

SEATTLE CHILDREN'S HOSPITAL RESEARCH INSTITUTE
STANDARD OPERATING PROCEDURES / POLICIES

DEPARTMENT: Research Support Services
POLICY NUMBER: CTM-101
REPLACES: New
EFFECTIVE DATE: April 2, 2007
REVISION DATE: _____

POLICY TITLE: StudyManager Security

POLICY:

The Office of Clinical Research and Research Information Technology will maintain processes and procedures that monitor the use and access of StudyManager. Access will be controlled to ensure security and privacy requirements are met. The StudyManager Security Grid (Appendix 1) will be used as a guideline to determine appropriate user level security.

PROCEDURE:

101.1 Security Profiles

- 101.1.1 Oversight and management of user training, study access, and security profiles will be the responsibility the OCR Research Manager/StudyManager.
- 101.1.2 Access management (initial set up and termination of an account) for StudyManager will be managed by OCR.
- 101.1.3 Security profiles and individual user permissions will be determined using the StudyManager Security Detail Grid (Appendix 1) as guidance and be managed by OCR.
- 101.1.3 In general, users will have access to the research studies with which they are associated.
- 101.1.4 To apply for a StudyManager account, the applicant will complete the online user account form (Appendix 2). This form will be approved by the Director of OCR or designee prior to any access.
- 101.1.5 Modifications to a user's access will require resubmission of the online user account form and must be approved by the Director of OCR or designee prior to any change in access.

101.2 User Requirements

- 101.2.1 All users must complete Children's required HIPAA and Human Subjects Protection training as well as StudyManager training prior to accessing StudyManager.
- 101.2.2 Non-Children's staff members will be required to complete a Confidentiality Agreement.
- 101.2.2 Do not share login information. If a team member requires access, they should complete a StudyManager Account Request Form.
- 101.2.3 Do not choose to have the computer remember your login information. This is a security violation and passwords should be manually entered every time you access StudyManager.

101.3 Termination of User Privileges

- 101.3.1 User privileges may be terminated without notice for any breach of security.

101.4 Failure by either the investigator and/or research staff to adhere to this policy may result in suspension of clinical research activities for the investigator, and other disciplinary actions for the research staff.

DEFINITIONS:

Active Directory

Active Directory stores information about users and user groups. Active Directory also stores information about network resources (such as databases) and makes those resources available to application users, according to the groups to which they have institutionally granted access. Active Directory enables users to access these network resources with a single login.

StudyManager


A clinical trial management system (CTMS) that is designed to standardize and organize the process of implementing, conducting, and tracking clinical research studies. This Web-based software program creates budgets, organizes and tracks research patient visits, procedures and financial data. In addition, StudyManager creates reports to monitor research studies.

StudyManager User

An individual accessing StudyManager for any aspect of clinical research studies at Children's. StudyManager users may include research staff and members of Business Services, OSR, ORF, OCR or other services supporting clinical research.


Submitting Office: Office of Clinical Research

Approved by:



Pam Joy
Director, Office of Clinical Research

3/9/07
Date



Leslie Pagilagan
Director, Research IT

3/9/07
Date

Appendix 1 – Security Manager Security Detail Grid

Security Detail	OCR & RIT Sys Admin	Office of Sponsored Research	Research Finance	Research Staff	Investigators	Others (Hosp Services, OBS, CRC)
CONTACTS	X	X	X			
Add Contact	X	X				
Edit Contact	X	X				
Delete Contact	X	X				
Contact Search	X	X				
View Providers	X	X				
Add/Edit/Delete Providers	X	X				
SCHEDULES	X					
Add Patient Appointments	X					
Edit Patient Appointments	X					
Cancel Patient Appointments	X					
Schedule Multiple Appointments	X					
STUDIES	X	X	X	X	X	X
Add Study	X	X				
Delete Study	X	X				
Edit Study Info	X	X				
Manage Visit Checklist	X	X		X		
Add Study Visit	X	X				
Edit Study Visit	X	X				
Delete Study Visit	X	X				
Add Protocol Procedures	X	X				
Edit Protocol Procedures	X	X				
Delete Protocol Procedures	X	X				
Add Organizational Procedures	X	X				

Security Detail	OCR & RIT Sys Admin	Office of Sponsored Research	Research Finance	Research Staff	Investigators	Others (Hosp Services, OBS, CRC)
Edit Organizational Procedures	X	X				
Delete Organizational Procedures	X	X				
Add Site Procedures	X	X				
Edit Site Procedures	X	X				
Delete Site Procedures	X	X				
Add Study Sites	X	X				
Remove Study Sites	X	X				
Manage Study	X	X				
Edit Manage Study	X	X				
Manage Users	X	X				
FINANCIALS	X	X	X			
Budgets	X	X	X			
Add Additional Procedures	X	X				
Copy Budget	X	X				
Edit Budget	X	X				
Study Site Financial Events	X	X	X			
Add Study Site Financial Events	X	X				
Edit Study Site Financial Events	X	X				
Delete Study Site Financial Events	X	X				
Checks	X	X	X			
Add/Edit/Delete Check Types	X	X	X			
Add/Edit/Delete Incoming Checks	X	X	X			
Add/Edit/Delete Applying Checks	X	X	X			
Add/Edit/Delete Outgoing Checks	X	X	X			

Security Detail	OCR & RIT Sys Admin	Office of Sponsored Research	Research Finance	Research Staff	Investigators	Others (Hosp Services, OBS, CRC)
Add/Edit/Delete Outgoing Check Tracking	X	X	X			
Invoicing	X	X	X			
Add/Edit/Delete Invoices	X	X	X			
Payment Milestones	X	X	X			
Add Standard Org Milestones	X	X	X			
Edit Standard Org Milestones	X	X	X			
Delete Standard Org Milestones	X	X	X			
Add Standard Sponsor Milestones	X	X	X			
Edit Standard Sponsor Milestones	X	X	X			
Delete Standard Sponsor Milestones	X	X	X			
Add Standard Site Milestones	X	X	X			
Edit Standard Site Milestones	X	X	X			
Delete Standard Site Milestones	X	X	X			
RECRUITMENT	X					
REPORT BUILDER	X	X	X	X	X	X
DOCUMENT TRACKING	X					
TASKS	X					
ADMIN	X	X				
Core Data	X	X				
Sites	X	X				
Add Sites	X	X				
Edit Sites	X	X				
Delete Sites	X					
Renummer Sites	X					

Security Detail	OCR & RIT Sys Admin	Office of Sponsored Research	Research Finance	Research Staff	Investigators	Others (Hosp Services, OBS, CRC)
Procedures	X	X				
Add/Edit/Delete Procedures	X	X				
Edit Procedure Site Info Only	X	X				
Contact Types	X					
Add/Edit/Delete Contact Types	X					
Therapeutic Areas	X	X				
Add/Edit/Delete Therapeutic Areas	X	X				
Indications	X	X				
Add/Edit/Delete Indications	X	X				
Traits Shortlist	X					
Add/Edit/Delete Traits Shortlist	X					
Organizations	X	X				
Add/Edit/Delete Organizations	X	X				
Departments	X					
Add/Edit/Delete Departments	X					
Hospitals	X					
Add/Edit/Delete Hospitals	X					
Master Schedule Groups	X					
Master Patient Searches	X					
Master Reports	X					
Document Types	X					
Interaction Types	X					
Task Types	X					
Patients	X					
Traits	X					
Add/Edit/Delete Traits	X					
Races	X					
Add/Edit/Delete Races	X					
Custom Fields	X					

Security Detail	OCR & RIT Sys Admin	Office of Sponsored Research	Research Finance	Research Staff	Investigators	Others (Hosp Services, OBS, CRC)
Add/Edit/Delete Custom Fields	X					
Recruitment	X					
Questionnaire Builder	X					
Add/Edit/Delete Questionnaire	X					
Recruiting Tracks	X					
Add/Edit/Delete Recruiting Tracks	X					
Recruiting Keywords	X					
Add/Edit/Delete Recruiting Keywords	X					
Recruiting Sources	X					
Add/Edit/Delete Recruiting Sources	X					
Media Events	X					
Add/Edit/Delete Media Events	X					
Interaction Statuses	X					
Add/Edit/Delete Interaction Statuses	X					
Financials	X	X				
Financial events	X	X				
Add/Edit/Delete Financial Events	X	X				
Accounting Codes	X	X				
Add/Edit/Delete Accounting Codes	X	X				
Schedule Builder	X					
Contact Custom Fields	X					
Study Custom Fields	X					
Study Site Custom Fields	X					
Security	X					

Security Detail	OCR & RIT Sys Admin	Office of Sponsored Research	Research Finance	Research Staff	Investigators	Others (Hosp Services, OBS, CRC)
Auditing	X					
PATIENTS	X	X	X	X	X	X
Add Patient	X			X		
Delete Patient	X					
Edit Patient Info	X			X		
Patient Visits	X	X	X	X	X	X
Add Patient Visits	X			X		
Edit Patient Visits	X			X		
Delete Patient Visits	X					
Add Patient to Study	X			X		
Edit Patient Enrollment Info	X			X		
Rescreen Patient	X			X		
Unenroll Patient	X					
Patient Search	X					
View/Add/Edit Adverse Events	X					
Delete Adverse Events	X					

STUDYMANAGER ACCOUNT REQUEST FORM

Instructions

1. All of the fields below are required to obtain a StudyManager account.
2. Have Supervisor/Investigator e-mail the completed form to StudyManager for account set up: clinton.vickers@seattlechildrens.org.
3. Account will not be activated until requestor has completed StudyManager training. You will be contacted by the Office of Clinical Research to schedule training.
4. For help with questions about this form, e-mail: clinton.vickers@seattlechildrens.org.

Requestor Information

Name: _____

Phone: _____

New Account Modify Account Termination

Department(s): _____

Role: (select one)

If other selected, define role: _____

Date Account Needed or Account Modification/Termination Effective: _____

Name of Supervisor/Investigator of Requestor: _____

For Office of Clinical Research Use Only

Account created by: _____ Date: _____

Date of scheduled training: _____