A Presentation for Clinical Research Coordinators

CLINICALTRIALS.GOV AT UVA

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SOM Clinical Trials Office
University of Virginia

Accreditation

- The University of Virginia School of Medicine and School of Nursing designates this live activity for a **maximum of 1.0 AMA PRA Category 1 Credits**.TM Physicians should claim only the credit commensurate with the extent of their participation in the activity.

- The University of Virginia School of Medicine and School of Nursing awards **1.0 contact hour** for nurses who participate in this educational activity and complete the post activity evaluation.

- The University of Virginia School of Medicine and School of Nursing awards **1.0 hour of participation** (consistent with the designated number of AMA PRA Category 1 Credit(s)TM or ANCC contact hours) to a participant who successfully completes this educational activity. The University of Virginia School of Medicine and School of Nursing maintains a record of participation for six (6) years.

Disclosures

- The speaker, Jodi Darring, BS, MS-Cert, CCRP, has no personal or professional financial relationships with a commercial entity producing healthcare goods or services.

- The planning committee members, Katie Rea, MSCR, BSN, RN, CCRC; Lori Elder, RN, BSN, CCRA, Amy Smith, MSHS Certificate ; Kimberly Underwood, BS, CCRC; and Maria Davenport, MPH, CCRP; have no personal or professional financial relationships with a commercial entity producing healthcare goods or services.

Activity Code: 149757

Instructions for claiming credits/contact hours can be found here.

Introduction

JODI DARRING, BS, MS-CERT, CCRP

SENIOR COMPLIANCE ANALYST

Objectives

KEY TOPICS IN THIS PRESENTATION

1. Provide **Overview** of ClinicalTrials.gov
2. Highlight Importance of Regulatory **Compliance**
3. Demonstrate **Practical Application**
4. Clarify **UVA-specific** Roles and Responsibilities

What is ClinicalTrials.gov?

ClinicalTrials.gov is a **website** and **online database** of clinical research studies and information about their results.

Things to Know

about ClinicalTrials.gov

ClinicalTrials.gov isn't just for researchers; it's also a tool for patients.

ClinicalTrials.gov is managed and operated by the United States National Library of Medicine (NLM), which is part of the National Institutes of Health (NIH).

It's not just a local thing. ClinicalTrials.gov isn't limited to the U.S.—it's a global player. You can find studies from all over the world.

ClinicalTrials.gov welcomes studies from both public and private sectors.

Trial Registry Purposes

and benefits to various groups

Registry Purpose	Group That Benefits
Fulfill ethical obligations to participants and the research community	Patients, the general public, the research community
Provide information to potential participants and referring clinicians	Patients, clinicians
Reduce publication bias	Users of the medical literature
Help editors and others understand the context of study results	Journal editors, users of the medical literature
Promote more efficient allocation of research funds	Granting agencies, the research community
Help institutional review boards (IRBs) determine the appropriateness of a research study	IRBs, ethicists

Source: Zarin DA, Keselman A. Registering a clinical trial in ClinicalTrials.gov. *Chest*. 2007;131(3):909-12. [Full Text]

Results Database Purposes

and benefits to various groups

Results Database Purpose	Group That Benefits
Provide a public record of basic study results in a standardized format	Researchers, journal editors, IRBs, ethicists
Promote the fulfillment of ethical obligations to participants and the overall contribution of research results to medical knowledge	Patients, the general public, the research community
Reduce publication and outcome reporting biases	Users of the medical literature
Facilitate systematic reviews and other analyses of the research literature	Researchers, policymakers

Source: Tse T, Williams RJ, Zarin DA. Reporting "basic results" in ClinicalTrials.gov. *Chest*. 2009;136(1):295-303. [Full Text]

Are clinical trials required to be registered?

Clinical trials registration and results reporting is required by law for all Applicable Clinical Trials, for clinical trials funded by NIH, and for investigators wishing to publish trial information in an ICMJE journal.

FDAAA & Final Rule Requirements

→ Requires researchers to register all applicable clinical trials (ACTs).

NIH Policy Requirements

→ Requires that all clinical trials funded either in whole or in part by the NIH must be registered.

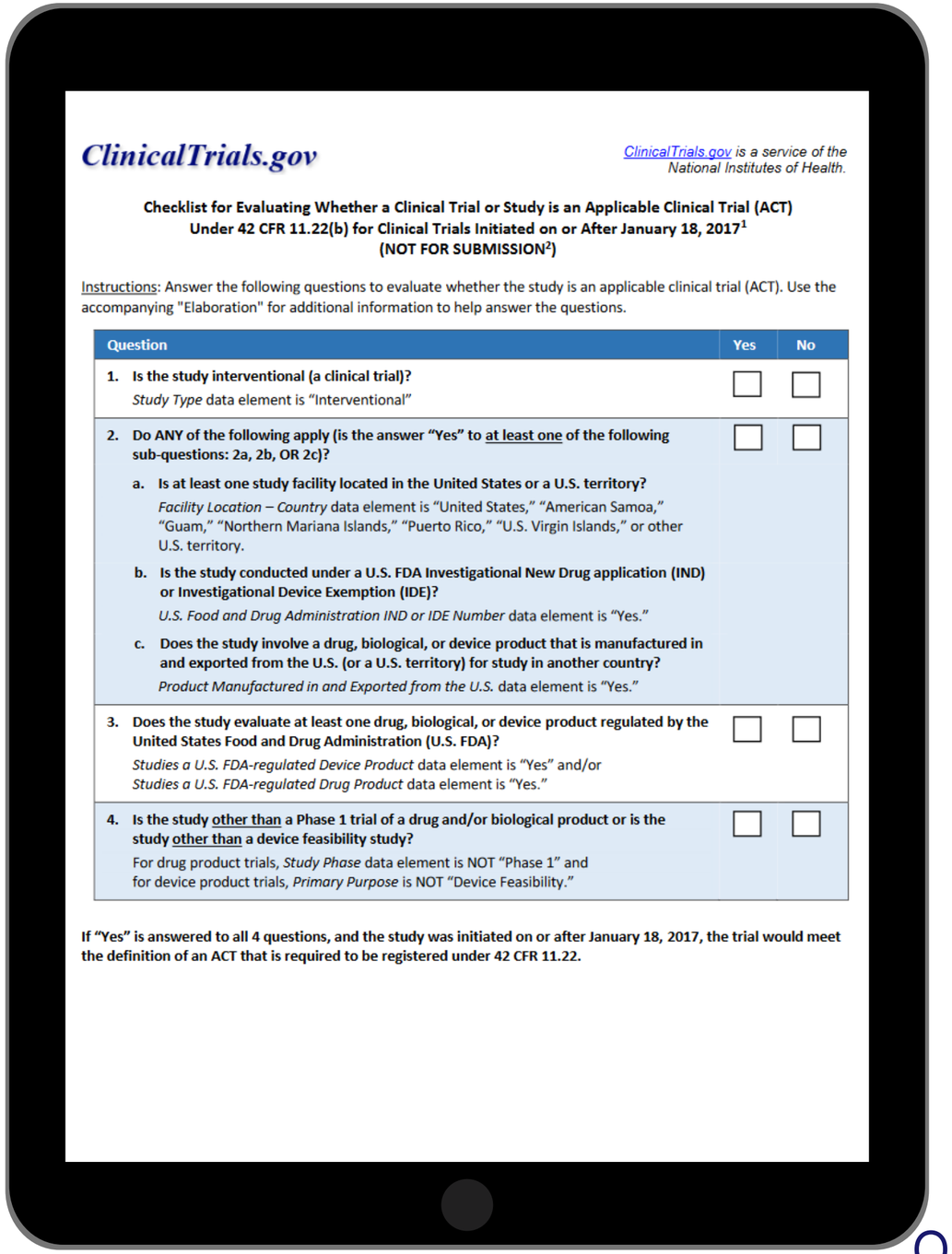
ICMJE Requirements

→ Requires researchers to register clinical trials prospectively in order to be published in ICMJE journals.

Applicable Clinical Trial

- FDA Regulated
- Controlled
- Human Participants
- Prospective

Checklist for Evaluating Whether a Clincial Trial is an Applicable Clinical Trial



ClinicalTrials.gov

ClinicalTrials.gov is a service of the National Institutes of Health.

Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial (ACT) Under 42 CFR 11.22(b) for Clinical Trials Initiated on or After January 18, 2017[1] (NOT FOR SUBMISSION[2])

Instructions: Answer the following questions to evaluate whether the study is an applicable clinical trial (ACT). Use the accompanying "Elaboration" for additional information to help answer the questions.

Question	Yes	No
1. Is the study interventional (a clinical trial)? *Study Type* data element is "Interventional"	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to at least one of the following sub-questions: 2a, 2b, OR 2c)?	☐	☐
a. Is at least one study facility located in the United States or a U.S. territory? *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.		
b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes."		
c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? *Product Manufactured in and Exported from the U.S.* data element is "Yes."		
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
4. Is the study other than a Phase 1 trial of a drug and/or biological product or is the study other than a device feasibility study? For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is required to be registered under 42 CFR 11.22.

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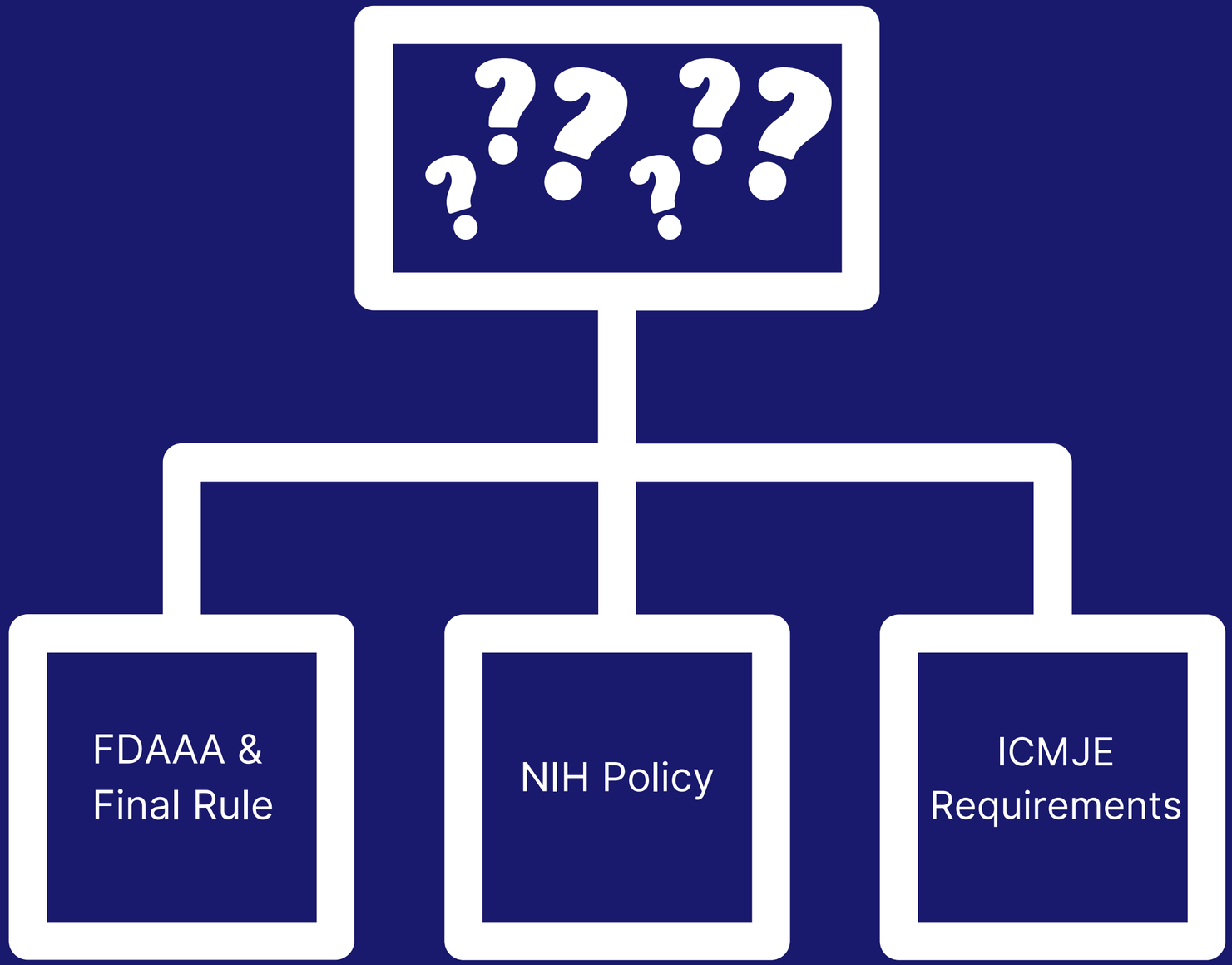
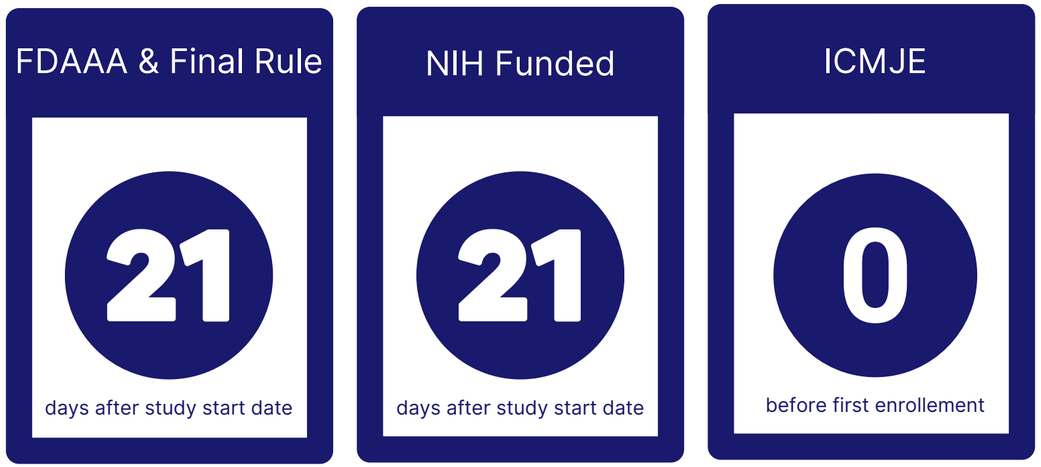


Overview

When does a study have to be registered?



UVA best practice is to register the clinical trial BEFORE enrolling the first participant.

Reporting Requirements Resource

Reporting Requirements	FDAAA Final Rule (effective January 18, 2017)	Final NIH Policy (effective January 18, 2017)	ICMJE Policy (effective 2005)
Scope	Registration and results	Registration and results	Registration
Phase	Not Phase 1	All	All
Intervention Type	Drug, biologic, devices regulated by FDA	All (including behavioral interventions)	All
Funding Source	Any	NIH	Any
Enforcement	Criminal proceedings and civil penalties (up to $13,237/day); loss of HHS funding	Loss of NIH funding	Refusal to publish
Registration timing	No later than 21 days post 1st subject enrolled	No later than 21 days post 1st subject enrolled	Prior to first subject enrolled
Results scope	Applicable clinical trials	Applicable clinical trials	Not applicable
Results timing	Not later than 1 year after "primary completion date"	Not later than 1 year after "primary completion date"	Not applicable
Informed consent/ statistical analysis plan	Required for applicable clinical trials	Required for applicable clinical trials	Not applicable

Who is responsible for registering a study?

A study only needs to be registered one time. Either the Sponsor or the Principal Investigator is the responsible party.

The Principal Investigator **can designate study staff to help** with the CT.gov requirements.

If you need access to a study record in ClinicalTrials.gov, email Jodi Darring (jgd7s@uvahealth.org)

When are results due?

In general, primary results are due no later than **one year** after the trial's primary completion date.

What results does CT.gov want me report?

- Description of Participants
- Findings from the Study
- Adverse Events
- Document Uploads (Protocol, ICF, Analyis Plan)

Regulatory Compliance

What is a potential legal consequence of noncompliance with ClinicalTrials.gov requirements?

A. Civil monetary penalties (i.e. fines)
B. Grant funding actions (i.e. hold on funding)
C. Civil or judicial actions (i.e. Notice of Non-Compliance Letter from FDA)
D. All of the Above

UVA Specific Roles and Responsiblites

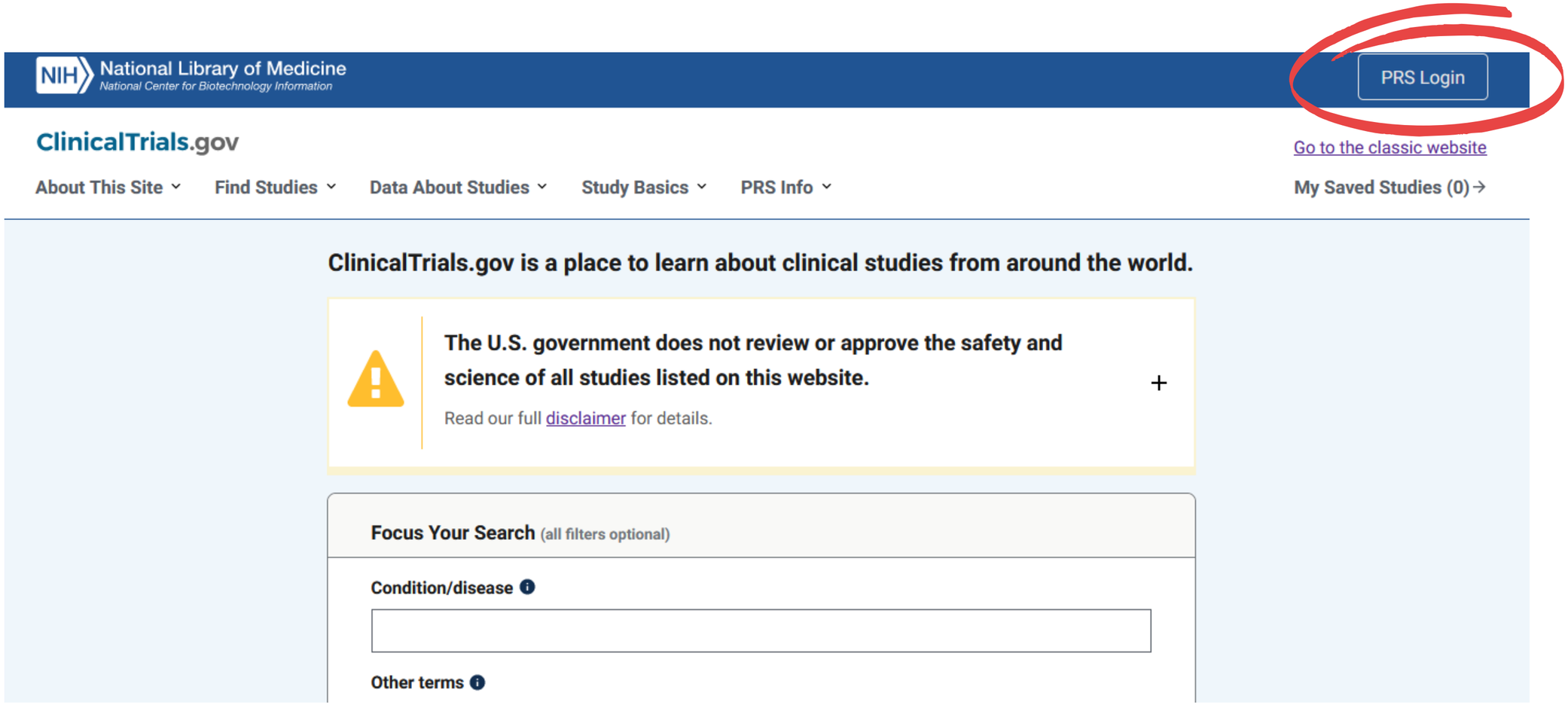
Are there two ClinicalTrials.gov websites?

Knowledge Check

Public-Facing Site → ClinicalTrials.gov

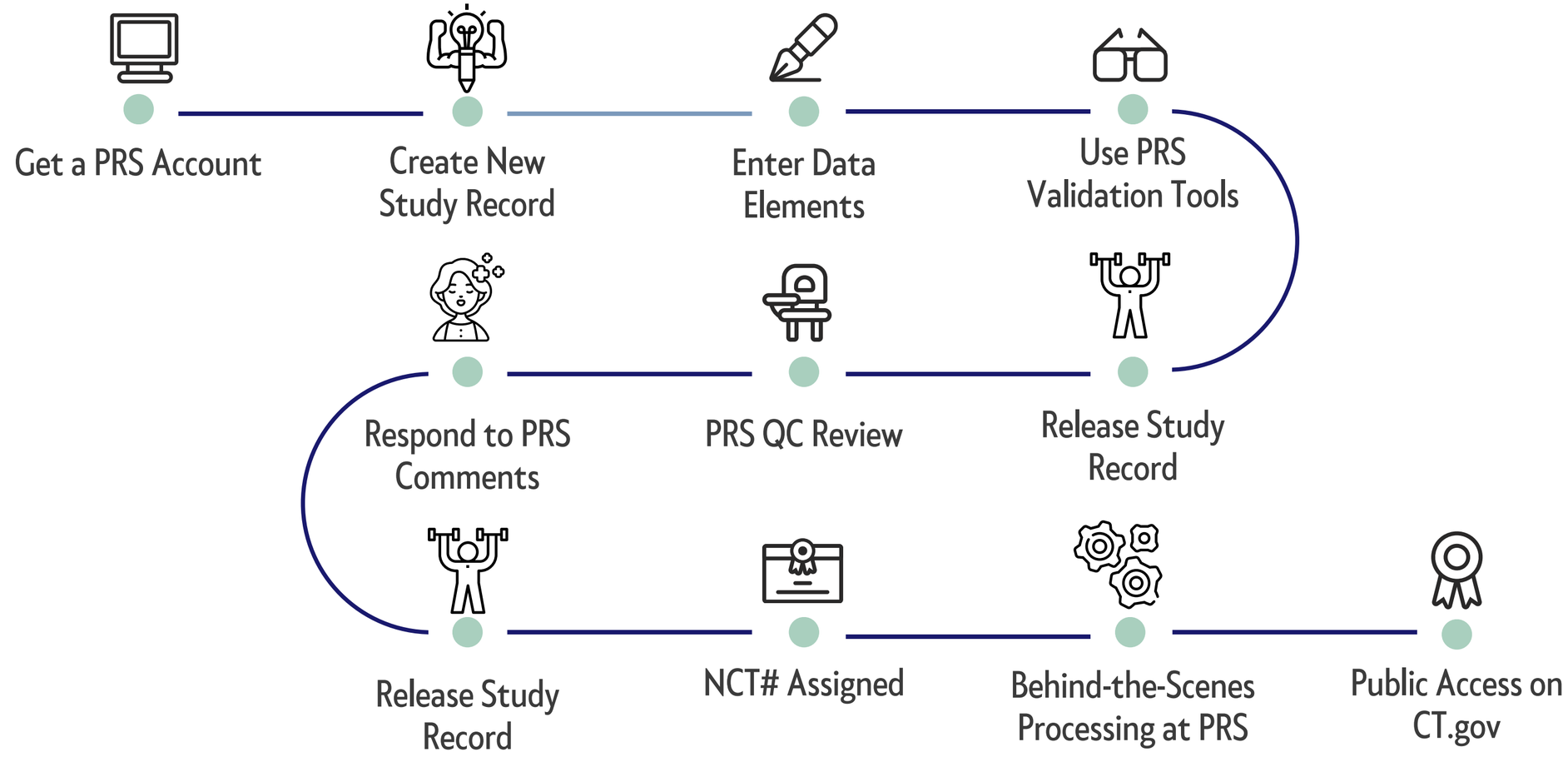
Private-Facing Platform → **Protocol Registration and Results System (PRS)**
Register.ClinicalTrials.gov

How to access PRS?



UVA Workflow

Roadmap for Registering a Trial



UVA Workflow

Principal Investigator

+

Clinical Research Coordinator

+

Study Team Members

MUST REGISTER THE PROTOCOL

The study team may enter the protocol and upload documents, but the PI must review and release the record in ClinicalTrials.gov.

UPDATE THE RECORD

The study team may update the record at the required intervals, but the PI must review and release the update.

ENTER THE RESULTS

The study team team may enter the results, but the PI must review and release the results for PRS review.

UVA Workflow

Common Questions about PRS

HOW DO I GET A PRS ACCOUNT?

Contact Jodi Darring in the Clinical Trials Office.

Getting an account is easy, we'll be happy to set it up for you.

HOW DO I RESET MY PASSWORD?

2 options. Click FORGOT PASSWORD on PRS login page or contact Jodi Darring.

We can also help your PI reset their password.

WHAT IS MY ORGANIZATION?

UVIRGINIA

Everyone at UVA uses this organization code when logging into the PRS system.

I FORGOT MY USER NAME - WHAT DO I DO?

Contact Jodi Darring in the Clinical Trials Office.

Email Jodi and she'll get you all of the information that you need.

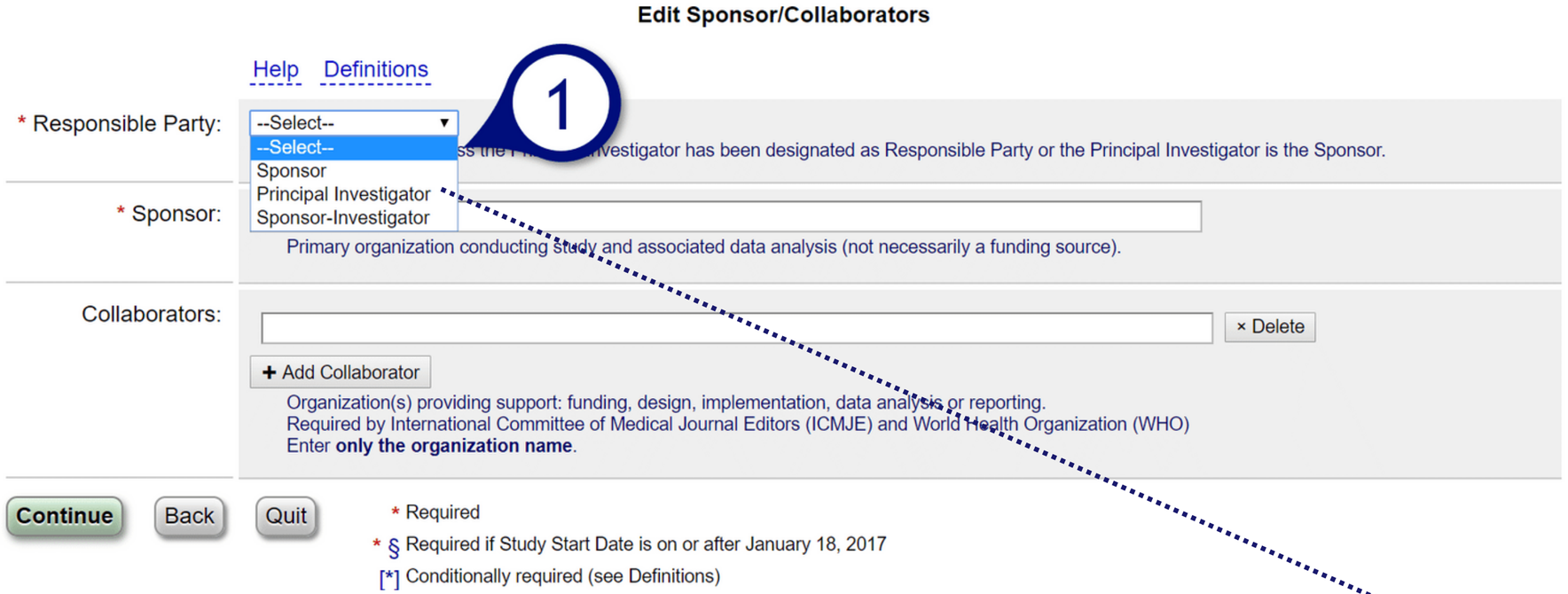
DOES MY PI NEED A PRS ACCOUNT?

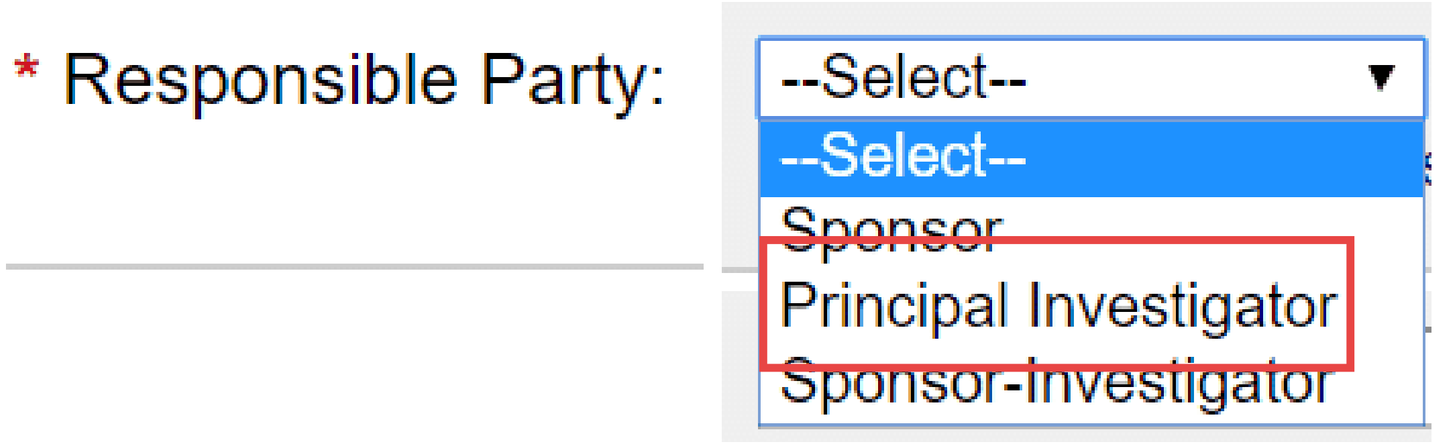
Yes!

The PI is typically the responsible party for investigator initiated studies so they will need an account.

UVA Workflow

Responsible Party in PRS System





UVA Workflow

HOW DO YOU ENTER THE RESPONSIBLE PARTY IF THE UVA PRINCIPAL INVESTIGATOR HOLDS THE IND OR IDE?

In this case, the IND or IDE holder is listed as the responsible party in the PRS system.

The UVA PI would be listed as the responsible party.

Do I need an NCT# to get IRB approval?

We do not require you to register your trial as part of the IRB process here at UVA.

But wait, there is more to that answer!

- If the study is an ACT and will be posted on CT.gov, the consent form must contain the required language
- NCT# is required to complete the Billing Coverage Analysis
- NCT# is required to sync a study from OnCore to Epic.

Resources

- School of Medicine Clinical Trials Website
- ClinicalTrials.gov
- ClinicalTrials.gov PRS offers guided tutorials
- PRS Administrator at UVA: Jodi Darring
- School of Medicine, Clinical Trials Office, Director: Lori Elder

Thank you!

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