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## 1. PURPOSE

- 1.1. The purpose of this procedure is to describe the acquisition and maintenance of Protocol Registration and Results Reporting (PRS) accounts.
- 1.2. This procedure begins when a new user requests a PRS login under the University of Massachusetts Medical School (UMMS) clinicaltrials.gov account.
- 1.3. This procedure ends when the accountholder departs UMMS.

## 2. POLICY

- 2.1. In order to perform required actions in clinicaltrials.gov, the Principal Investigator (as Responsible Party<sup>1</sup>) and designated study team members must have an account under the UMMS Clinicaltrials.gov Protocol Registration and Results System (PRS) account. When the Principal Investigator and designated study team members depart the Medical School or study team members are no longer assigned to the study which is the subject of the registration, the Principal Investigator must ensure the update of staff contact information or, in the event of Principal Investigator departure, notify the UMMS PRS administrator to take necessary action regarding the user account and record.

## 3. RESPONSIBILITY

- 3.1. The Principal Investigator (as Responsible Party) must keep staff information and access on the record up to date, removing departed study team members and requesting PRS accounts for new staff members.
- 3.2. The UMMS PRS administrator receives account requests, establishes accounts and assists with questions regarding staff updates on the registration record.

## 4. PROCEDURE

- 4.1. To obtain an account under the UMass Medical School (UMMS) Protocol Registration and Result System (PRS) account in Clinicaltrials.gov.
  - 4.1.1. The requestor must complete clinicaltrials.gov registration basic training.
  - 4.1.2. The requestor must email the PRS administrator and provide the individual's full name, email (all University business must use a University email) and telephone number.
  - 4.1.3. The UMMS PRS Administrator will establish the user account, and the PRS system will send a message to the user with access credentials.
- 4.2. If there are changes to study team members who have access to the record:
  - 4.2.1. Add or remove study team members within 15 days of effective date.
  - 4.2.2. If the study team member is departing UMMS, notify the UMMS PRS Administrator so the user account may be deactivated.
- 4.3. If the Responsible Party changes or departs UMMS
  - 4.3.1. Contact the UMMS PRS Administrator as the new Responsible Party may need an account or the registration record may need to be transferred to the Responsible Party's new institution. Transfer depends on IRB review, grant ownership, study status and status of Responsible Party as Investigator-Sponsor.
    - 4.3.1.1. If the Responsible Party departs UMMS, but the registration record is not transferred to the new institution, the Responsible Party and department/division must have a clear plan for ensuring timely completion of all requirements associated with the record. This may

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<sup>1</sup> Please see CTGov-002 for Responsible Party Determination.



## Clinicaltrials.gov PRS Account Request and Maintenance

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include designation of a new Responsible Party or data custodian within the department/division with access to all necessary information and data.

- 4.4. If the Responsible Party is arriving at UMMS and has active registration records at their prior institution
  - 4.4.1. Contact the UMMS PRS Administrator as the Responsible Party may need a UMMS account and to transfer registration record(s) to UMMS. Transfer depends on IRB review, grant ownership, study status and status of Responsible Party as Investigator-Sponsor.

## 5. REFERENCES

- 5.1. 42 CFR 11.4