Proposal Submission Form for IRB

IRB Use Only	FMS-20 -
IRB Study #	

1. PROJECT IDENTIFICATION

Project Title

1.2 Principal Investigator (PI)

Name (Last name, First name MI):	Phone Number:
Mailing Address:	Email Address:

1.3 Co-Investigator / Sub-Investigator

Co-Investigators, responsible for knowing and following the protocol, should be listed below. Include any individual who will have responsibility for the consent process, direct data collection from subjects, or follow-up.

Name (Last name, First name MI):	Phone Number:
Mailing Address:	

1.4 Supervisor

Name (Last name, First name MI):	Phone Number:
Mailing Address:	

2. FUNDING

2.1 Is this research funded by an internal or external agency?

☐ **Yes.**

Type of Funding Source:

☐ FMH Medical & Dental College ☐ Nur Foundation ☐ Pharmaceutical Industry ☐ Other, Specify _____

Name of Funding Source: ☐ If **No,** Explain how costs of research will be covered:

_____

_____

2. 2 Will this research be utilizing Fatima Memorial Systems resources or medical records?

☐ Yes ☐ No

2.3 If this study involves greater than minimal risk, provisions for safety monitoring are required to protect participants. Please indicate below the plan for monitoring safety in this study.

☐ **The study will be monitored by the investigator.**

Describe the plan for investigator oversight, including frequency of review and stopping rules

☐ **The study involves no greater than minimal risk; therefore, it does not require safety monitoring.**

2.4 Does this research involve?

	Strategies prevention	Treatment	Survivorship	Supporting care
No.	☐	☐	☐	☐
Yes.	☐	☐	☐	☐

3. SUMMARY OF ACTIVITIES

3.1 What is your research question?

State hypothesis or primary objective, and provide a brief background on subject population, treatment procedures, as rationale for conducting the study.

3.2 What research methods will you use by outlining your study design?

3.3 What will the subjects be asked to do?

3.4 If the study involves treatment, outline procedures which are conducted solely for study purposes.

3.5 Expected duration of study?

How many subjects do you plan to enroll?

Male:	**Female:**	**Total:**	**Sampling Frame:**		**Sample Size:**	

4. SUBJECT PROFILE

4.1 Age Range

Check all that apply:

☐ **0-7** (Include parental consent form) ☐ **8-17** (Include child's assent form and parental consent form)
☐ **18-64** ☐ **65 and older Exact ages to be included:** ☐

4.2 Subject Characteristics. Check all that apply:

☐ Inpatients ☐ Outpatients ☐ Healthy Volunteers ☐ Condition-matched Controls

4.3 Inclusion and Exclusion of Subjects in this Research Study

Inclusion Criteria:	**Exclusion Criteria:**

4.4 Location of subjects during research activity or location of records to be accessed for research:

Check all that apply:

☐ FMH College of Medicine & Dentistry , ☐ FMH Hospital, ☐ Nain Sukh, ☐ Lakhodair, ☐ Ahata Mol Chand, ☐ Other (specify): _____

4.5 Will the subjects be chosen from records?

☐ **Yes.** Who gave approval for use of the records: ☐ **No.**

If yes, are records "private" medical or student records?

☐ **Yes.** Provide the protocol, consent forms, letters, etc. for securing consent of the subjects of the records. Written documentation for the cooperation/permission from the holder or custodian of the records should be attached.

☐ **No.**

5. RISKS AND BENEFITS

5.1 Does the Research Involve?

Check all that apply:

- ▫ Any surgical process
- ▫ Administration of approved/unapproved drugs, chemical, or biological agents
- ▫ Administration of approved/unapproved devices Radioisotopes or other sources of ionizing radiation including X-rays
- ▫ Placebos
- ▫ Controlled Substances
- ▫ Genetic Testing
- ▫ Administration of physical stimuli
- ▫ Major changes in diet, exercise, or sleep
- ▫ **Other risks, specify**:_____
  _____
  _____
- ▫ Blood Draw
- ▫ Use of private records (medical or educational records)
- ▫ Possible invasion of privacy of subject or family
- ▫ Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses
- ▫ Any probing for personal or sensitive information in surveys or interviews
- ▫ Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading
- ▫ Use of a deceptive technique *(suggestion: if deception is part of the experimental design, the protocol must include a debriefing procedure, which will be followed upon completion of the study or upon withdrawal of a subject. Attach a description of the debriefing protocol and any related materials.)*

5.2 Describe the precautions that will be taken to minimize the risk to the subjects.

5.3 List any anticipated *direct and societal* benefits to participation in this research project. If none, state that fact here and in the consent form.

Direct Benefits	Societal Benefits
1.	2.

6. POTENTIAL BIOHAZARDS

☐ **Infectious Agents**

Will this research include identification or culturing of pathogenic organisms (in risk group 2 or above?

☐ Yes, ☐ No

If No, please explain:

6.1 Will this research include blood drawing, marrow biopsy sampling, biopsy of other tissues, etc.

☐ **Yes,** ☐ **No**

7. CARE OF SUBJECTS IN CASE OF ACCIDENT/ INJURY

If this research requires a potential for injury, how will you proceed with the case?

8. CONFIDENTIALITY OF DATA

8.1 Will data identifying the subjects be made available to anyone other than the Principal Investigator?

☐ Yes. ☐ No.

If yes, please explain and include in consent form:

9. INFORMED CONSENT PROCESS

9.1 In relation to the actual data gathering, when will consent be discussed and documentation obtained? Be specific.

9.2 Who will be obtaining the informed consent?

Please name the specific individuals who will obtain informed consent.

_____

12.6 If subjects are minors who will give their consent.

Father ☐ Mother ☐ Guardian ☐ Sibling (Major) ☐

_____	_____	_____	_____
Signature of Dept Head	Date	Signature of Investigator	Date

Date of Submission to IRB: _____

Please send soft copy of your synopsis/ research proposal on the following e-mail address:

ahsan.khan@fmhcmd.edu.pk