

Guideline for the Researchers

Purpose and scope:

This is a modified version of SOPs pertaining to the review process and it aims to inform the applicants regarding the standard processes at NBC-R-REC. It further aims to delineate the expectations of NBC-R from its applicants during their interaction with this body.

These may be read in conjunction with TORs of NBC as and when required.

Categories of Submission:

- A. Ethical review
- B. Exemption from NBC ethical review
- C. COVID project for ethical review
- D. Electro-medical Devices for NBC Clearance
- E. Extension of approved project
- F. Amendment in approved project.

Steps of the process:

Receiving of Projects (for Ethical Review)

- After online receiving of soft copy of the project by email a specific number is generated in the format NBC-001.
- Then it is checked for the completeness of application package as guided on our website and includes the followings:

Check list

- i. One copy of ERC Application form with checklist (*copy attached*)
- ii. One copy of Research Protocol in standard format
- iii. A copy of Drug Brochure or any supplementary information enclosed (if applicable)
- iv. One copy of informed consent in English and Urdu or any other local language of the population study.
- v. One copy of Questionnaire in English and Urdu administered during the study (if applicable).
- vi. Please above requirement full fill

Acknowledgement:

After check list is found complete an acknowledgement with allotted the specific NBC number is communicated to the applicant along with intimation of payment amount and process for processing fee to by email.

Payment of processing fee:

Proof of payment is requested in the form of receipt on hard and soft copy format

Meanwhile submission is processed for ethical review.

SOPs for review of Research studies submitted at NBC REC

1- SOPs for new study (routine review):

- The received study after being identified with a unique ID and thorough screening for mandatory supporting documents is sent to the Chairperson of REC via email.
- The Chairperson sends the study to REC members and if need is felt to involve the subject matter expert also suggests and takes on board the Coopted member.
- For routine submissions an online meeting is scheduled within 4 weeks of submission.
- The study is discussed in the online meeting (mostly every Tuesday at 10:00 pm) via zoom link.
- If for some reason zoom meeting is not possible members agree to submit independent reviews.
- Reviews either from zoom discussion or individual submission by members are collated by the REC Chairperson.
- Collated comments are received at the Secretariat via email.
- Comments are communicated with the applicant via email.
- When the applicant submits the response to the comments these are forwarded to the Chairperson for review of the committee and its decision.
- After the review of justifications, the REC chairperson communicates the decision of either it is approved, needs further clarifications/ modifications or its cannot be allowed with proposed methodology.
- This decision is communicated to the PI via email which either contains approval letter or in other cases the response of REC.
- The whole process is aimed to be completed within 6 weeks of submission provided the applicant responds within a week of the response from REC.

2- SOPs for COVID related studies (Rapid turnaround Review RTR)

- The received study after being identified with a unique ID and thorough screening for mandatory supporting documents is sent to the Chairperson of REC via email.
- The Chairperson sends the study to REC members and if need is felt to involve the subject matter expert also suggests and takes on board the Coopted member.
- For routine submissions an online meeting is scheduled within 1st week of submission.

- The study is discussed in the online meeting (mostly every Tuesday at 10:00 pm) via zoom link.
- If for some reason some member is unable to join zoom meeting he/she is requested to submit independent reviews.
- Reviews either from zoom discussion or individual submission by members are collated by the REC Chairperson.
- Collated comments are received at the Secretariat via email.
- Comments are communicated with the applicant via email.
- When the applicant submits the response to the comments these are forwarded to the Chairperson for review of the committee and its decision.
- After the review of justifications, the REC chairperson communicates the decision of either it is approved, needs further clarifications/ modifications or its cannot be allowed with proposed methodology.
- This decision is communicated to the PI via email which either contains approval letter or in other cases the response of REC.
- The whole process is aimed to be completed within 02 weeks of submission provided the applicant responds within a week of the response from REC.

(At the start of pandemic the process was conceived and executed within 72 hours with daily zoom meetings but as the pandemic has settled now it takes 2 week. However the timelines are flexible and responsive to the situations.)

3- SOPs for amendment requests in already approved submission:

- The received study after being identified with an ID for amendment stated elsewhere and thorough screening for mandatory supporting documents is sent to the Chairperson of REC via email.
- The Chairperson decides whether it is a minor amendment or a major one. Minor amendments are generally dealt y the chairperson herself and communicated with their approval status with the Secretariat.
- For major amendments if it is felt that all the members are required to review then the same process of review is followed and decision is made.
- Collated comments/ decision are received at the Secretariat via email usually with in 2-4 weeks)
- Comments are communicated with the applicant via email.
- When the applicant submits the response to the comments these are forwarded to the Chairperson for review of the committee and its decision.
- After the review of justifications, the REC chairperson communicates the decision of either approval of amendments, needs further clarifications/ modifications or its cannot be allowed with proposed methodology.
- This decision is communicated to the PI via email which either contains amendments approval letter or in other cases the response of REC.
- The whole process is aimed to be completed within 4 weeks of submission provided the applicant responds within a week of the response from REC.

- 4- SOPs for Extension in time periods of the approved study:
- REC approves any study for a period of 1 year in general but for Covid related studies to have a vigilant monitoring on progress approval is valid for 6 months.
 - For continuing beyond this time period NBC requires an application along with the progress report.
 - The received extension requests after being identified with an ID for extension stated elsewhere and thorough screening for mandatory supporting documents particularly the progress report on a scientific format and a covering letter by PI stating the justification for extension is sent to the Chairperson of REC via email.
 - The Chairperson decides about the period of extension which is usually for one year and communicates with their approval status with the Secretariat.
 - Decisions are received at the Secretariat via email usually within 2 weeks.
 - This decision is communicated to the PI via email which contains approval letter of extension in time period for another term.
 - The whole process is aimed to be completed within 4 weeks of submission provided the applicant responds within a week of the response from REC.

SOPs for Issuance of approval letter of all types:

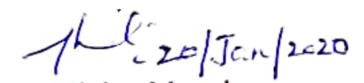
- If the REC approved the project, then send the draft approval letter for signature of the Chairperson REC.
- The Chairperson REC sends the signed copy of approval; the approval send for dispatch number after dispatched the hard copy to PI by post and soft copy to PI and incase a clinical trial to DRAP by email.

Follow up:

- To maintain an oversight the PI must submit progress reports (quarterly or as required in approval letter) to NBC and they will be mandatory for extension requests.
- Also read guidelines for Adverse events reporting.

Final report:

Upon completion of study final report (on format of HRI final report format) must be submitted to the NBC by the Principal Investigator.


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