SingHealth CIRB: Illuminaté
"To Énlighten... Ethics, above all"
Adapted version for researchers, investigator and study
SingHealth
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Research Reviewed via Exemption

The Exemption Categories have been revised. Details on each of the revised categories are explained in this newsletter.
Submissions which meet the following criteria will be reviewed via exemption review:

- Involve less than minimal risk to participant.
- Research activities that fall under any of the Exemption Categories S1 to S5.

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

The criteria for exemption review does not apply to:

- 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

Revised Exemption Categories >>>

Exemption Category S1:

Research conducted in established or commonly accepted educational settings that involves normal educational practices that are not likely to adversely impact student's opportunity to learn required educational content or the assessment of educators who provide instruction.

Example

- Research on regular and special education instructional strategies.
- Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exemption Category S2:

Research that only involves educational tests, surveys, interviews, or observations of public behavior that meets at least one of the following criteria:

(a) Information obtained is recorded by investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers to subjects;

(b) Any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to subjects' financial standing, employability, educational advancement or reputation; or

(c) Information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects and there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

Example

- Interview consisting of audio-recording but does not record any identifying information about the information. (This example meets criteria (a) above.)

Exemption Category S3:

Research involving benign behavioural interventions which are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(a) 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.

(b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing.

Example

- Research required participants to play online game, solve puzzle under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Exemption Category S4:

Secondary research using identifiable biospecimens or private information, if

a. It uses publicly available identifiable biospecimens or private information; or

b. The information will be recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.

Note: Secondary research is re-using information and/ or biospecimens that are collected for some other "primary" or "initial" study.

Example

- A researcher who examine an existing publicly-available database.

Exemption Category S5:

Taste and food quality evaluation and consumer acceptance studies, if

a. If wholesome foods without additives are consumed; or

b. 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.

Example

- Participants were asked to taste a set of novel snacks to determine consumers' preferences. The set of novel snacks contain food ingredients found to be safe.

Frequently Asked Questions (FAQs):

1. **Do I use the exemption application form if I am requesting for wavier of consent ?**
   Response: If the study meet the exemption criteria, please select exemption application form. If your study do not meet the exemption criteria, do not select exemption application form.
2. **I will be de-identifying the research data collected during data analysis stage, can I apply for exemption, category 4?**
   Response: No, it seems that idenfiable data would be collected during the conduct of the study. This would not meet the exemption criteria.

Ethics and Compliance Online System (ECOS) >>>

The Ethics and Compliance Online System (ECOS) would be launched on 3 May 2024 (planned and subject to confirmation). ECOS is a web-based platform accessible by both internal and external users, jointly developed by SingHealth and NHG. ECOS will be replacing the iSHaRe Institutional Review Board (IRB) module. In addition, it is also a one stop solution to support the research lifecycle from Study Initiation to Completion, to enable a more efficient management of research portfolios and ethics applications, the system includes the following modules:

- IRB
- Minimum Training
- Clinical Research Management System (CRMS)
- Compliance – DNC/SAE/PISAF*
- Quality – Monitoring and Audit*

*Modules would be rolled out on a later date.

The IRB Application Form has been revised significantly. We encourage you take time to go through it.

Major changes:
Section D1 – Revised Exemption Categories
Section D3 – More options are made available for study team to indicate the study nature
Section G – Research methodology and recruitment information in this section
Section J – The consent process and ICF documents can be found here
Section I – New Section on Medical Device
Section O – New Section on Wavier of Documentation of Informed Consent
Section P/Q – New Section on Wavier of Informed Consent during Emergency Situation
Section R/S – Improved Section on Wavier of Informed Consent
Section V – New Section on Use of Software/ Mobile Device

Takeaway message...

For studies which falls under the exemption categories S1-5, it would be reviewed via the exempt review. All other studies would be reviewed via expedited or full board review.