

Details of the 9/28/2020 RAMS-IRB Patch

Type of Change	Change Made	Details of the Change	Reason for Change
Smartform	Multiple revisions throughout the smartform	<ul style="list-style-type: none"> ● Removal of several questions that are captured in other ways. ● Rephrasing multiple questions that have been problematic, updating help text ● Updating broken weblinks ● Adding error checks 	These changes address common problem areas of the submission form and are intended to help improve the quality of IRB submissions.
Smartform	Major redesign of the Privacy and Confidentiality questions	<p>Checkbox selections were added to assist investigators in describing the privacy and confidentiality protections their study will use.</p> <p>The current free text response is still visible and approved in as the "Other protection" response</p>	This change is intended to help improve the quality of IRB submissions. These 2 questions are ones that the IRB frequently has to request changes on and educate researchers about.
Smartform	Report form reorganization	The page branching in the report form was streamlined and questions were reorganized to have a better flow.	This change is intended to help improve the quality of report submissions and the IRB's efficiency in reviewing the report.
Smartform	The closure form now has a question about data sharing	A similar question to that on the Data Sharing page of the smartform was added to the closure form.	Many investigators indicate in their smartforms that they will submit plans for future data sharing in an amendment, but end up closing without amending. This will enable the IRB to acknowledge the investigators' plans at the time of closure.
Researcher Experience	Expired studies will show in the PI's inbox and My IRB Studies tabs	Expired studies currently display in the Archive tab of the investigators' inboxes. Now, they will show in all 3 inboxes.	This will enable the PI to more easily locate and address expired studies before submitting new ones.
Researcher Experience	Modified timing of continuing review reminders	Continuing Review reminders will be sent on the following schedule: Expedited: 60, 45, 28, and 14 days Full Board: 60, 50, 40, and 20 days	Adding another reminder closer to the expiration date may decrease the number of studies that expire each month.

Researcher Experience	Availability of the “Update Protocol Editor” button	The “Update Protocol Editor” activity will now be available when a study is in an Expired state	This will enable PI’s (and the IRB) to add protocol editors to studies to assist with submission of continuations and closures when all current editors or the PI have left VCU or are unavailable.
Researcher Experience	Addition of a satisfaction survey link in approval letters	A new survey link was added to the end of all approval letters for all types of submissions.	This is a quality improvement initiative to enable investigators to give immediate feedback about each review experience
Workflow	Sponsor-required reports will no longer auto-acknowledge	All reports will be submitted to and reviewed by the VCU IRB.	Audits have shown that a number of reports were submitted incorrectly and should not have auto-acknowledged.
Workflow	New “Review Paused” state Emailed notices will be sent to investigators when studies enter and leave this state.	HRPP staff now have the ability to pause the screening or review of internal and external IRB studies and amendments. This will “stop the clock” on the review timeline. This state will be used when the HRPP is only waiting for ancillary reviews to occur and when the IRB’s review is otherwise complete or on hold and cannot move forward until an outside person/group takes action (e.g. when VCU is waiting on another IRB to complete a reliance agreement)	This will allow the HRPP to generate more accurate metrics about the time spent with the IRB and with researchers.
Workflow	All the studies currently in currently in the "Reliance Accepted" state will be moved to the "External IRB Review" state	All the studies currently in currently in the "Reliance Accepted" state will be automatically changed to be in the "External IRB Review" state	The IRB workflow for external studies has evolved, so this change will enable older studies to submit amendments and reports as the more recently approved external studies do.
Workflow	Workflow to transition studies from internal to external IRB and vice versa	The amendment workflow is being built out to accommodate the transition from VCU IRB to an external IRB and vice versa, within an amendment instead of needing to submit another separate study.	This change will support IRB record retention. It will also make things easier for PIs when a study changes IRBs after its initial approval.