



ERC APPLICATION FORM FOR EXEMPTION OF STUDIES

Documents Required for ERC Exemption Form Application

- Copy of ERC 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:

- The studies in which human subjects are not involved directly, or no intervention is done are often exempted from full review of Ethics Review Committee (ERC). Since majority of journals ask for approval by an Institutional Review Board or by ERC before accepting a manuscript for publication, it is necessary that the researchers get an approval or an exemption letter from ERC before starting the study as it is unprincipled for ERC to review studies retrospectively. It is the responsibility of researchers to obtain such a letter before any study is started.
- This point is again restated for emphasis: even if studies fall in the exemption category, they still need to be submitted to ERC for obtaining a letter of exemption prior to the commencement of the study as ERC does not allow retrospective review of studies, even for the purpose of publication.
- For Postgraduate students, trainees, and medical officers, HODs/Supervisors' signatures are required before sending Research Proposals/Case reports/Case series/Letters to the editor to the ERC, ensuring oversight and compliance.
- Faculty members, specialists, fellows, consultants, and junior consultants can submit Research Proposals/Case reports/Case series/Letter to editor forms directly to the ERC office or have them signed by the Executive Director, streamlining the review process for faster approval.
- Please ensure all questions are answered. It is the responsibility of the researcher to fill out the application form appropriately. Incomplete or inappropriate forms will not be accepted for review by the committee, which may result in delays in proposal approval.
- This form must be typed and not handwritten.



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.



SHAHEED MOHTARMA BENAZIR BHUTTO

INSTITUTE OF TRAUMA

Department of Research & Development

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	



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INSTITUTE OF TRAUMA

Department of Research & Development

Email	
Contact Number	
Signature	
Date	

ERC Application Form for Exemption of Studies from Ethics Review

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	
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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 \surd

	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?		