



IRB Staff – 118 Determination Steps Quick Bite

This document contains at-a-glance steps for noting a [46.118 determination](#) in ESTR.

1. Complete and submit Pre-Review via the normal process; request clarifications as needed
2. Assign Designated Reviewer
3. Continue with the non-committee review process; request clarifications as needed
4. When review is complete and a 118 determination can be made:
 - a. Click “Submit Designated Review”
 - b. Indicate a Not Human Research (Includes Not Research) determination
 - c. Complete the remaining items in the pop up
5. Prepare the Custom Letter (*the normal ‘finalize documents’ step may be skipped when a 118 determination is made*)
 - a. Click “Prepare Letter”
 - b. Select the Not Human Subjects Research Determination in the pop up
 - c. Click “Generate”
 - d. Download and save the draft letter
 - e. Edit the contents of the letter to indicate the correct (118) determination
 - f. Upload the revision to the Prepare Letter activity pop up
 - g. Click “ok”
6. If preferred and based on the nature of the submission, complete the Update Expiration Date activity. This step is based on preference, will set an end date on the determination, and will ensure continuing review reminders are sent in advance of the expiration date.
7. Click “Send Letter”

Submit Designated Review

1. * I do NOT have a conflicting interest:
2. * Determination:

Name	Related Worksheet
<input type="radio"/> Approved / Exemption Granted	HRP-314 - Worksheet - Criteria for Approval and Additional Considerations
<input type="radio"/> Modifications Required to Secure "Approved"	HRP-314 - Worksheet - Criteria for Approval and Additional Considerations
<input checked="" type="radio"/> Not Human Research (Includes Not Research)	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Modifications Required to Secure "Not Human Research"	HRP-310 - Worksheet - Human Research Determination
<input type="radio"/> Human Research, Not Engaged	HRP-311 - Worksheet - Engagement Determination
<input type="radio"/> Modifications Required to Secure "Human Research, Not Engaged"	HRP-311 - Worksheet - Engagement Determination
<input type="radio"/> Refer to Full-Committee Review	
3. Review level: (select one if "Approved" or "Modifications Required to Secure 'Approved'")

Name	Related	Leave blank
<input type="radio"/> Exempt	HRP-312 - Worksheet - Exemption Determination	
<input type="radio"/> Expedited	HRP-313 - Worksheet - Eligibility for Review Using the Expedited Procedure	
4. * Risk Level:
 - No greater than minimal risk
 - Greater than minimal risk
5. Approval interval in months: (specify an interval for "Approved" or "Modifications Required to Secure 'Approved'")
6. Data Security Level:
7. If modifications are required, enter them below:
8. Notes:
9. Supporting documents:

Add	name
<input type="button" value="Add"/>	<input type="text" value="Complete as appropriate, or leave blank"/>

 There are no items to display
10. * Are you ready to submit this review?
 - Yes
 - No
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