Document Number:	RCQA-704-01	Effective Date: 18 Apr 2017
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Title:	CTD PRS Administrator Operational Process	

1. PURPOSE

The purpose of this document is to outline the operational processes for the Protocol Registration and Result Reporting System (PRS) Administrator for the University of Miami.

2. DEFINITIONS

Applicable Clinical Trial (ACT)	The term used in the Food and Drug Administration Amendments Act (FDAAA) to designate interventional studies of drugs, biologics and devices for which information must be submitted to the Clinical Trial Registry Data Bank. An applicable drug clinical trial is a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of FDAAA. An applicable device clinical trial is either: (1) a prospective clinical study of health outcomes comparing an intervention with a device subject to sections 510(k), 515, or 520 (m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); or (2) a pediatric post market surveillance of a device as required under section 522 of the Food, Drug, and Cosmetic Act.
Approval	Mechanism used by the Protocol Registration and Result Reporting System (PRS) for the Responsible Party to indicate that the record is ready to be 'Released' to the PRS for the 'NIH PRS Review.'
CMS	Centers for Medicaid and Medicare Services
CTD	Clinical Trial Disclosure
FDAAA	Food and Drug Administration Amendment Act of 2007
FDAMA	Food and Drug Administration Modernization Act of 1997
IIT	Investigator Initiated Trial
Internal Approval	Approval obtained from Department Head or designee to indicate that the PRS Administrator may 'Approve' and 'Release' the record for NIH PRS Review within the PRS.
IRB	Institutional Review Board
NCT #	National Clinical Trial (NCT) number, another term for the ClinicalTrials.gov registry number unique to each record. The format for the ClinicalTrials.gov registry number is "NCT" followed by an 8-digit number, e.g.: NCT00000419

Principal Investigator (PI)	An individual, who actually conducts a clinical investigation under whose immediate direction the test article is administered, dispensed or used.
PRS	Protocol Registration and Result Reporting System
PRS Administrator	PRS Administrators are responsible for the process by which clinical trial information is released to ClinicalTrials.gov on behalf of their organization. This process includes creating accounts for PRS users and editing and approving clinical trial records prior to initial release and after record updates, if the Institution serves as Responsible Party. They serve as points of contact for the ClinicalTrials.gov team and resolve questions associated with the information that is provided.
PRS Review	Under review by (ClinicalTrials.gov) QA reviewers
Public	Posted on ClinicalTrials.gov public web site.
QA	Quality Assurance
RCQA	Office of Research Compliance and Quality Assurance
Record	An entry on ClinicalTrials.gov containing summary protocol information about a clinical study, such as recruitment status, eligibility criteria, contact information, and in some cases summary results.
Released	Submitted to ClinicalTrials.gov for review by Responsible Party
Responsible Party (RP)	The term used by FDAAA to designate the entity or individual responsible for the clinical trial and for the submission of clinical trial information. This can mean: • The sponsor of the clinical trial, or • The principal investigator if so designated
Sponsor	A person who initiates, but does not actually conduct, the investigation; that is, the investigational drug or device is administered, dispensed or used under the immediate direction of another individual.
Sponsor-Investigator	An individual who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug or device is being administered, dispensed or used.
Study Team	Principal Investigator, Sponsor-Investigator, Research Coordinator, Study Coordinator, etc.
UMiami Organization	Abbreviated organization name within the Protocol Registration and Result Reporting System for the University of Miami

VPR Vice Provost of Research

3. RESPONSIBILITY

3.1. CTD Function of RCQA

- Verification of UM users for Affiliation and continued employment
- Create and disable PRS User Account
- Generate User Account report
- Transfer record ownership
- Act as Responsible Party when needed

4. PROCEDURE

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.1. Creating an non-RCQA PRS Administrator User Account for University Employees				
4.1.1.	Notification that a PRS Administrator Account is needed	RCQA receives notification from a department that PRS Administrator Account is needed for UMiami organization.	Department leadership	As requested
4.1.2.	Review of request	RCQA reviews the request and determines if creating a PRS Administrative account is the most appropriate method to achieve the department's expectation.	CTD Compliance Officer or designee and ED RCQA	Within 14 calendar days of request
4.1.3.	Discussion of Request	Departmental Head and/or designee is notified of the decision of creating a departmental PRS Administrator Account.	CTD Compliance Officer or designee and ED RCQA	Within 7 calendar days of decision

ID	Step	Description	Responsible	Timeline
4.1.4.	Training of User	If request for PRS Administrator Account has been granted, training of the user(s) is arranged and completed. Training is documented on RCQA PRS Administrator Training Documentation Form. All non-RCQA PRS Administrator users must sign a University of Miami Office of Research Compliance and Quality Assurance Confidentiality Agreement prior to their PRS Administrator Account being granted.	CTD Compliance Officer or designee	Within 7 business days of request
4.1.5.	New User Account created	PRS User Account is created, indicating that type of account is 'ADMIN' and appropriate group is assigned at this time.	CTD Compliance Officer or designee	Within 3 business days of training being completed
4.1.6.	Modify User Account if applicable	Current users of the PRS will have their account modified to indicate that they are PRS Administrators for the appropriate group.	CTD Compliance Officer or designee	Within 3 business days of training being completed
4.1.7.	Notify User	User is notified that Administrator Account has been created or that account has been modified. *'Refer to Welcome eMail'*	CTD Compliance Officer or designee	Within 3 business days of training being completed

ID	Step	Description	Responsible	Timeline
4.2. Creating a PRS User Account				
4.2.1.	Email notification	PRS Administrator receives an email requesting a User Account for PRS with the following information: • Preferred Username (CaneID) • Full Name • Title • Department • Phone Number • Email Address • Unique Protocol ID (eprost number)	Individual requesting account	As needed
4.2.2.	Verification of UM affiliation	Verify via Outlook that user requesting access has an active University of Miami email address.	PRS Administrator	Within 48 hours of request
4.2.3.	Creation of New User Account	PRS User Account is created.	PRS Administrator	Within 48 hours of request
4.2.4.	Notify user	User is notified that an account has been created for them and assistance to register protocol is offered. *'Refer to Welcome eMail'*	PRS Administrator	Within 48 hours of request

ID	Step	Description	Responsible	Timeline
4.3. Assigning New User Account to Current Protocol				
4.3.1.	Creation of New User Account	Steps 4.2.1 to 4.2.4 are followed to create new user account.	CTD Compliance Officer or designee	Within 5 business days of request
4.3.2.	Verify User is Study Team Member	Review study in IRB electronic system (i.e. IRB7) to verify that team member is listed as part of the study team. If User is not listed, confirmation from Responsible Party indicating that User should be added to access list of the ClinicalTrials.gov record is requested.	CTD Compliance Officer or designee	In parallel with step 4.2.3
4.3.3.	Add User to Access list	Team member is added to access list of clinicaltrials.gov record.	CTD Compliance Officer or designee	In parallel with step 4.2.3

ID	Step	Description	Responsible	Timeline
4.4. Periodic Review of Active User Accounts on the PRS of ClinicalTrials.gov				
4.4.1.	Generate User Account Report	Report is generated from ClinicalTrials.gov.	CTD Compliance Officer or designee	Twice/year
4.4.2.	Save User Account Report	Report is saved as PRS User Accounts_YYYYMMDD in \\MEDFS02\Office-research-compliance\RCQA\Clinical Trial Disclosure\CTD Compliance.	CTD Compliance Officer or designee	Immediately
4.4.3.	Verification of continued employment	Report is reviewed and employee's current employment status is verified.	CTD Compliance Officer or designee	Within 1 week of generating report

ID	Step	Description	Responsible	Timeline
4.4.4.	Employment not verifiable	If employment cannot be verified, information will be forwarded to the VPR Office for verification.	CTD Compliance Officer or designee	Within 2 weeks of step 4.4.1
4.4.5.	VPR Office verifies employment	Operational team from VPR Office will review the list of employee(s) and verify the employment status. The list will be returned to the CTD Compliance Officer or designee with a determination of Yes or No for Currently Employed.	VPR Office team member	Within 48 hours of step 4.4.1

ID	Step	Description	Responsible	Timeline
4.5. Disabling PRS User Accounts for Employees who left UM				
4.5.1.	Disabling accounts for employees who left UM	Report is reviewed for those employees who left UM and their PRS User Account is disabled.	CTD Compliance Officer or designee	Within 6 weeks of generating PRS User Account report
4.5.2.	Document disabling of account	Date of account disabling will be documented on PRS User Account Report.	CTD Compliance Officer or designee	At time of account disabling
4.5.3.	Save report	Report will be filed as PRS User Accounts_YYYYMMDD in the \\MEDFS02\Office-research-compliance\RCQA\Clinical Trial Disclosure\CTD Compliance	CTD Compliance Officer or designee	Upon completion of report

ID	Step	Description	Responsible	Timeline
4.6. Unable to Disable PRS User Accounts for Employees who left UM				
4.6.1.	Transfer record to new RP	If the user who left UM is currently listed as the record owner and is not the RP , the record will be transferred to the RP.	CTD Compliance Officer or designee	Within 6 weeks of generating PRS User Account report
4.6.2.	Reassignment of record owner	If the user who left UM is the record owner and RP, then IRB 7 is searched to identify who is the current PI. The record is then reassigned to the current PI as listed in IRB7.	CTD Compliance Officer or designee	Upon completion of this step
4.6.3.	Notification of reassignment	The current PI who is now the RP is notified of the reassignment. The notification will include instructions of any outstanding issues that require resolution and any additional steps required to ensure compliance with applicable requirements .	CTD Compliance Officer or designee	Upon completion of this step
4.6.4.	Account creation and record assignment	If the current RP does not have an account, one will be created for them and they will be notified by the PRS administrator that an account has been created and record(s) have been assigned to them. *'Refer to Welcome eMail'*	CTD Compliance Officer or designee	Upon completion of this step

ID	Step	Description	Responsible	Timeline
4.6.5.	Notification of non-compliance	If PI is non-compliant with request(s) as outlined in notification, CTD compliance activities steps will be carried out as per SOP RCQA-701 or RCQA-706.	CTD Compliance Officer or designee And Responsible Party	Within 30 calendar days of notification of reassignment
4.6.6.	Record reassignment	If the study is closed and the RP has left the University, the Department Chair and sub-investigators will be contacted with a request that the study be reassigned.	CTD Compliance Officer or designee	TBD on a case by case basis
4.6.7.	Unable to reassign record	If the record cannot be reassigned, a risk analysis will be performed to determine if required actions should be made to the record and assigned to PRS Administrator.	Office of RCQA	Within 2 weeks of this step
4.6.8.	Record reassigned to PRS Administrator	If a determination is made (risk assessment) that the record should be corrected, the PRS Administrator will be assigned the study record.	CTD Compliance Officer or designee	Within 72 hours of risk analysis

ID	Step	Description	Responsible	Timeline
4.7. Assignment of record to the PRS Administrator				
4.7.1.	Record assigned to PRS Administrator	If record is assigned to the PRS Administrator, appropriate required actions will take place to the record. All available supporting documentation and system information will be reviewed to make the relevant modifications to the record for compliance.	PRS Administrator or designee	Within 14 calendar days of assignment to PRS Administrator
4.7.2.	Review of revised record	PRS Administrator or designee will forward the revised record via the Protocol Registration Preview Document or Protocol Registration and Results Preview Document to the Department Chair for review.	PRS Administrator or designee	Within 48 hours of completing corrective action(s)
4.7.3.	Internal approval of revised record	The Department Chair or designee will review the revised record via the Protocol Registration Preview Document or Protocol Registration and Results Preview Document and communicate approval to the PRS Administrator or designee that the record may be released for NIH PRS review. If the Department Chair or designee has comments and/or suggested changes, the comments and changes will be rerouted to the PRS Administrator and steps 4.7.2 will continue until the record is approved for release for the NIH PRS review.	Department Chair or designee	Within 14 calendar days of receiving Protocol Registration Preview Document or Protocol Registration and Results Preview Document

ID	*Step*	*Description*	*Responsible*	*Timeline*
4.7.4.	Approval and release of ClinicalTrials.gov record	Upon receipt of approval by the Department Chair of the record, the PRS Administrator will approve and release the record for NIH PRS review. If the NIH PRS reviewers return comments, will return to step 4.7.2 and continue until the record is made public.	PRS Administrator	Within 48 hours of receiving approval of Protocol Registration Preview Document or Protocol Registration and Results Preview Document

5. DOCUMENTATION

RCQA will maintain an electronic copy

6. REFERENCES

RCQA-701 Clinical Trial Disclosure Review Procedures
RCQA-706 Clinical Trial Disclosure ClinicalTrials.gov Compliance
PRS User Guide
UMMG Provider Off-Boarding Policy
Provider Off-Boarding Checklist

7. TEMPLATES/FORMS

PRS User Account Report
Risk Determination
Protocol Registration Preview Document
Protocol Registration and Results Preview Document
PRS Training Document
PRS Create User Account Guide
University of Miami Office of Research Compliance and Quality Assurance Confidentiality Agreement
Welcome eMail

8. REVISION HISTORY

N/A

9. SIGNATURES

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