

Guidance Document

ClinicalTrials.gov PRS Administrator RACI Matrix

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Problem

ClinicalTrials.gov Protocol Registration and Results System (PRS) Administrators may face challenges in making institutional leadership aware of the need for the resources and systems required to establish and maintain compliance with registration, maintenance, and results reporting requirements within their institution.

Solution

A RACI Matrix ([see linked example](#)) is a way to understand the reach of specific job tasks. The matrix itself is organized with specific tasks along the left side and relevant stakeholders along the top. For each task, there are groups Responsible for, Accountable to, Consulted, or Informed (RACI) by its completion.

Once a RACI Matrix is populated, it can be used as part of a conversation with leadership to highlight the resources required to prioritize compliance and transparency for institutional ClinicalTrials.gov records. This exercise can help PRS Administrators create a business case for resources, create opportunities for process efficiencies, reduce institutional risk, identify relevant policies to draft, and inform institutional outreach and educational efforts.

PRS Administrator Tasks

PRS Administrator tasks, groups to include across the top of the matrix, and guidance around the variability in who might be **Responsible**, **Accountable**, **Consulted**, and **Informed** by each PRS Administrator task follows.

Relevant PRS Administrator Tasks might include:

- Institutional ClinicalTrials.gov Education and Outreach
- Documentation of Study Conduct in Clinical Trials Management System (CTMS)
- Clear, Prompt Initial Communication with Study Team
- Determination of Registration and Results Requirements:
 - NIH Clinical Trial (ASSIST Access?)
 - ACT per FDAAA (Consult with institutional FDA-Regulated Research team?)
 - CMS (who is responsible for this determination?)
 - Publish per ICMJE
 - Voluntary
- Identify Scientific Protocol Materials
- Retrospective Institutional ClinicalTrials.gov Audit
- Initial ClinicalTrials.gov Registration Submission
- Submission of Required ClinicalTrials.gov Updates
 - Protocol Amendments (30 days)

- Study Status Changes (30 days)
- Actual Final Enrollment (30 days)
- Actual Primary Completion Date (30 days)
- Actual Study Completion Date (30 Days)
- Posting ICF per Revised Common Rule
- Informed Consent disclosure language verification
- Prepare Final Protocol for Upload with Results
- Results Module Submission

ClinicalTrials.gov Relevant Groups might include:

- Institutional
 - PRS Admins
 - Institutional Review Board (IRB)
 - Compliance Office
 - Leadership
 - FDA-Regulated Research Office
 - Research and Sponsored Programs or relevant Central Research Office
- Law, Funding, Policy
 - Federal Sponsors
 - NIH
 - FDA
 - CMS
 - Private Sponsors
 - Industry Sponsors
- Public

- Participant Obligation / Education
- Public Health Agencies
- Research Community
 - ICMJE
 - Potential Collaborators
- Transparency Advocates
 - FDAAA Tracker
 - All Trials

Responsible (R), Accountable (A), Consulted (C), or Informed (I)

With Respect to PRS Tasks, are there entities that will always be Responsible, Accountable, Consulted, or Informed by task completion? You may benefit from completing this exercise with institutional colleagues. Examples include:

Responsible

- The Responsible Party is always Responsible or Responsible / Accountable for timely, required registration (the PRS administrator may act in this role on behalf of the Institution, or the Principal Investigator (PI) may retain this role depending on the organizational set up)
- PI and/or study team delegate are responsible for maintaining CTMS

Accountable:

- Institutional Compliance group is Accountable for relevant registration to ClinicalTrials.gov

Consulted:

- IRB applications are consulted by the PRS Administrator to complete ClinicalTrials.gov registration – where PRS Administrators are delegated Responsibility for populating the record.

Informed:

- Transparency Advocates, the Public, and Research Community will always be Informed by PRS Tasks that maintain public record compliance.
- PRS Administrators may be Informed by CTMS, IRB applications, study team or PI

Glossary

ACT: Applicable Clinical Trial

CMS: Center for Medicare and Medicaid Services

CTMS: Clinical Trial Management System

FDA: Food and Drug Administration, federal agency of the US Department of Health and Human Services.

FDAAA: Food and Drug Administration Amendments Act

ICF: Informed Consent Form

ICMJE: International Committee of Medical Journal Editors

IRB: Institutional Review Board

NCT: National Clinical Trial, the NCT number is assigned by ClinicalTrials.gov upon acceptance of the registration record

NIH: National Institute of Health

PI: Principal Investigator

POC: Point of Contact

PRS: Protocol Registration and Results System

PRS Administrator: Person who releases [Institutional] ClinicalTrials.gov records for PRS Review

Study Team: This is the research group that includes the PI, study coordinators, and program managers per the IRB application / [CTMS]

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