IRB REVIEW PROCESS:

The researcher/ principal investigator must submit an application to obtain IRB approval. Two types of application may be submitted based on the categories of research as follows: Type 1: If a researcher/IRB (RC) secretary believes that the project meets the requirements for exemption, an application for exemption should be submitted. The Chair or designated member of the IRB will review the proposal to make sure that it meets the criteria for exemption. Type 2: If a project does not meet the criteria for exemption, an application for Expedited or Full Board Review may be submitted.

EXEMPTION FROM REVIEW

Guiding Principles:

1. Exemption policy will be in line with rules and regulation of National Bioethics Committee, Pakistan and Code of Federal Regulations USA.
2. Determination of exemption will be decided by the Chair IRB or his designee. Researcher cannot decide on their own that the research proposal is exempt.
3. Research involving children will be exempted only in case of educational studies.
4. Basic ethical standards are applicable even if the research has got an exempt status.
5. To achieve the exempt status, the research must involve no more than minimal risk to participants.

An Exempt Research; is the one which is not reviewed by the full board of IRB-Research Committee but only by one member. The research proposal is still bound to fulfil all prerequisites of protection of human subjects as well as informed consent in most cases. The reviewer will determine if the proposal satisfies the conditions of exempt status under at least one of the categories mentioned in the exemption policy of IRB-IMDC.

Minimal risk; means that the chance and extent of damage or distress projected in the research are not more in and of themselves than those ordinarily encountered in everyday life or during routine physical or psychological tests.

Exempt Status Categories:

Category I – Educational Exemption: To qualify for this category following requirements are to be fulfilled:

a. Research setting must be "***an established or commonly accepted educational setting"*** – place used for teaching and learning by an educational organization. These include classrooms, lecture halls and laboratories of schools, colleges, universities etc. A clinic, skill lab or operation room is a commonly accepted setting for a medical student or resident.

b. Investigation of ***normal educational practices*** may include regular or special instructional strategies, effectiveness of or comparison between instructional or assessment techniques, curricula or classroom management methods.

Caveats

1. Educational practices to be investigated are not likely to adversely affect students' prospects to learn the required content.
2. Research designs that withholds instruction from participants entitled to it will not be considered normal.
3. Data in the form of audio or video recordings of minors will not be considered for exempt status rather a full board review will be required.

Category II – Surveys, interviews, educational tests (cognitive, diagnostic, aptitude, achievement) and

observation of public behavior: The pre-requisites for this category are:

a. Research is conducted anonymously and identity of subjects cannot be discovered directly or indirectly.
b. Involves gathering of harmless information which could not be detrimental for the subjects.
c. Research with children, provided that the investigator does not interact with them.

Public behavior; behavior of people at places where permission is not required to visit (streets/parks/ bus stations/ cinemas/restaurants etc.) public forums and internet communications.

Caveats

1. Information can be recorded with the help of videos/ audios with the permission of the subjects provided that they are not identifiable.
2. Disclosure of responses outside the research should not place the subject/s at risk of criminal or civil liability or damage to financial standing, employability or reputation.
3. Observation of public behavior is only exempted if the investigator is not part of activity being observed.

Category III – Research involving Benign behavioral intervention:

a. Data can be collected with the help of audiovisual recording or responses (verbal or written) with subjects' consent and without revealing their identity.
b. ***Benign intervention*****;** is of short duration, physically non-invasive, non-offensive, non-embarrassing and does not have a prolong side effect. Examples include subjects asked to solve a puzzle or playing an online game etc.

Caveats

1. If deception of subjects is involved, exempt status is not given, save the subject agrees to the condition that he she will be unaware of or misled during the course of research.
2. Physiologic data collection (blood pressure monitoring, EEG, Fitbit etc.) not allowed under this category

Category IV – Secondary Research: Research using already existing data will be exempted from detailed review. In such a research although consent is not required but identifiable data/biospecimen are used for research when they are publicly available from sources like public libraries, website, some government or non-government organizations or from already done surveys.

a. Investigator documents information avoiding the disclosure of private information of the subjects/biospecimen etc.
b. Research is done on behalf of or supported by a government department or agency using the data collection by the government

Caveats

1. Investigator does not contact the subjects to re-identify them.

[SOURCES: Federal Register; Rules and Regulations USA, IRB Review process; University of Mary Washington, Research Ethics and compliance; University of Michigan, Exempt Status under Revised Common Rule; University of Kansas Medical Center]

EXPEDITED REVIEW

Research activities that present no more than minimal risk (e.g. risks of everyday life, or risks associated with routine medical and psychological tests) may be eligible for expedited IRB approval. Expedited review is conducted by the IRB Chair or designees of the Chair who exercise all of the authorities of the Board, except that disapproval requires full IRB review. They may seek advice of another IRB member or subject specialist with expertise in the particular area of research.

• Expedited review is not necessarily faster than full Board review.
• All Protocol and Consent requirements apply.
• All Primary requirements apply.

Expedited Review Categories

Category I. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases

the acceptability of the risks associated with the use of the product is not eligible for Expedited Review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category II. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults, weighing at least 110 pounds, the amounts drawn may not exceed 550 ml in an eight-week period and collection not more frequent than two times per week; or

(b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood collected may not exceed 50 ml or 3 ml per kg in an eight-week period and collection is not more frequent than two (2) times per week.

Category III. Prospective collection of biological specimens for research purposes by noninvasive means. For example:

(a) hair and nail clippings in a non-disfiguring manner

(b) excreta and external secretions (including sweat)

(c) permanent teeth if routine patient care indicates a need for extraction

(d) placenta removed at delivery

(e) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor

(f) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue

(g) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction

(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques

(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings

(j) sputum collected after saline mist nebulization.

Category IV. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) For Example: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the participant or an invasion of the participant's privacy; (b) determining body weight or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic

infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category V. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Category VI. Collection of data from voice, video, digital, or image recordings made for research purposes.

Category VII. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(Source: IRB Review process, University of Mary Washington)

Full Board Review

Human research not eligible for Exemption or Expedited Review is evaluated by the IRB at a convened meeting. IRB members are sent proposals for review immediately after submission and members are expected to review all the material prior to the meeting.

IRB meetings are conducted by the Chair or designee. For research to be approved, it must receive the approval of a majority of those members present at the meeting where a quorum is in attendance. Whenever possible, the IRB attempts to reach consensus on reviewed research. IRB decisions are recorded as unanimous when consensus has been achieved. When members are unable to reach consensus, the decision is made by majority vote, with members voting for approval or disapproval (or abstaining), or required changes, as identified in the minutes.

The IRB makes one of four decisions on reviewed research: (1) Approval, (2) Provisional Approval (the IRB authorizes the Chair or another member to review and approve required revisions), (3) Postponed (tabled, pending further information), or (4) Withheld (disapproved). The Chair may permit persons not affiliated with the IRB (e.g., consultants) to attend meetings, upon request. Investigators or their collaborators are not permitted to be present at IRB meetings during actual deliberations on their research proposals. However as needed, the IRB may decide to invite investigators to the meeting to answer questions about their proposed research.

(Source: IRB Review process, University of Mary Washington)