Summary of Change (last updated November 2025)

Updates

- **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
    - 4.7 Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) and Expected Serious Adverse Event (SAE)

- **Chapter 7.2.2 Use of Subject Identification Codes**

Data collection forms (DCFs) and Case Report Forms (CRFs) should not contain information directly identifiable to a subject (such as name, identity card number, address, etc.) unless it is to be used as a source document.

Each subject should be assigned a unique subject identification code to be used on DCFs, CRFs, serious adverse event reports, UPIRTSOs and any other research-related data. In addition to the subject identification code, subject initials may also be entered. The link between the subject identification code and the subject identifiers should be stored in a separate document.

In some instances, a combination of data elements collected on DCFs or CRFs may potentially identify a subject. Care should be taken to ensure that the information collected is appropriately coded such that it cannot be traced back to the individual without the linking code unless it is to be used as source records*.

**Source records are original or data (which includes relevant ^metadata) or certified copies of the original documents or data, irrespective of the media used. This may include research subjects' medical health/health records/notes/charts; data provided/ entered by research subjects (e.g., electronic patient-reported outcomes (ePROs)); healthcare professionals' records from pharmacies, laboratories and other facilities involved in the research; and data from automated instruments, such as wearables and sensors.*

^metadata - The contextual information required to understand a given data element. Metadata is structured information that describes, explains or otherwise makes it easier to retrieve, use or manage data. For research, relevant metadata are those needed to allow the appropriate evaluation of the research conduct.

Summary of Change (last updated September 2025)

Updates

a) The Investigator Manual has been
   a. updated to reflect the replacement of ROAM with ECOS
   b. Updated to include ICH GCP E6 (R3) updates (NB: updates will be carried out in phases.)

Other updates includes:

- **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 Special Considerations**
  [new] V. 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.
  - **Training Requirement for Investigators and Other Study Team Members Conducting Clinical Trials Regulated by HAS**

- **Chapter 3.3.1 Qualifications and Agreements**
  - If a service provider is engaged, the PI should ensure that the agreements clearly define the roles, activities and responsibilities for the research and documented appropriately. Where activities have been transferred or delegated to service providers, the responsibility for the conduct of the research, including quality and integrity of the research data, resides with the sponsor or investigator, respectively.

- **Chapter 3.3.2 Minimum Training Requirements for Staff from NHG and Partner Institutions**

- **[new] Chapter 3.2.3 Minimum Training Requirements for Staff involved in Collaborative Studies under the Mutual Recognition of IRB Reviews**

- **Chapter 3.2.4 Minimum Training Requirements for Staff from Other External Institutions**

- **Chapter 3.2.5 Minimum Training Certificate Validation and Labels on ECOS**

- **Chapter 3.3 Responsibilities of PI**
  - **[new]** g. There are no conflicting interests for any of the research personnel participating in the study, as well as their immediate family members. Should there be any conflicts of interest, the PI must ensure it is declared on the IRB application form and describe the plan to remove or manage the conflict of interest
  - **[new]** Research Manager or Clinical Research Unit (CRU) Manager are manager(s) of the research administration in the institution. For institutions that do not have a research manager, the duties and responsibilities of the research manager may be performed by the Research Administrator or Assistant Manager or Senior Executive or Senior Clinical Research Coordinator or Executive or Clinical Research Coordinator.
  - **[new]** Service provider is a person or organisation (commercial, academic or other) providing a service used by either the sponsor or the investigator to fulfil research-related activities.

- **Chapter 3.4.2 Changes in Study Team Members**
  - DSRB must be kept informed of any change(s) to the following study team members:

    - PI
    - Site-PI
    - Co-I(s)

    Any changes to the abovementioned study team members must be submitted to the DSRB through a study amendment for approval prior to implementation. The existing PI is responsible for submitting this amendment for review. If other non-investigator staff (e.g., research manager, study coordinator) or sponsor representatives (e.g., Clinical Research Associate) wishes to have access to the study information (e.g., IRB application form, study documents), they could be assigned the following roles on the ECOS Clinical Research Management System (CRMS).

  - Study Sponsor
  - Study Administrator – Not directly involved in research but only provides administrative support to the study
  - Study Team Member – Directly involved in research

  Addition or removal of the Study Sponsor, Study Administrator and Study Team Member on ECOS CRMS will not require IRB review and approval. Changes can be managed by the research team.

  PI must ensure that access to study information is removed for individuals who have left the research team.

- **Chapter 5: Informed Consent**
  - **Informed Consent Process**
  - **Conducting the Informed Consent Process**

    - **[new]** h. Varied approaches (e.g., text, images, videos and other interactive methods) may be used in the informed consent process including for providing information to the subject. The characteristics of the potential research population (e.g., subjects may lack familiarity with computerized systems) and the suitability of the method of obtaining consent should be taken into consideration when developing the informed consent materials and process. When computerized systems are used to obtained informed consent, research subjects may be given the option to use a paper-based approach as an alternative.

    - **[new]** i. Whether the informed consent process takes place in person or remotely, the investigator should assure themselves of the identity of the subject/LR in accordance with applicable regulatory requirements.

    - **[new]** j. Informed consent should be obtained before initiation of the study i.e. before any procedures that are being performed solely for the research.

    - **[new]** o. New information that could impact a subject's willingness to continue participation should be accessed to determined if re-consent is needed (e.g., depending on the stage of the study, consideration should be given to whether the new information is relevant only to new subjects or to existing subjects). If re-consent is needed (e.g., information on emerging safety concerns), new information should be clearly identified in the revised informed consent materials.

- **Chapter 5.2.1 Required Elements of Informed Consent**
  - a. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed (including all invasive procedures), and identification of any procedures which are experimental.
  - b. A description of any reasonably foreseeable risks, discomforts or inconveniences to the subject and when applicable, the subject's partner, to an embryo, foetus or nursing infant.
  - c. A description of any benefits to the subject or to others that may reasonably be expected from the research. When there is no intended clinical benefit to the subject, the subject should be made aware of this.
  - [new] d. The alternative procedure(s) or course(s) of treatment that may be available to the subject and their important potential benefits and risks.
  - e. A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained and that by agreeing to participate in the research, the subject/legal representative allows direct access to source records, based on the understanding that the

confidentiality of the subject's medical record will be safeguarded. This access is limited for the purpose of reviewing research activities and/or reviewing or verifying data and records by the regulatory authority(ies), the sponsor's representatives (e.g., monitors or auditors), IRB, in accordance with applicable regulatory requirements.

- h. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may decide to stop taking the investigational product (if applicable) or discontinue participation at any time, unless the immediate discontinuation will result in a risk of harm to the subject, without penalty or loss of benefits to which the subject is otherwise entitled.

- **Chapter 5.2.2 Additional Elements of Informed Consent**
  - Included GCP requirements

- **Chapter 5.2.3 General Considerations for the ICF**
  - **[new] For the ICFs or Assent Template to be used in Mutual Recognition of IRB Reviews for Collaborative Studies**

- **Chapter 5.4.1 General Requirements for Consent Documentation (refer to Key Updates to Proper Conduct of Research (PCR) SOP Summary of Changes)**

- **Chapter 6 Assent by the Child (refer to Key Updates to Proper Conduct of Research (PCR) SOP Summary of Changes)**

- **Chapter 7 – administrative changes (e.g., grammar, formatting)**