Office of Clinical Research (OCR)

Effective: December 1, 2022	Revised: N/A	Revision: 0
Responsibility: OCR		Page 1 of 3
Policy 1.3.3		

GUIDELINES FOR ELECTRONIC REGULATORY BINDERS IN COMPLION

Purpose: In Human Clinical Trials, the investigative site is responsible for maintaining adequate records to substantiate the regulatory requirements as per the U.S. Federal Regulations and Guidance Documents. This Standard Operating Procedure (SOP) describes the policies and procedures UT Health San Antonio human research investigators are to follow relating to electronic regulatory affairs, including but not limited to electronic signatures. Regulatory duties include collecting, filing, signing and storing regulatory documents and any affiliated records. This applies to all staff engaged in clinical trials and applies to all trials regardless of funding, or sponsorship.

Procedure: **UT Health San Antonio** has implemented an electronic system [Complion Platform] to meet the requirements as noted below. As required by the U.S. Federal Regulations and Guidance Documents for electronic/computerized systems [21 CFR11, ICH E6(R2) GCP, and FDA Electronic Data Guidance Documents (Computerized Systems Used in Clinical Trials and Electronic Records; Electronic Signatures - Part 11, Scope and Application)] UT Health San Antonio is in compliance with the electronic records and signatures regulations.

Confirmation of compliance was established by extensive Part 11 validation testing with and by the software vendor. Certification of compliance that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures was filed with the FDA. All system updates subject to the 21CFR11 requirements will be validated and documented accordingly to maintain compliance.

It is the site's responsibility to meet the regulatory criteria, and as such, a standard mechanism to create, maintain and store the clinical trial regulatory documentation has been developed in the Complion Platform. A standard Table of Contents for essential clinical trial documentation was developed following ICH GCP guidance and to fulfill FDA requirements. This standard is applied to all clinical trials conducted at UT Health San Antonio which use the Complion Platform. Regulatory documentation can be created, maintained, signed and stored within the Complion Platform.

Study documents that require a signature will be signed electronically within the Complion Platform. No special software is required on the part of the User to recognize and verify e-signatures. Any document utilizing an electronic signature should be routed through Complion to maintain Part 11 Compliance.

The regulatory criteria of “the ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency” is met by the viewing and/or downloading/printing of the pdf version of the document. As such, the system allows the monitor/Sponsor or designee the capability to obtain an electronic copy or print the documents if necessary. For any source documents, data, and signatures created, modified and retained in the Complion Platform, copies obtained directly from the Platform do not need to be certified.

For paper source or other source generated outside of the Complion Platform (example: Wet signature on a document), a certified electronic copy of the original will be stored in the Complion Platform and the original will be given to the Sponsor/CRO or destroyed. At the time the electronic scan is created, the individual making the scan must verify the electronic copy is the same as the original. The copy of the original will be placed in the Complion Platform which records the name of the individual certifying that the copy is the same as the original, and the date and time the item is uploaded into the system.

Users of the System will receive the necessary training required to perform their assigned tasks within the system. Training is available through the Complion Platform. Additional training can be provided as necessary by the department administrators who have received prior training from Complion.

Each User will have a unique identifier, their email address, consistent with their single sign-on for UTHSA. The User email address is affiliated with the First and/or Last name of the individual and will not be shared or reused. Upon entry into the system, each User will acknowledge this along with the e-Signature Agreement attesting that their e-signature is equivalent to a hand-written signature. Electronic signatures applied via Complion utilize a combination of email and password unique to the individual.

Monitors and Auditors may be granted access to the Regulatory Documentation as necessary either via direct access to the Complion Platform or will receive a copy of any requested documents. In terms of long-term record retention, this is managed on a trial-by-trial basis. Data and documents can be accessed, as necessary.

Recent interpretations of 21 CFR Part 11 suggest basing the decision on the value of the record over the length of time. Binders should be archived:

- After the final trial visit has been completed by the last trial subject
- When all trial data have been verified as accurate and complete by the PI
- When all data queries have been resolved and the data analyzed
- After the final report has been produced.
- The trial documents should be collated prior to archiving taking place.

Essential, electronic documents will be stored in the Complion System during the archive time period. All documents are converted to PDF A format and are located in same storage environment as during the trial. Documents can be archived by the site via a support request. Complion Support will then archive the binder and the binder will be removed from the user view of the binder list. Archived Binders

can be accessed by the site or designee via a support request from the site requesting binder access to be granted.

Applicable References to Regulations:

FDA Regulations:
U.S. Department of Health and Human Services Food and Drug Administration Center for Drug Evaluation and Research (CDER) Center for Biologics Evaluation and Research (CBER) International Council for Harmonization

Title 21 - Food and Drugs
Chapter I - Food and Drug Administration
Department of Health and Human Services
Subchapter D - Drug for Human Use
Part 312 Investigational New Drug Application
Subpart D--Responsibilities of Sponsors and Investigators
Sec. 312.60 General responsibilities of investigators.
Sec. 312.61 Control of the investigational drug.
Sec. 312.62 Investigator recordkeeping and record retention.
Sec. 312.64 Investigator reports. Progress reports, Safety Reports, Final Reports and Financial Disclosure Reports
Sec. 312.66 Assurance of IRB review.
Sec. 312.68 Inspection of investigator's records and reports.

ICH Guidelines
Guidance for Industry E6(R2) Good Clinical Practice: Consolidated Guidance
4. INVESTIGATOR
   4.1 Investigator's Qualifications and Agreements
   4.2 Adequate Resources
   4.4 Communication with IRB/IEC
   4.5 Compliance with Protocol
   4.6 Investigational Product(s)
   4.9 Records and Reports
   4.10 Progress Reports
   4.11 Safety Reporting
   4.13 Final Report(s) by Investigator
8. Essential Documents for the Conduct of a Clinical Trial
   (All sub-sections)