



Procedure Name: Protocol Registration and Results System	Number: SOP 17 v3.0
Subject: Clinical Research	Effective Date: February 01, 2023
Linked Policy: Clinical Research Operations & Compliance Policy	Revised Date: September 10, 2024

INTROUDUCTION:

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) is intended to improve public access to information to help patients find trials for which they might be eligible, enhance the design of clinical trials, prevent duplication of unsuccessful or unsafe trials, improve the evidence base that informs clinical care, increase the efficiency of drug and device development processes, improve clinical research practice, and build public trust in clinical research . The University requires compliance with clinical trials registration and results reporting in accordance with Title 42 Code of Federal Regulations (42 CFR Part 11) known as the “final rule”, which clarifies and expands the regulatory requirements for the registration of clinical trials. The Protocol Registration and Results System (PRS) (formally,ClinicalTrials.gov) is the federal web based system for the submission of clinical study information

PURPOSE:

To establish the procedures that align with institutional policy and federal regulations for the registration and submission of clinical trials to the PRS.

SCOPE:

This procedure applies to all clinical researchers conducting clinical trials on the George Washington University (GW) premises, using the GW staff, property or facilities.

RESPONSIBILITIES:

Principal Investigator (PI)

The PI is responsible for and ensures compliance with the registration and maintenance of information in the protocol registration system.



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Office of Clinical Research (OCR)

OCR provides institutional oversight for the regulation of and the implementation of clinical trials. The OCR is assigned the institutional role of Administrator for the PRS. The OCR maintains a record of all studies registered in the PRS and reports on PRS Admin queries for each trial.

OCR PRS Administrator (OCR PRS Admin)

The OCR Admin is the institutional administrator for the protocol registration system website. The OCR Admin assures compliance and completeness of the required reports, data fields within the protocol registration system. The OCR Admin retains the authority to query missing or incomplete information entered by the study team.

Responsible Party (RP)

For most industry-initiated clinical trials, the industry sponsor is the RP. For PI-initiated clinical trials, the PI is designated to be the RP. The lead institution or cooperative group will be the RP for most multi-site and collaborative group clinical trials. The RP acknowledges all requirements for registration and reporting in accordance with the federal regulation.

PROCEDURES:

Registration

Studies registered in the PRS must be registered through the GW University organization account.

1. The RP is the individual who will register the study in the PRS.
2. It is university policy that studies be entered BEFORE subject enrollment- preferably once the study is IRB approved. Once the IRB is approved or NO later than 21 days after the subject enrollment.
3. Additional registrations



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- i. **CMS:** The RP must register and input required clinical trial information into the PRS before submitting claims for such services to CMS.
- ii. **ICMJE:** The RP must register with an ICMJE qualified publicly-accessible registry at or before the first patient is enrolled in the study as a condition for publication in a participating journal

Record Maintenance

RPs are responsible to update clinical trial records, review the record for accuracy and verify that data-entry occurs within the required time frames.

- 1. Registration information must be updated **no less than once every six months.**
- 2. Recruitment/enrollment status changes (such as suspending recruitment or enrollment closed) must be input **within 30 days of any change.**
- 3. Trial closure (regardless of the reason for closure—completion, low enrollment, etc.) must be input **within 30 days of trial closure.**

Routine Reporting

RPs are responsible to ensure data-entry occurs within required timeframes, as follows:

- 1. Aggregate results and adverse event reporting must occur within 12 months of the primary completion date.
- 2. If the study qualifies as a clinical trial under FDAAA or NIH, results and event reporting must occur within 12 months of the primary completion date. If the study does not qualify as a clinical trial under FDAAA or NIH, results reporting is voluntary
- 3. Uploading the IRB-approved protocol and statistical analysis plan in a timely manner to the PRS.
 - a. A trial that is covered by multiple applicable entities, the most stringent timeframe for reporting applies
- 4. The RP is responsible for responding to queries in the PRS. See OCR Reporting and Compliance section 6.4.



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OCR Reporting and Compliance

OCR will confirm all registration requirements for the PRS are met by the RP. The OCR Admin will run routine PSR reports and solicit the appropriate response as outlined in the OCR operation manual.

1. OCR will monitor compliance and track non-adherence according to the OCR operations manual.
2. OCR internal reporting will follow procedures outline in the OCR operations manual and at a minimum will include ORIC.

Transfer of PI Responsibilities

During the course of a clinical trial, the RP may relocate to another institution or otherwise be unavailable to fulfill his/her role responsibilities as PR. Before leaving the University the PR must work with the OCR Admin to ensure an orderly transition of his/her responsibilities to the new PR at the University or to initiate transfer of the registry account/record(s) and PR responsibilities to the new institution.

1. If a clinical trial remains at the University and there are continuing reporting obligations without a named PR than the OCR Admin will appoint a PR to serve and assume any remaining reporting obligations.
2. If the PR fails to transfer the trial record and the trial is closed and results have been reported, the OCR Admin has the power to release the record.

Transferring a Record

GWU should initiate transfers of studies to other institutions if they are receiving the record from another institution. Transfers of studies from GW to another institution should be initiated by the other institution.



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1. Transfers must be coordinated between the organizations involved. If the receiving organization has an administrator, they are responsible for coordinating the transfer. For organizations without administrators, the RP must coordinate the transfer.
 - a. Records in a released state cannot be transferred.
2. Before requesting a transfer of the record to GWU, the individual initiating the transfer should identify the proper individual at the new institution has an established account in the system in order to complete the transfer successfully.
3. Request the transfer by emailing PRS Staff at Register@ClinicalTrials.gov.
 - a. The PRS Admin can be emailed directly from within the PRS system by click on the Contact ClinicalTrials.gov PRS link at the top right of the PRS page header.
 - b. CC the study PI, the OCR Admin, and, if known, the lead Co-PI at the current record holder institution.
4. To complete a record transfer, PRS Staff must receive:
 - a. Confirmation from the receiving organization or responsible party that the record will be accepted (a copy of email confirmation is acceptable). If GWU is receiving the record and initiating the request, this is not required.
 - b. Name of the receiving organization ([institution])
 - c. Username of the new record owner
 - d. The NCT# for the study.
5. Once the record is transferred, it will need to be updated. Most areas requiring update will be flagged with an error in the system.

REFERENCES:

[Clinical Trials Registration and Results Information Submission Public Health Service, Department of Health and Human Services Food and Drug Administration Amendment Act 2007](#)



Office of
Clinical Research

School of Medicine
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