1. Purpose

This PSOM procedure is established in response to the requirements of Health and Human Service (HHS) regulations (42 CFR 11), “Clinical Trials Registration and Results Information Submission,” and the “NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information.” The purpose of this procedure is to confirm our commitment to ensure clinical trials registration and results reporting occur in compliance with the varying regulatory requirements in the http://register.clinicaltrials.gov Protocol Registration and Results System (PRS).

2. Scope

The HHS regulations mandate registration and results reporting for applicable clinical trials (ACTs) regardless of funding type. Under the Final Rule, there are two types of ACTs: Applicable device and drug clinical trials. An applicable device clinical trial is an interventional prospective clinical study of health outcomes comparing an intervention with a device product subject to FDA regulation, not including device feasibility studies. An applicable drug clinical trial is an interventional controlled clinical investigation of a drug or biological product subject to FDA regulation, excluding phase 1 studies. More details are available at https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhichTrialsMustBeRegistered_and_the_checklist_for_determining WHETHER or NOT a study is an ACT is available at https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf.

The NIH policy mandates registration and results reporting for clinical trials funded in whole or in part by NIH, even if they are not ACTs. NIH defines a clinical trial (NIH-CT) as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which include placebo or other control, but excludes expanded access studies) to evaluate the effects of those interventions on health-related, biomedical or behavioral outcomes. (More details at http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy/clinical-research-policy/clinical-trials.

In addition, this procedure recognizes International Committee of Medical Journal Editors (ICMJE) recommendations to register clinical trials for publication as well as Centers for Medicare and Medicaid (CMS) policy which requires a ClinicalTrials.gov study identification number (NCT#) when billing for routine care associated with applicable clinical trials.
3. Requirements

1) Clinical trial disclosure in the PRS is a sponsor (the entity that initiates the study) responsibility. Any Penn researcher, in the role of sponsor, or who conducts an investigator-initiated clinical trial (refer to exceptions listed in the "Scope" section above), should be designated as the Responsible Party (RP). The RP must ensure that registration, required record updates, and results reporting are completed in a timely manner, according to the HHS regulations, the NIH, and this procedure.

2) Record maintenance in accordance with the PRS requirements is mandatory. Noncompliance with the HHS regulations or NIH policy to submit results (no later than 12 months after the Primary Completion Date) for an ACT or NIH-CT or repeated violations of the HHS regulations, NIH policy, or this procedure, can result in loss of federal funding or civil penalty.
   i) In the case of trials with more than one primary outcome measure with different completion dates, the term refers to the date on which data collection is completed for all primary outcome measures.
   ii) if there are limiting factors as to why results may not be available for reporting including but not limited to study termination, removal of study personnel, and inadequate data, results may still need to be submitted. Please contact your local PRS Administrator for guidance on how to report partial outcome measure data, or how to indicate data is unavailable for terminated trials.

3) Any researcher planning to leave the institution who is the RP for a study posted on ClinicalTrials.gov must notify the local Protocol Registration System (PRS) Administrative team at ocrt@gov@pobox.upenn.edu to determine if record will need to be transferred to the new institution or who the new RP will be. If the record is completed RP is responsible for ensuring all necessary steps are taken to close study out in ClinicalTrials.gov.

4) If a Responsible Party is arriving at the institution and wishes to transfer records into Penn’s PRS system, RP must contact the local PRS Administrator and provide justification for acceptance of record, including but not limited to: local IRB approval of study, study status at all participating sites, and referral from PRS Administrator at prior institution.

5) Registration prior to enrollment of first subject is recommended for any clinical investigator that meets the definition of an Applicable Clinical Trial (ACT) or is NIH funded, per ICMJE guidelines. Registration is required for ACTs and NIH funded Clinical Trials no later than 21 days following first subject enrollment.

6) Clinical Trials approved by IRBs on or after January 1st, 2019 must include a data sharing plan in the trial’s registration on ClinicalTrials.gov. Data sharing statements must indicate the following: whether individual deidentified participant data (including data dictionaries) will be shared ("undecided" is not an acceptable answer); what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analysis plan, etc.); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Refer to the following ICMJE Table, which provides examples of Data Sharing Statements that fulfill these requirements.

7) ICMJE policy and Regulation 42 CFR 11.48(a)(5) requires a copy of the protocol (redacted as needed) and statistical analysis plan (if not included in the protocol) to be submitted as
part of clinical trial results posting for any Applicable Clinical Trial (ACT) with a primary completion date on or after January 18, 2017. The submission of these documents is not required for ACTs with a primary completion date before January 18, 2017.

8) The informed consent must contain the required language by 21 CFR 50.25 "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."

9) The NCT number is required for all trial/registry/study-related claims if it qualifies for the Clinical Trial Policy (CTP), is an Investigational Device Exemption (IDE) study, or is a Coverage with Evidence Development (CED) study. Trials that have budgeted patient care charges billed to Medicare or other third-party payers must provide an NCT number in the Clinical Trial Management System (CTMS) to receive a Research Billing Number (RBN). The NCT number entered into CTMS is a direct feed into PennChart to ensure claims are processed without any denials.

4. Roles and Responsibilities

1) Users
   a) Users include any person, who has access to the PRS system, and can create and/or edit records. Users can create their own records (Record Owners) and edit any record for which they have access to (Access List). Users include Sponsors (Industries, Institutions, and Investigators) as well as individuals (investigators, nurses, managers, coordinators, and other research personnel). Users are responsible for the records they create and have access to and are expected to maintain their records in accordance with the regulations outlined above.

2) Administrators
   a) Administrators are users with administrative level access to the PRS system.
      i) Local Administrators work for the Office of Clinical Research (specifically the Compliance Group) at the University of Pennsylvania and have the ability to create, remove (per NIH guidelines), and edit all records in the University of Pennsylvania PRS system. Administrators are responsible for ensuring the total universe of PRS records maintain a compliant status via outreach, education, and assistance. Administrators also serve as liaisons for record transfer and central PRS administrators. Local administrators can be contacted using the email below in the resources section of this procedure.
      ii) Central Administrators work for the NIH and ClinicalTrials.gov and have the ability to see all PRS records at all institutions globally. These administrators have the responsibility to determine which records are fit to publish to the main ClinicalTrials.gov site, and to provide assistance with site navigation and troubleshooting. Central administrators can be contacted through the PRS system on any page using the "Contact ClinicalTrials.gov PRS" link, or, local administrators can reach out to them per request.
b) Ancillary Personnel
   i) These personnel work for the University Of Pennsylvania Office Of Clinical Research and include but are not limited to Finance and Operations. These groups will check that studies listed as interventional have registered and received an NCT number before continuing on to other stages of study start up outside of ClinicalTrials.gov. Failure to comply can lead to withholding of Research Billing Numbers, and other prohibitory actions.

5. Resources

The Office of Clinical Research (OCR) PRS Administrators are available to set up accounts and provide guidance. To contact OCR’s PRS administrators, please e-mail psom-ocrctgov@pobox.upenn.edu.

Additional information can be found in the Penn Manual for Clinical Research https://www.med.upenn.edu/pennmanual/secure/clinicaltrials.gov-web-posting.html

Frequently Asked Questions can be found on the OCR website https://www.med.upenn.edu/ocr/clinical-trials-gov.

KnowledgeLink Training for how to create and maintain ClinicalTrials.gov PRS records
ClinicalTrials.Gov PRS System Online Module - OCR

COURSE UP.40009.I"EM.HSRWS163