

E-COMS FUNDAMENTALS

AN INTRODUCTION TO THE ELECTRONIC COMS REGISTRATION

STUDY TYPES

What is a “Study Type”?

A Study Type is a defined business process. Study Types work together to streamline workflow, track data & keep users informed.

There are 2 Study Types in eCOMS: COMS and IACUC.

The COMS Study:

The COMS Study is an online form that a Principal Investigator fills out to document their research and request approval by the COMS Committee. There are mechanisms in place to track the review of a COMS Study throughout the review process. Principal Investigators can add designees who can fill out a draft of the COMS Project and submit to the Principal Investigator for review and submittal to COMS.



REVIEW CYCLE

The following represents the basic **Review Cycle** for each eCOMS submission.

Each review process involves key users with specific tasks to complete in order for a COMS Study submission to be approved.

This process is designed to mimic the review cycle you are currently used to.



USER ROLES

User Roles allow people to have access to studies when they require review. By default, everyone has Safety User assigned for basic access.

In addition to the Safety User Role, the following User Roles can be assigned:

1. Safety User
2. Principal Investigator
3. Biosafety Officer
4. COMS Staff
5. COMS Committee Member
6. COMS Committee Chair



SMARTFORM

The COMS SmartForm tracks submission details, including general information, address information, related research, hazard identification, DURC acknowledgement and more

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: - Hazard Identification Continue >>

Hazard Identification

1. The following questions determine the type of study for COMS review.

- * 1.1 Does this project involve the use of Human Research Participants? ☐ Yes ☒ No Clear
- * 1.2 Does this project involve the use of Animals? ☒ Yes ☐ No Clear
- * 1.3 Does this project involve the use of Tissues, Blood, or Body Fluids? ☐ Yes ☒ No Clear
- * 1.4 Does this project involve the use of Culture of Primary Cells or Cell Lines? ☒ Yes ☐ No Clear
- * 1.5 Does this project involve the use of Bacteria, Yeast, Fungi, or Parasites? ☐ Yes ☒ No Clear
- * 1.6 Does this project involve the use of Viruses or Prions? ☐ Yes ☒ No Clear
- * 1.7 Does this project involve the use of Select Agent Toxins? ☒ Yes ☐ No Clear
- * 1.8 Does this project involve the use of any Recombinant or Synthetic Nucleic Acids? ☐ Yes ☒ No Clear

ADDITIONAL TOOLS

PI's and their staff have a variety of tools in addition to the SmartForm to simplify the review process & provide information about the study.

Including:

1. Supporting Documents

Documents relevant to the study that may be uploaded by all users

2. Personnel

A log of the Study Staff involved in the PI's lab (including PI Designee)

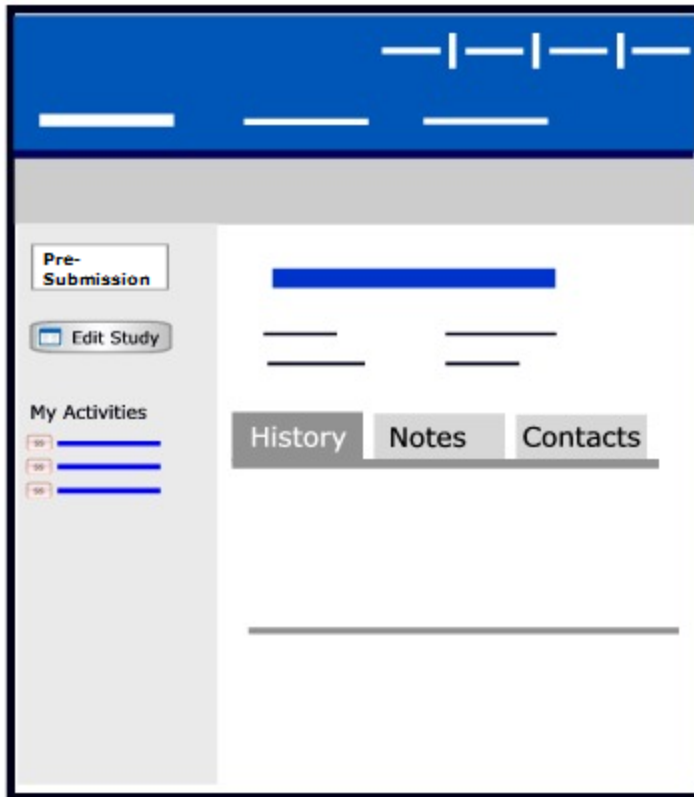
3. History Log

Tracks the review process in a step-by-step list of events

4. Amendments & Annual Renewals

Both are tracked and processed in the eCOMS system within the COMS Study

COMS STUDY WORKSPACE



The **COMS Workspace** is where the PI & Study Staff list information for reviewers to access. It is where the SmartForm lives and where a Activities can be executed.

SmartForm: Users can either see or edit the SmartForm depending on the State and that user's User Role.

State: Tells you where along in the review process a study is currently. (COMS Review)

Activities: Activities allow for State Transitions, and the addition of Study details.

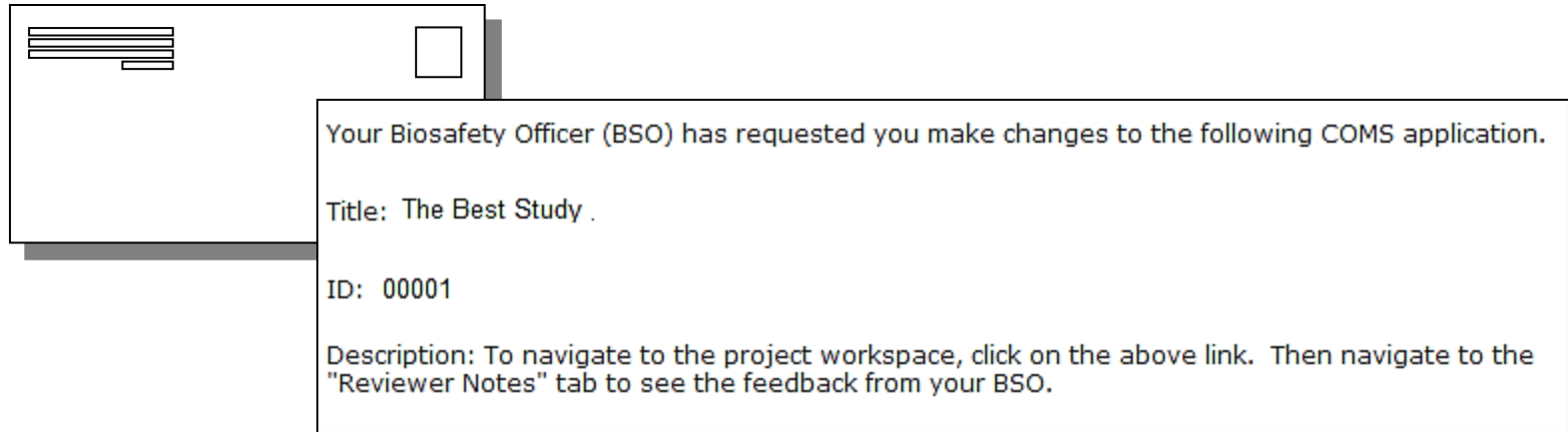
Examples: Submit Study, Request Changes, Withdraw

Tabs also allow for the organization of important information about that particular study, such as documents, personnel and the history log.

NOTIFICATIONS

In addition to seeing COMS studies in your Inbox, you will also receive an email **Notification** that will alert you when a study requires you to perform an activity.

Example: When performing their review of a study, one of the Activities available to a Biosafety Officer is to “Request BSO Changes.” This will automatically trigger an email notification sent to the PI and the PI Designee notifying them that the study requires changes or clarifications.



MY INBOX PAGE

When you log into eCOMS, you will be presented with your **My Inbox Page**. This will serve as a Home Page for eCOMS Users when they log into the system. From here, you can access a Safety Study by clicking on it's Name. This will take you to it's Study Workspace.

Tip: The [My Inbox](#) link at the top of every page will get you here!

Inbox My Reviews My COMS Upcoming Meetings				
My Inbox				
Filter by  ID Go Clear Advanced				
ID	Name	Date Created	☒ Date Modified	State
 14-043	Biofilms and Antibiotic Resistance in Chronic Sinusitis	4/28/2014 9:28 AM	4/30/2014 4:48 PM	COMS Review
 14-046	Intro of Therapeutic Proteins in Rats	4/28/2014 10:52 AM	4/30/2014 11:04 AM	COMS Review
◀ 1 to 2 of 2 ▶				10 / page

The **Inbox** tab will always contain studies that require your attention. This means that the State of the submission requires that you complete an Activity in order for it to advance through the review process.

COMS TAB

The COMS Tab is available in all Safety User's Inbox. Here you can find COMS studies divided into different categories depending on where they are in the review process.

These studies are organized in tabs: **In-Progress**, **Approved**, **Amendments**, **Archived**, **All Biosafety**

IACUC

COMS

COMS

Subscribe

Help

Create...

New COMS Study

Welcome to the Harvard University Committee on Microbiological Safety electronic submission system (eCOMS). This page will allow you to navigate to any COMS registration according to its submission status.

In Progress

Approved

Amendments

Archived

All Biosafety

Filter by ?

ID

Go

Clear

Advanced

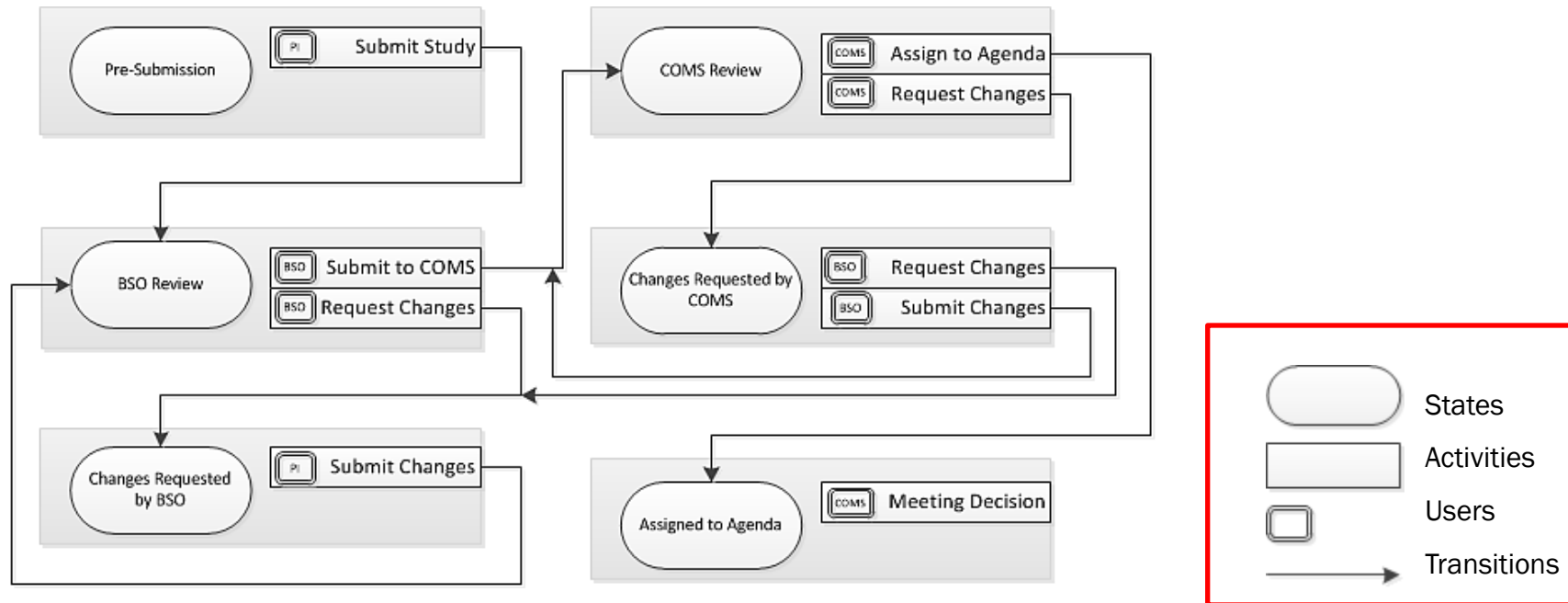
ID	Name	Date Modified	State	PI
14-028	Rob's test for non-rDNA STANDARD REVIEW	5/1/2014 11:40 AM	COMS Review	Simms (pi)

Note:

- PI's and Study Staff access is limited to only include their own studies in the COMS tab.

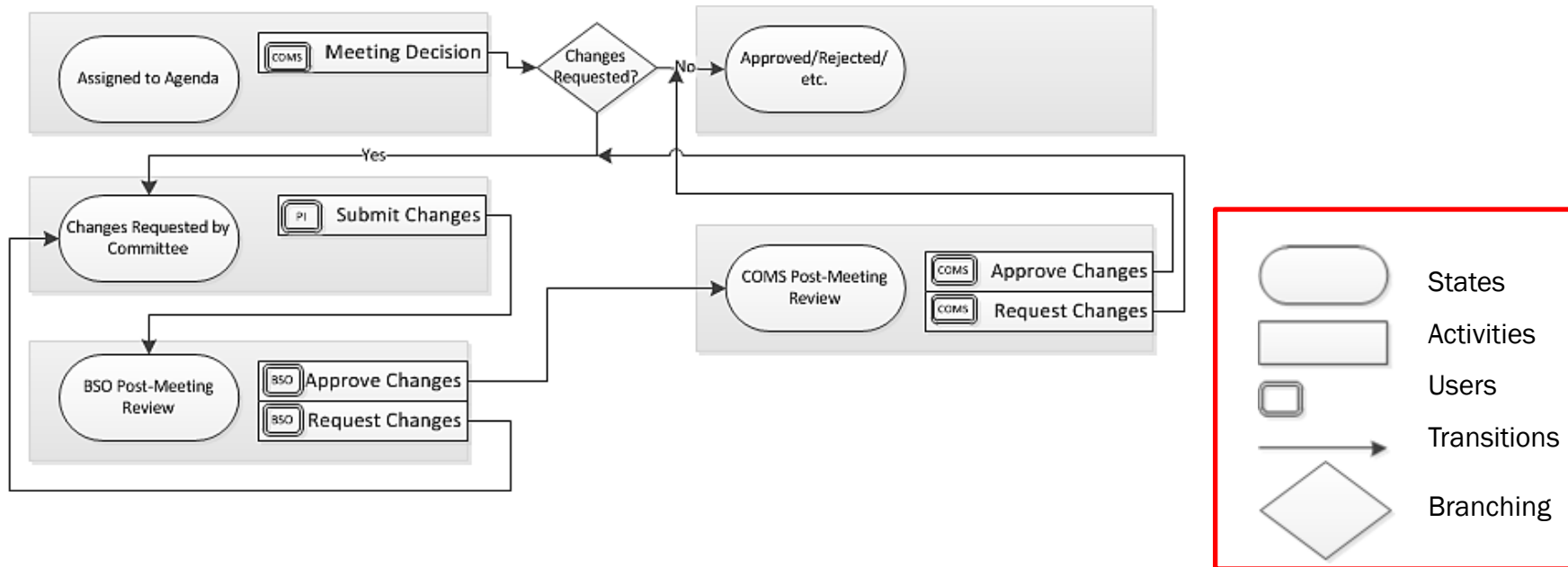
SYSTEM OVERVIEW: PRE-MEETING

The diagram below is a simplified representation of the **States**, **Activities** and **Users** involved in the eCOMS Safety Project review process.



SYSTEM OVERVIEW: POST-MEETING

The diagram below is a simplified representation of the **States**, **Activities** and **Users** involved in the eCOMS Safety Project review process.



FOR MORE INFORMATION

More information related to your specific User Role or Review Process can be found in the following documentation and user guides.

eCOMS User Guides:

<http://hms.harvard.edu/departments/committee-microbiological-safety>

For any additional questions please contact:

COMS Office: COMS@hms.harvard.edu *or*

eCOMS support: esupport@hms.harvard.edu