

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

	Register No:	
ায়	Received Date :	
	Meeting Date :	l

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	:				
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7.	Duration	:				
8.	Total cost	:				
9.	Funding Agency(If 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.						
Princ	cipal Investigator/Student		Co- Investigator/Guide			

Put Tick sign ($\sqrt{\ }$) against appropriate answers to each of the following statement (If not Applicable, Please write NA)

1.	1. Source of Population:				Are	t?	
	(a)	Patients	□Yes □ No		(a)	Nature and purposes of study	☐ Yes ☐No
	(b)	Healthy Subjects	☐ Yes ☐No		(b)	Procedures to be followed including	
	(c)	Minors or person under guardianship	☐ Yes ☐ No			alternative used	Yes No
					(c)	Physical risks	Yes No
2.	Doe	es the study involve:			(d)	Private questions	Yes No
	(a)	Physical risks to the subjects	S Yes No		(e)	Mental risks	Yes No
	(b)	Social Risks	☐ Yes ☐ No		(f)	Benefits to be derived	Yes No
	(c)	Psychological risks	☐ Yes ☐ No		(g)	Right to refuse to participate or to withdraw from study	Yes No
	(d)	Discomfort to subjects	☐ Yes ☐ No		(h)	Confidential handling of data	Yes No
	(e)	Invasion of the body	☐ Yes ☐ No		(i)	Compensations:	
	(f)	Invasion of Privacy	☐ Yes ☐No		(1)	(where there are risks or loss of working time or	
	(g)	Disclosure of information damaging to subject or others	☐ Yes ☐No			privacy is involved in any particular procedure)	☐ Yes ☐ No
				5.	Sig	ned consent form will be obtain	ed:
3.	Doe	es the study involve :			(a)	From Subjects(If adult)	Yes No
	(a)	Use of records :- (Hospital, Medical, Death, Birth or other)	Yes No		, ,	From parent or guardian (if subjects are minor)	☐ Yes ☐No
	(b)	Use of foetal tissues or abortus	☐ Yes ☐No	6.		Il precautions be taken protect anonymity of subjects?	∏Yes ∏ No
		Use of organs or body fluids	☐ Yes ☐No		o prosou anony m		

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.