Summary of Change (last updated 21 Nov 2023)

Updated

- Chapter 7
    - Updated chapter according to the Healthtech Instruction Manual-Data Management(HIM-DM)
    - Revisions to definition (i.e., Revised the definition of 'Anonymised Data' and added the definition of 'De-identified Data')

For more information on the updates, refer to Summary of Changes on NHG :: RDO :: Proper Conduct of Research SOPs & Templates

- Chapter 8
    - Administrative updates to words (i.e., standing database to Standing Database) throughout chapter
    - Revisions to definition
        - Removal of Research Data Oversight Committee (RDOC)
        - Inclusion of additional definitions (i.e., Research Data Institutional Deputy (ID))
    - Update to Table 14 NHG Standing Database Applications Review Process

Reminder:

- **NHG custodians** should refer the NHG Research Data Policy and applicable institution requirements for more information on how research data should be managed.
- **Non-NHG Institutions** custodians would need to adhere to their own institution requirements for standing database maintenance.

Summary of Change (last updated 18 Oct 2023)

Newly added

- Chapter 1.5.2 Examples of Research-Like Activities that May Not Require DSRB Approval

[Effective 1 Nov 2023] Studies Involving Anonymised Data and/or Human Biological Materials – These studies do not meet the definition of human subjects research, as there is no use of identifiable private information or identifiable biospecimens. These studies do not require review and approval by the DSRB.

Updated (bolded)

- 1.4.1 Definition of Research and Other Important Definitions

V. US DHHS Regulations

HUMAN SUBJECT **or participant** is a living individual about whom an investigator conducting research:

a. Obtains data information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens

b. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

VI. US FDA Regulations

CLINICAL INVESTIGATION is any experiment that involves a test article and one or more human **participants** and that is one of the following:

a. Subject to requirements for prior submission to FDA; or
b. Not subject to requirements for prior submission to FDA, but the results of which are intended to be submitted later to, or held for inspection by FDA as part of an application for a research or marketing permit.

- Chapter 3.3.9 Records and Reports

For clinical trials regulated by HSA, the essential documents should be retained at least until the later or the latest, as the case may be, of the following:

a. the date where there is no more pending or contemplated application for registration under the Health Products Act of the therapeutic product/for a product licence for the medicinal product being tested in the clinical trial;

b. the expiry of 2 years after the last of such registrations is granted/after the last approval of such application for the medicinal product to be tested in Singapore;

c. where the clinical trial is terminated, the expiry of 2 years after HSA has been informed of the termination of the trial under regulation 12 of the Health Products or Medicines (Clinical Trials) Regulations 2016;

d. the expiry of 6 years after the conclusion of the clinical trial;

e. the expiry of such other period as HSA may direct in any particular case.