INTRODUCTION TO CLINICALTRIALS.GOV

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RESEARCH NAVIGATOR
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If using this document to develop a similar resource, kindly acknowledge the Johns Hopkins Institute for Clinical and Translational Research (ICTR).
PRESENTATION OBJECTIVES:

- Explain what ClinicalTrials.gov is and what it can do
- Explain why and when registration is required
  - FDAMA
  - FDAAA
  - ICMJE
  - Voluntary (recruitment)
- Identify who is responsible for registration
- Explain how registration works at Johns Hopkins
  - JHSPH, SKCCC, JHSOM
- Provide practice examples
- Identify institutional and national resources
The registration and reporting processes are very complex!

This PowerPoint presentation is just an introduction to an involved topic.

Several resources including the ICTR Drug and Device Resource Service (DDRS) will be provided to you at the end of the presentation.
WHAT IS CLINICALTRIALS.GOV?

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.
WHAT CAN CLINICALTRIALS.GOV DO?

• ClinicalTrials.gov can be searched in real time to find enrolling and completed trials by:
  – Condition
  – Interventions
  – Outcome measures
  – Sponsors/collaborators
  – Locations
  – Phases
  – Dates (e.g. Start and completion dates) Results
WHAT IS THE RATIONALE FOR DEVELOPING THE CLINICALTRIALS.GOV REGISTRY?

• Initially, the registry was established to help patients with serious and life-threatening illnesses learn about and access clinical trials

• The intent of the registry expanded over time to increase research funding transparency

• Now, the registry provides a means of broad access to information regarding a wide range of clinical trials
1997: FDA Modernization Act (FDAMA) establishes ClinicalTrials.gov

2000: ClinicalTrials.gov launched

2005: ICMJE requires registration of trials (including at ClinicalTrials.gov)

2007: FDAAA expands ClinicalTrials.gov to require registration of more studies and results and adds penalties for noncompliance

2008: ClinicalTrials.gov adds basic results modules, including adverse events
Which trials must be registered?

- Registration is required for ‘Applicable Clinical Trials’

Under FDAAA, ‘Applicable Clinical Trials’ are those that meet all of the following:

- Interventional studies (drugs, biologics, devices)
- Controlled
- Phase 2 – 4
  - Phase 1 drug and small feasibility device studies are excluded*
- US FDA jurisdiction (e.g. IND/IDE or US site)
- Studies initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007
Some Phase I trials, though they are not Applicable Clinical Trials under FDAAA, are required to register under FDAMA – the earlier law – which is still in effect.

These involve primarily experimental treatments to assess efficacy of a drug or biologic treatment for serious or life-threatening diseases whether using an IND, Group C Cancer drug, or other FDA regulated product.

Thus, many studies for cancer and other serious and life-threatening diseases (e.g. cancer, ALS, AIDS) must register regardless of Phase.

See FDA Guidance for Industry entitled, “Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions”
When to register?

- Under FDAAA, registration of **applicable clinical trials** is required **within 21 days** of enrollment of the 1\(^{st}\) subject

- Registration should be **updated at least every 12 months** with certain exceptions that should be updated **within 30 days**:
  - Changes in recruitment status
  - Changes in primary completion date
WHAT INFORMATION IS NEEDED TO REGISTER UNDER FDAAA?
FDAAA REQUIRED DATA ELEMENTS FOR REGISTRATION

- Organization's Unique Protocol ID (e.g. NA_000XXX number)
- NIH Grant Number as a Secondary ID (if applicable)
- Brief Title and Official Title
- Study Type (e.g. Interventional/Observational/Expanded Access)
- IND/IDE Trial information (e.g. IND number)
- IRB Approval status/number
- IRB Name (e.g. JH SOM IRB, Affiliation, Board Contact)
- Sponsor
- Primary Completion Date (Defined as “the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome”)
- Interventional Study design
- Study Phase
- Time perspective (e.g. prospective, retrospective, cross-sectional, other)
- Primary Outcome measures (Specific key measurement(s) or observation(s) used to measure the effect of experimental variables in a study)
- Arm labels
- Intervention Type (e.g. drug, device, biologic, procedure, radiation, behavioral, genetic, dietary supplement, etc.)
- Conditions or focus of study
- Study population description
- Eligibility Criteria
- Institution Contacts
- Brief summary
- Recruitment status
Who is responsible for registration?

FDAAA designation of the “Responsible Party”:

The responsible party can be designated by the Sponsor to a PI who:

• Is responsible for conducting the study
• Has access to and control over the data
• Has the right to publish the trial results, AND
• Has the ability to meet the requirements
Which trials must submit results?

Required for:

- Applicable Clinical Trials
- In which the study product is approved (for any use) by FDA

When:

- **Within 12 months** of Primary Completion Date (final data collection for primary endpoint)
- If product not approved by Primary Completion Date but is approved later, **then results due 30 days after approval**
- Delays are possible, primarily for manufacturer or under limited special circumstances (can request extensions for good cause)
Registration is required for **Applicable Clinical Trials** defined as:

- Intervenational studies (drugs, biologics, devices)
- Phase 2 – 4 *
- US FDA jurisdiction (e.g. IND/IDE or US site)
- Studies initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007

Registration is required within 21 days of enrollment of the 1st subject.

Updates required at least every 12 months with certain exceptions including changes in recruitment status & primary completion date. These should be updated within 30 days.

Results reporting required for applicable clinical trials in which the study product is approved (for any use) by FDA.
ADDITIONAL FDAAA REQUIREMENTS

Required language in Informed Consent

• “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”
IND/IDEs

FDA also requires sponsors of an IND or IDE to submit a signed Form 3674 when filing certain types of investigational and/or marketing and post-marketing applications and submissions.
ADDITIONAL FDAAA REQUIREMENTS

NIH Funding

All applicable clinical trials supported in whole or in part by an NIH grant must be in full compliance with FDAAA.
Consequences of non-compliance

FDAAA enforcement provisions include:

- Notices of non-compliance
- Monetary sanctions (up to $10,000 per day for the responsible party NOT the institution)
- Withholding or recovery of NIH grant funding for federally funded trials
INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS (ICMJE)
ICMJE created the Uniform Manuscript Requirements primarily to help authors and editors in their mutual task of creating and distributing accurate, clear, easily accessible reports of biomedical studies.

Per ICMJE, registration helps:

- "to promote the public good by ensuring that everyone can find key information about every clinical trial whose principal aim is to shape medical decision-making"

- to foster conditions in which decisions about care "rest on all of the evidence, not just the trials that authors decided to report and that journal editors decided to publish".
The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry.

The registry must be/include:

- accessible to the public at no charge
- open to all prospective registrants
- managed by a not-for-profit organization
- a mechanism to ensure the validity of the registration data
- electronically searchable
The ICMJE accepts registration in the following registries:

- www.anzctr.org.au
- www.clinicaltrials.gov
- www.ISRCTN.org
- www.umin.ac.jp/ctr/index/htm
- www.trialregister.nl
- https://eudract.ema.europa.eu/

**NOTE:** FDAAA recognizes only www.Clinicaltrials.gov
ICMJE REGISTRATION REQUIREMENTS

What studies must be registered?

Required for Prospective studies that:

- Assign subjects to an intervention or concurrent comparison or control groups
- Study the cause/effect relationship between medical intervention and a health outcome.

ICMJE scope is much broader than the scope of FDAAA:

- *Interventions* include *procedures*, *behavioral treatments*, *dietary interventions*
- *Health outcomes* include any biomedical or health-related measure obtained in participants, including *pharmacokinetic measures* and adverse events
ICMJE Registration Requirements

When to register?

- ICMJE requires that registration occurs **PRIOR** to enrollment of 1st subject

- ICJME doesn’t require results submission

- ICMJE will not consider results data posted in the tabular format required by ClinicalTrials.gov to be prior publication
Who is responsible for registration?

Per ICMJE, anyone can register the trial, but the **author** is responsible for ensuring complete registration.
Failure to Register

The consequence of not registering, if a journal editor thinks the study should have been registered, is refusal by a journal to publish the work.
## COMPARISON OF FDAAA AND ICMJE REQUIREMENTS

<table>
<thead>
<tr>
<th>Question</th>
<th>FDAAA</th>
<th>ICMJE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Which trials should be registered?</strong></td>
<td>Interventional Studies</td>
<td>Interventional studies</td>
</tr>
<tr>
<td></td>
<td>- Not Phase 1/feasibility*</td>
<td>- All Phases</td>
</tr>
<tr>
<td></td>
<td>- Drugs, Biologics, Devices</td>
<td>- All Intervention Types</td>
</tr>
<tr>
<td><strong>When should they be registered?</strong></td>
<td>Within 21 days of enrollment of first participant</td>
<td>Prior to enrollment of first participant</td>
</tr>
<tr>
<td><strong>What items are needed for registration?</strong></td>
<td>ClinicalTrials.gov and FDAAA data items</td>
<td>WHO data items</td>
</tr>
<tr>
<td><strong>Where should the trial be registered?</strong></td>
<td>ClinicalTrials.gov</td>
<td>ClinicalTrials.gov or WHO Primary Registry</td>
</tr>
<tr>
<td><strong>When should results be reported?</strong></td>
<td>Within 12 months of the final data collection for the primary outcome of the study</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
SO WHY IS REGISTRATION IMPORTANT?

• It’s the law!
  
  – FDAAA added enforcement provisions including up to $10,000/day in civil monetary penalties and withholding remaining or future grant funds

• Your investigator wants to publish!
HOW TO DETERMINE IF REGISTRATION IS NECESSARY

• Decide if your trial meets the definition of an Applicable Clinical Trial under FDAAA

• Ask if your PI wishes to publish the results of the trial

• Determine if the trial is supported completely or in part by NIH funding
HOW REGISTRATION WORKS AT JOHNS HOPKINS

Institutional Accounts

Oncology

Monica Owens (carltmo@jhmi.edu) in the Oncology Clinical Research Office is responsible for clinicaltrials.gov user account set-up

JHSPH

Elizabeth Peterson (epeterso@jhsph.edu) in the JHSPH IRB is responsible for clinicaltrials.gov user account set up
Individual Accounts

JHSOM

• If you or your investigator do not already have one, you will need to establish an individual PRS account for yourselves.

• Obtaining an account is usually a quick process taking a day or two at most.
HOW TO ESTABLISH AN INDIVIDUAL PRS ACCOUNT

To request an account, go to the main ClinicalTrials.gov site

- Choose “Submit Studies”
- Choose “How to Apply for An Account”
- Then choose “Apply for a PRS Account”
**REQUESTING AN INDIVIDUAL PRS ACCOUNT**

**Investigator Information**

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigator Name *</td>
<td>Your name here</td>
</tr>
<tr>
<td>Affiliation (if not the sponsor):</td>
<td></td>
</tr>
<tr>
<td>Investigator Phone *</td>
<td>Please enter a valid phone number, including area code.</td>
</tr>
<tr>
<td>Investigator Email *</td>
<td></td>
</tr>
</tbody>
</table>

**Regulatory Information:** The regulatory authority may be a national or international health authority, an institutional review board or an ethics committee.

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Authority *</td>
<td>JHM IRB</td>
</tr>
<tr>
<td>Regulatory Authority Address</td>
<td>1620 McElderry St. Reed Hall - B130 Baltimore, MD 21205-1911</td>
</tr>
</tbody>
</table>

To the best of my knowledge, the above information is true and correct. Questions about this form and the Protocol Registration System (PRS) may be sent to register@ClinicalTrials.gov.

**Submit Application**
REQUESTING AN INDIVIDUAL PRS ACCOUNT

From: ClinicalTrials.gov Registration [mailto:register@clinicaltrials.gov]
Sent: Tuesday, April 23, 2013 10:58 AM
To: J Doe@jhmi.edu
Cc: ICTR Navigators;
Subject: ClinicalTrials.gov Password reset

Dear Jane Doe

We have created an account for you, the login information will be sent in a separate email.

Thank you,
PRS TEAM
ClinicalTrials.gov
HOW TO REGISTER A TRIAL

https://register.clinicaltrials.gov/

Welcome to the ClinicalTrials.gov Protocol Registration System (PRS).

Organization: 
Username: 
Password:  
Forgot password

Login

Johns Hopkins University
NOTES FOR FIRST TIME REGISTRATION

- You will need to change your password. In the upper left-hand menu, choose ‘change password’ and follow instructions.

- Read the quick start and users guides!

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ClinicalTrials.gov
Protocol Registration System

Main Menu

Our records show that your current email address is: cschoebi@jhu.edu. If this is not correct, please contact your PRS Administrator to make the correction.

Protocol Records
Create
Modify
View
QA Review Comments
Problems: CSchoebeltein Records
Undelete

User Account
Change password
Modify Information
PRS Administrator(s)

Help
Quick Start Guide
Frequently Asked Questions (FAQ)
Responsible Party FAQ
What’s New Mar 20, 2013
User’s Guide
Protocol Data Element Definitions
HOW TO REGISTER A TRIAL

ClinicalTrials.gov
Protocol Registration System

Main Menu

Our records show that your current email address is "C-schebel@jhu.edu". If this is not correct, please contact your PRS Administrator to make the correction.

Protocol Records
Create
Modify
View
QA Review Comments
Problems: CSchebel20064 Records
Undelete

User Account
Change password
Modify Information
PRS Administrator(s)

Help
Quick Start Guide
Frequently Asked Questions (FAQ)
Responsible Party FAQ
What's New: Mar 24, 2013
User's Guide:
Protocol Data Element Definitions

Send message to ClinicalTrials.gov PRS
Help us improve: PRS Survey

Johns Hopkins University

CTSA Clinical & Translational Science Awards
How to Register a Trial

ClinicalTrials.gov
Protocol Registration System

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. Section 801 studies may only be registered by the Responsible Party. If this is an applicable clinical trial as defined by US Public Law 110-85, Title VIII, Section 801, ensure that your organization is the Responsible Party as defined by the law before registering the study.

2. IND/IDE studies may only be registered by the IND/IDE holder. If the study is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE), ensure that your organization is the IND/IDE holder before registering the study.

3. For NIH-funded studies, coordinate with the relevant Institute or Center. If this is a US National Institutes of Health (NIH) funded study, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.

4. Multi-site studies are NOT registered by individual sites. If this is a multi-site study it must be registered only once, by the sponsor (primary organization that oversees implementation of study and is responsible for data analysis) or its designated principal investigator (PI).

5. Coordinate with all collaborators before registering. If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization, as sponsor or its designated PI, is registering the study.

6. Refer to the ClinicalTrials.gov Review of Protocol Submissions document for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.

Unique Protocol ID: *

Brief Title: *

* Required by ClinicalTrials.gov

Required to comply with US Public Law 110-85, Section 801

May be required to comply with US Public Law 110-85, Section 801

Use NA_000XXXX as Unique ID
<table>
<thead>
<tr>
<th><strong>Title:</strong> Test Study</th>
<th><strong>ID:</strong> NA_000XXXX</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unique Protocol ID:</strong></td>
<td><em>IDAAA</em> NA_000XXXX</td>
</tr>
<tr>
<td><strong>Brief Title:</strong></td>
<td>Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer</td>
</tr>
<tr>
<td><strong>Acronym:</strong></td>
<td>If there is an acronym or abbreviation used to identify this study, enter it here.</td>
</tr>
<tr>
<td><strong>Official Title:</strong></td>
<td>Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate</td>
</tr>
<tr>
<td><strong>Study Type:</strong></td>
<td>Interventional, Observational</td>
</tr>
<tr>
<td><strong>FDA Regulated Intervention?</strong></td>
<td>Select if this trial includes an intervention subject to US Food and Drug Administration regulations.</td>
</tr>
<tr>
<td><strong>IND/IDE Protocol?</strong></td>
<td>Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE).</td>
</tr>
</tbody>
</table>

*Required by ClinicalTrials.gov

Required to comply with US Public Law 110-85, Section 801
Secondary Identifiers include but are not limited to US NIH grant numbers, other grant/funding numbers and identifiers from other clinical trial registries (e.g., ISRCTN).

Add a Secondary ID to this study.

There are no Study Secondary IDs currently listed for this study.

* Required by ClinicalTrials.gov
  FDAAA
  Required to comply with US Public Law 110-85, Section 801

(FDAAA) May be required to comply with US Public Law 110-85, Section 801
### Protocol Registration System

Provide information for the human subjects review board, such as an Institutional Review Board (IRB), ethics committee or equivalent group, that is responsible for the review and monitoring of this protocol. For studies involving multiple review boards, provide information only for a single board.

**Board Approval:**
If review board approval has been granted, enter the approval number below. If the board does not assign numbers, enter date in mm/dd/yyyy format.

- **Status:** Submitted, pending
- **Approval Number:**

**Board Name:**
Johns Hopkins Medicine IRB

**Board Affiliation:**

**Board Contact:**
(Not made public)

SAFE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov.

- **Business Phone:**
- **Extension:**
- **Business Email:**
- **Business Address:**

**Data Monitoring Committee?**
Has a group been appointed to monitor safety and scientific integrity of the study?
- **Yes**
- **No**

**Oversight Authority:**
(One per line)
- **Enter:** [List of oversight authorities]

- **Examples:**
  - United States: Food and Drug Administration
  - Germany: Federal Institute for Drugs and Medicinal Devices
  - United States: Institutional Review Board

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* Required by ClinicalTrials.gov

[Continue][Quit]
Primary Completion Date

- Required by ClinicalTrials.gov for records first released on or after December 1, 2012
- Definition: As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data.

Key Trial Dates

Study Start Date

Primary Completion Date

Study Completion Date

Final data collection date for the study.

For suspended, terminated, or withdrawn studies, briefly explain why the study was stopped.

ID: NA_00046072

Why Study Stopped:

Options:
- Select -- Year:
- Select -- Year:
- Select -- Type:
- Select -- Type:

ERROR: Overall Status is a required field.
ERROR: Verification Date is a required field.
WARNING: Study Start Date has not been entered.
NOTE: Study Completion Date has not been entered.
ERROR: Primary Completion Date has not been entered.
### Detailed Description:

*NOTE: Detailed Description: data not entered.*

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Record Verification Date</td>
<td>April 2013</td>
</tr>
<tr>
<td>Overall Status</td>
<td>Recruiting</td>
</tr>
<tr>
<td>Study Start Date</td>
<td>January 2012</td>
</tr>
<tr>
<td>Primary Completion Date</td>
<td>June 2015 [Anticipated]</td>
</tr>
<tr>
<td>Study Completion Date</td>
<td></td>
</tr>
</tbody>
</table>

*NOTE: Study Completion Date has not been entered.*

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study Design</td>
<td></td>
</tr>
<tr>
<td>Study Purpose</td>
<td></td>
</tr>
<tr>
<td>Study Phase</td>
<td></td>
</tr>
<tr>
<td>Intervention Model</td>
<td></td>
</tr>
<tr>
<td>Number of Arms</td>
<td></td>
</tr>
<tr>
<td>Masking</td>
<td></td>
</tr>
<tr>
<td>Allocation</td>
<td></td>
</tr>
<tr>
<td>Enrollment</td>
<td></td>
</tr>
</tbody>
</table>

**ERROR: Study Characteristics must be specified.**

**WARNING: Enrollment has not been entered.**

*NOTE: A single arm study should have Intervention Model specified as Single Group.*

*NOTE: A single arm study should have Allocation specified as N/A (not applicable).*

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome Measures</td>
<td></td>
</tr>
<tr>
<td>Primary Outcome Measure</td>
<td></td>
</tr>
<tr>
<td>Secondary Outcome Measures</td>
<td></td>
</tr>
</tbody>
</table>
MODIFYING A SAVED REGISTRATION

ClinicalTrials.gov
Protocol Registration System

Main Menu

Our records show that your current email address is “Cschoel@jhu.edu”. If this is not correct, please contact your PRS Administrator to make the correction.

Protocol Records
- Create
- Modify
- View
- QA Review Comments
- Problems: CSchoel Records
- Undelete

User Account
- Change password
- Modify Information
- PRS Administrator(s)

Help
- Quick Start Guide
- Frequently Asked Questions (FAQ)
- Responsible Party FAQ
- What’s New: Mar 26, 2013
- User’s Guide

Send message to ClinicalTrials.gov PRS
Help us improve: PRS Survey

FDA

CTSA Clinical & Translational Science Awards
### MODIFYING A SAVED REGISTRATION

**ClinicalTrials.gov**

**Protocol Registration System**

#### Select Protocol Record - Edit

<table>
<thead>
<tr>
<th>Protocol ID</th>
<th>ClinicalTrials.gov ID</th>
<th>Brief Title</th>
<th>Overall Status</th>
<th>Owner</th>
<th>Responsible Party</th>
<th>Updater</th>
<th>Updated</th>
<th>Record Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edit</td>
<td>NA_00°0XXXX</td>
<td>Pilot Study of Metformin-induced CBP Phosphorylation at the Cellular Level and Corresponding Clinical Dose Response in Adults and Children</td>
<td></td>
<td>Jane Doe</td>
<td>Dr. Smith</td>
<td>04/25/2013 11:18</td>
<td>In Progress</td>
<td></td>
</tr>
</tbody>
</table>
**PRC TEST SYSTEM**

**ClinicalTrials.gov**  
Protocol Registration System

**Edit Protocol/Results Record**

Record status changed to In Progress.  
Errors in protocol or results data. See messages below.  
Additional information may be required per US Public Law 110-85. See WARNING messages below.

**Main Menu**  
Select  
Preview  
Spelling  
Edit All  
Problems  
Delete  
Download XML

**Title:** Test Study  
**ID:** NA_000XXXX

**Next Action:** Complete  
Tip: Remember to update Record Verification Date when reviewing or updating a protocol record.

**Record Status:**  
In Progress | Completed | Approved | Released  
Upload: Allowed [Set...]

**Owned by:** LPost  
Access List  
Last updated: 06/25/2013 12:43 by LPost

Initial release: [not yet rele...]

**Add**  
Record Log: None

**Edit**  
Unique Protocol ID: NA_000XXXX
ClinicalTrials.gov ID:
### Completing Registration

**ClinicalTrials.gov**

**Protocol Registration System**

**Edit Protocol/Results Record**

- **Record status changed to In Progress.**
  - Errors in protocol or results data. See messages below.
  - Additional information may be required per US Public Law 110-85. See WARNING messages below.

<table>
<thead>
<tr>
<th>Main Menu</th>
<th>Select</th>
<th>Preview</th>
<th>Spelling</th>
<th>Edit All Problems</th>
<th>Delete</th>
<th>Download XML</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title:</strong> Test Study</td>
<td><strong>ID:</strong> NA_000XXXX</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Next Action:** Complete

**Tip:** Remember to update **Record Verification Date** when reviewing or updating a protocol record.

**Record Status:**

- In Progress
- Completed
- Approved
- Released

**Upload:** Allowed [Set]

**Owned by:** LPost

**Access List**

**Last updated:** 06/25/2013 12:43 by LPost

**Initial release:** [not yet released]

**Add**

**Record Log:** None

<table>
<thead>
<tr>
<th><strong>Edit</strong></th>
<th><strong>Unique Protocol ID:</strong> NA_000XXXX</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>ClinicalTrials.gov ID:</strong></td>
</tr>
</tbody>
</table>

**Johns Hopkins University**

**CTSA Clinical & Translational Science Awards**
The last step in the process is for the Responsible Party (PI) to log in to PRS and release the study record.

- Log in to PRS in at this URL: [https://register.clinicaltrials.gov/](https://register.clinicaltrials.gov/)

- Enter Organization Name, Username, and Password.

- Once logged in, click “Modify,” and a list of studies for the account with appear.
RELEASE OF RECORDS

• Click “Edit” for the study to be released.

• Some study fields may have “Alert” and “Warning” messages associated with them—these messages will not prevent the record from being released.

• If an “Error” message is associated with a field, you must resolve the Error prior to releasing the study record.

• If the record has not been edited since it was last approved by ClinicalTrials.gov staff, it may look like this:

```
Optional Actions: Reset to Completed  Reset to In-Progress

Record Status:
In Progress  |  Completed  |  Approved  |  Released  |  Upload: Allowed [Set…]
Owned by: abradfield  Access List  Last updated: 10/24/2012 13:23  by abradfield
Initial release: 12/23/2000  Last release: 10/24/2012  Download Receipt (PDF)
Quality Assurance Review: COMPLETED
```
If no changes are being made to the study record, click “Reset to Completed” in the “Optional Actions” line. The screen will then change to look like this. Click “Complete” in the “Next Action” line:

If changes are being made in the record, the top portion of the record will automatically change to look like the screenshot above. Just click “Complete” in the “Next Action” line.
• Once “Complete” is selected the screen will look like this:
AFTER RELEASE: EDITS REQUESTED

- PI must log in and select “release”
- If the PRS Team has edits, the PI may see something similar to this:

To: PI/Study Team Member
From: ClinicalTrials.gov Registration register@clinicaltrials.gov

Hi There,

The record was reviewed on [date] but was reset for the following reason(s).

1. Reason number 1 (may give you a suggestion on how to edit)
2. Reason number 2 (additional suggestions on improving)

EXAMPLE:
“The time frames entered are ‘14 days past Week 8 study visit’. I think ‘Week 10’ would be best”.

[Insert PI name] will need to modify the record, fix the listed issues and COMPLETE, APPROVE AND RELEASE.

Thank you,
PRS TEAM
ClinicalTrials.gov

In this case, the PI must log in and select “complete”, “approve” and “release” again
After Release: Approval

- PI must log on and “release” (or “re-release” if this is a re-submission following edits requested by the PRS team.)
- If the PRS Team has no edits, PI may see something similar to this:

From: ClinicalTrials.gov Registration
[register@clinicaltrials.gov]  Sent: Wednesday, June 12, 2013 9:34 AM
To: YOUR PI
Cc: register@clinicaltrials.gov
Subject: ClinicalTrials.gov Protocol Record NA_00046072

Johns Hopkins University Protocol Record NA_SudyNumber, Title of Study, has been reviewed and will be published on the ClinicalTrials.gov public site.

RECORDS USUALLY APPEAR ON ClinicalTrials.gov WITHIN 2 BUSINESS DAYS of the receipt of this message.

QUESTIONS? Contact us at: register@clinicaltrials.gov
Thank you,
Quality Assurance Team
ClinicalTrials.gov
ClinicalTrials.gov Identifier: NCT01876992

- The record should be live in about 2 business days.
• For specific questions or comments: register@clinicaltrials.gov.

• General ClinicalTrials.gov information: http://clinicaltrials.gov/ct2/about-site

• FDAAA related information: http://clinicaltrials.gov/ct2/manage-recs/fdaaa

• Office of Extramural Research (OER): http://grants.nih.gov/Clinicaltrials_fdaaa/


• Instructions for Authors sections of ICMJE journals all have information regarding clinical trial registration
Local ICTR Contact: Johns Hopkins Drug and Device Service

Linda E. Post, RN, BSN, CCRP
Research Navigator
ICTR_Navigators@jhmi.edu
Thank you!!!!!