

Committee-PI Interactions



HOW DO I FOLLOW THE FLOW OF INFORMATION BETWEEN THE COMMITTEE AND THE PI?

<u>Packages</u> and <u>Board Documents</u> are the keys to understanding the flow of information between the committee and PI!

To demonstrate this, please follow the example below:

PACKAGES = PI Action

BOARD DOCUMENTS = Committee Action

- 1. PI submits a new project: [333333-1] New Study.
- 2. It is reviewed via a convened committee, and the action taken is Modifications required (Approval pending).
- 3. A Board Document describing the necessary changes or edits is published.
- 4. In response to the Board Document, the PI submits a new package [333333-2] to address issues and make response.
- 5. It is reviewed via designated member review, and the action taken is Modifications required (Approval pending).
- 6. A Board Document describing the necessary changes or edits is published.
- In response to the Board Document, the PI submits another new package [333333-3] to address issues and make response.
- 8. It is reviewed via designated member review, and the action taken is Approval.
- A Board Document is published (Approval letter).

To follow this interaction simply select Reviews from the left-hand navigation bar when viewing a package.

Reviews [283803-6] "A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate University of South Alabama Institutional Review Board (IRB), Mobile, AL Reviews: Project Ref# Agenda Review Type Туре 02/23/2012 Adverse Event (non-UP) 09-100 Unassigned Pending Review 02/23/2012 09-100 03/20/2012 **Full Committee** Pending Review 09-100 02/14/2012 02/20/2012 05/11/2012 02/03/2012 11/18/2011 11/30/2011 05/11/2012 07:00 AM 11/17/2011 ent/Modification 09-100 12/13/2011 Full Committee 12/13/2011 05/11/2012 11/08/2011 Adverse Event (non-UP) 09-100 Unassigned Expedited Review 11/18/2011 05/11/2012 11/15/2011 05/11/2012 Approved 07:00 AM Board Documents: Pkg Document Type Last Modified 09-100 stamped IB 02/20/2012 04:04 PM 12/05/2011 02:24 PM Acknowledgment Letter 12/05/2011 03:55 PM Completed Adverse Event Form 12/16/2011 01:22 PM 12/16/2011 01:36 PM 09-100 stamped consent dated October 4, 2011 2 Acknowledgment Letter 11/18/2011 12:35 PM

12/05/2011 11:02 AM

12/05/2011 10:55 AM

Please reference the guides on the webpage below and your respective committee's webpage for assistance. For additional assistance, please contact the appropriate personnel below:

Decision Letter

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Office of Research Compliance and Assurance

AE dated July 5 complete

Completed Adverse Event Form

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