Introduction to the REDCap 21 CFR Part 11 Validated System

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University of Pittsburgh

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Background

The Food and Drug Administration issued the final 21 CFR Part 11 regulations on Electronic Records, Signatures, and Records in March 1997.

Background

On October 10, 2023, Senior Vice Chancellors Shekar and Rutenbar jointly announced the availability of a 21 CFR Part 11 validated instance of REDCap for studies **conducted under an investigator held IND or IDE**.

What is Part 11 REDCap?

- Electronic Data Capture System (EDC)
- A validated system to facilitate electronic records which is required for studies conducted under an **IND/IDE**
- All changes to the system are validated and documented
- Streamlines multi-center studies

Differences

Standard

- Password only log in
- Study teams can build forms
- No validation performed

Validated

- Multi Factor Authentication log in
- HSIT builds forms
- Study team validates forms
- ECS involvement with review
- All form changes must go through HSIT
- Official sign off from the study team prior to going live

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Past and Current State

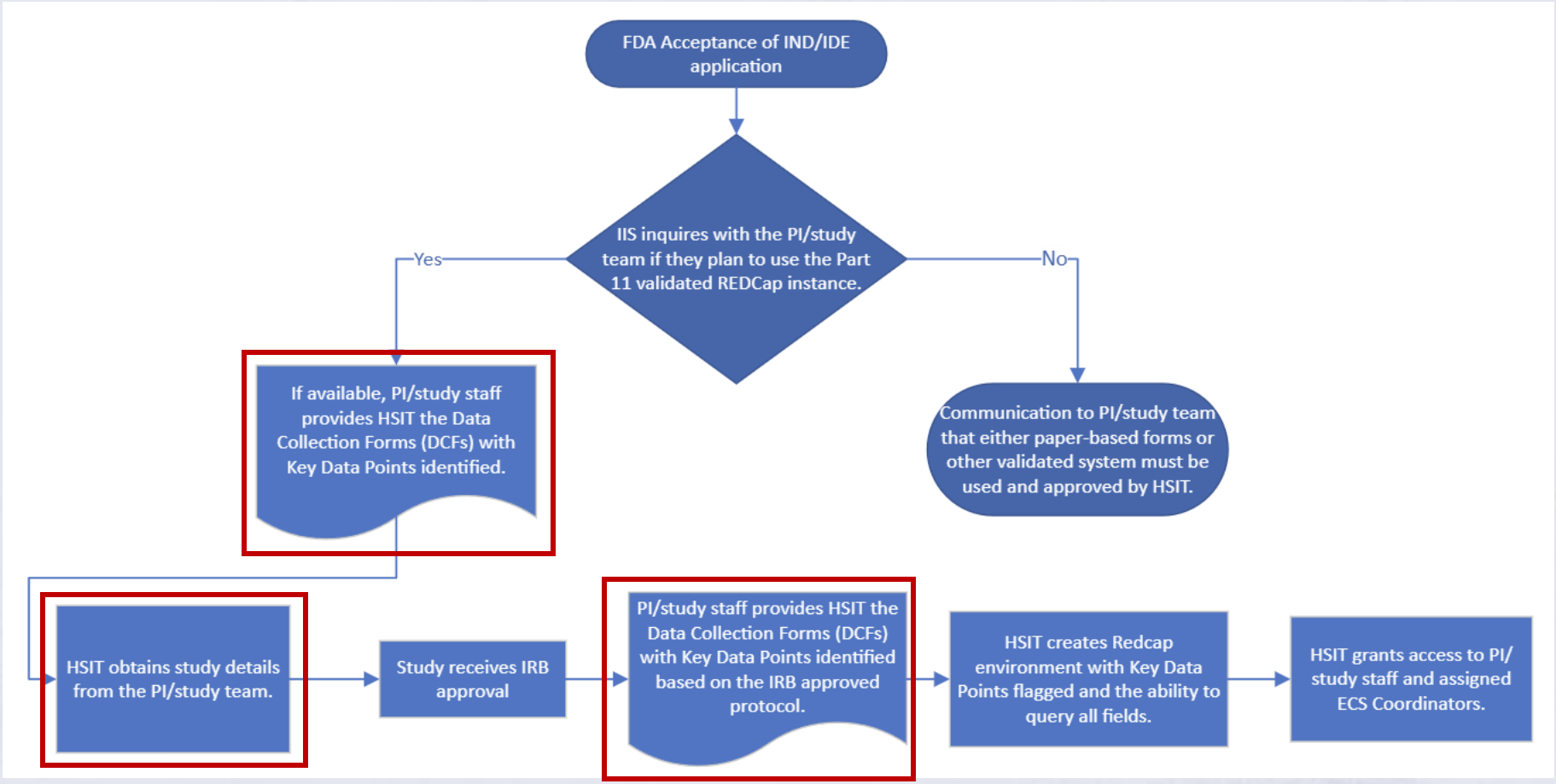
Pre January 1, 2024

- Paper-based Case Report Forms acceptable.
- 21 CFR Part 11 validated system became available in October 2023, not mandatory.
- IND/IDE studies that used EDC or electronic Informed Consent (eIC) were conducted in Standard REDCap

As of January 1, 2024

- Paper-based Case Report Forms remain acceptable
- For IND/IDE studies that will use EDC or **eIC**, the validated instance of REDCap is mandatory
- Use of any other EDC system must be validated to be 21 CFR Part 11 compliant and approved by HSIT

The Process Flow



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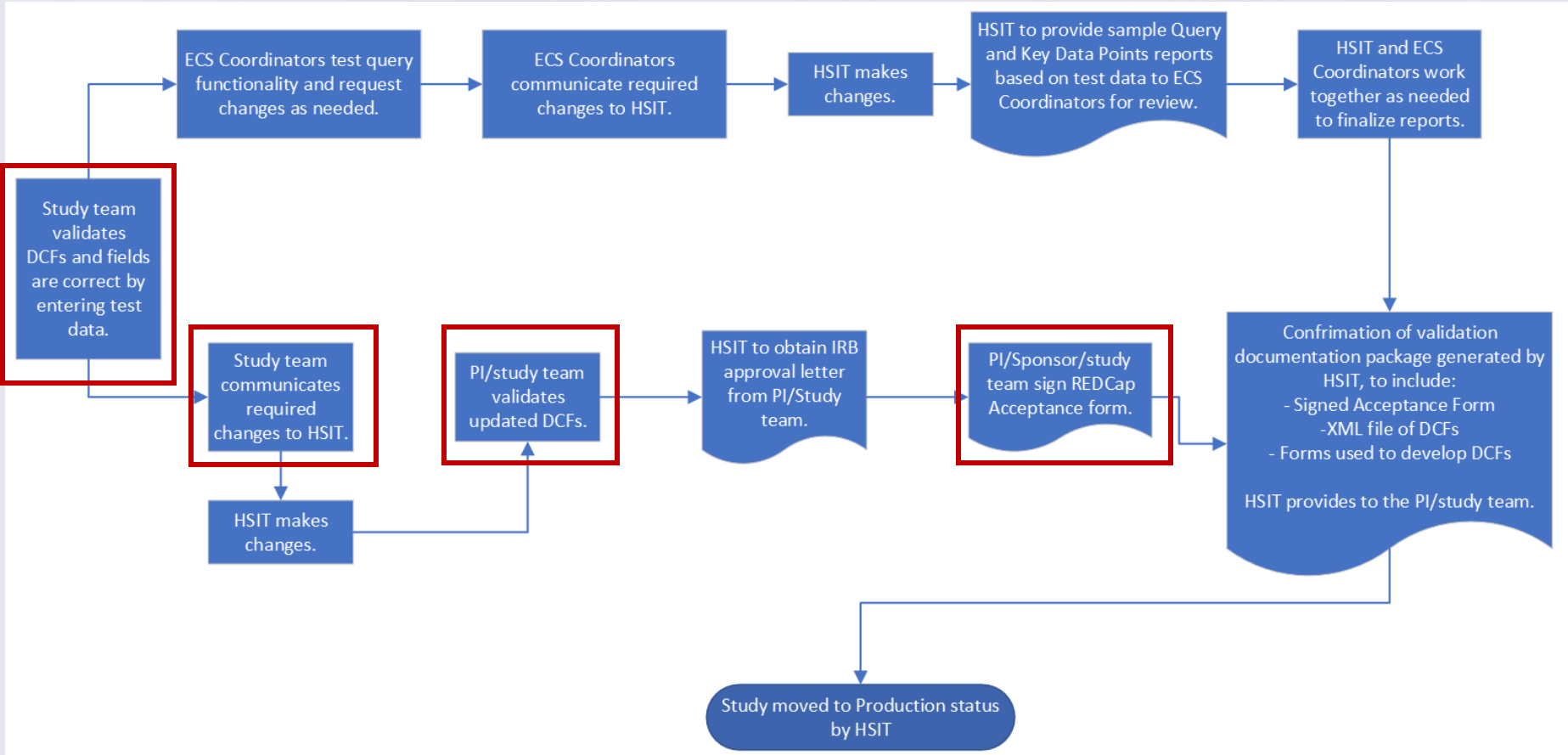
The Process Flow



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	Task	Responsible Individual(s)	Time Frame	Task Completed Date
1	Forms assessment during protocol development			
2	Set up meeting with HSIT to discuss project needs			
3	Review template forms in catalog to determine which will be used and which will need edits			
4	Develop data collection forms in Word or Excel file (carefully consider the functionality of each form field and request specific features to be built in)			
5	Identify Key Data Points if risk based monitoring will be implemented			
6	Provide forms to HSIT			
7	Validate all fields on each instrument. If an instrument is repeated only validate once.			
8	Communicate changes to HSIT			
9	Validate revised fields in each form			
10	Sponsor/PI to review each form and field functionality for acceptance			
11	Sponsor/PI signs Acceptance Form			

Next Steps

- Developing a catalog of template commonly used forms.
  - Eligibility Checklist
  - Adverse Event/Serious Adverse Event Form
  - Demographic Form
  - Medications Form
  - Medical and Surgical History Form
  - Protocol Deviation Form
  - Study Disposition Form

- Upcoming training with demonstrations on form development, validation, eIC. Dates to be announced.

- New project development starting after fiscal year 2025 (July 1, 2024), a fee structure will be implemented based on the complexity of the build.

Moving Toward Compliance

- Developing template standard operating procedures
- Developing a template data management plan

Contacts

More information about the University of Pittsburgh REDCap instances is available at: https://redcap.hs.pitt.edu/

Questions about the use of REDCap or to initiate a new project, contact hs.appsupport@hs.pitt.edu

Completely new to REDCap Part 11 compliance and need help, contact IIS@pitt.edu

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Part 11 Guidance Documents

- Part 11 Electronic Records; Electronic Signatures - Scope and Application

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

- Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations Questions and Answers

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-systems-electronic-records-and-electronic-signatures-clinical-investigations-questions

Part 11 Guidance Documents

- Electronic Source Data in Clinical Investigations

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-source-data-clinical-investigations

- Use of Electronic Informed Consent Questions and Answers

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers

- Use of Electronic Health Record Data in Clinical Investigations

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-health-record-data-clinical-investigations-guidance-industry

Questions?