IRB APPLICATION FORM FOR EXEMPTION OF RESEARCH STUDIES

Documents Required for IRB Exemption Form Application

- Copy of IRB Exemption 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 (if applicable)

All submissions will be done electronically to 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.

Studies which may qualify for exemption from ethical review:

1. Retrospective review of clinical data without any identifiable information about patients. The data may be obtained from patient's charts. (Details of data which can be extracted is given elsewhere).
2. Prospective data collection from patient's charts without any identifiable information about patients. (same as in #1).
3. Analysis of laboratory data without any identifiable information about patients. (Details of data which can be extracted is given elsewhere).
4. Clinical audits.
5. Evaluation of practice guidelines without identifying information about the users of those guidelines.
6. Case reports without identifying the study subjects or photographs unless written consent has been obtained from study subject or his/her legal guardian.
8. Other studies in which humans are not involved, such as, research on policy documents. However, if the policies are termed as 'classified', consent from the appropriate authorities should be obtained for their use in research or resulting publications.
9. Autobiographical studies in which the sample is the researcher himself/ herself.
10. Quality assurance performance review studies. In such studies organizations may evaluate their programs to improve their services, such as reports internal to the organization. Findings from these studies may be relevant to other stakeholders.
11. Review of studies involving public data, for instance, published biographies, newspaper accounts of individuals' activities and published minutes of meetings, educational tests and survey procedures. Care should be taken to handle the information in such a way so as not to pre-empt any disclosure.
12. Auto ethnographical studies where researcher uses his/ her own experiences in order to gain deeper understanding of a group's culture and/ or theorize modes of human behavior within a group and across different groups. Research in such studies would involve documentary evidences available publicly. Examples of auto ethnography can be found in the 'Journal of the Society for the Study of Symbolic Interactionism', 'Journal of Contemporary Ethnography' and the Journal of Humanistic Ethnography. Care should be taken to not disclose personal information about others with whom the writer has had a close relationship. For example, a teacher in his/ her autobiography cannot publish details or personal views, photographs and confidential statements of his/ her students without permission.
13. Reflective practice/ professional development studies where practitioners can develop a greater level of self-awareness about the nature and impact of their performance for professional growth and development. Examples of such studies can be found in journals of reflective practice.

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	

IRB Application Form for Exemption of Studies from

Please mark the appropriate box as √

Types of study		Yes/No
a.	Retrospective review of patient's charts	
b.	Prospective data collection from patient's charts	
c.	Analysis of laboratory/ radiology data	
d.	Clinical audit	
e.	Evaluation of practice guidelines	
f.	Case reports	
g.	Others; please specify	
6. Period of data collection		
From		to

Summary of data to be collected		Yes/No
a.	Demographics of the patients i.e. name addresses, phone numbers, e-mail address, MR#	
b.	Clinical notes	
c.	Photographs	
d.	Laboratory data/ radiology data	
e.	Management data	
f.	Other, please specify	

Utilization of data to be collected: Will it be used for		Yes/No
a.	Publication of papers in journals / newspapers	
b.	Oral / poster presentation in meetings / conferences	
c.	Students / residents' teaching	
d.	Planning subsequent larger studies	

Summary of Objectives & Methods of Study including selection and exclusion criteria of study subjects, sample size, analysis plan etc.

Please answer the following questions and mark the appropriate box as √

	Questions	**Yes/No**	
a.	Will any photographs be used/taken for publication?		
b.	If yes, has written permission been obtained from study subject or guardian?		
c.	Has the study been reviewed by departmental research / review committee		
d.	Was any ethical concern raised by departmental committee?		
e.	If yes, what were the ethical issues?		
f.	Were those concerns of ethics resolved?		