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 4.7.2 (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)

Summary of Change (last updated November 2025)

- **Chapter 4: Submissions to DSRB**
    - 4.1.2 Timeline for Submission of Applications
    - 4.1.5 Mutual Recognition of IRB Reviews for Collaborative Studies
    - 4.7 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.