বঙ্গবন্ধু শেখ মুজিব মেডিক্যাল বিশ্ববিদ্যালয়
Bangabandhu Sheikh Mujib Medical University
শাহবাগ,ঢাকা-১০০০।

Register No :
Received Date :
Meeting Date :
Approved/Not Approved/Revised/Correction

Application for Institutional Review Board (I.R.B) Clearance

1. Title of the study :

2. Principal Investigator(PI)/ :

3. Guide/Adviser :

4. Co- investigator :

5. Place of the Study :

6. Type of the study :

7. Duration :

8. Total cost :

9. Funding Agency(lf Applicable):

We agree to obtain approval of the Institutional Review Board of BSMMU for any changes involving the rights and welfare of subjects or any changes of the Methodology before making any such changes.

Principal Investigator/Student

Co- Investigator/Guide

Put Tick sign (√) against appropriate answers to each of the following statement
(If not Applicable, Please write NA)

1. Source of Population:

(a) Patients ☐ Yes ☐ No

(b) Healthy Subjects ☐ Yes ☐ No

(c) Minors or person under guardianship ☐ Yes ☐ No

2. Does the study involve:

(a) Physical risks to the subjects ☐ Yes ☐ No

(b) Social Risks ☐ Yes ☐ No

(c) Psychological risks ☐ Yes ☐ No

(d) Discomfort to subjects ☐ Yes ☐ No

(e) Invasion of the body ☐ Yes ☐ No

(f) Invasion of Privacy ☐ Yes ☐ No

(g) Disclosure of information damaging to subject or others ☐ Yes ☐ No

3. Does the study involve :

(a) Use of records :- (Hospital, Medical, Death, Birth or other) ☐ Yes ☐ No

(b) Use of foetal tissues or abortus ☐ Yes ☐ No

(c) Use of organs or body fluids ☐ Yes ☐ No

4. **Are subjects clearly informed about?**

(a) Nature and purposes of study ☐ Yes ☐ No

(b) Procedures to be followed including alternative used ☐ Yes ☐ No

(c) Physical risks ☐ Yes ☐ No

(d) Private questions ☐ Yes ☐ No

(e) Mental risks ☐ Yes ☐ No

(f) Benefits to be derived ☐ Yes ☐ No

(g) Right to refuse to participate or to withdraw from study ☐ Yes ☐ No

(h) Confidential handling of data ☐ Yes ☐ No

(i) Compensations: (where there are risks or loss of working time or privacy is involved in any particular procedure) ☐ Yes ☐ No

5. Signed consent form will be obtained:

(a) From Subjects(If adult) ☐ Yes ☐ No

(b) From parent or guardian (if subjects are minor) ☐ Yes ☐ No

6. Will precautions be taken to protect anonymity of subjects? ☐ Yes ☐ No

INSTRUCTIONS FOR PREPARATION OF AN ABSTRACT FOR THE INSTITUTIONAL REVIEW BOARD(I.R.B)

An abstract should be submitted according to the instructions given bellow:

1. The abstract should summarize the purpose of the study, the methods and procedures to be used.
2. State the requirements in respect of the subject population and explain the rationale for using population of special groups such as children or groups whose ability to give voluntary informed consent is questionable.
3. Describe and assess any potential risks - physical, psychological, social, legal or other and assess the likelihood of methods of research create potential risk. Describe other methods, if any, that may be considered as safe and why they can not be used. If their is any potential benefit please mention it .
4. Describe procedures for protecting against or minimizing potential risks and assessment of their effectiveness.
5. Please state the methods of confidentiality or protecting anonymity.
6. Describe the process of obtaining informed consent. When there are potential risks to the subject, or the privacy of the individual may be involved the investigator is required to obtain a signed informed consent form the subject (For minors, informed consent must be obtained from the authorized legal guardian or from parent of the subject).

   a) If signed consent will not be obtained, explain why this requirement should be waived and provide an alternative procedure such as a verbal consent.

   b) If information is to be withheld from a subject, justify it.

   c) If there is a potential risk to the subject or privacy of the individual or loss of work time is involved in any particular procedure, include a statement in the consent form stating whether any compensation will be available.

7. If the study involves an interview, describe where and in what context the interview will take place. State approximate length of time required for interview.
8. Assess the potential benefit to be gained by the individual subject as well the benefits which may fruitful for the society in general as a result of this work. Indicate how the benefits may outweigh the risks.
9. If experimental drugs will be used, provide information about its status of registration for open sale in Bangladesh and in other developed countries.
10. For experimental “new drugs” as well as which are not registered in Bangladesh, provide full information about the toxicity studies carried out in animals or human volunteers. Published papers on this subject should be annexed.
11. If placebo is to be used justify its uses and explain why the study can not be done without placebo.
12. For an experimental “New” drug study, give a statement regarding its sponsorship and conditions for such sponsorship.
13. Describe if the study requires the use of records (hospital, medical, birth, death or other) organs, like body fluids, the foetus of the abortus.

“New drugs” means one which is not registered for free and open sale in Bangladesh)

Check documents being submitted here with to Board (Total 14 copies should submit):

- Project proposal.
- Proposal Summary.
- Abstract for Institutional Review Board as per attachment (Obligatory).
- Informed consent form (From Subject/Guardian) in Bangla/Local Language.
- Procedure for maintaining confidentiality.
- Questionnaire or interview schedule.
- A description of the areas to specific questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
- Examples of the type of specific question to be asked the sensitive areas.
- An indication as to whom the questionnaire will be presented to the Board review.
- Detailed budget.
- Time table of Study/Flow chart.

Serial Should be Maintained as Follow :-

1. Application
2. Permission from the Departmental Chairman.
3. Check list
4. Abstract for IRB
5. Informed Consent form.
6. Study Protocol Proper.
7. Numbering of Page is Mandatory.