



General Directorate of Qassim health affairs
Planning & Training Administration



**Continuing Medical Education & Research Center
Qassim Region Research Ethics Committee (QREC)
Proposal submission Checklist**

Dear Principal Investigator (PI),

This checklist has been designed by QREC based on regulations of the National Committee of Medical & Bioethics (NCBE) to help investigators to ensure that all elements necessary for the development of a complete and ethically sensitive protocol are covered. Therefore, please ensure that enough time is given to complete this checklist. If some of the checklist items are missing from your protocol, please make changes to include them. Meanwhile, you should also know that this checklist covers only part of the ethical considerations involved in research with human subjects/participants. Therefore, you should be aware that further issues and considerations may arise during ethical review procedure. If so, you will be contacted by QREC accordingly.

Research title:

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PI name:

Date:

PI contact:

E-mail:

Land line:

Mobile No:

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Please note the following:

- For all studies, the principal investigator (PI) is responsible for completing this checklist and submitting it to QREC.
- In case of experimental studies, special form can be requested from QREC.
- Written ethical approval from QREC must be obtained before field work is commenced.

Please, check the appropriate responses for the following items. For items that do not apply to your research proposal/project, leave the choices empty.

Research title:

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SECTION A: NCBE requirements

Item	Yes	No
Cover letter from Principal Investigator (PI) institute	<input type="checkbox"/>	<input type="checkbox"/>
Research proposal/protocol	<input type="checkbox"/>	<input type="checkbox"/>
Data collection tools (e.g. Questionnaire)	<input type="checkbox"/>	<input type="checkbox"/>
Informed consent (if needed)	<input type="checkbox"/>	<input type="checkbox"/>
Information sheet (if needed)	<input type="checkbox"/>	<input type="checkbox"/>
Principal Investigator and Co- investigator(s) C.Vs	<input type="checkbox"/>	<input type="checkbox"/>
Registration Certificate FROM king Abdul-Aziz City for Science and Technology (KACST); http://bioethics.kacst.edu.sa/	<input type="checkbox"/>	<input type="checkbox"/>

SECTION B: Research proposal/protocol

No.	Item	Yes	No
1.	Cover page: study title, PI name, institution name and contact details (telephone number and email). All must be provided	<input type="checkbox"/>	<input type="checkbox"/>
2.	Background and Rationale	<input type="checkbox"/>	<input type="checkbox"/>
3.	Objectives: primary& secondary objectives	<input type="checkbox"/>	<input type="checkbox"/>
4.	Study design: specify, e.g. cross –sectional, case-control, case series, cohort, ...etc	<input type="checkbox"/>	<input type="checkbox"/>
5.	Study setting	<input type="checkbox"/>	<input type="checkbox"/>
6.	Study population, including details of the study subjects/participants	<input type="checkbox"/>	<input type="checkbox"/>
7.	Inclusion & exclusion criteria	<input type="checkbox"/>	<input type="checkbox"/>
8.	Sampling technique: sample size determination	<input type="checkbox"/>	<input type="checkbox"/>
9.	Study procedures, if any	<input type="checkbox"/>	<input type="checkbox"/>
10.	Study duration	<input type="checkbox"/>	<input type="checkbox"/>
11.	Statistical analysis Plan	<input type="checkbox"/>	<input type="checkbox"/>
12.	Ethical considerations & confidentiality	<input type="checkbox"/>	<input type="checkbox"/>

13.	References	<input type="checkbox"/>	<input type="checkbox"/>
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