

## **Notifications and Default Recipients**

By default, notifications from ESTR-IRB are sent to the Principal Investigator, Faculty Sponsor (if there is one), and Primary Contact when an action needs to be taken. These emails will always include the study title, PI name, and other identifying information, as well as information on next steps. To view or add notification recipients, please see related job aids:

- <u>View Current Notification Recipients</u>
- Add Notification Recipients

<b>Common Noti</b>	ifications
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Туре	Schedule	Suggested Next Steps*
Notice that Items are in Pre-Submission	Notices are sent when a submission has been created and not yet been sent to the IRB after 7, 14, 21, 40, and 90 days.	<ul> <li>Navigate to the study workspace from the email by clicking on the "Submission Link" text (see <u>example below</u>).</li> <li>In the submission workspace, click the option available (based on your role in the project): "Submit", or "Submit and Provide Assurance". Clicking one/all of these activities will allow IRB review to proceed.</li> </ul>
Reminder of Approaching Deadline for Continuing Review	Notices are sent 60, 30, and 5 days prior to study expiration (even if a continuing review request has been submitted)	<ul> <li>Navigate to the study workspace from the email by clicking on the "Submission Link" text (see <u>example below</u>).</li> <li>Check to see if a new Continuing Review has been created and submitted by clicking on the "Follow-On Submissions" tab in the study workspace.</li> <li>If a Continuing review needs to be created and submitted, click the silver button "Create Continuing Review" or "Create Study Closure"</li> </ul>
Notice and reminder of lapsed approval	Notices are sent on the day a study expires and if approval remains lapsed, 14 days later (even if a continuing review request has been submitted)	<ul> <li>Navigate to the study workspace from the email by clicking on the "Submission Link" text (see <u>example below</u>).</li> <li>Check to see if a new Continuing Review has been created and submitted by clicking on the "Follow-On Submissions" tab in the study workspace.</li> <li>If a Continuing review needs to be created and submitted, click the silver button "Create Continuing Review" or "Create Study Closure"</li> </ul>
Notice that Clarifications have been requested and reminder that a submission requires attention	Notices are sent when the reviewer has identified the need for additional information, and then 14, 21, 42, 84, and 140 days after the first notice of requested clarifications, required modifications or deferral.	<ul> <li>Navigate to the study workspace from the email by clicking on the "Submission Link" text (see <u>example below</u>).</li> <li>Complete the requested revisions within the SmartForm</li> <li>In the submission workspace, click "Submit", "Submit and Provide Assurance", or "Submit Changes". Clicking one/all of these activities will allow IRB review to proceed.</li> </ul>
Notice and Reminder that Department or Faculty Review are required	Notices are sent when the study goes into Faculty Sponsor or Department Review, and then 5, 10, 20 & 40 days after a study remains in this state.	<ul> <li>Navigate to the study workspace from the email by clicking on the "Submission Link" text (see <u>example below</u>).</li> <li>Review the SmartForm and attachments</li> <li>In the submission workspace, click "Issue Departmental Approval" or "Submit and Provide Assurance".</li> </ul>

\*Please see materials on the *ESTR support site* for more details regarding suggested next steps.



## Navigating via the Notification

HARVARD Human Research Protection Program					
Notification of Requested Clarifications					
То:	Kara Thrace				
Subject:	Clarifications requested for				
Submission Link:	Summertime rainbows	Navigate to the study workspace from the			
Study Title:	Summertime rainbows	email by clicking on the Submission Link text.			
Principal Investigator:	Kara Thrace				
Clarifications have been requested on this submission. To respond, you or a member of the study team should click on the link above to view the request, and:					
<ol> <li>Respond to the request within the system; and</li> <li>Click on "Submit Changes" (on the left side of the submission workspace marked with a red arrow).</li> </ol>					
If you have any questions or concerns about how to respond to a request for clarifications, please review the ESTR Study Submission Guide or contact your IRB/IRB Review Specialist.					
This is an automated notification email. Please do not reply to this email.					
University Area IRB http://cuhs.harvard.edu Longwood Medical Area IRB http://www.hsph.harvard.edu/ohra/					
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ESTR uses the preferred email address associated with a person's HUID. If anticipated notices are not being received; please <u>view the email address on file</u> with the directory and take <u>the needed steps to</u> <u>update this information</u> (following update, ESTR will reflect the email address change within approximately three days).