Details of the 9/15/2022 RAMS-IRB Patch

Type of Change	Change Made	Details of the Change	Reason for Change
Smartform	**Several minor revisions**	• New required questions and revised wording to clarify meanings of questions • Expanded help text (see blue question mark buttons in RAMS-IRB) • Added "Tobacco Product" as an option under types of FDA regulated products on the Federal Regulations page • Added "IV contrast administration for research-related imaging" on the Project Details page. This selection will branch to the Drugs page. • Added "iMedConsent (Veterans Affairs studies)" as an electronic consent signature platform. • Added new question about the role of the funder in the research study.	These changes were implemented to capture necessary information and improve clarify of questions.
Workflow and Researcher Experience	**Removing the Appeals workflow from RAMS-IRB**	The Appeal Committee Decision activity has been removed from RAMS-IRB.	Based on OHRP guidance, VCU HRPP policies are being revised to remove the process to appeal IRB decisions.
Workflow and Researcher Experience	**Changing the timing of continuing review deadline reminders for full board studies**	Investigators for full board studies will now receive continuing review deadline notices sooner and more frequently at 75, 60, 45, and 30 days prior to expiration. The Continuing Review Due Date is now set for 60 days before expiration.	This change will give study teams more advanced notice about upcoming expirations and help avoid study expiration.
Researcher Experience	**Error check on the Study Completed activity for exempt studies**	Exempt studies using the Study Completed activity will receive an error message if they attempt to close the study if there are any open amendments, continuing reviews or closures, or reports.	This change will prevent a study from closing until all submissions have been approved or withdrawn.
Notifications	**Update to Not Human Subjects Research determination letter**	Language was added to the Not Human Subjects Research letter template informing investigators accessing VCUHS PHI they may still need to consult with ancillary committees (Informatics, PROC, HIPAA, etc.).	When a project is not human subjects research, other institutional and regulatory requirements may still apply.

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Researcher Experience	**Added link to external IRB website in the IRB Study Workspace**	For external IRB studies where WCG, Advarra, or NCI is the IRB of record, a link to the external IRB's website is now included in the main study workspace.	This quickly provides a link to the external IRB's website.