

## ***NBC-REC, Tor's version 1.2***

### **Background:**

The purpose of this document i-e ***NBC-REC, TORs version 1.2***; is to ensure that there are practical and effective actions put in place to ensure that a robust but rapid research ethics review is undertaken. Given the public health emergency, this guidance is being implemented on urgent basis for the sole purpose of facilitating the researchers in finding the best possible treatments and prevention to save the human lives.

These TORs are only applicable to the applications that have a COVID-19 research element and meet the scope of NBC Pakistan's REC review and must be read as an addition to the TORs in version 1.2.

All other research applications will continue to be reviewed under the previously placed REC TORs and NBC SOPs. While COVID-19 is a public health emergency, the ethical principles and values that are fostered by NBC for ethical review processes must continue to be upheld.

While the REC acknowledges that during pandemic situation, certain routinely applicable procedures considered essential in normal times may not be possible to be carried out to the fullest while conducting clinical and epidemiological studies. However, this does not mean that ethical parameters for human subject research can be ignored during crisis times, and safety of human participant will be kept paramount. The speed of review by the REC, and any possible discussion that goes on between the REC and the researchers will be compressed to be accomplished in the shortest possible time, but the stringency of review by the REC will not be compromised.

### **Enforcement and scope of the TORs:**

These TORs approved by circulation by NBC Members will remain active from the date of its approval until the current Pandemic remains our "national emergency". Only new applications having a COVID-19 research element and meet the scope of NBC REC will be covered by these TORs.

The REC emphasizes that all human subject research involving the Corona Pandemic is subject to the already defined guidelines and processes as defined by the NBC. No study will be exempt from review. All studies, whether they are clinical trials, epidemiological studies, observational studies, social sciences studies, clinical audits or any other kind of studies will have to be presented to the REC for ethical review.

It is also emphasized that additional ethical review by institutional ethics committees will be applicable as in normal review processes, and the NBC review does not imply that institutional processes may be bypassed or ignored. The NBC has already issued directives to the institutions to institute similar Rapid Turnaround Review processes in order to facilitate research.

### **Emergency Review process for Rapid Turnaround Review**

1. To be easily identified, "COVID-19" should be in the study title and researchers are encouraged to use this in their title for submission.
2. The Secretariat will keep a separate record of applications and substantial amendments reviewed with specific Identification number i-e COVID-(e.g number of project).
3. Application requirements and secretariat validation of new applications will be the same as previous.
4. In addition to the usual documents, (Protocol, CVs etc.) following should be submitted in addition.
  - a. Letter of collaboration (MOUs) with institutions including study sites.
  - b. Monitoring and safety management plan especially for the clinical trials, if applicable.

- c. Both data sharing and Material Transfer Agreements (MTA) for data and human biological material especially if they are being exported out of the country (a draft may be submitted initially).
  - d. Procedures for updating the community regarding the research outcome.
  - e. Plans to provide the results to the Provincial and Federal Government of Pakistan for utilizing them for public policy and required interventions.
5. The application will only enter this Rapid Turnaround Review timeline after all related documents as described in the requirements are filed with the REC. It will be the sole responsibility of the PI or corresponding person to provide the Secretariat with the complete documents and RTR time of review will commence from there onwards. Incomplete applications will not be entertained.
6. All applications and amendments must receive a decision within 3 working days (72 hours) from the date of completely filled application form along with the required documents submission.
7. Any responses to provisional approvals or decisions other than approvals will be provided within 24 hours.
8. The review process will be online. Meetings of the REC members whenever required will be established electronically on mutually agreed time as and when floated by the Chairperson REC.
9. The Rapid Turnaround Review process involves members of the REC however any subject matter expert if required may be co-opted by the Chairperson of REC.
10. Identification of subject experts and having experience/ knowledge of ethics (both in-country and abroad) that would be willing to serve as ad hoc or co-opted members during the pandemic will be identified and contacted in advance and their list will be available in Secretariat.
11. The quorum for any REC review meeting is one-third of the members (including the Chair).
12. In order to expedite the process of communication, the REC Chairperson/ REC Representative may wish to establish telephonic contact or a tele conference with PI and his/her team as per requirement to seek clarifications.
13. After the PI addresses the concerns the REC will be approving within the prescribed time.
14. The decision will be based on consensus of the Committee.
15. The Secretariat will issue the electronic copies of the approval letter signed by the Chairperson REC.
16. The hard copies will be sent through courier only after the emergency is over.
17. If decision is not communicated within this timeframe the researcher should contact the Secretariat.
18. In the spirit of RTR, in case the researcher/team does not respond to any queries made by the REC in connection with the application within 2 weeks of the receipt of the REC queries, the application

will be deemed to have been abandoned/ withdrawn. Upon resubmission it will be considered as a new project.

19. All communications will be documented and archived at Secretariat.
20. **The fee structure remains the same as prescribed by NBC however, in view of the present situation of limited access/ lock down and the few administrative constraints in the country the fee submission may not affect the processing and approvals.**

### **Serious Adverse Event (SAE) Report.**

It is mandatory for the Principal Investigator to report any Serious Adverse Event to the NBC immediately (within 48 hours) of the report.

It is further mandated to submit the report of Data Safety and Monitoring Board's decision to the NBC on immediate basis.

The reporting should mention mitigation measures; follow up strategy, the treatment and financial arrangements for cases.

Upon failure to do so the study loses the approval for onwards continuation and will be proceeded against as per TORs of NBC.

### **Acknowledgments:**

*In preparation of this document the guidance for procedures was solicited from the WHO's draft document "Rapid research ethics review during disasters/epidemic/outbreaks: suggested Standard Operating Procedures for National (Research) Ethics Committees (N(R)EC)"*