# Tips and Instructions for ClinicalTrials.gov use

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#### 1. How do I request a user name and password?

- 1.1. Provide the following information to Partners PRS Administrator, Jennifer Ballard <u>ipballard@partners.org</u>:
  - PHS user name
  - Full name
  - Home institution
  - Email address
- 1.2. PRS Administrator sends profile request to CT.gov
- 1.3. ClinialTrials.gov emails Investigator notifying of account (within 2 days)
- 1.4. You may now log into the ClinicaTrials.gov Protocol Registration System: <u>https://register.clinicaltrials.gov/</u>

ClinicalTrials.gov Protocol Registration System	
Login	
Welcome to the <u>ClinicalTrials.gov</u> Protocol Registration System (PRS).	OMB NO: 0925-0586 EXDIRATION DATE: 04/30/2012 Burden Statement
Organization: User Name: Password:	Forgot password
Login	

# 2. How do I access ClinicalTrials.gov?

- 2.1. Go to the ClinicaTrials.gov Protocol Registration System: https://register.clinicaltrials.gov/
- 2.2. Using your assigned user name and password, log in.
- \* If you do not have a user name and password, see 'How do I request a user name and password?'

# 3. What is my Organization name?

Institution	Organization name
Brigham and Women's Hospital	BrighamHospital
Massachusetts General Hospital	MassGH
McLean Hospital	Mclean
Newton-Wellesley Hospital	Newton-WellesleyH
North Shore Medical Center	NorthShoreMC

# 4. How do I complete the 'Board name, affiliation, and contact information?

For Partners Human Research Committee approved protocols (MGH/BWH):

<u>Board Name:</u> *	Partners Human	Research Committee	
Board Affiliation: *	Massachusetts General Hospital		
Board Contact: *	NOTE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov.		
(Ivot made public)	Business Phone:	617-424-4127 Extension:	
	Business Email:	ehohmann@partners.org	
	Business Address:	Partners Human Research Committee 116 Huntington Avenue, Suite 1002 Boston, MA 02116	
	Business Phone: Business Email: Business Address:	61/-424-412/ Extension: ehohmann@partners.org Partners Human Research Committee 116 Huntington Avenue, Suite 1002 Boston, MA 02116	

Note: Board Affiliation should reflect the IRB panel that reviewed the protocol

# 5. What is the Standard Function menu?

The Standard Function menu is the main console for working in ClinicalTrials.gov. From here you can create/modify protocol records, view QA review comments, and change your password and/or email associated with your user name. The 'Help' section in the Standard Function menu provides helpful tools that can be used during protocol registration or results reporting.

ClinicalTrials.gov Protocol Registration System	Send	<u>message to PRS</u>				
Main Menu						
	U.S. Public Law 110-85 (FDAAA) About Results Data Entry					
	Standard Functions					
	Protocol Records         Create         Modiffy         View         QA Review Comments         Problems: SWhite Records         Undelete         User Account         Change password         Change Email Address         PRS Administrator(s)         Help         Quick Start Guide         Frequently Asked Questions         What's New Apr 7, 2011         User's Guide         Data Element Definitions         Results Data Element Definitions         FDAMA 113 Requirements         Simple Results Forms         XML Upload         Upload protocol records					
	<u>Check upload status</u> <u>Protocol XML Schema</u> <u>Results XML Schema</u> <u>Results Pick-list Normalization</u>					
	Session Logout					

6.	How do I	update my registration?	

ICMJE policy requires you to update/verify your registration at least every 6 months. FDAAA requires updates/verification annually, or within 30 days of status change.

- 6.1. Log into ClinicalTrials.gov
- 6.2. Go to Modify

6.3. If changes have been made to the protocol that effect information listed in the ClinicalTrials.gov registration, make appropriate changes.

6.4. If no changes have occurred in the last 6 months, update the Record Verification Date by clicking the 'Edit' button next to the field.

Edit	Record Verification Date:	January 2010
	Overall Status:	Completed
	Study Start Date:	May 2005

6.5. Record current month and year.



#### 7. I forgot my password, Help!

Contact Jennifer Ballard, PRS Administrator at jpballard@partners.org. She can reset your password.

Standard Functions
Protocol Records

**QA Review Comments** 

Problems: SWhite Records

Create Modify

<u>Undelete</u> User Account

Help

<u>Change password</u> Change Email Address

PRS Administrator(s)

**Quick Start Guide** 

User's Guide

Frequently Asked Questions

What's New Apr 7, 2011

Data Element Definitions Results Data Element Definitions

Simple Results Forms

FDAMA 113 Requirements

# 8. How do I change the email address associated with my username?

- 8.1. Go to: https://register.clinicaltrials.gov/ and log into your ClinicalTrials.gov account
- 8.2. Select Change Email Address in User Account of the Standard Function list
- 8.3. Enter new email address. Note, messages from ClinicalTrials.gov will be sent to this address.

ClinicalTrials.gov Protocol Registration System	1	Send message to PRS	Ŀ	CAN HEADY	FDA
	Change Email Address				
Organization:	BrighamHospital				
Username:	SWhite				
Email Address:	Enter your full email address. Example: jsmith(	@mail.nih.gov			
Importa	nt messages from ClinicalTrials.gov will be	e sent to this address.			

# 9. PRS User's Guide

This document, created by National Library of Medicine provides step-by-step instructions for entering, modifying, and releasing protocol records using the ClinicalTrials.gov Protocol Registration System.

- 9.1. Go to: <u>https://register.clinicaltrials.gov/</u> and log into your ClinicalTrials.gov account
- 9.2. Select *User's Guide* in Help Section of the Standard Function list

#### Standard Functions

Protocol Records

<u>Create</u> <u>Modify</u> <u>View</u> <u>QA Review Comments</u> <u>Problems: SWhite Records</u> Undelete

#### User Account

<u>Change password</u> <u>Change Email Address</u> <u>PRS Administrator(s)</u>

#### Help

Quick Start Guide Frequently Asked Questions What's New Apr 7, 2011

#### User's Guide

Data Element Definitions <u>Results Data Element Definitions</u> FDAMA 113 Requirements

Simple Results Forms

#### 10. Local contacts

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