BAHRIA UNIVERSITY OF HEALTH SCIENCES
INSTITUTIONAL REVIEW BOARD
Research Proposal FORM #1

Proposal Submission Form for IRB

IRB Use Only	BUHS-IRB- receiving Date
IRB Study #	

1. PROJECT IDENTIFICATION

Project Title

1.2 Principal Investigator (PI) (*The PI should be directly communicating with IRB)*

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

1.3 Co-Investigator / Sub-Investigator

Co-Investigators responsible for knowing and following the protocol should be listed below. Include any individual accountable for the consent process, direct data collection from subjects, or follow-up. Please list the team members' names (if any, outside the BUHS) as part of the annex.

Name (Last name, First name):	Phone Number; e-mail
Mailing Address:	

1.4. Other team members of the research from BUHS

Name (Last name, First name):	Phone Number; e-mail	**signature**

2. FUNDING/FINANCIAL SUPPORT

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

☐ **No** (please skip questions related to funding source)

☐ **Yes.** (if yes, please share details)

Type of Funding Source:

☐ BUHS Medical & Dental College ☐ Donors/bilateral agencies ☐ Pharmaceutical Industry

☐ Other, Specify _____

Name of Funding Source:

☐ If **No,** Explain how the costs of research will be covered:

_____

_____

2. 2 Will this research utilize BUHS, Karachi Campus 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 investigator will monitor the study.**

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

☐ **The study involves minimal risk and does not require safety monitoring.**

2.4 Does this research involve?

	Intervention (physical/ experimental with drugs/ Preventive intervention	**Treatment**	**Survivorship**	**Supporting care**
No.	☐	☐	☐	☐
Yes	☐	☐	☐	☐
N/A	☐	☐	☐	☐

If the research does not apply to any of the above statement, please select a type:

☐ **Behavioral study**

☐ **Population-based survey**

☐ **The study involves teaching/learning of various disciplines & teachniques.**

3. SUMMARY OF ACTIVITIES

3.1 What is your research question?

State the hypothesis or primary objective, and briefly describe the subject population, treatment procedures, and rationale for conducting the study.

3.2 What research methods will you use; describe your study design.

3.3 What will the subjects be asked to do?

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

3.5 Expected duration of the study?

3.6 Expected Outcomes of the study? (in terms of research objective and/or any other anticipated outcome)

4. SUBJECT PROFILE

How many subjects do you plan to enroll?

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

4.1 Age Range

Check all that apply:

☐ **0-7** (Include parental consent form) ☐ **8-17** (Include child's assessment 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
☐ General Public ☐ Women of reproductive age ☐ students (any) ☐ students of BUHS
☐ Faculty/staff of BUHS ☐ Any other (specify……..

4.3 Inclusion and Exclusion of Subjects in this Research Study

Inclusion Criteria:	Exclusion Criteria:

_____

4.4 Will the subjects be chosen from records?

☐ **Yes.** Who approved the use of the records:

☐ **No.**

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

☐ **Yes.** Provide the protocol, consent forms, letters, etc., for securing the 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, chemicals, 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 ▫ Significant 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 variable psychology sensory deprivation, social isolation, psychological stresses ▫ Any probing for personal or sensitive information in surveys or interviews ▫ Presentation of materials that 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 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 identifying or culturing 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, a biopsy of other tissues, etc.

☐ **Yes,** ☐ **No**

7. CARE OF SUBJECTS IN CASE OF ACCIDENT/ INJURY

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

8. CONFIDENTIALITY OF DATA

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

☐ Yes. ☐ No.

If yes, please explain and include in the consent form:

9. INFORMED CONSENT PROCESS

9.1 Concerning 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._____

9.3 If subjects are minors who will give their consent.

Father ☐ Mother ☐ Guardian ☐ Sibling (Major) ☐

Signature of Dept Head	Date	Signature of Principal Investigator	Date

Date of Submission to IRB: _____

Please send a soft copy of your synopsis/ research proposal to the IRB also.

Annex:

Annex I

(please fill if applicable)

Other team members of the research outside BUHS

Name (Last name, First name):	Phone Number; e-mail	**Signature and designation in the research team**