Office of the
Research & Publication
Fatima Jinnah Medical College/
Sir Ganga Ram Hospital, Lahore.
Ph: 99200281 Fax: 99203716
No._____/IERB Dated: _____/2014

FATIMA JINNAH MEDICAL COLLEGE
INSTITUTIONAL ETHICAL REVIEW BOARD(IERB)

Name of Principal Investigator (PI):-_____
Address where correspondence is to be sent;-_____
Mobile/Land Line NO:- _____**Study in Department**:-_____
Title of Study:-_____

If the Pl is a student provide the following student information:-

Discipline:-_____Department_____

Name & Email Address of Faculty Advisor:-
_____

Estimate beginning date of study:-_____Estimated duration of study:-_____

Type of Project:-
□ thesis □ professional paper □ dissertation □Class project

(Check all that apply)
□faculty research □pilot □other_____

Signatures:-

Principal Investigator (PI):- Signature certifies that the investigator has primary responsibility for all aspect of the research project.

_____ _____
Principal Investigator **Date**

Faculty Research Supervisor:-(for student research only):- Signature certifies that the faculty member has read, reviewed, and approved the content of the application and is responsible for the supervision of this research study.

_____ _____
Signature Faculty Research Supervisor **Date**

Methodology:-

Please refer to instructions when completing this form. The application must be typed using a font no smaller than 11-point.

1. **Describe tha purpose of study, including research questions and/or hypotheses.**
2. **Participant Information:- (use additional paper)**

   a. Description of participants in study.

   b. Approximate number of participants:-

   c. Vulnerable populations as participants(check all that apply):-

      Pregnant women:- ----------□
      Fetuses/neonates:- ----------□
      Fetuses/neonates:- ----------□
      Minors:- ----------□

   d. Age (or age range) of participants:-_____
      Provide the rationale for inclusion, exclusion on the basis of age:
   e. Sex of Participants:- …… □Male □Female □Both
      Provide the Rationale for inclusion/exclusion on the basis of sex:-
   f. Participants will be excluded based on ethnicity:-……..…□Yes□No
      If yes, provide a description of the exclusion criteria and the rationale for using these criteria:-
   g. List and provide rationale for any other inclusion/exclusion criteria.
3. **Describe the participant recruitment process in detail. Attach any recruitment materials or scripts.**
4. **Describe in detail the research procedures. (use additional paper)**
5. **Does study require follow up. □Yes□No**
   If yes:-
   Duration:-……..……
6. **Site/location of the study.**
   a. will Participants be affiliated with a specific non-FJMC/SGRH agency, institution, or organization?.....□Yes □No
   If yes:-
   Name of the Site(s)?
   Affiliation of the principal investigator to this site(s)?
   Affiliation of the participants to this site(s)?
   Agency approval letters are required by the IRB before data can be collected at a site. If you answered “yes” to 6a, attach the signed agency approval letter on letterhead from each agency. If agency approval cannot be obtained priorto submitting the IRB application, explain here.
   b. Describe the setting of the study (i.e. Physical location, surrounding, privacy aspects, etc.)

POTENTIAL RISKS AND PROTECTION OF PARTICIPANTS

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

RISK	STEPS TO MINIMIZE RISK
RISK	STEPS TO MINIMIZE RISK
RISK	STEPS TO MINIMIZE RISK
RISK	STEPS TO MINIMIZE RISK

(Use Continuation pages if necessary)

8. Will participants be told about the intent of the study prior to participating?. Yes □No

If "no" provide and explanation of why deception is necessary and the debriefing method to be used to fully infor the participants of the study's intent.

9. Explain when and how the participants will be given the opportunity to ask Question.

10.Identifiable data

outline the steps to ensure the confidentiality of identifiable data. Identifiable data includes documents, audio and video recordings, electronic data, and blood or other human specimens.

a. Explain what identifiable data, if any, will be collected.
b. where will identifiable date, if any, will be collected.
c. where will identifiable data be stored? (Specify precise location, preferably in a locked file cabinet with limited access.)
c. Give the date that identifiable data will be destroyed (mm/dd/yy). If identifiable data will be stored for and indefinite period of time, please explain.
d. identify specific ways that identifiable data will be destroyed at the end of this period of time.

BENEFITS/REMUNERATION

11. **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)?

12. What are the generalizable benefits of this study?(e.g contribution to knowledge in field).

13. Explain when and how the participants will be provided with the result of the study.

INFORMED CONSENT PROCEDURES

14. If you will use written informed consent, explain how that consent will be obtained and attach a copy of the consent form.
15. If you will not use written informed consent, provide a detailed rationale and explain how informed consent will be obtained.

RESEARCH TEAM MEMBERS

16**. Provide a list of all research team members, including the investigator and faculty supervisor (if investigator is a student), and their role on the project. Attach copies of current human subjects training certificates. Note that the human subjects training should not be confused with the responsible conduct of Research (RCR) training (these are separate requirements). The RCR Training Certificates don NOT need to be submitted to the IERB.**

NAME OF TEAM MEMBER	ROLE ON PROJECT	TRAINING CERTIFICATE ATTACHED
		☐
		☐
		☐
		☐
		☐

ATTACHMENTS:-

17. List and describe all attachment (include form, scripts, flyers, consent form, National/International Bioethical committee agency approval letters, signed confidentiality agreement form, referral lists, survey, questionnaires, or any other instrument used in the study.

SUBMISSION INSTRUCTIONS

a. the application should be submitted to the IERB(ETHICAL REVIEWER BOARD) The meeting of board is held quarterly.
b. Please attach with proforma of informed consent filled in local language.