**Sindh Institute of Physical Medicine and Rehabilitation**

**Institutional Review Board**

**Policy for Exempt Research in IRB**

**Purpose:**

This policy indicates the criteria and procedures for exempting research studies/projects from full or fast track review by the Institutional Review Board (IRB). The aim is to ensure the protection of human participants while simplifying the review process for research studies that pose minimal risks to participants.

**Scope:**

This policy applies to all research studies/projects conducted within SIPM&R that pursue exemption from full or fast track IRB review. The exemption will not be given to

a. Any research protocol involving investigators or institutions outside of SIPM&R.

b. If the research protocol requires the samples of SIPM&R patients to be sent to any other institution/organization.

**Policy:**

All the research studies involving the human subject must be reviewed in full board or in fast track by the IRB of SIPM&R, unless it has been determined in prior that the study falls in one of the Exempt categories. It should be noted that all the application for exempt studies must be submitted to the office of IRB, SIPM&R for determine the exemption, record keeping and issuing an ‘Exempt study’ certificate. The researcher CANNOT himself or herself decide if the research project is IRB exempt for review.

Even when research is exempt from IRB review, basic ethical standards still apply.

* Except in the case of chart reviews or database research, potential subjects must be provided enough information to be able to choose whether or not to participate. The information would typically include the voluntariness of their participation, the purpose of the research, the nature of the subject’s involvement, time commitments, and contact information for the investigator.
* Research data must be handled and stored securely, in compliance with institution policy.
* Access to research data must be limited to study team members and other authorized personnel.
* All members of the research team must have basic knowledge of human subjects’ research and must have a current conflict of interest disclosure.

**Categories for Exempt studies:**

**Category 1**: Secondary research, involving the previously existing data, documents, records, and pathological and diagnostic specimens, if one of the following criteria is met.

1. These private identifiable information or private pathological or diagnostic specimens are publicly available
2. If the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects.

Information of vulnerable populations, such as children, pregnant women and decisional impairment person would be allowed. Prisoners are also allowed, as far as the study is not designed especially for this population.

**Category 2**: 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. This includes instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Information of vulnerable populations, such as children and pregnant women and would be allowed. Prisoners are also allowed, as far as the study is not designed especially for this population.

Category 3: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

Information of vulnerable populations, such as pregnant women and would be allowed. Prisoners are also allowed, as far as the study is not designed especially for this population. Children is eligible for this exemption only when it related to educational tests or observations.

Category 4: Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained OR documentation of informed consent or waiver of documentation of consent was obtained.

Information of vulnerable populations, such as children and pregnant women and would be allowed. Prisoners are also allowed, as far as the study is not designed especially for this population.

**Determining Exemption Eligibility:**

* Principal Investigators (PIs) shall submit an exemption request to the IRB, using the designated application form, including a clear justification for the exemption.
* The IRB Chair or designated member(s) shall review the research proposal using the IRB internal checklist and determine if the research study meets the criteria for exemption. When one or more of the exemption categories apply to the research, the IRB Chair or designated member(s) documents the applicable category(ies) using the internal checklist and makes the final exemption determination.
* If the IRB Chair or designated member(s) determines that the research does not qualify for exemption, it will be subject to full or fast track IRB review.
* The IRB Chair or designated member(s) will provide written notification to the PI indicating the decision regarding exemption status.
* The exemption for review will be documented properly as per policy for the category under which the exemption is granted.

**Documentation and Reporting:**

* In case of exemption by the Chairman IRB himself (without involving the committee) it should be mentioned in the approval letter that “The Chairman IRB has reviewed the protocol and has granted an exemption for review”.
* PIs of exempted studies must maintain records of the research activities, informed consent (if applicable), and any other required documentation.
* Exempted studies may be subject to post-review audits by the IRB to ensure compliance with applicable regulations.
* The IRB will maintain a record of all exempted studies, including the exemption justification, for internal reference and reporting purposes.

**Modifications to Exempted Studies:**

* Any modifications to exempted studies that could potentially affect the exemption status must be submitted to the IRB for review and approval before implementation.
* The IRB Chair or designated member(s) will evaluate the modifications and determine if the research study remains eligible for exemption or requires full IRB review.

**Reporting Adverse Events:**

* PIs of exempted studies must promptly report any adverse events, unforeseen risks, or unanticipated problems that arise during the course of the research to the IRB.
* The IRB will evaluate the reported events and determine if additional actions or a change in exemption status is warranted.

**IRB Exempt Review Checklist**

Date of Review: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title of Study or Project: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator Information:**

|  |
| --- |
| Name: Title (Prof., Dr., Mr., Ms.)…… First……………….. Middle ………….  Last ……………….  |
| Department or Unit: |
| Institution: |
| Designation: |
| Mailing address:  |
| Phone (Res.) & Cell:  | Email:  |
| Signature of PI:  | Date:  |

**Co Investigators Information:**

**1.**

|  |
| --- |
| Name: Title …… First……………….. Middle …………. Last ……………… |
| Designation:  | Department or Unit:  |
| Mailing address:  |
| Phone (Res.) & Cell:  | Email:  |
| Signature of Co-Investigator:  | Date:  |

**2.**

|  |
| --- |
| Name: Title …… First……………….. Middle …………. Last ……………… |
| Designation:  | Designation:  |
| Mailing address:  |
| Phone (Res.) & Cell:  | Email: |
| Signature of Co-Investigator:  | Date: |

If more than three authors, please write down only name and institution for other authors.

Please check the appropriate boxes and provide the necessary information:

Exemption Category (check all that apply):

□ 1

□ 2

□ 3

□ 4

Justification for Exemption:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Documentation Attached (check all that apply):

□ Research Protocol

□ Informed Consent Form (if applicable)

□ Data Collection Instruments

□ Recruitment Materials (if applicable)

□ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Modifications (if applicable):

PI's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**IRB Chair/Designated Member's Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**