Research Advisory Committee /Institutional Review Board (RAC/IRB)

Wah Medical College

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Research Advisory Committee /Institutional Review Board Terms & Conditions

1. **Title:**

   Wah Medical College Research Advisory Committee/Institutional Review Board (WMC-RAC/IRB).

2. **RAC/IRB Mandate:**

   All researches taking place at WMC by its faculty and students at any site, which involves human subjects, tissues, products of fetus or genetic material from human subjects, whether dead or alive, will need approval by the IRB before the research can commence.

3. **Committee Responsibilities:**

   The Research Advisory committee/Institutional Review Board (RAC/IRB) is responsible for considering the ethical implications of proposed research studies conducted at WMC by its faculty and students at any site and determining whether or not these are acceptable on ethical grounds. The RAB/IRB shall:

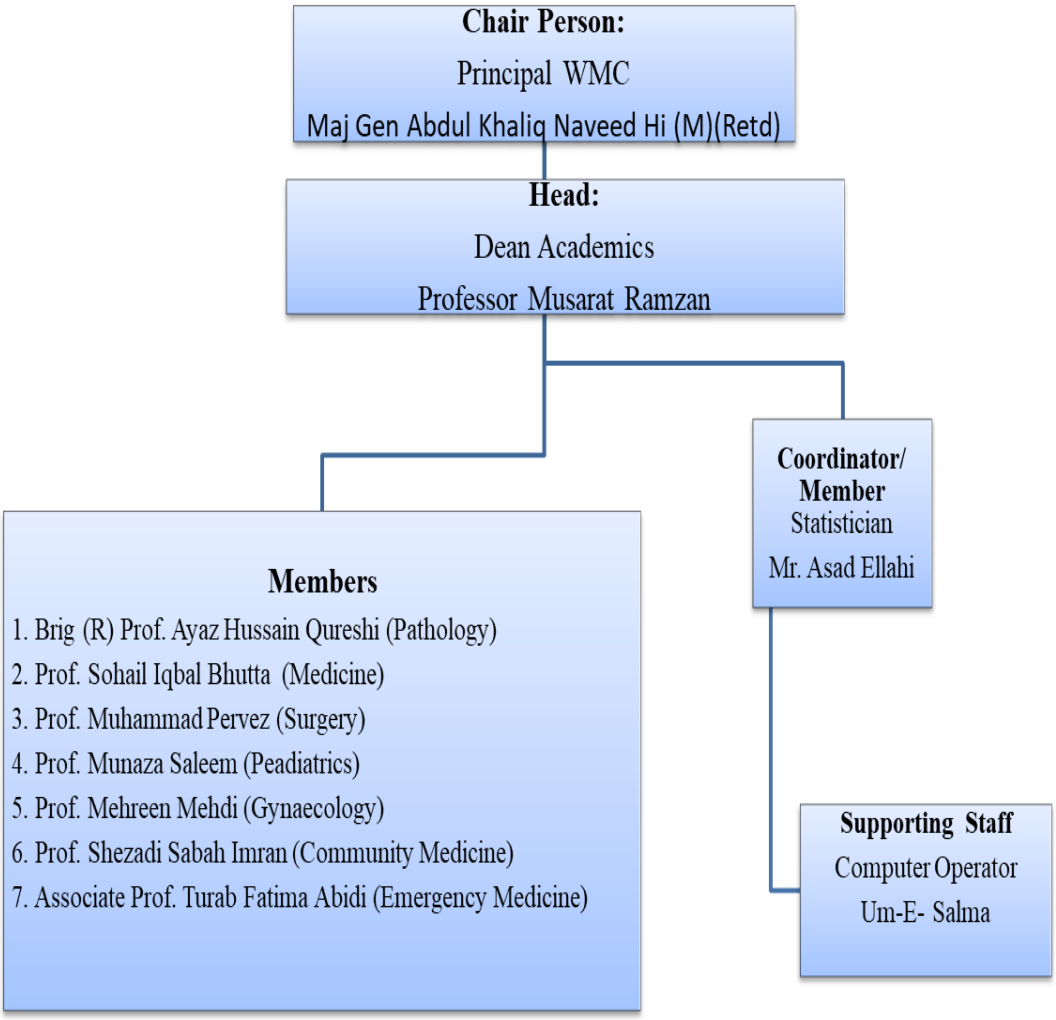
   i. Review and approve either with or without modification or withhold approval regarding proposals for research on human subjects, tissues, products of fetus and genetic material whether dead or alive by faculty members, students and visiting scholars on the basis of ethical considerations.

   ii. Regularly review ongoing researches being conducted in the college or hospital for any unethical practices.

   iii. Maintain a Record in database, information pertaining to all research proposals including name, addresses and qualifications of the Principal Investigator(s), title of the project, research methodology and the research objectives.

4. Working Body of RAC/IRB

i. Organogram



ii. Chairperson:

Heads the committee and allows final approval of research.

iii. Head:

Chairs the meetings and acts in the capacity of the Chair in his absence.

iv. Coordinator:

Assigns primary reviewers in consultation with the head, receives and anatomize all the protocols, maintains record in safe custody, maintains

follow-up, when necessary, responsibility to schedule the meetings and archiving of the proceedings in her safe keeping.

v. **Role of Members:**

- **a.** Advise on all matters related to research development.
- **b.** Review and recommend polices and processes relevant to proposed research protocol.
- **c.** Undertake extensive review of materials from time to time.
- **d.** Establish policies and guidelines as deemed fit.
- **e.** Participate in meetings/teleconferences as called by the Chair/Head
- **f.** Submit feedbacks and updates timely to the RAC/IRB.

vi. **Reporting Relationship:**

The coordinator will report directly to the head on periodic basis.

vii. **Appointments:**

New members if required will be appointed by the Chairperson/Head.

viii. **Chair/Head**:

One of them must be present at the meeting.

ix. **Revocation of Membership:**

If a member is absent for three (3) consecutive meetings without assigning a reason, despite being informed of the meeting, his/her membership will be revoked.

5. Meetings Schedule:

i. **Frequency of Meetings:**

At least one meeting per month would be conducted with flexible number of researches depending upon the number of proposals.

ii. **Consideration of the proposal for the meeting:**

Only those proposals will be considered for IRB meetings which are submitted timely (at least one week before the meeting).

6. Synopsis Approval Policy:

i. **Submission of Researches:**

Researches will be submitted to the coordinator who is responsible to forward it to the Chairperson, Head and members of the RAC/IRB committee.

ii. **Presentation to Committee:**

The proposal would be presented by the researcher within five to eight minutes and He/She would be asked for any clarification about synopsis or proposals in the committee on the specified date.

iii. **Decisions of the Committee Members:**

The research proposal would be rejected in whole or in part if the majority of the committee members are not satisfied. The willingness of 4 out of 8 members for the acceptance of the research proposal is mandatory.

iv. **Issue Number:**

The RAC/IRB number will be assigned on the date of receiving the research proposal.

v. **Duration of Review:**

The review will be finalized in maximum two meetings.

vi. **Specialist Advice:**

The Chair/Head may invite any relevant individual to attend a particular meeting and give specialist advice to the committee. Such individuals should not participate in the final decision of the Committee.

vii. **Conflict of Interest:**

Committee members must inform the Chair if they have a financial or personal interest in a research proposal. The Chair will decide whether the interest disqualifies the member from the discussion. Members will not be included in the meetings/proceedings if their own or of their candidate proposal is under review/discussion.

7. Committee Powers:

The Committee may:

i. Revoke approval if dissatisfied with the conduct of the research or of the researcher.

ii. Defer consideration of a research proposal to a subsequent meeting if substantial modification is required or where significant additional information is needed.

iii. Authorize the researcher to proceed without requiring any amendment.

iv. Require clarification or modification of parts of the submitted research. The Chair/Head will normally be granted authority to approve the amendments without requiring further deliberations by the full Committee.

8. Cancellation of Approval:

The RAC/IRB will have the authority to cancel approval if a progress report is not submitted even after it is sought. The approval may also be withdrawn if new risks/side effects are revealed or disclosure of any adverse incident during the course of a study even if the incident is not directly related to the study (e.g., a complaint by a subject, etc). The approval may also be withdrawn if the RAC/IRB comes to know of misconduct by the Author, breaching the contract of trust between the Principal Investigator and the RAC/IRB.

9. Mechanism of Informing Principal Investigator:

The Principal Investigator will be informed through an official letter sent by the Chairperson.

10. Renewal:

At the end of three years, Principal Investigator should submit a progress report for further extension in the approval if required.

11. Applicant's Responsibilities:

The applicant is responsible for:

i. Reporting any adverse incident during the course of a study to the Committee, even if the incident is not directly related to the study (e.g., a complaint by a subject, etc).

ii. Notifying the Committee of any change in protocol and obtaining further ethical approval as appropriate.

12. Confidentiality:

Proceedings of the meetings, minutes and archives will be considered highly confidential. All records/data shall be kept in safe custody.

13. Indemnity:

No indemnity will be provided to the researchers for any financial loss and liabilities.

References:

The RAC/IRB document was developed after online guidance from the following websites:

- ***https://www.lumhs.edu.pk/rec/documents/ERCToR.pdf***
- ***http://www.fjmu.edu.pk/Institutional_Ethical_Reviewer_Board***
- ***http://numspak.edu.pk***

Wah Medical College
RAC/IRB 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).

3 x Copies of application form.

3 x Copies of Research Protocol.

3 x Copies of informed consent form (English/Urdu).

3 x Data Collection Forms (surveys, questionnaires)

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

Investigators' curriculum vitae (if applicant is outsider).

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

3. I have submitted the application form, research protocol and informed consent with Urdu translation by e-mail at rac-irb@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