Details of the 3/16/2022 RAMS-IRB Patch

Type of Change	Change Made	Details of the Change	Reason for Change
Workflow	**Autowithdrawal workflow**	• Autowithdrawal from IRB review will occur at **30 calendar days instead of 60 days** • Submissions will **revert to an 'In Development' state** instead of going to a 'Withdrawn' state • When resubmitted, **the submission will begin the IRB review process from the beginning**, not where they left off when autowithdrawal happened. Initial studies will go through departmental review again.	If a submission is in a PI Action state for 30 calendar days without being resubmitted, it will be withdrawn from review and sent back to 'In Development'. The PI can continue working on the reviewer note requests and resubmit when ready. This change is being made for 3 reasons: 1) investigators can have as much time as they need to make changes once the study is back In Development; 2) to help shorten review timelines 3) to enable investigators and the IRB to continue working on a submission without losing any of the previous reviewer notes or review history.
Workflow	**New workflow for requesting and completing Post-Approval Monitoring Self Evaluations and Data Security Questionnaires**	• Investigators may receive requests from the HRPP's Post-Approval Monitoring and Quality Improvement team requesting completion of the PAMQuIP Self-Evaluation Tool • The HRPP will also be requesting Data Security Questionnaires from investigators on behalf of Information Security	This will facilitate a workflow for the PAMQuIP team to request and receive evaluations. Data security reviewers will also have a workflow to review completed data security questionnaires.
Workflow	**New reporting workflow for External IRB studies**	• The External IRB report smartform was revised to facilitate submission of reports about instances of general noncompliance • The HRPP will be able to write and send general noncompliance letters and require amendments to address issues brought up in reports	All instances of general noncompliance for external IRB studies are to be reported to the HRPP per WPP VIII-9, "*the VCU HRPP has a responsibility to ensure compliance with the reviewing IRB's determinations (VCU IRB or external IRB), the institution's FWA, and the terms of any reliance agreements (if applicable).*"

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Smartform	**Several revisions throughout the smartform**	• Questions from the 12/2021 patch that were not marked as required questions are now required. • External IRB studies will be asked to complete the Review Setup page of the smartform • A new question was added to the continuing review smartform asking for VCU sponsor-investigators (who hold and IND or IDE) to upload their FDA annual reports.	These changes were capture necessary information, especially the questions that are used in the HRPP's Continuity of Operations plan.
Smartform	**Reviewer note functionality**	• The reviewer note window will be expandable • Investigators who are also IRB members will be able to re-submit studies and the required question flags will clear if a reply is logged	These changes will help improve user experiences when working with reviewer notes.
Researcher Experience	**New 'Study Completed' button for exempt studies**	Exempt studies will be able to close from IRB oversight using a new 'Study Completed' button instead of submitting a closure form to the IRB.	This change is being made to make it easier for exempt studies to close IRB oversight when they are completed. If a study is mistakenly marked as complete, contact the HRPP for assistance.
Researcher Experience	**External IRB study email notifications**	A notification will be sent to the PI and protocol editors when departmental review is completed for an External IRB study and it routes to the HRPP	This notification was being sent for VCU studies but not for External IRB studies