eIRB/Technical Tutorial

March 14, 2016

University of Massachusetts Medical School

Objectives

- Promote proficiency in navigating eIRB, and uploading and organizing new study documents.

- How to maximize eIRB functioning
  - Naming conventions for documents and submissions
  - File management
  - Document organization
  - Job Aids

- Q & A

Version Control/Naming Conventions

- **File management in eIRB is very important**
- Version Control:
  - File Name
  - Version/Date in the document (e.g. in the header)
  - eIRB Document Title *(Recommendation: Use the File Name)*
- Naming Conventions:
  - File Name & eIRB Document Title:
    - Study Title/Docket Number, Document Type, Version, Date Created/Modified
  - Examples:
    - Cat Scratch Fever_ISP_v.1_ 20160114
    - H0008006_HIPAAauthorization_v.2_20160114

H00008019_1: TEST

Principal Investigator   PI Test
IRB Owner
Study Expiration Date   9/16/2016
Submission Type   Modification
Submission Review Date

| Documents | Clarifications Requested | Full History | Summary History |

Updated	Document Category	Original Submitted File	Date Modified	Stamped Version	Date Modified
*	Investigator Study Plan	TEST_REV_ISP_9.2.2015.docx - 0.05 | History	1/8/2016 1:48 PM	TEST_REV_ISP_9.2.2015.docx - 0.01| History	9/17/2015 4:05 PM
*	Advertisements	Study Ad - 0.02 | History	1/8/2016 1:49 PM	- |	
*	Consent Document(s)	ICF_revised - 0.04 | History	1/8/2016 1:48 PM	TEST_ICF_8.28.2015..pdf - 0.01| History	9/17/2015 4:05 PM
	HIPAA	TEST_HIPAA_9.2.2015.docx - 0.02 | History	9/17/2015 4:02 PM	TEST_HIPAA_9.2.2015..pdf - 0.01| History	9/17/2015 4:05 PM

H00008019_1: Enrollment Increase, Additional Blood Draw, New Ad

Principal Investigator   PI Test
IRB Owner
Study Expiration Date   9/16/2016
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Submission Review Date

| Documents | Clarifications Requested | Full History | Summary History |

Updated	Document Category	Original Submitted File	Date Modified	Stamped Version	Date Modified
*	Investigator Study Plan	TEST_ISP_v.2_12.15.2015.docx - 0.04 | History	1/8/2016 1:38 PM	TEST_REV_ISP_9.2.2015.docx - 0.01| History	9/17/2015 4:05 PM
*	Advertisements	TEST_Flyer_v.1_12.30.2015 - 0.01 | History	1/8/2016 1:41 PM	- |	
*	Consent Document(s)	TEST_ICF_v.2_12.15.2015.docx - 0.03 | History	1/8/2016 1:38 PM	TEST_ICF_8.28.2015..pdf - 0.01| History	9/17/2015 4:05 PM
	HIPAA	TEST_HIPAA_9.2.2015.docx - 0.02 | History	9/17/2015 4:02 PM	TEST_HIPAA_9.2.2015..pdf - 0.01| History	9/17/2015 4:05 PM

"Do Not Use" vs. "No Longer in Use" – Best Practices

- "Do Not Use"
  - Study documents uploaded to section 7.0 Attachments in error
  - Study documents that have **<u>not</u>** been reviewed and approved by the IRB
  - May be "recycled"
- "No Longer in Use"
  - Study documents that are no longer in use
  - Study documents that <u>have</u> been reviewed and approved by the IRB
  - <u>Recommendation:</u> Retain the original eIRB document title and **ADD** "No Longer in Use" (e.g. "No Longer in Use – H0000845_Summary of Changes Protocol v.3_20160114).
    - Helpful for audit trails/study monitoring

Document History

H00008006: Test Study

Principal Investigator	PI Test
IRB Owner	Sarah Saliba
Submitted Date	8/13/2015
Approval Date	12/18/2015
Expiration Date	12/17/2016
Letter	Approved Letter_H00008006..pdf(0.01)

Documents	Project Personnel	Follow-On Submissions	Clarifications Requested	RNI	Full History	Summary History	Respond to IRB Decision

Category	Original File Type		Date Modified	Stamped Version		Date Modified
Investigator Study Plan	TestStudy_ISP_20150801.docx - 0.03	History	12/18/2015 10:09 AM	TestStudy_ISP_20150801.docx - 0.02	History	12/18/2015 10:10 AM
Advertisements	TestStudy_StudyFlyer_20150801.docx - 0.03	History	12/18/2015 10:10 AM	TestStudy_StudyFlyer_20150801..pdf - 0.02	History	12/18/2015 10:10 AM
Consent Document(s)	TestStudy_ICF_20150801.docx - 0.03	History	12/18/2015 10:09 AM	TestStudy_ICF_20150801..pdf - 0.02	History	12/18/2015 10:10 AM
HIPAA	TestStudy_HIPAAauth_20150801.docx - 0.03	History	12/18/2015 10:10 AM	TestStudy_HIPAAauth_20150801..pdf - 0.02	History	12/18/2015 10:10 AM

Document History (continued)

Document History (continued)

- Replacing documents in eIRB is like stacking pancakes...

Most Current Version

Version 0.03

Version 0.02

Version 0.01
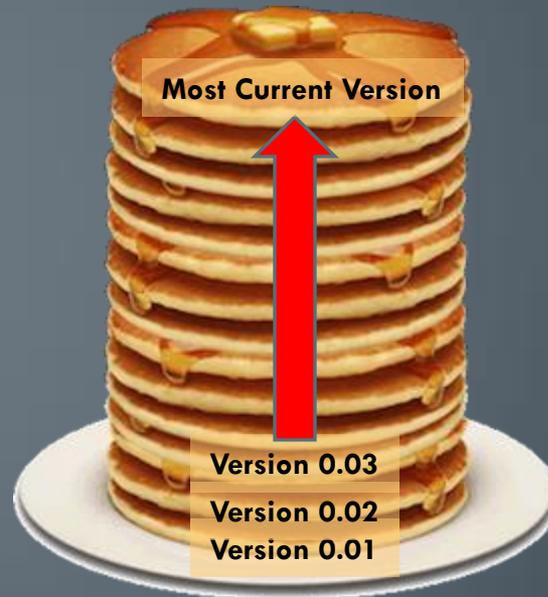
How to Find "Add Documentation"

- What is the "Add Documentation" feature used for?
  - Non-UMass Personnel List (HRP-215)
  - IRB Authorization Agreements (IAA)
  - IRB Checklists
  - Correspondence (e.g. email correspondence between IRB and Study Team)

- How can I access it?
  - "Full History" tab

There's a Job Aid for that…

- eIRB Job Aids

    - Instructional, point-and-click documents

    - Outline the most common actions in eIRB

    - Some include short demo videos

    - Used by IRB staff to assist users frequently

Questions?