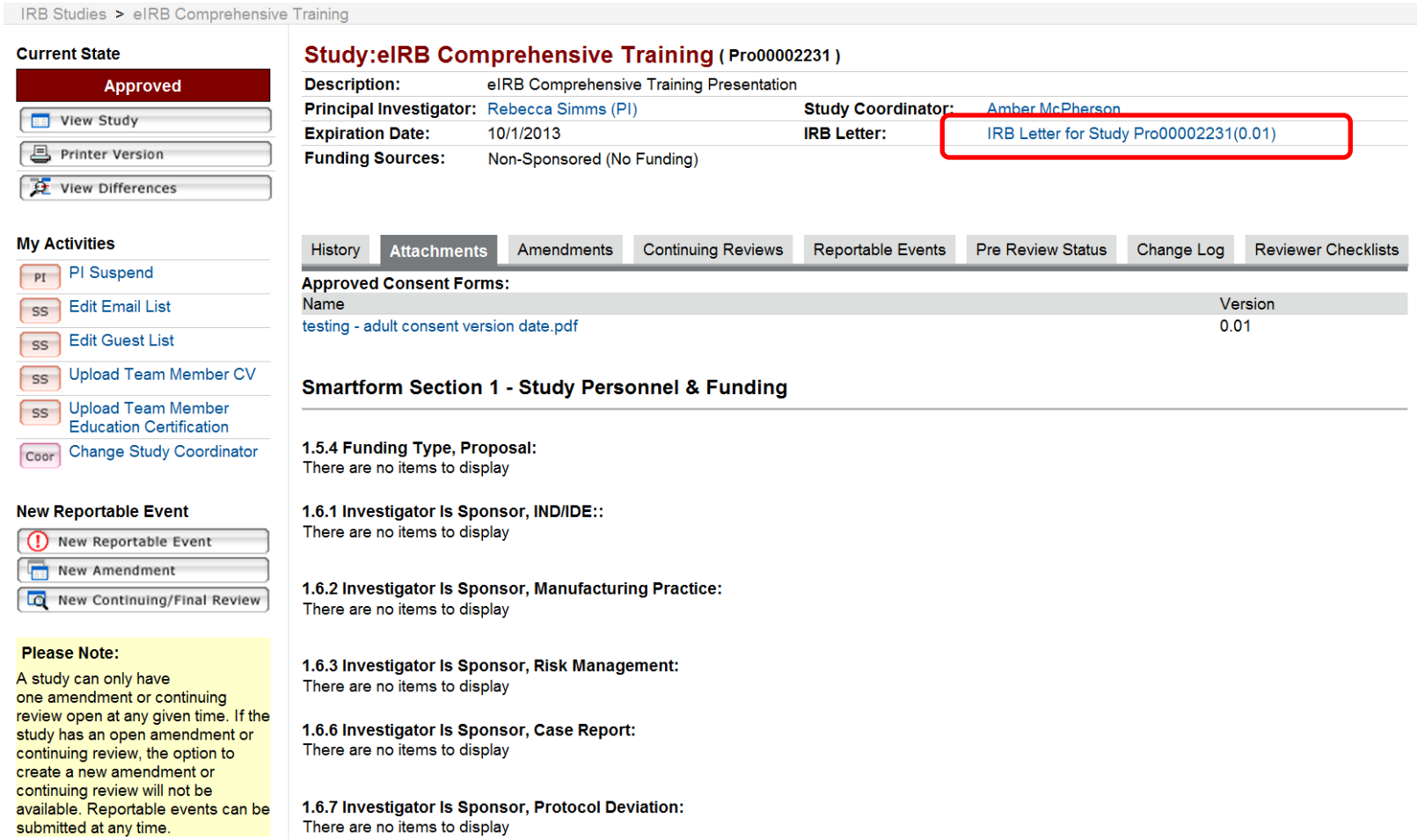
IRB Approval, Now What?

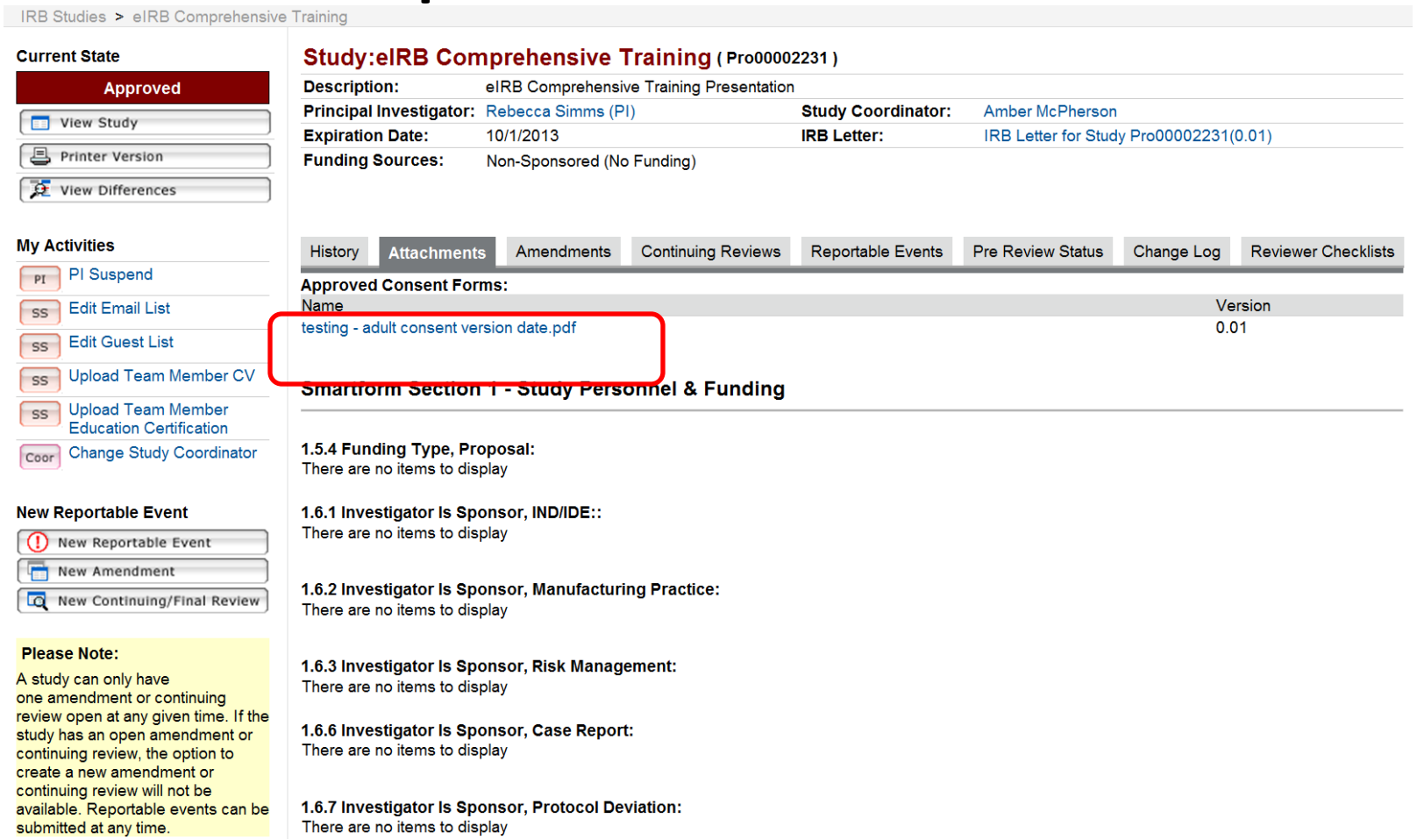
4/16/2014,
4/17/2014


CELEBRATE!

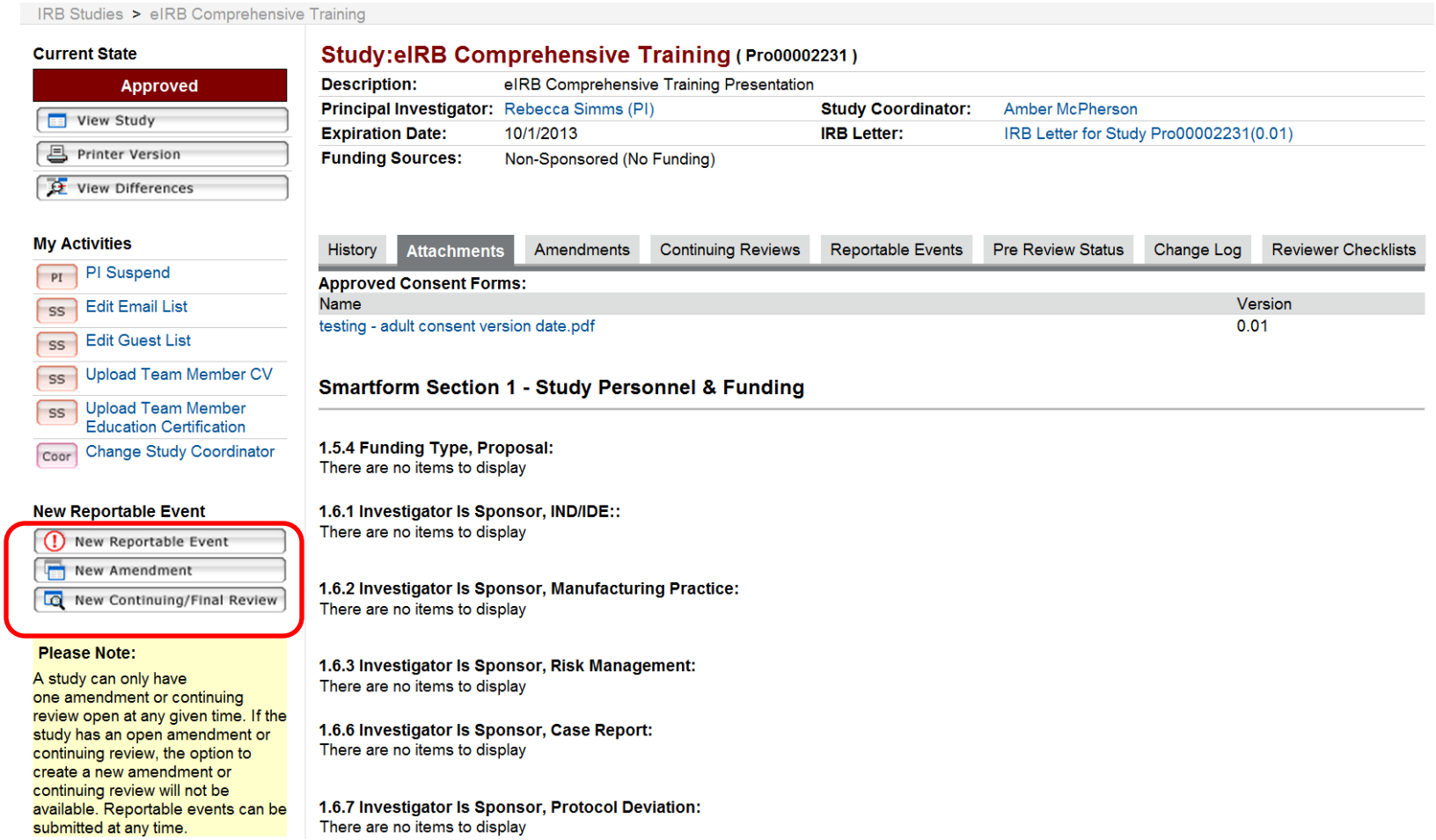
IRB Approval Letter



Stamped Consent Form



Additional Submissions



Amendments

- Don’t go changin’ without IRB approval

Amendments

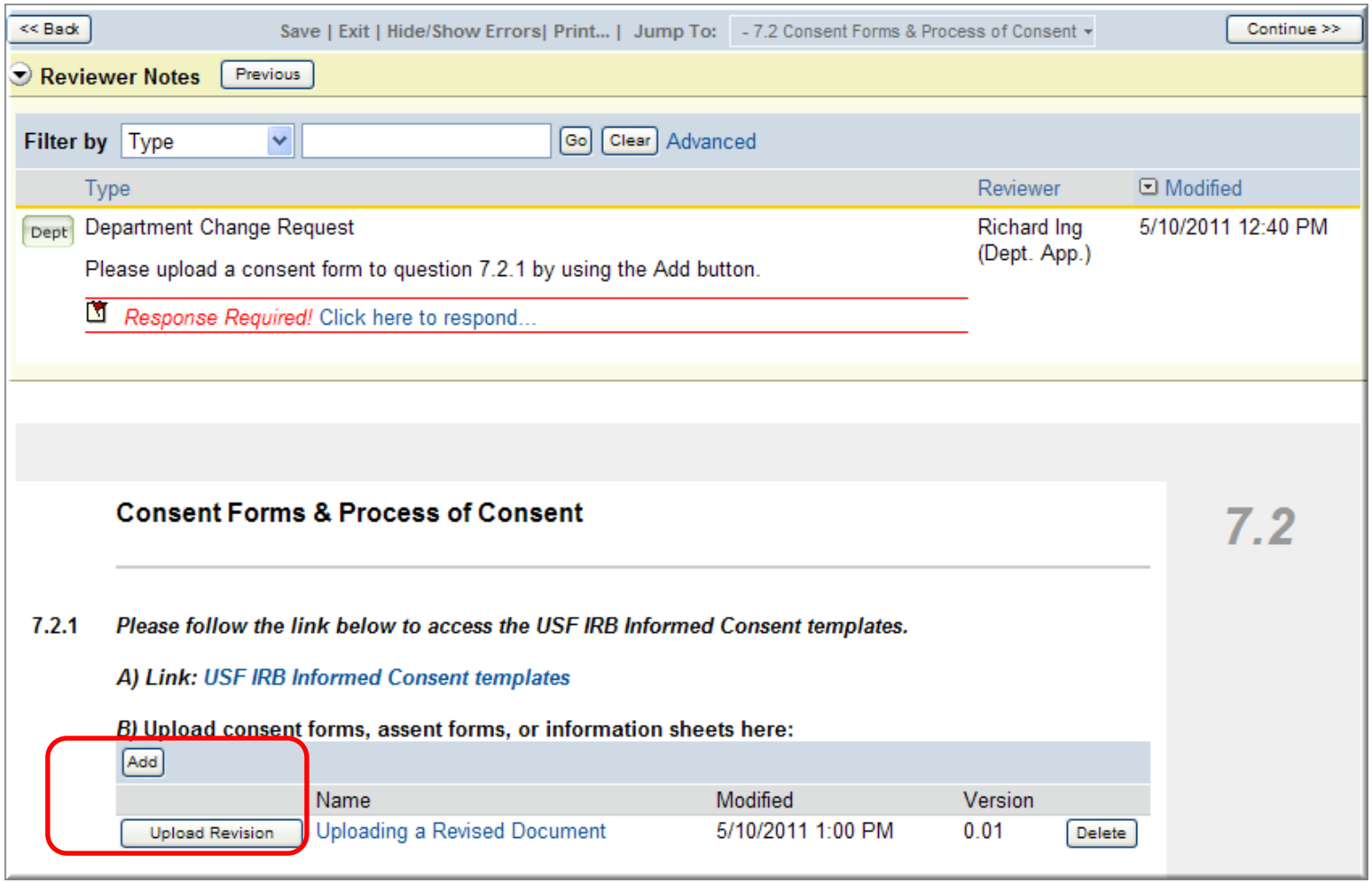
- Submit an amendment to the IRB prior to:
  - Add, remove or change PI, Co-I or Study Staff
  - Revisions to the Protocol: Risk, Methods
  - Revisions to the Consent Form
  - Revisions to Recruitment
  - Increase Enrollment Goal (don't over-enroll)

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
Dept
Department Change Request
Richard Ing (Dept. App.)
5/10/2011 12:40 PM
Please upload a consent form to question 7.2.1 by using the Add button.
Response Required! Click here to respond...
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:
Add
Name
Modified
Version
Upload Revision
Uploading a Revised Document
5/10/2011 1:00 PM
0.01
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

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

<u>Submit with Continuing Review, not RE:</u>

- 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

<u>Submit to the IRB immediately:</u>

- 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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