

## Details of the 7/27/2022 RAMS-IRB Patch

Type of Change	Change Made	Details of the Change	Reason for Change
Smartform	<b>Several minor revisions</b>	<ul style="list-style-type: none"> <li>• Hyperlinks for ancillary committees were corrected</li> <li>• Studies submitting to Advarra IRB will no longer see any branching special population pages</li> </ul>	These changes were capture necessary information, especially the questions that are used in the HRPP's Continuity of Operations plan.
Smartform and Researcher Experience	<b>New form and workflow for the submission of IND and IDE information to the FDA Regulatory Program into the RAMS-IRB system</b>	See <a href="#">this document</a> for full details.	The FDA regulatory program is phasing out their REDCap submission system. <b>This change is not being made for the HRPP or IRB. The IRB will not see or review the New IND/IDE page.</b>
Researcher Experience	<b>New comments box in the Submit Study activity</b>	Studies will now be able to write comments to communicate with the departmental approver and/or the HRPP when a new study is submitted.	This change will enable investigators to communicate timeline needs and other context to the IRB and others.
Researcher Experience	<b>“Approved by External IRB” button available in amendments</b>	The “Approved by External IRB” button is available to study teams in external IRB amendment submissions.	Study teams did not have access to this button.
Researcher Experience	<b>Behind-the-scenes changes in how person names are displayed</b>	Behind the scenes changes in how person names are displayed	These changes will help to fully implement the Call Me by My Name initiative
Notifications	<b>Revised notification language</b>	Revisions to the email subject line and language of the notification sent when a submission reverts to In Development.	These changes emphasize that the submission is reverting back to an In Development and is not completely withdrawn.
Workflow	<b>Reviewer notes can be logged in the Amendment Cover Sheet</b>	Reviewer note functionality was corrected	Reviewer notes were not able to be responded to, which prevented resubmission of the amendment.