INSTITUTIONAL ETHICS COMMITTEE, NDCH

Project Submission Application Form for Initial Review for Clinical Trials

Please fill in the details in legible hand writing. Incomplete forms are likely to be rejected.

Tick √ in the box for the appropriate answer/ Write NA if question is not applicable

IEC, NDCH Protocol No. (to be filled by IEC, NDCH Secretariat at time of submission)			
Protocol title:			
Details of research study team	Name	Designation & Department	Affiliation
Principal Investigator / PG student			
Co-Investigator / Guide			
Co-Investigator / Co-guide			
Co-Investigator			
If additional collaborators attach details and letter of consent by the collaborator (s) on a separate page			
Study is sponsored: Yes / No			
If sponsored Total Budget: Rs._____ From where is the study being funded a) Research fund is being utilized from in-house funding authority b) External funding agency (specify):			
Type of study: (tick whichever is applicable) a) Prospective / Retrospective / Cross-sectional b) Observational / Interventional			

If interventional, does the study involve

Testing of a new drug? Yes / No

Any deviation from routine/standard of care practices? Yes / No

If yes to any of above questions, please provide details

2. What is the type of intervention being researched? (tick whichever is applicable)

a. Drug

b. Alternative medicine

c. Medical device

d. New technique (surgical, OT, PT, etc)

e, New diagnostic kit/method

f. Other (please specify):

g. Is the test/drug/device marketed or to be marketed in India? Yes / No

If yes to any of the above questions please provide relevant regulatory authority permissions (wherever applicable). Also please attach a copy of the package/product insert.

3. Participant selection:

a. Number of participants to be selected at this centre:

If multicentric: Total no. of centres:

Total no. of participants from all centres:

b. Vulnerable population: Yes / No (tick whichever is applicable)

c. Pregnant women / Illiterate / Seriously/terminally ill / Children / Neonates / Mentally challenged / Elderly / Physically challenged / Economic/social backwardness / Institutional employees / Students / Others (please specify)

Note: If your study involves vulnerable populations please download relevant vulnerable group form and submit along with other documents at time of initial submission

4. Does the study involve use of:

a. Fetal tissue or abortus Yes / No

b. Organs or body fluids Yes / No

c. Gene therapy/genomics/proteomics Yes / No

If yes for gene therapy, then please attach copy of permission from Genetic Engineering Advisory Committee (GEAC)

d. Ionizing radiation / Radioisotopes Yes / No

If yes, please submit a copy of Bhabha Atomic Research Centre (BARC) Permission.

e. Infectious / bio-hazardous specimens Yes / No

f. Will pre-existing / stored / left over samples be used for future research Yes / No

g. Will samples be kept for banking / future research purpose Yes / No

h. Will any sample be sent abroad Yes / No

If yes, please submit a copy of Director General of Foreign Trade (DGFT) permission

i. Is there any collaboration with an external institution, laboratory or clinic (either domestic or foreign) Yes / No
   a. If yes, please attach copy of MoU between NDCH and that organization.
   b. If yes for foreign collaboration, please submit a copy of Health Ministry Screening Committee (HMSC) approval *or any other funding agency requirements (as applicable).*

5. Will any advertising be done for recruitment of subjects? (Posters, flyers, brochures, etc)
   If yes, kindly attach a copy for IEC, NDCH review

6. Is there compensation for participation (travelling allowance)?
   If yes, then Monetary / Kind
   If monetary, then specify amount:
   If kind, then provide details:

1. Are there any arrangements for compensation / treatment of trial related injury?
   If yes, then who will provide: Sponsor / Insurance company / Investigator / Others
   Please provide relevant copies

2. Do you (or your PG guide) have any conflict of interest in the present study? (financial / non – financial/ any other) Yes / No
   If yes, specify

3. Is any other department involved in participant recruitment / investigation, but not co-investigators or collaborators? Yes / No
   If yes, give details:
   Attach relevant copy of other department with HOD signature

We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.

Signature of Principal Investigator:

Signatures of Guide/Co- investigators:

Signatures (with seals) of forwarding authorities (as predetermined by NDCH) / Letter of approval from Institutional Ethical / Review Board of respective colleges (other than NDCH)