ClinicalTrials.gov Updates & Best Practices

OCTRI Research Forum
October 28, 2026

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Agenda

Purpose

Regulations

Process

Technical Challenges

Operational Challenges

Developments

Exercises

Q&A

Why does disclosure matter?

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Purpose of public trial registries

Ethical obligation
to participants, care providers, and research community

Promote transparency
in research, science, and healthcare

Public awareness and participation
through accessible study opportunities and outcomes

Minimize publication bias
by mitigating selective outcome reporting [cherry-picking]



ClinicalTrials.gov is the primary clinical trial registry in the United States

Research involving international sites may require disclosure in other regional registries to satisfy local regulation(s)

Disclosure regulations

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ClinicalTrials.gov disclosure rules

ICMJE

International Committee of Medical Journal Editors
Requires interventional studies (including behavioral/educational interventions) prospectively register to the database, as a condition of journal publication, prior to first participant enrollment

- Registration

FDAAA

U.S. Food and Drug Administration Amendments Act
Requires an "applicable clinical trial" (ACT) to prospectively register to the database and post results within 1 year of primary completion

- Registration
- Results

NIH

National Institutes of Health
Requires an NIH-defined "clinical trial", supported by NIH funding, to prospectively register to the database and post results within 1 year of primary completion

- Registration
- Results
- Informed Consent Form

Common Rule

Revised Common Rule
Requires a study supported by <u>any</u> Common Rule agency (e.g., NIH) to upload one (1) template informed consent form (ICF), used to enroll at least one (1) participant, no earlier than when recruitment closes but no later than 60 days after last participant visit, as defined per the study's IRB-approved protocol;

Posting too soon or too late are both forms of noncompliance

- Informed Consent Form

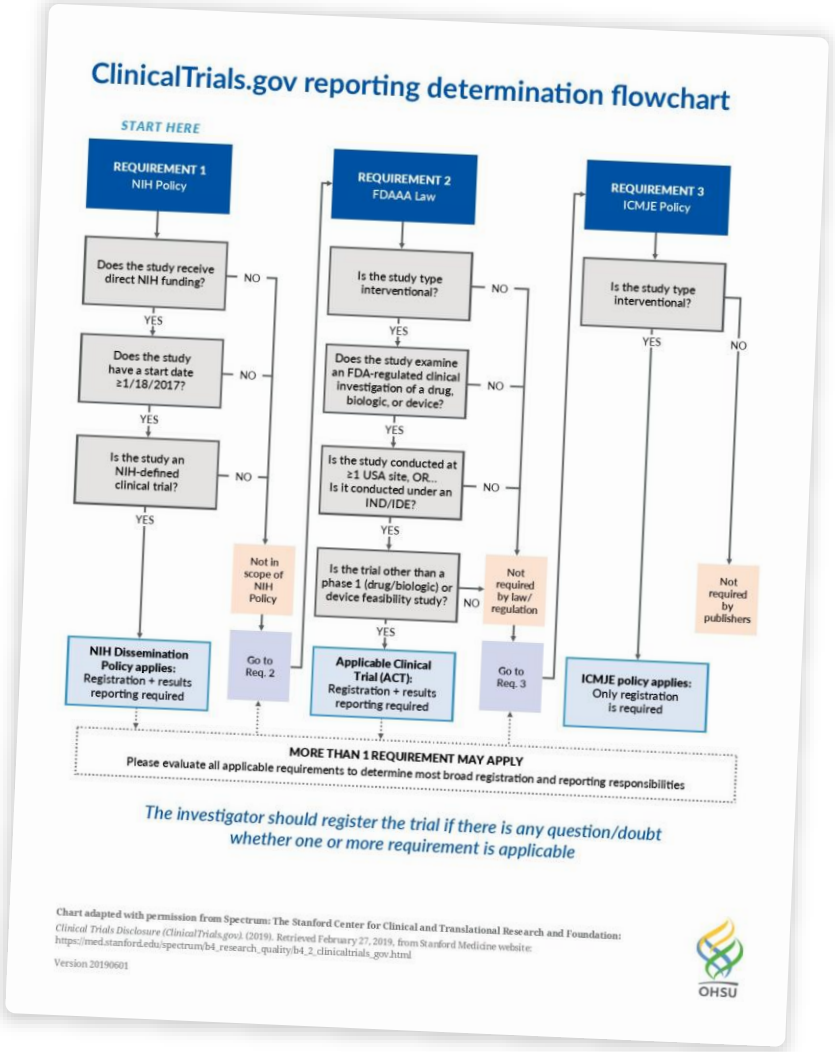
Additional disclosure requirements may apply per sponsor/agency

U.S. DoD, PCORI, WHO, CMS…

Policy applicability flowchart

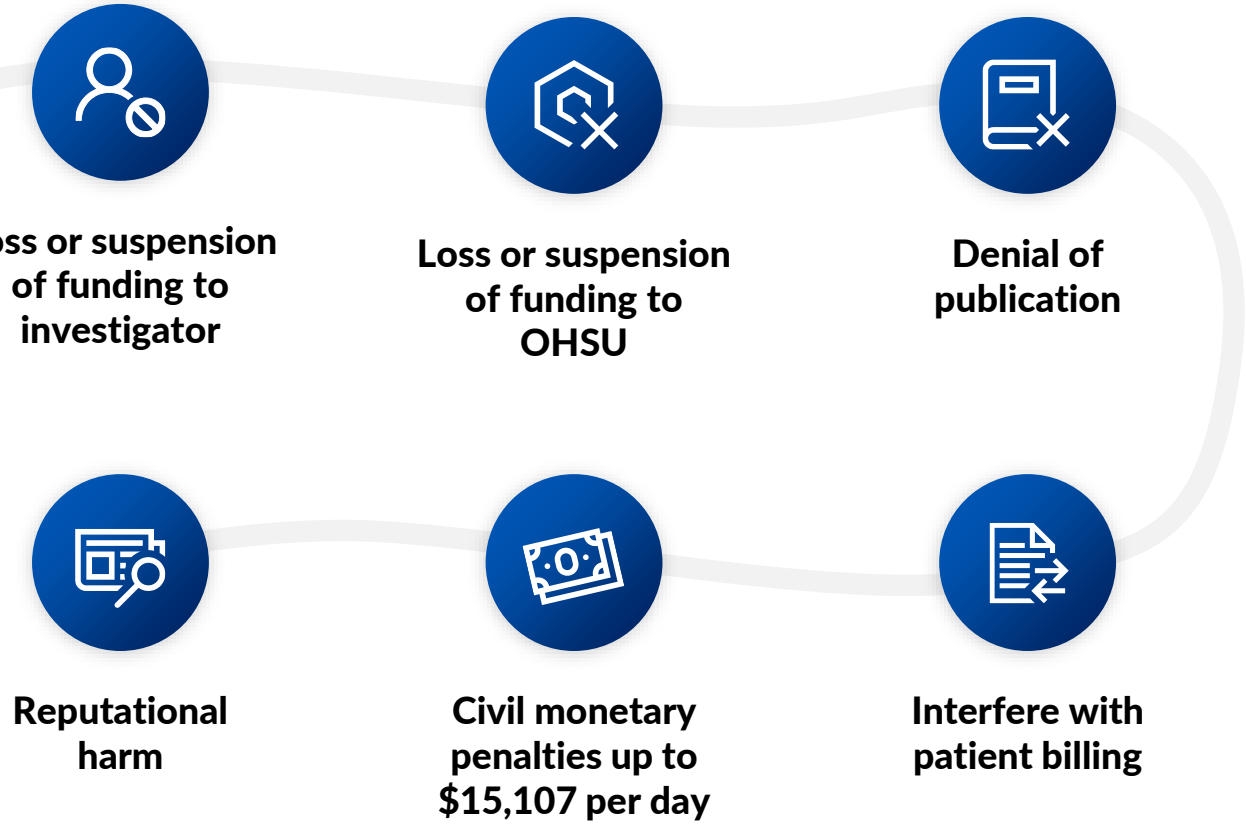
- Covers NIH, FDAAA, and ICMJE policies
- Does not include Common Rule (informed consent form) or other funder-specific requirements
- Flowchart available via SharePoint

View document | Go to SharePoint



Assessing noncompliance

Problem Type
Missing or late registration
Inaccurate registration information
Failure to timely maintain registration
Missing or incomplete results overdue
Failure to address major PRS Review Comments
Missing or early/late informed consent form



Who is responsible for disclosure?

Responsible Party

Principal Investigator
At OHSU, the PI of an investigator-initiated trial is designated the Responsible Party and must submit information about the study to ClinicalTrials.gov, routine and timely update the study record, and makes sure that the requirements for submitting study information are fulfilled.

The Principal Investigator is qualified to be the Responsible Party if/when the investigator…

- Conducts the study
- Has access to and control over study data
- Has the right to publish the results of the study



Process

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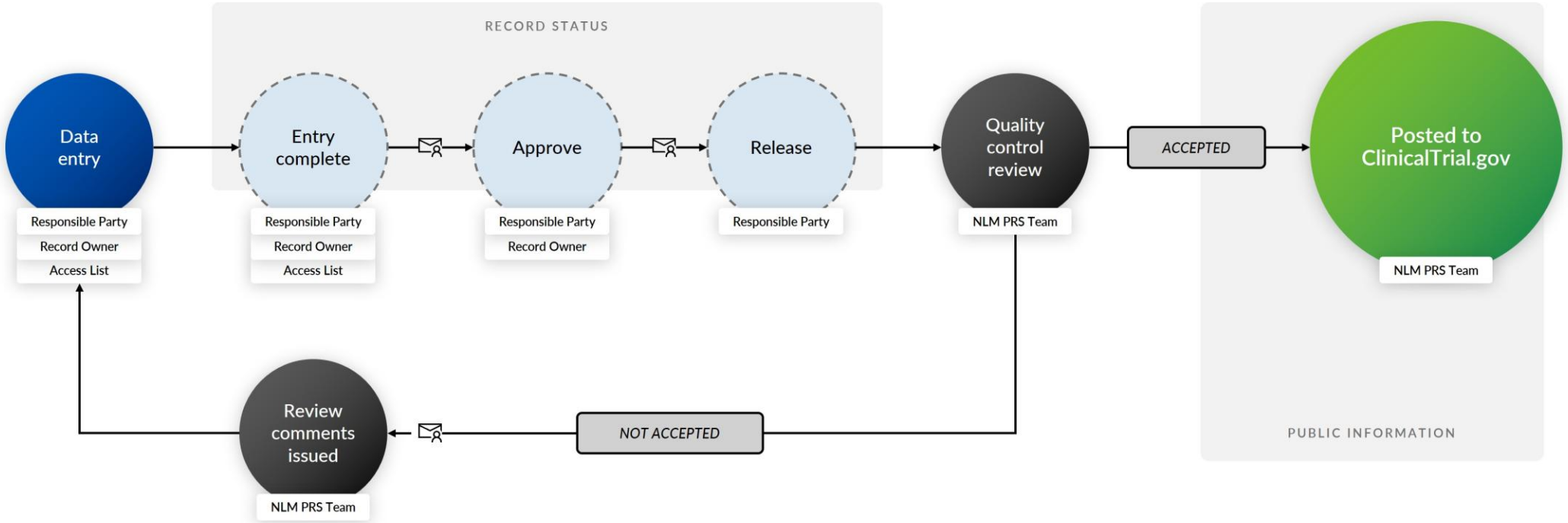
Process: Overview of the PRS

- Protocol Registration and Results System (PRS)
- Back-end, editable interface of ClinicalTrials.gov
- Responsible Party, Record Owners, those added to the Access List can view and edit their own ClinicalTrials.gov records
- Records should be high-level summary, *not* the full protocol
- Most Common QC Issues
  - Multiple outcome measures mentioned in one outcome
  - Lack of specificity in outcome measure timeframes
- Optimal time to start registration?… Before IRB Approval

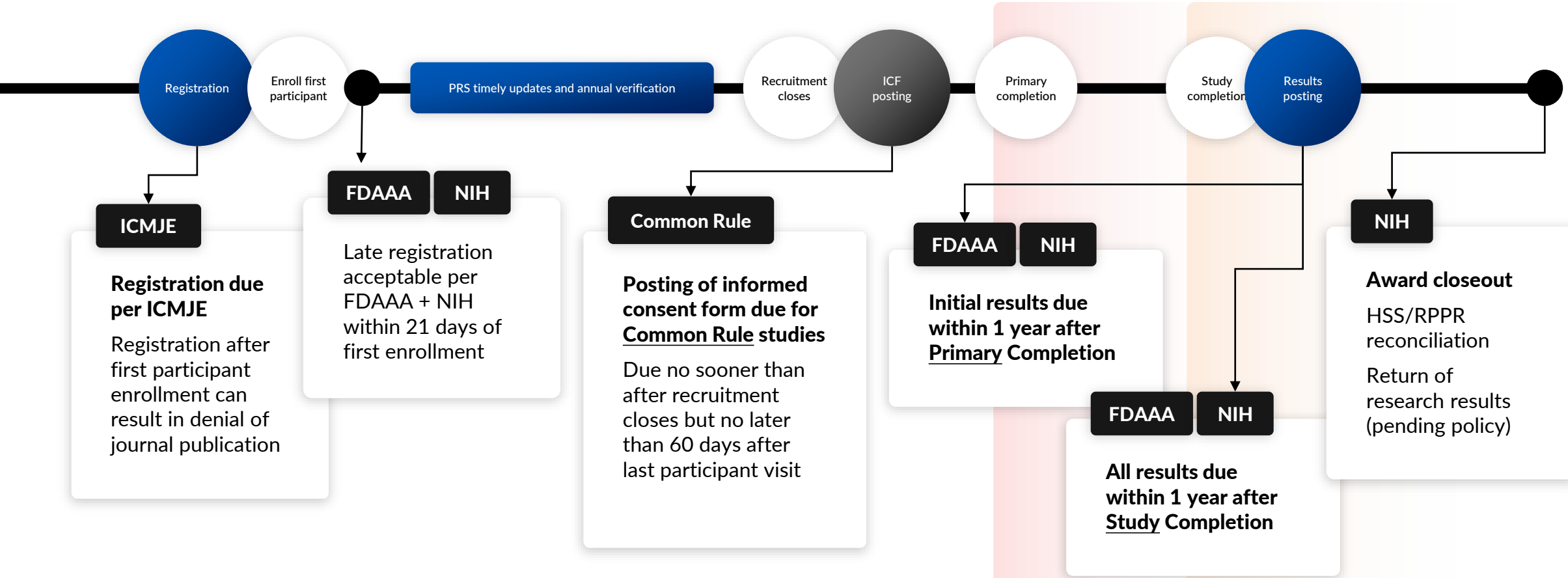
Process: High-level PRS steps

#	PRS Activities	Initial	Updates	Results
1	Obtain CTgov PRS user account password & **login**	**Duration (days)**		
2	**Create new record** or **open existing** record or **start Results**			
3	**Fill out all** sections (new/results) - OR - **edit existing** and save	2-10	1-2	365
4	Click **[Entry Complete]** action/button			
5	Click **[Approve]** action/button			
6	Click the **[Release]** action/button (only Responsible Party can do this step)			
7	PRS **QC Review** (done CTgov PRS analysts)	5-7	2-3	30
**	*Doesn't pass QC review – edit & resolve (repeat steps 1-7)*	1-5	1-2	2-10
8	**Passes QC, record is published** to www.ClinicalTrials.gov (NCT# assigned if new)	2	2	2

Workflow: PRS to ClinicalTrials.gov



Compliance Clock



Results Reporting Timelines

Due one year after actual primary completion date for ACTs and NIH-funded clinical trials

Suggested action timeline starting at primary completion date…

- **Month 0:** Confirm actual primary completion date with investigator(s) and study team
- **Months 0-3:** Confirm analysis populations and outcome measure structuring
- **Months 3-6:** Perform analyses and assemble data tables
- **Months 6-9:** Enter results into the results section of the PRS
- **Months 9-10:** Perform an internal review of entered data
- **Months 10-11:** Submit/release to ClinicalTrials.gov (QC wait queue = approx. 1 month)
- **Month 12:** Results due! Resolve QC issues within corrections timeline

Key message: Teams should not wait until month 12 to start results reporting process

Common Misconceptions

- Extensions are possible but ‘Pending publication’ is not a valid reason to delay posting results. ICMJE states that required ClinicalTrials.gov tabular results reporting is not consider ‘prior publication’
- Study stopped early (terminated)? You are still on-the-hook. If participants enrolled, then results are still required.
- “Not an ACT” does not necessarily mean “no ClinicalTrials.gov obligation”
- Start Date (date of first enrollment) is not the same and Open to Accrual date in OnCore. Especially important with NIH funded clinical trials. *If you’re OPEN but haven’t enrolled, keep date as [Anticipated]*

Key Takeaways

- Be aware of what rules apply to your study (it can be multiple)
  - If unsure, reach out and ask
- Plan early and develop a process to meet the requirements
  - Get familiar with the PRS system
  - Cancer-related studies can get additional support from NCI (CTRP) for initial registration and updates (not results)
  - Lots of resources online, plus CITI training available to OHSU
- ClinicalTrials.gov registration & maintenance should part of routine study conduct, similar to IRB continuing reviews and OnCore CTMS entry & updates

Technical Challenges

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PRS: Modernized vs. Classic interface

- Modernized is the new & “improved” PRS system
  - Access to the ‘Classic PRS’ system is still available
  - Classic is being phased out in stages (sunset expected 2027)

- Utilize the Modernized PRS as much as possible
  - PRS developers welcome feedback via yellow feedback tab (right)
  - **Exception:** Classic PRS still offers better user experience during entry of study results



NIH: HSS RPPR ⇆ ClinicalTrials.gov

- NIH funded studies may have issues with grant progress reports in HHS RPPR system
- Data feeds back and forth between ClinicalTrials.gov and HHS
- HSS ⇆ PRS data reconciliation points of concern
  - Title
  - Grant number
  - NCT number
  - Recruitment status
  - Enrollment total
  - Start date
  - Primary completion date
  - Study completion date
  - Results-reporting status
- Grant records, IRB records, HSS, and ClinicalTrials.gov should tell the same story
- **Best practice:** Ensure ClinicalTrials.gov (public) is updated **first** before reporting in HSS
  - Edits to the study's PRS (back-end, not public) record won't update instantly on ClinicalTrials.gov
  - Edits released from the PRS may require up to 30 days to pass QC review → **plan accordingly**

Other integrations

- Center for Medicare/Medicaid Service (CMS) – ClinicalTrials.gov ID required in OnCore to facilitate correct clinical service research billing
- Applying for new grants? Your existing ClinicalTrials.gov records s/be in good standing

- **Best Practice:** Ensure interventional study is registered and the ClincalTrials.gov NCT# is documented in OnCore and in local study records. ** Important even if not an OHSU IIT**

PRS: FDAAA vs. NIH results due dates

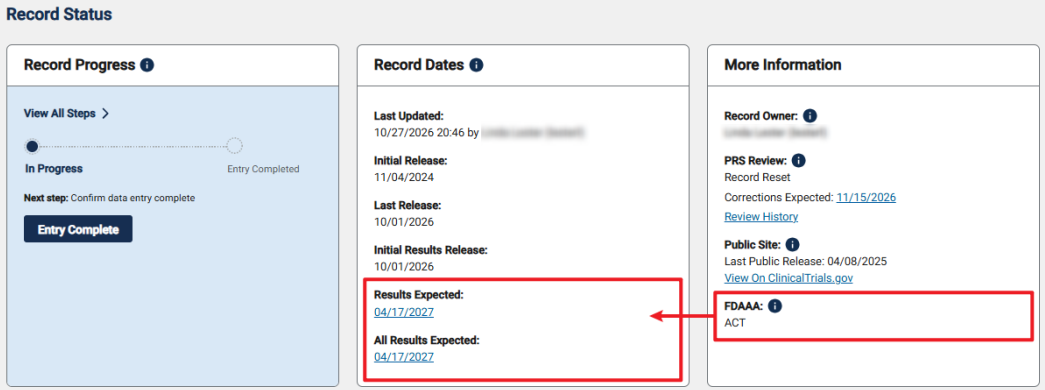
FDAAA

U.S. Food and Drug Administration Amendments Act
Study is not an applicable clinical trial (ACT) per FDAAA law

NIH

National Institutes of Health
Study is supported by NIH funding and is a “clinical trial” per NIH definition

EXAMPLE



Results due dates NOT displayed in PRS
Although the PRS is an NIH system, the interface does not display results due date(s) if the study is not an applicable clinical trial (ACT) but still requires results reporting per NIH disclosure policy

Operational Challenges

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Primary Completion Date (PCD) vs. Study Completion Date (SCD)

- Definitions
  - **Primary Completion Date:** Date the final participant was examined or received an intervention for final collection of data for the primary outcome measure.
  - **Study Completion Date:** Date final collection is completed for primary outcomes, secondary outcomes and adverse events.
- Why these matter?
  - For studies that require results, the actual primary completion is the trigger and starts the ClinicalTrials.gov results ‘clock’
- This is not the same as closing to accrual
- This relates to data collection only, does not include data analysis
- Be very aware of that last patient visit/date of last data collected as this can sneak up on you, especially in very slow accruing studies

Multisite Collaborative Study Considerations

- Who is Responsible Party?
- Who controls the PRS record?
- Who posts consent forms?
- Which site tracks the final protocol-required visit?
- Who handles results submission?
- What happens when the PI or coordinator changes?
- Multisite studies need a written ownership plan for registration, maintenance, results, consent posting, and all communications

Keeping Contact Information Current

- What to update:
  - Public recruitment contacts
  - Study officials
  - Responsible Party contact
  - PRS account access
  - Institutional backup contacts
- Risks of outdated contacts:
  - Participants cannot reach the study team
  - PRS notices are missed
  - Deadlines are overlooked
  - Records become orphaned after staff turnover
- People may leave but NCT records remain…

Staff Transitions and Record Ownership

- PI leaving – create departure checklist – use OHSU's Researcher Snapshot report
  - Change PI / Responsible party to another OHSU researcher
  - Wrap up study (terminate/complete, post results, if applicable)
  - Study and ClinicalTrials.gov record moves to PI's new organization
- Other staff leaving – update record owner and/or access list staff
- Institutional ClinicalTrials.gov PRS administrator involvement
- Take home: every record should have a record owner, backup (access list), accountable PI/Responsible Party

Modify existing record vs. create new

- Usually modify preexisting registration when:
  - Protocol is amended
  - Enrollment target changes
  - Recruitment status changes
  - Sites added or removed
  - Contact info changes
- Create new when:
  - New protocol with new cohort
  - New research question(s)
  - Distinct intervention/comparison
  - Scientifically separate study
- Key Message: New grant, new PI, new staff, protocol mod does not automatically mean a new NCT record and creating new record does not erase reporting obligations of old record.
- Check with your sponsor / grant program officer if unsure.
- **Best Practice: 1 IRB protocol for 1 ClinicalTrials.gov (NCT#) record.**

The Never-Ending Study

- Umbrella/Master protocols with multiple sub-protocols under a single ClinicalTrials.gov record where each sub-protocol is added as an ‘arm’
- These should be limited in scope or avoided entirely
  - Anticipated completion dates are meaningless when sub-protocols continue to be added
  - Contrary to the intent of disclosure
  - Results reporting can become very complicated
- Best Practice: register each sub-protocol distinctly as a separate ClinicalTrials.gov record

Recent and impending developments

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NIH: BESH study updates

- Basic Experimental Studies Involving Humans (BESH) definition– studies that have the purpose of understanding fundamental aspects of phenomena without a direct application towards clinical processes or products.
  - See "Is my Project a Clinical Trial, Basic Experimental Study Involving Humans, or an Observational study involving Humans"
- NIH:
  - BESH studies are no longer classified as clinical trials in all competing applications submitted on or after 5/25/2026.
  - BESH studies are now exempt from registration and results posting in clinicaltrials.gov
  - Grants approved before 5/25/2026 must still continue to follow the previous registration/results posting rules. **Check with your grant Program Officer (PO) if unsure.

NIH: Return of Research Results

August 27, 2026 – NOT-OD-26-113 requesting comment on a draft policy for sharing summary-level study results with research participants (comment period closed Oct. 26, 2026)

Draft policy applies broadly to NIH-support clinical research, including both clinical trials and non-clinical trials, requiring plain language summary-level results (PLS) be provided or offered to study participants

- Distinct from individual participant results (separate draft policy impending)
- Distinct from ClinicalTrials.gov tabular/structured results

Considerations

- Planning during study startup
- Participant communication methods
- Possible IRB/institutional review
- RPPR/closeout implications

Expectations

- **NIH-supported clinical trials:** Draft policy ties the proposed summary results timeline to 1 year after primary completion date or other applicable ClinicalTrials.gov reporting deadline, which ever is later…
- ClinicalTrials.gov is not the mechanism fulfilling draft policy requirements; However the existing disclosure deadlines may help define the timeline

Scenario-based exercises

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#1

- PI has an NIH funded 5 year R01 that includes 2 parts
  - Part 1 – retrospective chart review study that will help define protocol inclusion/exclusion criteria for part 2.
  - Part 2 – interventional drug study (not FDA regulated). Participants will receive study drug for 1 month with primary health outcome (end point data) collected at 1, 3, 6, and 12 months. Data for secondary endpoint collected at 24 months.
- *Register one or both?*
- *Timepoint for primary completion date?*
- *Timepoint for study completion date?*
- *Are results required and when?*
- *Upload a consent form and when?*

#2

- Same PI, same study, but gets new funding/grant and now plans to enroll 200 more participants. New study endpoints based on long term follow-up so some patients would roll over from the existing study, and some new participants would be enrolled. Participants would be followed for a duration of 3 years.
  - Do you register this as a new ClinicalTrials.gov record?
  - Should you update the primary completion date on the original clinicaltrials.gov record for the new 3 year outcome data?
  - When do you post the consent form?

Closing remarks

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Key takeaways from today

- “Disclosure by design” → Consider reporting obligations during grant proposals, protocol development, and throughout conduct
- Register before enrollment begins (ideally before IRB approval)
- Treat primary completion date as a major compliance milestone
- Start results reporting early
- Maintain ownership and contact information throughout the study lifecycle
- Verify expectations with your PO (NIH funded) or funder contact



Q&A

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View accessory resource

Go to SharePoint

Acknowledgments

- Clinical Trial Registration and Results (CTRR) Taskforce: https://ctrrtaskforce.org/resources/
- Bridget Adams (OCTRI)

Resources

- ICMJE Policy: https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
- ClinicalTrials.gov:https://clinicaltrials.gov/policy/reporting-requirements
- FDAAA ACT Checklist: https://cdn.clinicaltrials.gov/documents/ACT_Checklist.pdf
- FDAAA: https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission
- NIH Policy: https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information
- CTRR Taskforce: https://ctrrtaskforce.org/resources/
- ClinicalTrials.gov Tutorials: https://cdn.clinicaltrials.gov/documents/tutorial/content2/index.html#/
- ClinicalTrials.gov QC Review Criteria: https://clinicaltrials.gov/submit-studies/prs-help/protocol-registration-quality-control-review-criteria
- ClinicalTrials.gov QC Results Criteria: https://clinicaltrials.gov/submit-studies/prs-help/results-quality-control-review-criteria
- ClinicalTrials.gov Definitions: https://clinicaltrials.gov/policy/protocol-definitions

Resources (continued)

- HSS Quick Guide for Warnings and Errors: https://www.era.nih.gov/files/HSS-error-and-warning-PI-and-SO-quick-guide.pdf
- eRA Enhancements: New Errors for Non-Compliance with Clinical Trial registration and reporting at time of Award and in RPPR https://www.era.nih.gov/news/era-enhancements-new-errors-non-compliance-clinical-trial-registration-and-reporting-time
- BESH: https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/clinical-trial-besh-or-observational-study-involving-humans
- Researcher Snapshot: https://o2.ohsu.edu/research-integrity
- New NIH Policy: Your Voice Matters: https://osp.od.nih.gov/events/development-of-a-draft-nih-policy-for-responsibly-sharing-summary-level-study-results-with-participants-in-nih-funded-clinical-research/
- COGR Comments on NIH Policy: https://www.cogr.edu/blog/cogr-comments-proposed-nih-policy-sharing-summary-level-study-results-participants
- OHSU Sharepoint page describing new NIH draft policy

Glossary

PO: Grant/Program Officer

- Related to NIH funding but may be used interchangeably to refer to study sponsor/funder contact

PRS: Protocol Registration and Results System

- Responsible Party
- Record Owner
- Access List

BESH: Basic Experimental Studies involving Humans (BESH)

- Studies that have the purpose of understanding fundamental aspects of phenomena without a direct application towards clinical processes or products

PLS: Plain language summary

RPPR: Research Performance Progress Report (NIH)