Wah Medical College
Research Advisory Committee /Institutional Review Board
Covering Letter

To:

The Chairperson (WMC-RAC/IRB)

Subject: Request for RAC/IRB Approval

Dear Sir,

1. I intend carrying out a research study/clinical trial entitled "_____"

at "_____" (institution/hospital/college).

2. Following documents are enclosed (as per IRB requirements) in hard form.

a. Application form.

b. Synopsis (Introduction, Objectives, Methodology, Ethical concern if any, References).

c. Informed consent form (English and Urdu).

d. Data Collection Forms (surveys, questionnaires)

e. Drug/Medical Device Brochure and any available safety information (if applicable).

f. Investigators' curriculum vitae (if applicant is outsider).

Or any other additional document that will be required for approval.

3. I have submitted all the required documents as mentioned in point 2, by e-mail at trc@wahmedicalcollege.edu.pk . Approval is requested for the attached study protocol.

Date: _____

Principal Investigator:

Name: _____

Signature: _____

RESEARCH ADVISORY COMMITTEE/ INSTITUTIONAL REVIEW BOARD APPLICATION FORM

Name of Principal Investigator (PI): ----------

Designation ---------- **Department** ----------

Address for correspondence ----------

Mobile/Land Line NO. ---------- **E-mail:** ----------

Title of Study ----------

If the PI is a student provide the following information:

Discipline/Subject ---------- Department ----------

Name & e-mail Address of Faculty Advisor----------

Proposed beginning date of study ----------**Estimated duration of study** ----------

Type of Project (Check all that apply)

PhD Thesis Master's Thesis Study Dissertation Class Project

Faculty research Pilot Other (specify) ----------

Please refer to instructions while completing this form.

The application may be typed (Calibri 12)

- **Describe the purpose of study, including Rationale& Objectives.**

- **Study subjects/participants' Information (use additional paper if required)**

1. Description of participants in study
2. Approximate number of participants
3. Vulnerable populations as participants (check all that apply)

Pregnant women Fetuses/neonates Minors

0thers (Please specify) _____

4. Age (or age range) of participants: _____
5. Gender of Participants Male Female Both

- **Describe in detail the research procedures under following heads (use additional paper)**

a. Magnitude of problem and current local, national and international information available on the research topic

b. Study design

c. Methodology

d. Statistical analysis

e. References (not older than 5 years, must include local or national study)

- **Does study require follow up?** Yes No

  If yes:

  Duration_____

- **Location of Study**

  i). Outpatients ii). Inpatients iii). WMC Department

  iv). Other than WMC (please specify location) If multi-institutional or multi-unit

  Approval by the concerned head/in charge

  Name _____

  Designation_____

  Signature with stamp_____

- **Potential Risks and Protection of Participants**

  Explain the potential risks to the human participants involved in this research. All risks must be identified and listed on the consent form (If applicable).

- **Risk:** _____

Steps to Minimize Risk: _____

(Use Continuation pages if necessary)

- **Funding?**

  Yes No

- **Source of Funding** _____
- **Confidentiality and Data Storage:**

  How will confidentiality of data collected be maintained?

_____

_____

Benefits/Remuneration:

What will the participant receive for taking part in the study?

(i.e., financial remuneration free services, access to information, and access to an intervention)?

_____

_____

What are the generalizable benefits of this study?

(Contribution to knowledge in field).

_____

Discuss **Ethical Issues** involved in the study.

_____

_____

_____

- **Adverse Effects:**

  Describe adverse effects/risks expected to the subjects involved in the investigation during the study?

  _____

  _____

  _____

- **Informed Consent:**

  Consent form of proposed study as per ethical guidelines attached**?**

  Yes No

- **Assurance:**

I, _____, from_____

Principal Investigator for the Research titled hereby declare that I have read and understood the information/terms/condition required in the application form and the information provided by me is correct.

Name_____ Date _____

Faculty Research Supervisor (for student research only) **Signature certifies that the faculty member has read reviewed, and approved the content of the research and is responsible for the supervision of this research.**			
Supervisor Name	Stamp	Signature	Date

For RAC/ IRB official use only:

Date application received: _____ **Date application Approved/Decline: _____**	**Research no: _____**
(WMC-RAC/IRB) committee decision **This request for ethical approval has been:** • **Approved (no additional information is required)** • **Approved with conditions (see below comments)** _____ _____ • **Declined**	
_____ **Dean of Academics** **Prof. Musarat Ramzan** **Head RAC/IRB**	_____ **Principal** **Maj Gen(R) Abdul Khaliq Naveed HI (M)** **Chairperson RAC/IRB**