

# IRB Approval, Now What?

4/16/2014,  
4/17/2014



*CELEBRATE!*

# IRB Approval Letter

IRB Studies > eIRB Comprehensive Training

## Current State

Approved

- [View Study](#)
- [Printer Version](#)
- [View Differences](#)

## My Activities

- [PI Suspend](#)
- [Edit Email List](#)
- [Edit Guest List](#)
- [Upload Team Member CV](#)
- [Upload Team Member Education Certification](#)
- [Change Study Coordinator](#)

## New Reportable Event

- [New Reportable Event](#)
- [New Amendment](#)
- [New Continuing/Final Review](#)

### Please Note:

A study can only have one amendment or continuing review open at any given time. If the study has an open amendment or continuing review, the option to create a new amendment or continuing review will not be available. Reportable events can be submitted at any time.

## Study: eIRB Comprehensive Training ( Pro00002231 )

Description: eIRB Comprehensive Training Presentation  
Principal Investigator: [Rebecca Simms \(PI\)](#) Study Coordinator: [Amber McPherson](#)  
Expiration Date: 10/1/2013 IRB Letter: [IRB Letter for Study Pro00002231\(0.01\)](#)  
Funding Sources: Non-Sponsored (No Funding)

[History](#) [Attachments](#) [Amendments](#) [Continuing Reviews](#) [Reportable Events](#) [Pre Review Status](#) [Change Log](#) [Reviewer Checklists](#)

## Approved Consent Forms:

Name	Version
<a href="#">testing - adult consent version date.pdf</a>	0.01

## Smartform Section 1 - Study Personnel & Funding

### 1.5.4 Funding Type, Proposal:

There are no items to display

### 1.6.1 Investigator Is Sponsor, IND/IDE::

There are no items to display

### 1.6.2 Investigator Is Sponsor, Manufacturing Practice:

There are no items to display

### 1.6.3 Investigator Is Sponsor, Risk Management:

There are no items to display

### 1.6.6 Investigator Is Sponsor, Case Report:

There are no items to display

### 1.6.7 Investigator Is Sponsor, Protocol Deviation:

There are no items to display

# Stamped Consent Form

IRB Studies > eIRB Comprehensive Training

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# Additional Submissions

IRB Studies > eIRB Comprehensive Training

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# Amendments

- Don't go changin' without IRB approval



# Amendments

- Submit an amendment to the IRB prior to:
  - Add, remove or change PI, Co-I or Study Staff
  - Revisions to the Protocol: Risk, Methods
  - Revisions to the Consent Form
  - Revisions to Recruitment
  - Increase Enrollment Goal (don't over-enroll)

# Amendments

- Revise IRB application to be consistent with revisions in other documents (Protocol, ICD)
- Do not implement changes until IRB approval is received



# Amendments

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - 7.2 Consent Forms & Process of Consent Continue >>

Reviewer Notes Previous

Filter by Type  Go Clear Advanced

Type	Reviewer	Modified
<input type="checkbox"/> Dept Department Change Request Please upload a consent form to question 7.2.1 by using the Add button. <u><input type="checkbox"/> <i>Response Required!</i> Click here to respond...</u>	Richard Ing (Dept. App.)	5/10/2011 12:40 PM

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## Consent Forms & Process of Consent

# 7.2

7.2.1 Please follow the link below to access the USF IRB Informed Consent templates.

A) Link: [USF IRB Informed Consent templates](#)

B) Upload consent forms, assent forms, or information sheets here:

Name	Modified	Version
<input type="button" value="Add"/> <input type="button" value="Upload Revision"/>	Uploading a Revised Document	5/10/2011 1:00 PM
		0.01 <input type="button" value="Delete"/>



# Continuing Review

- Annual report to the IRB of research activity
  - A snapshot in time
  - Ensure all human subject protections certifications are current
  - Answer questions fully with brief description of activity
  - No changes may be made to the original application during the Continuing Review (CR)
  - Any changes that are requested would be submitted as an Amendment after the CR is approved

# Continuing Review

- System will send automatic reminder emails at 60, 45 and 30 days prior to expiration.
- Requests for continuing review that are submitted to the IRB less than 45 days prior to the annual renewal date are not guaranteed to receive approval before they expire and constitute noncompliance with HRPP policy.

(HRPP policy #703)

# Continuing Review

## Participant Enrollment

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IRB-Approved Enrollment:

4600

Actual Participant Enrollment:

- 6.1.1 \* Total Participant Enrollment locally since the study began (the total number of subjects consented to participate in the research study):  
1710
- 6.1.2 \* Total Participant Enrollment locally since the last initial or continuing IRB review (the total number of subjects consented to participate in the research study):  
48
- 6.1.3 Total Participant Enrollment at all sites since the study began:  
1989
- 6.1.4 \* Did any enrolled participants fail screening?  
 Yes  No
- If Yes, how many?
- 6.1.5 \* Were any enrolled participants withdrawn or dropped from the study?  
 Yes  No
- If Yes, State how many withdrew/dropped and why:
- 6.1.6 \* Have any research activities stopped since the last IRB review?  
 Yes  No

# Continuing Review

- Upload 2 most recent signed consent forms since the last CR
- Include all pages
- Redact the participant name, signature and any identifier
- Retain the date signed by the subject
- Retain the information from the person obtaining consent

# Continuing Review

Submit with Continuing Review, not RE:

- Non-Serious Protocol Deviations: recorded on a protocol deviation log and submitted with Continuing Review

**Serious deviations** affect subject safety, rights, welfare or data integrity

# Reportable Events

Submit to the IRB immediately:

- Unanticipated problems involving risks to human subjects or others (see HRPP policy 212)
- Serious Protocol Deviations
  - Potential to increase risk(s) to subjects
  - Potential to decrease benefit(s) to subjects
  - Potential to recur
- Data Safety Monitoring Board (DSMB) reports

# UPIRHSO

OHRP	FDA
Unexpected	Unexpected
Related or Possibly Related	Serious
Increased Risk of Harm	Implications for the conduct of the study



# Reportable Events

- UPIRHSOs must be submitted to the IRB immediately upon the investigator becoming aware of the event.
- SAEs that do not meet the definition of UPIRHSOs do not require prompt reporting and should be reported at the time of Continuing Review.

# Final Report

- Will not need to go back to original source data
- Can still be in the process of writing the report
- Closes out the study so the 5 year clock to destroy documents can start

**\*\* BONUS \*\***

## HIPAA Authorization or Waiver

- HIPAA authorization or waiver needed if:
  - Information is identifiable,
  - Contains health information, and
  - Covered entity

**\*\* BONUS \*\***

## HIPAA Authorization or Waiver

- HIPAA authorization or waiver NOT needed if:
  - Potential participants are the Researcher's patients
  - Moffitt does not require HIPAA waiver for Moffitt patients
  - JAHVA always requires a HIPAA waiver for recruitment of VA patients

# Questions?



# Contact Information

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University of South Florida

Research Compliance and Integrity

[cepps@usf.edu](mailto:cepps@usf.edu)

<http://www.research.usf.edu/dric/>