Summary of Change (last updated April 2026)

Updated

- **Chapter 4.3.1 Categories of Review**
  - IV. Not Human Subjects Research - Studies involving **anonymised data or human biological materials (HBM)** will not require review by DSRB as these studies do not meet the definition of human subject research (for the definition of human subject, refer to 1.4.1), if there is no use of identifiable private information or identifiable biospecimens, and no interactions or interventions with human participants in the study.

    If submitted to DSRB, the study will receive a '*Review Not Required*' outcome.

- **Chapter 4.7.2 Reportable Events**
  - **Expected SAE (only for HBRA-regulated studies)**

    Expected SAE(s) reportable to DSRB are events that are (1) expected (2) serious (3) related to the HBR study.

    Both local and overseas expected SAE(s) should be reported. For example, for multi-centre HBR studies involving collaborations from local and overseas research sites for the same research protocol, any expected SAE which occurs in a participant during the research at the overseas site must also be reported to the DSRB.

    Only research studies regulated by the HBRA will need to submit expected and related SAEs to the DSRB using the Expected SAE Report Form. For related SAE which are unexpected, use the UPIRTSO Report Form for submission to DSRB.

    For studies approved by other IRB(s) via mutual recognition arrangement (e.g., NHG Health study approved by CIRB), expected SAE(s) reporting should follow the requirements set by the approving IRB.

- **Chapter 7.2.2 Use of Subject Identification Codes**
  - *[1]Data collection forms (DCF) and Case Report Form (CRF) is a data acquisition tool (DAT)* designed to record protocol-required information to be reported by the investigator to relevant parties (e.g. sponsor) on each research subject.*
    **DAT is a paper or electronic tool designed to collect data and associated metadata from a data originator in a research according to the protocol and to report the data to the relevant parties. The data originator may be a human (e.g., the subject or research staff), a machine (e.g., wearables and sensors) or a computer system from which the electronic transfer of data from one system to another has been undertaken (e.g., extraction of data from an electronic health record or laboratory system). Examples include but are not limited to CFRs ,interactive response technologies, clinical outcome assessments, including patient reported outcomes (PROs) and wearable devices, irrespective of the media used.*

- **Chapter 7.2.4 Data Protection**

- **Chapter 7.2.5 Data Management**
  - [new] e. The access to shared drive folders containing research data files must be restricted to authorised personnel only.
  - [new] f. Relevant meta data associated with data of higher criticality, including audit trials, must be recorded, maintained and reviewed throughout research. Examples of metadata are (not exhaustive):
    i. Logs of user account creation, changes to user roles and permissions and user access.
    ii. Data changes (initial data, subsequent change, deletion, reason of change)
    iii. Workflow actions relating to data, e.g. status change, form routing.
    iv. Stud documents version control, documents status such as draft, complete and approved.
    v. Lab data such as normal reference range, data/time sample collected and processed.
    vi. Dates of data review, data lock and data analysis.
  - [new] Considerations for HSA Regulated Trials

- **Changed 'Capturing' to "Acquisition'**

- **[new] Data Review and Correction**

- **[new] Data Finalisation**

- **Chapter 7.2.5 Transferring, Sharing or Releasing of Research Data**

- **Chapter 7.2.6 Management of Research Data Upon Study Completion**

Summary of Change (Last updated February 2026)

Update

- **Chapter 4.5 Study Amendments**
    - Any deviation from, or a change of, the approved study/ protocol to eliminate an immediate hazard should be documented and promptly reported to the DSRB via the Study Deviation or Non-Compliance (DNC) Report within 14 calendar days after first knowledge by the investigator.

- **Chapter 4.6.3 Study Status Reporting**
    - e. Completed - There will be no more research activities, including contact with participants or any data analysis **on identifiable information**. The PI must indicate the completion date.

Summary of Change (last updated January 2026)

Updates

- **Cover and Foreword - administrative changes (e.g., grammar, formatting)**

- **Content page - administrative changes (e.g., grammar, formatting)**

- **Chapter 1 - administrative changes (e.g., grammar, formatting)**

- **Chapter 4 – administrative changes (e.g., grammar, formatting)**

- **Chapter 4.7.3 (2) Expected SAE (only for HBRA-regulated studies)**
    - Only research studies regulated by the HBRA will need to submit expected and related SAEs to the DSRB using the Expected SAE Report Form. For related SAE which are unexpected, use the UPIRTSO Report Form for submission to DSRB.

- **Chapter 4.8.3.1**

- **[new] Chapter 4.11 – Important Reminders**
    - 4.11.1 ECOS Submission Prerequisites and Validation
    - 4.11.2 Who Can Edit and Submit IRB Forms on ECOS

- **References -** administrative changes (e.g., grammar, formatting, weblinks updated)