IRB Research Protocol Submission Form

Documents Required for IRB Application

- Copy of IRB Application form
- Copy of research proposal
- Copy of questionnaire/Performa for the study
- Drug brochure or any other relevant information related to the study (if applicable)
- Copy of consent forms in both Urdu and English or any other regional languages.

All submissions will be done electronically on the email address researchanddevelopment@smbbit.gos.pk

Instructions/Guidelines for Researchers – IRB Submissions

1. **IRB Approval or Exemption:**
   All studies, including those not involving direct human participation or intervention, must be submitted to the IRB for approval or an exemption letter *before* starting the study. Retrospective approval is not allowed.
2. **Postgraduate Students, Trainees, and Medical Officers:**
   Must obtain signatures from their HOD/Supervisor before submitting Research Proposals, Case Reports, Case Series, or Letters to the Editor to the IRB.
3. **Faculty, Specialists, Fellows, Consultants, and Junior Consultants:**
   May submit directly to the IRB office or obtain Executive Director's signature for streamlined review.

Research Title:_____

Name & Signature

Principle Investigator

Date

Name & Signature (Along with Stamp)

HOD/Supervisor/Executive Director

Date

Principal Investigator (PI) Information:

Principle Investigator Name	
Designation	
Department or Unit Name	
Email	
Contact Number	
Signature	
Date	

Co-Investigators Information:

If there are more than three authors, please write down only the names and institutions of the remaining other authors.

1.

Co-Investigator Name	
Designation	
Department or Unit Name	
Email	
Contact Number	
Signature	
Date	

2.

Co-Investigator Name	
Designation	
Department or Unit Name	
Email	
Contact Number	
Signature	
Date	

3.

Co-Investigator Name	
Designation	
Department or Unit Name	
Email	
Contact Number	
Signature	
Date	

Title of Research/Project:	

Select one of the categories for your research project. Put this mark on your selected answer	a. Clinical trial on a medicine/drug b. Clinical trial on a medical device c. Experimental/ surgical procedure/s d. Study administering questionnaires/interviews for quantitative or mixed qualitative/quantitative methods. e. The study involves qualitative methods only f. Study is limited to working with human tissue samples, other human biological samples, and data g. Research database (secondary data analysis only) h. Research involving animal subjects
If there is any other category, then please write it down in the space given	

What is the purpose/Scientific justification/ rationale of the study?	

Enumerate the objectives of the study	

Brief description of methods used in the protocol. (Please mention here the process the participant will have to go through to be part of the study.)	
a) Methods	
b) The expected time duration of the study will take till completion	
c) Expected duration of study on each subject	

Study Subject information.			
a) Group:	☐ Patients	☐ Students	☐ Others
b) Hospital Medical Records:			
c) Study subject age range:			
d) Sex	☐ Male	☐ Female	☐ Both
e) If subjects are children, pregnant women, mentally handicapped persons, prisoners, or if it includes foetal research, please provide justification for the need to use these particular subjects.			

Criteria for inclusion and exclusion of patients and controls.	

Location of study:	☐ Outpatients units ☐ Inpatients units ☐ SMBBIT Department ☐ Outside SMBBIT: _____(please specify the location)

How will the confidentiality of the subjects be ensured?	

Describe possible adverse outcomes/risks potential that may affect the subjects.	
a) What is the provision for managing these adverse outcomes?	
b) Who will pay for them?	
In such cases where the therapeutic needs of the research subject are identified during the study:	
a) What is the provision for managing these needs of the subjects?	
b) Who will pay for them?	

Please indicate the source of funding.	
If yes Has funding been approved?	

Compensation (If any to research subject):	
Monetary:	☐ No ☐ Yes If Yes Amount:_____
Other:	☐ No ☐ Yes If Yes Specify:_____
Reimbursement of expenses:	☐ No ☐ Yes Type & Amount:_____

What are the actual potential benefits, if any, to be obtained?	
a) By participants.	
b) By society as a result of this study?	
c) Please specify the benefit of the study to the funding agency or sponsors.	
d) Please specify the benefit of the study to the institution where the study is being conducted.	

Will the study findings be shared with	☐ Study subjects ☐ Community at large If yes, please indicate how:

Please point out any ethical issues involved in the study.	

Is any other information relevant to the study in the context of Pakistan?	

Has this study been conducted elsewhere earlier?	