

**IRB Staff – Completing the Pre-Review Activity**

The Pre-Review Activities allow for recording of significant review features. This allows for indication of special determinations and review features in the system for reporting and display on determination letters.

- The [Submit Pre-Review] activity must be completed as part of the workflow. For modifications to study staff only, the activity is read-only.
- Pre-Review Activities are available to edit for initial completion [Submit Pre-Review] and then edit [Edit Pre-Review] from when the submission is sent to the IRB through Post-Review for all submissions except modifications for study staff only.
- Some sections of the Pre-Review Activity form will fill in from previous reviews. Visit the most recent review workspace or the most recent approval letter to identify the correct recently selected determinations.
- **All relevant items must be marked with every review (even if the submission represents only a minor change).**

ITEM ON PRE-REVIEW	COMPLETION NOTES: BASED ON SUBSTANTIVE REVIEW OF SUBMITTED MATERIALS
1: Regulatory Oversight	Mark all items that apply based on study funding or site
2: Special Populations and Waivers	<ul style="list-style-type: none"> • Mark all items that apply based on the indicated study population, or requested waivers or alterations • If marked, the related checklist may be attached on a review activity and with the first time review of the item becomes relevant <p><i>Special Note: FERPA may be previously marked and will display here. This will affect what appears in the determination letter. To manage this, either: 1. De-select FERPA here and mark it with #3 OR 2. Remove FERPA from the special determinations or waivers section on the letter.</i></p>
3: Additional Harvard Determinations	<ul style="list-style-type: none"> • Mark all items that apply based on elements of the study • Use related optional worksheets to reference relevant policies
4: Initial Risk Level Determination*	Items marked as “Greater than minimal risk” must be reviewed by the Full Committee
5: Type of Research*	Select appropriate items
6: Initial Data Security Level	<ul style="list-style-type: none"> • Select the appropriate determination as soon as enough information is available • See Data Security Level Job aids for details on this determination
7: Did the Investigator or Faculty Sponsor provide assurance with the initial submission?	Assurance must be provided with the initial submission. If “no” displays here, reference the main study workspace to determine if this is a migrated study or if assurance was provided via alternate means.
8: Is Department Review required at initial submission?	HLMA only: required if initial review meets Expedited criteria or must be reviewed by the full committee. Otherwise, may be null.
9: Missing Materials	Fill in, as needed and based on the IRB office-required process.
10: Suggested Contingencies	Fill in, as needed and based on the IRB office-required process.
11: Add Supporting Documents	Fill in, as needed and based on the IRB office-required process.
12: Are you ready to submit this pre-review*	<p>Only visible on [Submit Pre-Review]</p> <ul style="list-style-type: none"> • Mark Yes to transition to the state: pre-review complete • Mark No to save entries and complete the form later

*required item