SingHealth CIRB: Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study coordinators

SingHealth
Defining Tomorrow's Medicine

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Definitions >>>

Minimal Risk: Minimal risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests".

Scientific Member: A person who has such professional scientific or clinical qualification, knowledge or experience as to enable that person to assist the IRB in understanding particular aspects of the research under review by the board.

Lay Member: A person who does not fall within any of the following descriptions:
- A person who is or was a healthcare professional;
- A person who possesses or previously possessed a qualification or registration, in a country or territory outside Singapore, which is equivalent to or corresponds with any of the qualifications in paragraph (a) to (f) of the definition of "Healthcare Professional" as defined in the Human Biomedical Regulations 2017;

1. Full Board >>>

For submissions that:

- pose more than minimal risk to the participants; or
- are sensitive and need deliberation of special ethical concerns.

The Board will conduct Full Board Review at a convened meeting which a quorum is present. The Board will meet every month (except for December). Adhoc meeting(s) may be arranged if required.

Meeting Quroum:

- At least 5 Members
- At least one external Scientific Member
- At least one external Lay Member
- The Chairperson must be a registered medical practitioner

The Board will discuss the study keeping in mind the criteria for approval and arrive at a decision.

All decisions will be made through by unanimous agreement however, where unanimity appears unlikely, decision by vote will be taken. The CIRB will accept the decision of the simple majority and the names of the minority will be documented in the minutes. In the case of an equality of votes, the research is deemed to have been rejected.

If quorum is temporarily lost, the meeting will not make a decision until quorum is restored.

Declaration of any Conflict of Interest (COI) at Meeting

Conflict exists when a Member has a financial, professional or personal interest that may affect their responsibility to protect safety and wellbeing of research participants.

Members of IRB must declare at every meeting the nature & extent of all or potential conflicts in relation to a matter under consideration.

The Member shall not participate in the review of any research proposal in which the Member has a conflicting interest. However the Member may be asked to provide information as requested by CIRB, but may not participate in the deliberation and voting. Members with conflicting interest cannot count towards quorum.

2. Expedited >>>

For submissions that:

- Presents no more than minimal risk to research participants
- Risks related to invasion of privacy and breach of confidentiality are no greater than minimal
- The research is not classified
- The research activity is listed in the Categories of Research

The Chairperson or designee is responsible for conducting Expedited Review.

Expedited Review process may be used for:

- Initial review of new research proposals
- Continuing review
- Review of study amendments
- Review of modifications requested by CIRB to secure approval

When submissions were expedited by the Chairperson or Designee, the listing of the expedited submissions that were reviewed and approved would be provided to all the members in the following month's Full Board agenda.

Categories of Research:

1. 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 is not required.
   b) Research on medical devices for which (i) an investigational device exemption application 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
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through non-invasive 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.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. 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.

<u>For Continuing Review:</u>

8. Continuing review of research previously approved by the convened IRB as follows:
   a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   b) where no subjects have been enrolled and no additional risks have been identified; or
   c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Exemption >>>

For submission that:

- Involves less than minimal risk to participants
- Research activity that falls under any of the exemption categories 1 to 6[#].

The Chairperson or Designee will determine if the research meets the institution's ethical standards and recommend additional protection for participants, if needed.

However, the criteria for exemption dose not apply for

- Research involving prisoners
- Research involving children when the research involves survey or interview procedures or observations of public behaviour, except when the investigator(s) do not participate in the activities being observed
- FDA-regulated research
- Restricted Human Biomedical Research

When exemption applications were reviewed and approved by the Chairperson or Designee, the listing of the submissions that were granted exemption would be provided to all the members in the following month's Full Board agenda.

Exemption Categories:

Category 1 – Normal Educational Practices and Settings

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular and special education instructional strategies, or

(ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2 – Anonymous Educational Tests, Surveys, Interviews, or Observation

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Category 3 – Identifiable Subjects in Special Circumstances

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Exemption category 2, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4 – Collection of Existing Data

Research involving the collection or study of <u>existing</u> data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. The reviewed material should be in existence at the time the research is proposed and should not be prospectively collected.

Category 5 – Public Benefit or Service Program

Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

Category 6 – Taste and Food Evaluation and Consumer Acceptance Studies

Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

4. IRB Determination >>>

For submissions that do not fall within the definition of "Research". The Chairperson or Designee will review the submission and determine that the proposed study doesn't meet the definition of human subject research. Hence, it is outside the purview of CIRB. However, Principal Investigator should seek Institution's advice with regards to compliance with other applicable guidelines and regulatory requirements. For example:

Service Evaluation Looking at capacity and capability of staff, as well as processes to improve efficiency, save costs, reduce error rates or undesired outcomes.	Clinical Audit Looking at processes and capability of staff.	Surveillance Human subjects or information derived from human subjects (in the form of data or human biological materials).	Outbreak Investigation Human subjects or information derived from human subjects (in the form of data or human biological materials).

Under some circumstances, research involving only unidentifiable/ de-identified* or coded* private information or biological specimens is not human subjects research because investigators cannot readily ascertain the identities of the individuals to whom the data or samples belong.

For such cases, submission to CIRB is not required, unless the research is a restricted research as defined under HBRA.
*Principal investigators or study team does not have the linkage key.

Takeaway message...

The review type is determined based on the level of risk in which research participants are exposed to. Submissions which do not fall within the definition of "Research" would be outside the purview of CIRB. These projects should be conducted in compliance with institutional policy.

If you have any questions, please contact CIRB at irb@singhealth.com.sg