Guidance for 21 CFR Part 11 Compliance

# What is 21 CFR Part 11?

CFR (Code of Federal Regulations) - Title 21 (Food and Drugs) - Chapter 1 (Food and Drug Administration, Department of Health and Human Services), Subchapter A (General) - [Part 11 (Electronic records; electronic signatures)](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)

This applies to electronic records and electronic signatures that are part of projects regulated by the FDA, including but not limited to studies involving investigational new drug (IND) applications and investigational device exemptions (IDE).

# Where to find resources?

In addition to internal, central resources, there may be non-enterprise-wide solutions study teams can employ independently. However, it is important to remember that some systems may be 21 CFR Part 11 compliant only with specific workflows. There are both software and implementation requirements for 21 CFR Part 11 compliance, and it is the responsibility of the research team to ensure compliance is met. Additionally, any new data systems or tools should go through a security review with ITG. Sponsored studies are encouraged to discuss sponsor-owned or funded options with their sponsor.

Some general guidance from the FDA can be found at the following sites:

* [FDA Use of Electronic Informed Consent](https://www.fda.gov/media/116850/download)
* [FDA Use of Electronic Health Record Data in Clinical Investigations](https://www.fda.gov/media/97567/download)

Internal Resources, specific to OHSU can be found at the Research Data Website [here](https://ohsuitg.sharepoint.com/sites/CT.Research-Data2/SitePages/Compliance-with-21-CFR-Part-11.aspx). Questions can be addressed to the Research Data Concierge at researchdata@ohsu.edu.