## 1. OBJECTIVE

To ensure that the Principal Investigator (PI) and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies. This Standard Operating Procedure (SOP) applies to the written procedures followed by all members of a clinical research team involved in the conduct of human subjects' research at LSU Health New Orleans, including the Health Sciences Center (HSC), the Stanley S. Scott Cancer Center (SSSCC) and the Healthcare Network (HN), hereafter called the investigational site. These detailed instructions promote compliance in conducting clinical research.

**SOP 1.04** documents standard processes and procedures for use of electronic signatures on clinical trial agreements and other research-related contracts at HSC or SSSCC.

## 2. RESPONSIBILITY

The HSC, SSSCC and HN Clinical Trials Offices develop, implement, and maintain SOPs. The need to write a new or revise an existing SOP is based upon changes to federal regulations, guidelines, institutional policies, or procedures. These documents will be provided to departments and research teams conducting human subjects' research. Departments or research teams may develop additional research SOPs or a Research Procedure Addendum (RPA) to expand on an existing SOP, however this need should be limited.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks. It is the responsibility of all members of the clinical research team involved in supervising, managing, or conducting study-related activities to follow the SOPs. The clinical research team may include but is not limited to the following members:

**Research Team Members**

| | |
|---|---|
| Principal Investigator (PI) | Clinical Research Coordinator (CRC) |
| Sub-Investigator (Sub-I) | Other Research Staff |
| Clinical Research Nurse Coordinator (CRM) | Administrative and Support Staff |

## 3. DEFINITIONS

**Clinical Trial Agreement (CTA)**: A legally binding agreement that manages the relationship between the sponsor that may be providing the study drug or device, the financial support and /or proprietary information and the institution that may be providing data and/or results, publication, input into further intellectual property.

**Subcontract**: A written, dated and signed agreement between two or more involved parties that sets out any arrangements on delegation and distribution of tasks and obligations and, if appropriate, on financial matters, for work done as part of a larger

**Contract Research Organization (CRO)**: A person or an organization (commercial, academic or other) contracted by a Sponsor to perform one or more of that Sponsor's clinical study-related duties and functions.

**Sponsor**: An individual, company, institution or organization that takes responsibility for the

initiation, management and/or financing of a clinical study.

**Wet Ink Signature**: A term used to describe the process of signing a physical paper document, form, or contract with pen and ink that is used to distinguish pen and paper signatures from electronic signatures.

*Please refer to the SOP Glossary document for other detailed definitions of commonly used clinical research terminology.*

## 4. PROCEDURES

LSU Health uses AdobeSign to collect electronic signatures on clinical trial agreements and other research-related contracts. AdobeSign enables compliant electronic signatures to be captured on documents in accordance with ICH-GCP and FDA regulations. Signatures, approvals, or acknowledgement of documents by site users will be collected in the system.

LSU Health does not require FDA Part 11 compliant signatures on Clinical Trial Agreements covering research regulated by FDA; however, if a sponsor requires Part 11 compliant signatures, LSU Health will use the BioPharma setting within AdobeSign to obtain signatures that comply.

If the use of AdobeSign for obtaining electronic signatures is impracticable and wet ink signatures need to be used, the wet ink signatures should be obtained prior to obtaining electronic signatures via AdobeSign to enable the preservation of the audit trail attached to each individual electronic signature.

## 5. APPLICABLE REGULATIONS AND GUIDANCE

| Regulation/Guidance/Policy | Title |
|---|---|
| **FDA Part 11** | Electronic Records; Electronic Signatures - Scope and Application, 2003 |
| **CFR Title 21** | CFR Title 21, Part 2 |

## 6. MATERIALS

6.1. None

**Approved by:**

Jawed Alam
Jawed Alam (Feb 24, 2023 08:26 CST)

Jawed Alam, PhD, MBA
Executive Director, Office of Research Services

# SOP 1.04 Use of Electronic Signatures

Final Audit Report 2023-02-24

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