





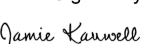



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Dataverse Enterprise

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1 Introduction

The purpose of this document is to assess the regulatory impact of using Dataverse for the archival and retrieval of clinical study records.

The user requirements as identified by the Odum Institute, UNC Chapel Hill, will be used to assure that the Dataverse archival solution has met the intended use of the system.

2 Scope

The scope of these user requirements is applicable to the three components of the Dataverse project:

- SecNAS-The initial storage area of the clinical documents to be archived.
- A 21 CFR Part 11 compliant electronic signature tool used to verify the ingest package is complete.
- Dataverse-The open-source archival tool that will receive the approved clinical documents to be archived from SecNAS.

3 Glossary

3.1 List of Acronyms and Definitions

| Term | Definition |
|----------------------|--|
| CFR | Code of Federal Regulations |
| FDA | United States Food and Drug Administration |
| GxP | Set of compliance regulations including but not limited to, Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), and Good Clinical Practice (GCP) |
| Electronic Record | Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. (Ref. [1]) |
| Electronic Signature | A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature. (Ref. [1]) |
| eTMF | Electronic Trial Master file: In order to comply with government regulatory requirements pertinent to clinical trials, every organization involved in clinical trials must maintain and store certain documents, images and content related to the clinical trial. |
| SecNAS | Secure Network Attached Storage |



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4 Background

4.1 System Overview

The Dataverse is an open-source data repository platform developed by the Institute for Quantitative Social Science at Harvard University. Dataverse enables researchers from any discipline to share, archive, cite, access, and explore research data. The Dataverse stores collections of data in customized virtual repositories (or sub-dataverses) where datasets can be organized, managed, and discovered.

The Dataverse platform will be implemented at UNC Chapel Hill to comply with industry standard archiving and retrieval requirements as outlined by the “21 CFR part 11 Dataverse Project” proposal. This proposal, along with guidance from “ISPE GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems,” the “ISPE GAMP® Records and Data Integrity Guide,” and the “ISPE GAMP® Good Practice Guide: Validation and Compliance of Computerized GCP Systems and Data,” will be the baseline for qualifying the Dataverse implementation and any upgrades that have been assessed to have an impact on current system.

4.2 Intended Use of the System

The intended use of Dataverse by UNC is to archive approved clinical study records and associate them with relevant metadata for easy retrieval.

5 User Requirements

The GxP Risk column, if marked Yes, means that that requirement must be directly tested and traced.

| Req # | Description | GxP Risk (Y/N) |
|-------|---|----------------|
| R01. | Dataverse must support authentication process where all users login via UNC Shibboleth using Two-factor authentication. | Y |
| R02. | Dataverse must allow the ability to define groups, define user roles, and assign user roles to groups. | Y |
| R03. | Dataverse must support study and dataset creation where the archivist must be able to create a new Sub-Dataverse. | N |
| R04. | Dataverse must support study and dataset creation where the archivist must be able to edit Sub-Dataverse properties. | N |
| R05. | Dataverse must support study and dataset creation where the archivist must be able to create a new metadata template. | Y |

| Req # | Description | GxP Risk (Y/N) |
|-------|--|----------------|
| R06. | Dataverse must support study and dataset creation where the archivist must be able to edit a metadata template. | N |
| R07. | Dataverse must support study and dataset creation where the archivist must be able to create controlled vocabulary. | N |
| R08. | Dataverse must support study and dataset creation where the archivist must be able to edit controlled vocabulary. | N |
| R09. | Dataverse must support study and dataset creation where the archivist must be able to create a new dataset/study. | N |
| R010. | Dataverse must support study and dataset creation where the archivist must be able to edit properties of dataset/study. | N |
| R011. | Dataverse must support dataset/study management where the archivist must be able to create metadata. | N |
| R012. | Dataverse must support dataset/study management where the archivist must be able to edit metadata. | N |
| R013. | Dataverse must support dataset/study management where the archivist must be able to ingest existing data files. | N |
| R014. | Dataverse must support dataset/study management where the archivist must be able to review data set/study metadata. | Y |
| R015. | Dataverse must support dataset/study editing and versioning where the archivist must be able to ingest new version of an existing file. | N |
| R016. | Dataverse must support dataset/study editing and versioning where the archivist must be able to add a new file. | N |
| R017. | Dataverse must support dataset/study editing and versioning where the archivist must be able to add comments defining changes to dataset/study. | Y |
| R018. | Dataverse must support dataset/study publication where an archivist must be able to review materials for publication. | Y |
| R019. | Dataverse must support dataset/study publication where an archivist must be able to sign a document stating dataset/study represents ingest package submitted PI. | N |
| R020. | Dataverse must support dataset/study publication where an archivist must be able to publish the dataset/study verify that they have compared the pre and post publishing checksum of the file. | N |
| R021. | Dataverse must support Dataset and study discovery where archivists and compliance officers are able to search metadata for individual studies. | Y |
| R022. | Dataverse must support Dataset and study discovery where archivists and compliance officers are able to view metadata and data files. | Y |



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| Req # | Description | GxP Risk (Y/N) |
|-------|--|----------------|
| R023. | Dataverse must support Dataset and study discovery where archivists and compliance officers are able to view version history. | Y |
| R024. | Dataverse must support Dataset and study discovery where archivists and compliance officers are able to browse Dataverse. | Y |
| R025. | Dataverse must support exporting archived packages for audits where archivist and compliance officers must be able to export a dataset/study and audit trail in human readable form for delivery to auditor. | Y |

End of User Requirements