populations;
5. Clear research objectives hypothesis, objectives and end points (outcome variables), if applicable);
6. Type of study, and location of the study.
7. Eligibility criteria and participant recruitment procedures (sampling) procedures (including screening in-person or using various digital modes of communication including but not limited to email, phone calls, message services, social media, etc.).
8. Detailed description of the methodology of the proposed research, including sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded, etc.), types of data collection, intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures, if any and a flow chart;
9. Duration of the study;
10. Justification for placebo, benefit–risk assessment, plans to withdraw. If standard therapies are to be withheld justification for the same;
11. Procedure for seeking and obtaining informed consent with a sample of the patient/participant information sheet and informed consent forms in English and local languages. Av recording if applicable; informed consent for stored samples;
12. Audiovisual (AV) recording if applicable; informed consent for future use of stored samples; or a request for waiver of consent.
13. Plan for statistical analysis of the study;
14. Plan to maintain the privacy and confidentiality of the study participants;
15. case record form (or research Performa, screening, or diagnostic tools, etc.), permission to use the licensed or copyrighted material, or plans for payment or commercially available material should also be enclosed wherever required.
16. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period.

17. For research involving more than minimal risk, an account of management of risk or injury;
18. Proposed compensation, reimbursement of incidental expenses and management of research related injury/illness during and after research period;
19. Provision of ancillary care for unrelated illness during the duration of research;
20. An account of storage and maintenance of all data collected during the trial or research study including physical form and digital form (site, server, country of location of the server, etc. in case of digital storage with duration of storage, the policy for retrieval when required, free or paid.
21. Plans for publication of results – positive or negative – while maintaining confidentiality of personal information/ identity. and authorship criteria incase more than one investigator are there and ethical considerations and safeguards for protection of participants.
22. Ethical considerations and safeguards for protection of participants.