



# SHAHEED MOHTARMA BENAZIR BHUTTO

## INSTITUTE OF TRAUMA

Department of Research & Development

### RESEARCH APPLICATION FORM ETHICS REVIEW COMMITTEE (ERC)

#### Documents Required for ERC Application

- Copy of ERC 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](mailto:researchanddevelopment@smbbit.gos.pk)

#### Instructions/Guidelines for Researchers:

- 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.

**Research Title:** \_\_\_\_\_

Name & Signature

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**Principle Investigator**

-----  
**Date**

Name & Signature (Along with Stamp)

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**HOD/Supervisor/Executive Director**

-----  
**Date**



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### 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	



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<b>Title of Research/Project:</b>	
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<b>Select one of the categories for your research project.</b>  Put this mark on your selected answer	<ol style="list-style-type: none"><li>Clinical trial on a medicine/drug</li><li>Clinical trial on a medical device</li><li>Experimental/ surgical procedure/s</li><li>Study administering questionnaires/interviews for quantitative or mixed qualitative/quantitative methods.</li><li>The study involves qualitative methods only</li><li>Study is limited to working with human tissue samples, other human biological samples, and data</li><li>Research database (secondary data analysis only)</li><li>Research involving animal subjects</li></ol>
If there is any other category, then please write it down in the space given	

<b>What is the purpose/Scientific justification/ rationale of the study?</b>	
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<b>Enumerate the objectives of the study</b>	
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<b>Brief description of methods used in the protocol.</b> (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	

<b>Study Subject information.</b>	
a) Group:	<input type="checkbox"/> Patients <input type="checkbox"/> Students <input type="checkbox"/> Others
b) Hospital Medical Records:	
c) Study subject age range:	
d) Sex	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> 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.	



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<b>Criteria for inclusion and exclusion of patients and controls.</b>	
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<b>Location of study:</b>	<input type="checkbox"/> Outpatients units <input type="checkbox"/> Inpatients units <input type="checkbox"/> SMBBIT Department <input type="checkbox"/> Outside SMBBIT: _____(please specify the location)
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<b>How will the confidentiality of the subjects be ensured?</b>	
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<b>Describe possible adverse outcomes/risks potential that may affect the subjects.</b>	
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a) What is the provision for managing these adverse outcomes?	
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b) Who will pay for them?	
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<b>In such cases where the therapeutic needs of the research subject are identified during the study:</b>	
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a) What is the provision for managing these needs of the subjects?	
--	--

b) Who will pay for them?	
---------------------------	--

<b>Please indicate the source of funding.</b>	
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If yes Has funding been approved?	
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<b>Compensation (If any to research subject):</b>	
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Monetary:	<input type="checkbox"/> No <input type="checkbox"/> Yes If Yes Amount: _____
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Other:	<input type="checkbox"/> No <input type="checkbox"/> Yes If Yes Specify: _____
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Reimbursement of expenses:	<input type="checkbox"/> No <input type="checkbox"/> Yes Type & Amount: _____
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<b>What are the actual potential benefits, if any, to be obtained?</b>	
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a) By participants.	
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b) By society as a result of this study?	
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c) Please specify the benefit of the study to the funding agency or sponsors.	
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d) Please specify the benefit of the study to the institution where the study is being conducted.	
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<b>Will the study findings be shared with</b>	<input type="checkbox"/> Study subjects <input type="checkbox"/> Community at large If yes, please indicate how:
<b>Please point out any ethical issues involved in the study.</b>	
<b>Is any other information relevant to the study in the context of Pakistan?</b>	
<b>Has this study been conducted elsewhere earlier?</b>	