

## **Guidelines for Thesis Protocol**

The protocol for a research proposal (including thesis) is a study plan, designed to describe the background, research question, aim and objectives, and detailed methodology of the study. In other words, the protocol is the 'operating manual' to refer to while conducting a particular study.

The candidate should refer to the NBE guidelines for preparation and submission of Thesis Protocol before the writing phase commences. The minimum writing requirements are that the language should be clear, concise, precise and consistent without excessive adjectives or adverbs and long sentences. There should not be any redundancy in the presentation.

The development or preparation of the Thesis Protocol by the candidate will help her/him in understanding the ongoing activities in the proposed area of research. Further it helps in creating practical exposure to research and hence it bridges the connectivity between clinical practice and biomedical research. Such research exposure will be helpful in improving problem solving capacity, getting updated with ongoing research and implementing these findings in clinical practice.

Research Ethics: Ethical conduct during the conduct and publication of research is an essential requirement for all candidates and guides, with the primary responsibility of ensuring such conduct being on the thesis guide. Issues like Plagiarism, not maintaining the confidentiality of data, or any other distortion of the research process will be viewed seriously. The readers may refer to standard documents for the purpose.

### **PROTOCOL REQUIREMENTS**

1. The thesis protocol should be restricted to the following word limits:

Title	: 120 characters (with spacing)
Synopsis [structured]	: 250-300
Introduction	: 300-500
Review of literature	: 800-1000
Aim and Objectives	: Up to 200
Material and Methods	: 1200-1600
10-25 References [ICMJE style]	

2. It is mandatory to have ethics committee and scientific research committee approval before initiation of the research work.

3. The concerned NBE accredited hospital shall be required to evaluate the thesis protocol at its own level through Institutional Ethics Committee (IEC) and Scientific Research Committee (SRC) and approve the thesis protocol for carrying out the research work. The constitution of IEC & SRC has to be in accordance with the guidelines prescribed by NBE.
4. After the thesis protocol has been assessed and evaluated by IEC & SRC and has been approved for carrying out the research work, the same has to be submitted to NBE within 3 months of joining of DNB candidate in the concerned hospital for DNB training.

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### **Constitution of Institutional Ethics Committee:**

1. The accredited hospital should have an Institutional Ethics Committee (IEC) which is multidisciplinary and multi-sectorial in composition. The Institutional Ethics Committee (IEC) shall review all ethical aspects of the project proposals received by it from DNB trainees in an objective manner & shall provide advice to researchers on all aspects of the welfare and safety of all the concerned after ensuring the scientific soundness of the proposed research through appropriate Scientific Review Committee.
2. The accredited hospital / institute is required to have an Institutional Ethics Committee (IEC) as per Biomedical Research Guidelines of ICMR. It should be registered with the Drug Controller General of India (DCGI).
3. The number of persons in an ethics committee should be kept fairly small (8 - 12 members). It is generally accepted that a minimum of five persons is required to form the quorum without which a decision regarding the research should not be taken. The IEC should appoint from among its members a Chairman who should be from outside the Institution to maintain the independence of the Committee. The Member Secretary should be from the same Institution and should conduct the business of the Committee. Other members should be a mix of medical/nonmedical, scientific and non-scientific persons including lay persons to represent the differed points of view.

The composition may be as follows:

- Chairperson
  - One - two persons from basic medical science area
  - One - two clinicians from various Institutes
  - One legal expert or retired judge
  - One social scientist/ representative of non-governmental voluntary agency
  - One philosopher/ ethicist/ theologian
  - One lay person from the community • Member Secretary
4. In case the institution does not have an Institutional Ethics Committee (IEC) registered with DCGI, the accredited hospital may tie up with a nearby institution to utilise its DCGI registered IEC. A Memorandum of Understanding in this regard shall be required to be submitted to Accreditation Department of NBE

### **Constitution of Scientific Research Committee/Institutional Research Committee:**

1. In addition to the Institutional Ethics Committee (IEC), the applicant hospital should also have an Institutional Research Committee/Scientific Research Committee (SRC) to mentor & review the research projects in the hospital.
2. The SRC shall comprise of following members: • Head of the Institute - Shall be the Chairman of the Committee • Statistician • Local teaching faculty of the level of Professor/Sr. Consultant from other hospitals/institutions • Guide & Co-Guide(s) of concerned DNB trainee • Basic Sciences Faculty
3. Further members can be incorporated as a part of the above committee and all Guide/Co-Guides will act as ex-officio members.
4. SRC has to be constituted in-house (as per composition prescribed above) as it includes thesis guides of DNB candidates. The thesis protocols of DNB trainees shall be required to be approved by the IEC and SRC.

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(To be issued only on Official letterhead of the hospital)

Ref. No:

Dated:

To,  
Deputy Director,  
National Board of Examinations  
Medical Enclave, Ansari Nagar,  
Mahatma Gandhi Marg (Ring Road)

New Delhi-110029

Subject: - Thesis Protocol Approval Letter (Institutional Ethics Committee & Scientific Research Committee and its Composition)

Sir,

This is for your kind information that the research proposal/thesis protocols of below listed DNB candidates have been considered and reviewed by the Scientific Research Committee (SRC) of the Institute/hospital in its meeting held on \_\_\_\_\_ and by the Institutional Ethics

Committee (IEC) in its meeting held on \_\_\_\_\_. S.N. Name of Candidate Specialty

Session Testing ID/Roll No. Thesis Topic Title The IEC which reviewed the proposals is duly registered with the Drug Controller General of India (DCGI) and SRC of the hospital is composed as per guidelines prescribed by NBE for the purpose. The authenticated copies of composition of both the committees are enclosed herewith. Both the committees i.e. IEC and SRC have approved conducting the study on above listed research proposal(s) of DNB candidate(s) for the purpose of writing their DNB theses. It is further certified that the proposed research protocol(s) have not been/shall not be submitted elsewhere for any degree, fellowship or any other titles for recognition. The minutes of aforesaid meetings of IEC and SRC are available with the hospital and can be reproduced before NBE, if so required, at any point of time.

Name & Signature of the  
Academic Head/DNB Coordinator

Name & Signature of  
Administrative Head of the Institute

Encls.:

1. Composition of Institutional Ethics Committee (IEC)
2. Composition of Scientific Research Committee (SRC) Please affix official stamp of the Hospital Please affix official stamp

