Summary of Change (last updated Jun 2025)

Updated

The Investigator Manual has been updated to reflect the replacement of ROAM with ECOS.

Other updates are as follows:

- **Chapter 1. 5.2 Examples of Research-Like Activities that May Not Require DSRB Approval**
  - For more information on the updates, go to this link Reclassification of Studies involving Anonymised Data and or Human Biological Material.
- **Chapter 3.1.2 Mutual Recognition of IRB Reviews for Collaborative Studies**
  - [Effective 1 April 2025] With effect from 1 April 2025, all new IRB applications involving A*STAR, NHG, NTU, NUHS, NUS and SingHealth sites, or their Partner Institutions, are eligible to benefit from the IRBs mutual recognition arrangement (Single IRB Review) and have their studies reviewed by 1 IRB.
  - For more information on the updates or Mutual Recognition FAQ, go to this link Mutual Recognition of IRB Reviews for Collaborative Studies.
- **Chapter 3.2.1 Training Courses: GCP**
  - [Effective 1 April 2024] PI, Site PI and Co-I(s) conducting clinical trials regulated by HSA; must complete GCP training Requirement on top of the CITI program prior to IRB submission.
  - Study Team Members (STMs) who perform the significant trial related activities / tasks(e.g., informed consent process, eligibility assessment, investigational product management, key efficacy, and safety assessments) will also need to complete GCP training before study involvement
  - Study staff who perform other significant study tasks may need to undergo GCP training, at the discernment of the Principal Investigator (PI, before study involvement.
  - The DSRB will recognise generic GCP courses (such as CITI GCP) and trainings as meeting the acceptable minimum training standard. PI, Co-Is and other study team members may participate in either local or overseas GCP training programmes, e.g., ICH GCP training organized by NHG and SingHealth, CITI GCP modules, general GCP training provided by sponsor companies.
- **Chapter 3.3.2 Minimum Training Requirements for Staff from NHG and Partner Institutions**
- **Chapter 4: Submissions to DSRB**
  - 4.1.2 Timeline for Submission of Applications
  - 4.1.5 Mutual Recognition of IRB Reviews for Collaborative Studies
  - 4.2.1 Minimum Training Certification Validation Requirements
  - 4.3.1 Categories of Review, Exempt Categories

- [Effective 30 May 2024] The Exemption Categories have been updated with the intention to align with the US Final Rule and adapted to be relevant to the local context. Exemption Category 5 - Public Benefit or Service Program has been removed. Table below reflects the updates to the exemption categories and its updated definition and key changes.

Category	Updated Definition	Key Changes
Exemption Category 1	Normal Educational Practices and Settings 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. Examples of such research are: 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.	The condition that the research should not be likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instructions has been added explicitly.
Exemption Category 2	**Educational Tests, Surveys, Interviews, or Observations** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behaviour (including visual or auditory recording) if at least one of the following criteria is met: i. The information obtained is recorded by the investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or ii. Any disclosure of the human subjects' responses outside of the research would not reasonably place subjects at risk of psychological harm or criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or iii. The 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 the IRB conducts a limited IRB review to determine adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data are in place. If research includes children, only observation of public behaviour and educational tests without investigators' intervention is permitted. Education tests, surveys, and interviews with investigators involvement as well as conditions meeting point (iii) above may not be applied to children.	Identifiable information can be recorded by the investigator if DSRB determines that adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data are in place.
Exemption Category 3	**Benign Behavioural Interventions** 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: i. 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; or	This is a **new category**. The previous category "Identifiable Subjects in Special Circumstances" has been removed.

	ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of psychological harm or criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or iii. The 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 the IRB conducts a limited IRB review to determine adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data are in place. A. For the purpose of this provision, benign behavioural interventions 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else. B. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorises the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.	
Exemption Category 4	**Secondary Research for which Consent is Not Required** Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: i. The identifiable private information or identifiable biospecimens are publicly available; or ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, and the investigator will neither contact the subjects nor re-identify the subjects.	It is no longer a requirement for data or biospecimens to be existing. Data or biospecimens may be collected prospectively, provided the information is either publicly available, or is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, and the investigator will neither contact nor re-identify the subjects.
Exemption Category 5	**Public Benefit or Service Programs**	This category has been **removed** as it is not applicable to the local context.
Exemption Category 6	**Taste and Food Evaluation and Acceptance Studies** Taste and food quality evaluation and consumer acceptance studies, i. if wholesome foods without additives are consumed; or	No revisions were made to this category.

	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.	

- 4.4 Outcome of Review

- **Chapter 5: Informed Consent**
  - 5.2.3 General Considerations for the ICF, For the ICFs or Assent Template to be used in Mutual Recognition of IRB Reviews for Collaborative Studies