# What is Part 11 and How Do I Comply?

**An Analysis of Part 11 and How IRBs, PIs, and the IT Support Team Can Work Together in Applying it to HHS-Regulated Human Subject Research**

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# Purpose:

This presentation serves as guidance for:

- Understanding when Part 11 is required?
- Developing a general understanding of Part 11 regulations
- Learning how to meet Part 11 requirements and who is involved

# When is Part 11 Required?

**Required**

- For FDA-regulated studies that use electronic format in place of paper format
- When maintaining FDA-regulated data or submitting info to the FDA

**NOT Required**

- Studies that require wet signatures due to other applied regulations
- Non-FDA-regulated studies
- When using computers to generate paper printouts

# Subpart A – GENERAL PROVISIONS

| | |
|---|---|
| 11.1 (Scope) | • All electronic records and signatures should be just as trust-worthy as their paper equivalents |
| 11.2 (Implementation) | • Records submitted to FDA must be in an acceptable format (92S-0251) |
| 11.3 (Definitions) | • Defines terms like “Open and Closed Systems”, “Digital Signatures”, “Biometrics”, etc. |

# SUBPART B – ELECTRONIC RECORDS

**11.10 Controls for closed systems**

- Document how electronic records are created, modified, maintained, or transmitted.
- Document procedures and controls that ensure (i) Authenticity, (ii) Integrity, (iii) Confidentiality, and (iv) Irrefutability

**11.30 Controls for open systems**

- Same requirements as Closed Systems
- If access is not controlled by the people who control the content, there are additional requirements.

**11.50 Signature manifestations:**

- Information on signed electronic records must:
  - Be in human-readable format
  - Display printed name, date and time of signature, and the meaning of that signature (e.g., they confirm it is accurate, etc.)

**11.70 Signature / record linking**

- Linking Records
  - Document the process of how records are linked to their signature
  - Ensure signatures are linked, correspond, and are never removed or transferred from their record

# SUBPART C – ELECTRONIC SIGNATURES

**11.100 General requirements:**

- Unique signatures
- Identity verification prior to signing
- Delegate signature: system requires at least two people to sign (e.g., witness)
- Institution notifies FDA of use

**11.200 Electronic signature components and controls:**

- Biometric signatures have specific design requirements
- Non-biometric signatures made up of at least two distinct parts (i.e., user ID and password)
- Biometric signatures ONLY used by individuals assigned to.

**11.300 Controls for identification codes/passwords:**

- Unique user ID, password, and process for checking password issuance
- Loss management plan (i.e., deauthorization, detecting unauthorized attempts to access user ID/password, etc.)
- Testing passcode tokens before issue

# Roles and Responsibilities

Who is responsible for ensuring Part 11 Compliance?

## IT Support

- Computer system validation
- Proof of validation must be documented and available for FDA audits
- Advises on System Functionality

## IRB

- Confirms Signature Validation Requirements
- Identifies and advises on state-defined terms for electronic signatures.
- Documents and Records procedures and controls for study record retention, storage, and maintenance

## Study Team

- Consults with IT Support and follows guidance
- Completes IRB Application with relevant information (See checklist)

# Getting Your Platform Part 11 Compliant

## What Needs Done and Who Does What?

### The following must be addressed in documented procedures and controls:

| | | | Roles | | |
|---|---|---|---|---|---|
| | **Documentation Item** | **Description** | **PI / Study Team** | **IRB** | **IT Support** |
| 1 | Validation | Documenting procedures for internal and external auditors to show how the system can be trusted (how it's accurate, reliable, shows consistently performing as intended, and able to discern invalid or altered records) | (i) Follow IT guidance; (ii) document on **IRB Application and study files** how this will be done | Ensure description is on the IRB Application | Provide guidance to PI on how this can be done |
| 2 | Rendering Records | Making sure all electronic records can be provided in language and format that humans (not just computers) understand | (i) Follow IT guidance; (ii) document in study files how this will be done | N/A | Provide guidance to PI on how this can be done |
| 3 | System Access | Ensuring only authorized individuals have access to the system | (i) Follow IT guidance; (ii) document on **IRB Application and study files** how this will be done | Ensure description is on the IRB Application | Provide guidance to PI on how this can be done |
| 4 | Record Retention (Storage and Maintenance) | Protecting documentation and making it readily available if needed for auditing or other reasons, as well as stored for the required duration | (i) Follow IT guidance; (ii) document on **IRB Application and study files** how this will be done | Ensure storage and maintenance duration and procedures are on IRB application | Provide guidance to PI on how this can be done |
| 5 | Study Personnel Accountability | Holding individuals accountable for their actions related to electronic records and signatures | Document in study files how this will be done | Review of study personnel qualifications and training, and description of study team roles is on IRB Application | N/A |
| 6 | Workflows | Making sure (via operational system checks) electronic workflows function correctly and as expected | (i) Follow IT guidance; (ii) document in study files how this will be done | N/A | Provide guidance to PI on how this can be done |
| 7 | Authority Checks | Limiting user access (at both system and record level) and verifying each user can only perform their authorized functions | (i) Follow IT guidance; (ii) document on **IRB Application and study files** how this will be done | Review of (i) Protocol Application, (ii) study personnel qualifications and training, and (iii) description of study team roles is on IRB Application | Provide guidance to PI on how this can be done |
| 8 | Study Team Qualifications | Confirming study team qualifications and training are complete and relevant | (i) Follow IT guidance; (ii) document on **IRB Application and study files** how this will be done | Review of (i) study personnel qualifications and training, and (ii) description of study team roles is on IRB Application | N/A |
| 9 | Device Checks | Verifying the validity of source of data input and proper operational functions | (i) Follow IT guidance; (ii) document in study files how this will be done | N/A | Provide guidance to PI on how this can be done |
| 19 | Document Control | Control of documents for system operation and maintenance, including preservation of complete history of changes made to these documents | (i) Follow IT guidance; (ii) document in study files how this will be done | N/A | Provide guidance to PI on how this can be done |

# IT Checklist

Use this checklist when working with IT Support.

| Part 11 Checklist for IT Review & Support | |
|---|---|
| Comprehension | Ensure all electronic records can be provided in a language and format that humans (not just computers) can understand; |
| Roles & Access | Ensure only authorized individuals have access to the system<br>(ii) Limit user access (both system & record level)<br>(iii) Verify each user only performs authorized duties (e.g., a “roles matrix”) |
| Retention | Protect documents for easy access (for audits)<br>(ii) Retention plan (duration, location, etc.) per federal and institutional policies (Note: duration depends on institution, sponsor, IRB, etc.) |
| System Checks | Conduct operational system checks to confirm electronic workflows function as expected (e.g., semi-yearly testing) |
| Data Integrity | Verify validity of source of data input and proper operational functions (e.g., semi-yearly testing; PI and IT should work together on this) |
| Version Control | Control the documents for system operation and maintenance, including the preservation of complete history of changes made (e.g., audits & logs) |

# IRB Checklist

Use this checklist when filling out your IRB application.

**Note:** Data-Only studies (chart reviews, big data, and projects that test algorithms or develop medical software (SaMD such as CDS/PDS, mobile medical apps, medical devices, etc.) are also subject to Part 11.

## Part 11 Checklist for IRB Application

- ❑ In the IRB **Protocol Application** include:
  - ❑ A summary of tests conducted to ensure the platform(s) are:
    **(i)** reliable
    **(ii)** accurate
    **(iii)** consistently perform as intended
    **(iv)** can discern invalid or altered records
  - ❑ A description of authorized users and *how* limitations will be enforced
  - ❑ A description of:
    **(i)** how the electronic records will be stored and made readily available for auditing
    **(ii)** record retention duration (per federal and institutional requirements)
- ❑ Ensure all individuals that may create, modify, maintain, or transmit electronic records/electronic consent forms are:
  **(i)** listed as Study Personnel on the IRB application
  **(ii)** roles are clearly indicated
  **(iii)** CV and trainings are up to date

**For further information please visit the following FDA websites:**

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11&showFR=1

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application

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