Sindh Institute of Physical Medicine and Rehabilitation 

Purpose, Scope, membership and Standard Operating System of

Institutional Review Board

Purpose:

* The purpose of establishing Institutional Review Board (IRB) of Sindh Institute of Physical Medicine and Rehabilitation (SIPMR) is to review the research projects/synopses, research papers for scientific (academic & clinical) and ethical values.
* To ensure that the studies conform internationally and locally accepted ethical guidelines, monitor studies once they have begun and where relevant take part in follow-up action and surveillance after the end of the research
* The objective is to facilitate the researcher by indicating the appropriate corrections and suggestions to bring the project/synopsis to the minimum acceptable standard.

Scope:

* Research based environment would encourage the faculty and students to keep pace with the modern era.
* The establishment of IRB will in future encourage the faculty and students towards continuous research and will not only encourage them towards research but also towards writing research papers and moreover it will also lead to improving the writing skills.

Membership criteria

* IRB should include scientists, health care professionals, lawyers, nurse, religious scholar and persons with specific expertise in ethics. Other useful disciplines include epidemiology, clinical pharmacology, pharmacy, psychology, sociology, and biostatistics.
* **Tenure of membership for the board will be two years.**

Meeting Schedule

* IRB – SIPMR will conduct its meeting at the last Saturday of every second month (one time in two months).
* Procedure
* The principal investigator or one of the authors of the project will submit the application form, protocol and required documents for IRB review to the Institutional Review Board (IRB) office at least 3 weeks before the meeting date.
* Data collection/ interview with the participants or any other field activity must not be initiated before a written approval by the IRB.
* The principal investigator is responsible to submit **01 hard copy** to IRB office with soft copies of all the relevant documents, given in the list below and each document should be labeled appropriately. For example if revised document is submitted then it should be labeled as VERSION 2 and so on:
	+ \*SIPM&R IRB Submission Form
	+ \*Research protocol(s)/amendments(s) with questionnaire/other study tools
	+ Investigator’s brochure (if applicable)
	+ \*Informed Consent form(s) in all languages (depends on the targeted population of the research) (If the study is retrospective on charts or unknown medical tissues then no need of consent form)
	+ Advertisements to be used for subject recruitment (if necessary)
	+ Any gift/cash/compensation that will provided to the participants on their participation
	+ Adverse events reports
	+ Quality control report (frequency of quality control reports to be mentioned in the protocol)
	+ \*Approval from other institution(s), if the PI is from that institution and/or the study is being initiated there.
	+ \*The consent from the institution’s head of SIPM&R, if the PI is from other institution and data will be collected from SIPM&R.
	+ \*Reports of any changes in the study protocol after obtaining IRB approval
	+ PI’s current curriculum vitae or other documentary evidence of qualifications

\* These documents must be submitted

* The application form with protocol and necessary documents will be sent from IRB office through email to each member of IRB at least 2 weeks before the scheduled meeting.
* Complete documents are sent to at least two members of IRB of the related field for review of the protocol from IRB office.
* If IRB does not have any specialist in the related field then protocol is sent to the specialist(s) outside.
* Applicants are informed about the date, place and time of IRB meeting through email and phone calls (if required).
* The protocol is discussed with the applicant in the light of reviewers in the IRB meeting, if it is required by the reviewers or IRB members.
* If the protocol is accepted, then the approval letter will be ready in a week only **one time** by the IRB office. The PI should be responsible to collect the approval letter.
* The revised protocols should also be submitted before the 14th of the month for re-consideration.
* If the revised protocol is not submitted within three months of the IRB meeting, in which the protocol was discussed, then the file will be closed and the revised protocol will be discussed as a new application
* Only the approved consent form will be used for recruiting the study participants. IRB encourages designing an informed consent form in a simple and understandable language, according to the guidelines available at Research Department.
* The principal investigator or his/her designee will submit all protocol amendments (and related consent form revisions) to the IRB for approval prior to implementation, except whereas to eliminate immediate hazards to subjects. NOTE: All revisions will be submitted to the IRB as soon as possible after immediate danger to subjects has been resolved.
* A final report will be submitted to the IRB after the completion of the research project.
* **Type of review:**
* **IRB exempted studies**: Chairperson will review the protocol and issue the IRB approval
	+ Type of synopsis for IRB exempted:
	+ Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.
	+ Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), which cannot identity of the Human Subjects, directly or indirectly
	+ Retrospective patients’/subjects record based study, where the patients/subjects are not identifiable.
	+ Secondary research uses of identifiable private information or identifiable bio-specimens, if the information is publically available.
* **Fast Track**: Chairperson and one of the IRB board members will review the protocol and issue the IRB approval.
	+ If the study is questionnaire based. survey procedures, interview procedures or observation of public behavior (including visual or auditory recording)
	+ Any study which does not have any type of risk
	+ **Full board review:**
		- All other studies will be tabled for full board review