# Maintenance of Essential Documents

## Purpose and Scope

To describe requirements and define the standard procedures for maintaining the documents essential for clinical trials conducted within SIREN. In general, essential documents are those required to demonstrate the compliance of the investigator, sponsor, and the monitor with all applicable regulatory requirements and the International Conference on Harmonization's Good Clinical Practice Guidelines (ICH-GCP). Essential documents also assist in the successful management of the study by the investigator, sponsor, and monitor, and confirm the validity of the conduct of the clinical investigation and the integrity of the data collected.

## Responsible Individuals

SIREN Award Hubs, Hubs, Spokes, other sites, the SIREN CCC and DCC, and the leadership of individual trials.

## Definitions and Abbreviations

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| CFR | Code of Federal Regulations |
| CIRB | Central Institutional Review Board |
| Clinical investigator - An individual who actually conducts a clinical investigation, or people under whose immediate direction a drug, treatment, biologic, or medical device is administered or dispensed to a human subject in a clinical trial (21 CFR §§312.3, 812.3). | |
| FDA | Food and Drug Administration |
| FWA | Federal Wide Assurance. An Institutional Review Board's assurance to the government to protect research participants and their rights. |
| IND | Investigational New Drug Application |
| IRB | Institutional review board – The board within an institution providing oversight of research as described in 45 CFR Part 46. |
| GCP | International Conference on Harmonization's Good Clinical Practice Guidelines |
| CCC | SIREN Clinical Coordinating Center |
| DCC | SIREN Data Coordinating Center |
| SOP | Standard Operating Procedure |
| WebDCU | Web-based central trial management system developed and maintained at the DCC |

**Procedure**

1. Essential Documents

    a. Are to be present and up-to-date in WebDCU or the investigative site's regulatory file.

    b. The accuracy and completeness of document collection and maintenance will be verified by the CCC project management staff.

    c. A regulatory parameters document is created for each trial conducted in the network that describes the essential documents required for that trial. The specific documents required may vary somewhat based on the specifics of a trial including the regulatory framework under which it is conducted. Essential documents for all trials will typically include the following categories.

        i. Protocol documents including amendments and addenda

        ii. Documentation of study personnel qualifications and delegated responsibilities

        iii. Applications, forms, and communications with regulatory bodies including IRB and FDA

        iv. Site certifications and regulatory approvals including Federal Wide Assurances and labs

        v. Documents pertaining to manufacturing, use, and accountability of study materials

        vi. Monitoring reports and audit documents

        vii. Master subject logs and consent documentation

    d. The parameters document also describes who is responsible for collecting, maintaining, updating and curating each essential document.

2. Record maintenance and retention

    a. Essential documents are generally maintained in electronic formats (typically PDF), but may also be maintained as physical documents when necessary. If a document must also be maintained in a physical format (such as a form requiring "wet ink" signatures, that requirement will be described in the trial's parameters document.

    b. Most essential documents are primarily maintained in WebDCU, but others are maintained only in local research files at sites. WebDCU is considered the regulatory binder of record for the documents maintained there. Sites are not required by SIREN to keep duplicate documents locally, as they will have access to all regulatory documents submitted into WebDCU, but they

may choose to keep local redundant copies of their complete research files uploaded to WebDCU. Sites may also have local institutional requirements.

c. Essential documents with expiration dates are to be kept current in WebDCU and are updated on a schedule described in each trial's parameters document.

d. The duration of record maintenance and retention vary and depend on several factors including the regulatory framework under which a trial is conducted, whether further regulatory approvals of the test item(s) are pursued, as well as local institutional policies and processes. In general, records should be maintained for a given trial as directed by the sponsor of the trial or per applicable regulatory requirements. Minimum retention requirements frequently range from 3 to 10 years. Retained records can be archived but must be retrievable for inspections or audits.

e. Regulatory files for Spokes (enrollment sites within a hub) without durable infrastructure may be maintained in a central location by the Hub as permitted by the participating institutions.

SIREN CCC PI Sign-off:  Robert Silbergleit 2026.03.13 12:56:43 -04'00'

SIREN DCC PI Sign-off: Valerie Durkalski-Mauldin Digitally signed by Valerie Durkalski-Mauldin Date: 2026.03.13 16:08:59 -04'00'

NIH Administrative PO Sign-off: GRETCHEN C. SCOTT -S Digitally signed by GRETCHEN C. SCOTT -S Date: 2026.03.13 16:48:13 -04'00'