Research Data Retention Plan

Health Sciences Research Ethics Committee

Version 01

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HEALTH SCIENCES
UFS

Definitions:

Study Data: Refers to any data generated by an investigator in the course of performing the study. Including, but not limited to: case report forms, clinical findings and results, investigator reports, adverse event reports, and human biological specimens.

Health Sciences Research Ethics Committee: Research Data Retention Plan

- This guidance document should be read in conjunction with the HSREC standard operating procedure regarding Protection of Personal Information as well as the UFS Research Data Management Policy (https://ufs.libguides.com/rdm/policy)
- Health sciences research data should not only be retained while the research is being conducted, but also after the research is completed.
- There are different regulations and requirements depending on the type of research data and the purpose of the data.
- It is thus important to familiarise yourself with the requirements of the University of the Free State, the Health Sciences Research Ethics Committee (HSREC) your department, and/or the sponsor of the research project.
- **Researchers are always required to keep research data to comply with the longest regulation that applies to their research.**
- The **minimum duration** that research data should be retained is 3 years.
- Please ensure that there is adequate and appropriate storage space (virtual or physical) to store research data according to the regulations.
- Certain institutions may have specific requirements, e.g. the military, certain institutions for vulnerable participants, etc. Adhere to their regulations.
- All UFS research data should be stored on the Figshare site (https://ufs.figshare.com/). Guidance and training on how to use Figshare is provided by the Library and Information Services' Digital Scholarship Centre (UFS Digital Scholarship Centre) (https://ufs.libguides.com/rdm/figshare). You can apply online for Figshare storage on this webpage. Researchers are advised to engage with the UFS Digital Scholarship Centre for further information and guidance. A Digital Object Identifier (DOI) will be generated for any data stored on Figshare, this may be linked to publications if required.
- Researchers are advised to include a data management plan (DMP) in their protocols. Links to DMPs are found on Library and Information Services' Digital Scholarship Centre (UFS Digital Scholarship Centre) website https://ufs.libguides.com/c.php?g=977378&p=8142054 Researchers may obtain an a Data Management Plan (DMP) template adapted from the NRF (National Research Foundation) from by contacting the HSREC.

Regulation	Elucidation
UFS data management and retention policy (https://ufs.libguides.com/rdm/policy)	• Research data should be kept no longer than 10 years, unless there is a reason to keep it for longer. • Post-graduate research data should be kept for 3 years, unless there is a reason to keep it for longer.
HSREC (in line with OHRP- Office for Human Research Protection. hhs.gov)	• Research Records must be maintained a minimum of three years (adults) to six years (children) after the research is completed and the study closed with the HSREC. • No study that has not been closed with the HSREC may destroy any data.
Publication	• Original data must be retained for at least 5 years from the date of publication.
Departmental rules	• The HOD may decide to preserve original research data for a given number or for the life of the unit.

ICH GCP	Research data should be retained for: • 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region OR • At least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. • A longer period if required by the applicable regulatory requirements or by an agreement with the sponsor.
Any question on data validity	• In the event of any questions or allegations about the validity of the data or appropriate conduct of the research, all of the completed original research data must be retained until such questions or allegations have been completely resolved.
Health Insurance Portability and Accountability Act, USA requirements (HIPAA)	POPIA required de-identification of data where possible. Any research that involves collecting **identifiable** health information should retain data for at least 6 years after: • The participant has signed informed consent OR • The last participant has completed the study OR • The date of last disclosure of identifiable health information from study records The latest date should be applied
Contract pharmaceutical research	Retain data for 15 years after completion or termination of the study. • Comply with any terms for record retention detailed in the contract with sponsors. • Ensure adequate funding for storage. • Storage may be extended for drugs to be marketed or other reasons.
Contract research involving children	• Retain records until the child reaches the age of 23.
Patents	• Any research data that is used to support a patent through the UFS must be retained for the life of the patent. Refer to the UFS Intellectual Property Policy (not sure if we have one)
FDA: new drug development	• Retain records and reports for 2 years after a marketing application is approved for the drug or biologic that was tested in humans OR • if an application is not approved for drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA so notified OR A longer period if required by the sponsor
FDA: New device development	Maintain the records for a period of 2 years after the latter of the following two dates: • the date on which the investigation is terminated of completed, OR • the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.

References:

1. https://irb.ufl.edu/index/data/investigator-requirements-for-retaining-research-data.html
2. https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/record_retention.html
3. https://vcccalliance.org.au/what-we-do/research-development/clinical-trials-expansion/investigator-initiated-trials/data-management/data-storage-and-retention/