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How to Proceed After Approval and
- 
How to Resubmit an Application

IRB Reviews Submission and Renders Decision To PI

Once you have submitted your application to the Office of Research Compliance, the IRB will review your submission and render one of the following decisions:



1) Approved - If the IRB approves your submission then you can begin your research. The application will appear in your Form List under “Approved Forms” with the approved PDF packet. You will also receive an email containing the approval memo and approved application submission packet in pdf format with official stamp and watermark. The approval period of the application will be noted in your approval memo. The approval period is valid for 1 year and then either a continuation /modification or final report must be submitted. Email reminders 30, 60, and 90 days will be sent to notify you of the approaching expiration dates. Through out the life of an application it can also go through other states. (See below “Other states of an application” for additional information.

Approved Forms				
Click on the form title to view the final approved version.				
Title	Status	Packet	Approved Date	Expiration Date
(25-ST) classroom - stipulation app	Stipulation	View PDF Packet	2012-10-22	2013-10-22
(32-A) 32 adverse event (44)	Approved	View PDF Packet	2012-10-22	2013-10-22
(51-CP) app 51 - classroom project	Completed	View PDF Packet	2012-10-12	2013-10-12
(52-C) app 52 - orig app for future cont/mod	Continued	View PDF Packet	2012-10-12	2013-10-12
(53-A) app 53 - continuation/mod for app 52	Approved	View PDF Packet	2012-10-12	2013-10-12
(54-FR) 54 - Project (Final Rpt for 51)	Finalreport	View PDF Packet	2012-10-12	2013-10-12
(58-A) 7548: legacy form2	Approved	View PDF Packet	2011-12-30	2012-12-29



2) Returned – The IRB will return your submission with comments requesting changes or additional information or if items are missing. You will need to follow this guidance given by the IRB by editing the form, finalize the form to your approval team, and reinitiate the form process.

Returned Forms			
Click on the form title to view comments - Click Amend to begin amendment			
Title	Version	Last Edit	
(11-R) app 11	1.0	2012-10-22 16:23:21	Amend
(47-R) 35 project title	1.0	2012-10-12 08:12:16	Amend
(50-R) app 50 - project title - put in returned status	1.0	2012-10-12 08:38:14	Amend

You can click to view the application and comments in “Form Preview” mode or you can click the <Amend> link to open the application in edit mode to view the comments and make any necessary changes. Once you have addressed all IRB comments, you will need to finalize and start the review & approval process again. After your approval team has signed off you can resubmit your application to the compliance office.

**Application to Use Human Subjects in Research (Expedited or Exempt)
(47-R) 35 project title**

Version 1.0 last updated on 10/04/2012 [Get PDF Version](#)

Overall Submission Comments (1)

Approximate number of human subjects to be included in your ... IRB Member on 2012-10-23 14:12:34

1 General Information

(1) Your First Name	<input type="text" value="Michelle_PI"/>
(2) Your Last Name	<input type="text" value="Gavin"/>
(3) Your E-Mail	<input type="text" value="rmgavin_PI@yahoo.com"/>
(4) Your Department	<input type="text" value="Research Integrity & Ethics"/>
(5) *Project Title	<input type="text" value="35 project title"/>
(6) Submit Date	<input type="text" value="2012-10-12 08:18:23"/>
(7) Date Approved/Rejected	<input type="text" value="2012-10-23 14:14:17"/>
(8) Expiration Date	<input type="text" value=""/>
(9) Application Type	<input checked="" type="checkbox"/> Exempt <input type="checkbox"/> Expedited <input type="checkbox"/> Continuation <input type="checkbox"/> Modification <input type="checkbox"/> Final Report <input type="checkbox"/> Adverse Event <input type="checkbox"/> Classroom Project
(10) Type of Review Requested	<input type="radio"/> Full Board <input checked="" type="radio"/> Exempt <input type="radio"/> Expedited
(11) Category: More Information	<input type="text" value="1"/> <input type="text" value="2"/> <input type="text" value="3"/> <input type="text" value="4"/>
(12) Project Purpose	<input checked="" type="checkbox"/> Publication <input type="checkbox"/> Thesis <input type="checkbox"/> Dissertation <input type="checkbox"/> Class Assignment

[Comments \(1\)](#)

NOTE: there are overall submission comments that may include the CARE form comments as well as comments that are provided for a specific question or item.

The reviewer’s overall & CARE comments correspond to the PI’s section 17 “Assistance Submission Checklist”.

3) Rejected – Once the IRB rejects a submission it can never be resubmitted and no further action can be taken. This rarely happens but is possible. Rejected applications will appear in the Inactive Forms section of “Your Forms” Form List.

Inactive Forms		
These forms are inactive and may not be worked on or submitted.		
Title	Status	Last Edit
(33-X) 33 rejected app	Rejected	2012-10-22 16:06:54
(34-DM) 34 dismissed app	Dismissed	2012-10-22 16:10:43
(40-T) 40 terminated app	Terminated	2012-10-22 16:14:52
(41-WD) 41 - withdrawn app	Withdrawn	2012-10-15 16:42:05
(44-SU) 44 suspended app	Suspended	2012-10-15 16:38:56

Other States of an Application

Inactive Forms		
These forms are inactive and may not be worked on or submitted.		
Title	Status	Last Edit
(33-X) 33 rejected app	Rejected	2012-10-22 16:06:54
(34-DM) 34 dismissed app	Dismissed	2012-10-22 16:10:43
(40-T) 40 terminated app	Terminated	2012-10-22 16:14:52
(41-WD) 41 - withdrawn app	Withdrawn	2012-10-15 16:42:05
(44-SU) 44 suspended app	Suspended	2012-10-15 16:38:56

Through out the life of an application other states can occur which include the following situations:

- 1) An approved application (parent) will move from approved to continued, modified, continuedmod, and final report when a follow on (child) application such as continuation/modification or final report form are submitted and approved. The application will remain in the approved forms section of “Your Forms” Form List. A status of completed will be used when the final report has been approved and the research is complete.
- 2) If an Adverse Event Form is generated then the approved application’s status will be changed to suspended until investigation is complete and the adverse event is resolved. The application will be moved back to approved.
- 3) Other states available if needed are dismissed, withdrawn, and terminated. A status of terminated will be used if the IRB Committee and Office of Research Compliance determine the application can no longer remain actively approved. A status of withdrawn will be used when an application has been submitted to the Office of Research Compliance but the PI requests that the application be dismissed prior to final approval. The state dismissed will used similar to the withdrawn state except it is used after the final approval has occurred.
- 4) The Final Report will complete and close the application process. The application will be available for 3 years and then archived.