Details of the 6/17/2021 RAMS-IRB Patch

Type of Change	Change Made	Details of the Change	Reason for Change
Smartform	**Multiple revisions throughout the smartform**	• New questions about societal benefit, e-signature platforms for consent, and discovery of reportable diseases. • New questions on the External IRB Study Summary page • Adding a new Contingency Plan page as a placeholder page for IRB use only • Updating broken weblinks • Expanding help text for partial waivers of HIPAA authorization • Adding VCU Health Tappahannock Hospital as a site selection • New document types are available	These changes respond to the expanding use of e-signature platforms in the consent process, and capture of information on external IRB submissions. The IRB is also developing a business continuity plan and some smartform questions will capture information that can be used in an emergency situation to quickly tier studies and give instructions.
Smartform	**Revisions to the questions ancillary committees ask within the smartform**	• Adding a new smartform question for **VCU Health Protocol Review Oversight Committees** (PROCs) • The Community Engagement question is more focused to community engaged research. • The GDPR question has been expanded to cover **Research Data Privacy** across all foreign locations, not just the European Economic Area • The **Information Security** section has a new acknowledgement question regarding the requirement for studies with Category 1 data to have a Data Management Plan on file in the DMS system. • Two new questions have been added to the **VCUHS Department of Pathology** section • The **Institutional Biosafety Committee** question was revised to encompass the various types of biohazardous agents that need IBC review • The **Radiation Safety Committee** question was revised to clarify that all radiation given for research purposes requires RSC review	The IRB is facilitating communication for the various ancillary committees to help keep investigators aware of when review by other groups is necessary. These changes were made to reflect current practices in how ancillary committees operate Questions about these requirements should be directed to the ancillary committee (contact information is provided for each one in the smartform) **IMPORTANT NOTE:** Initial submissions of studies using VCUHS patients, data, or facilities that do not see a PROC listed yet for your topic area at https://onetrac.vcu.edu/ should provide the IRB with an uploaded Note to File explaining that a PROC is not operating yet for [insert name] topic area. Questions about PROCs should be directed to Mary Harmon at mary.harmon@vcuhealth.org

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Researcher Experience	**New reminder added to all approval letters about obtaining PHI from Informatics**	For data requests, including preparatory to research, investigators obtaining PHI from VCU Health are reminded to contact informatics@vcu.edu or go to https://informatics.vcu.edu to request the desired PHI. Informatics staff are also available for a consultation on alternate methods to obtain the data.	VCU Health System Authority and Affiliates Policy COMP-014 (effective 4/26/21) directs members of the study team (including principal investigators) to obtain PHI by consulting with VCU Informatics or using another method approved by the VCUHS Privacy Office to obtain the PHI from VCU Health records. This does not include obtaining data for which the study team has patient authorization. Questions about this policy should be directed to the Privacy office at 804-828-0500 or complianceservices@vcuhealth.org
Researcher Experience	**Revised "types" of reviewer notes**	Reviewer note types now consist of: 1. Required by Regulations 2. Required by VCU Policies 3. Required to correct missing, incomplete, or inconsistent information	This change is intended to communicate more clearly the reason why a change is being requested rather than the requestor's role.
Researcher Experience	**Updated email communications**	• Approval comments will pipe into external IRB amendment approval notifications • The name of the "Other IRB" and expiration dates will correctly pipe into notifications • Terms of Approval for reliance on External IRBs have been updated • Broken web links were fixed	These small changes will provide more detailed, study-specific communications from the IRB.
Department Approver Experience	**Added links to guidance and training for department approvers**	Resources and tools to assist the Department Reviewer can be found at https://research.vcu.edu/human-research/hrppirb/department-reviewer-resources/	Linking to guidance and training will support Department Approvers in performing their role, which will improve the quality of IRB submissions.
Department Approver Experience	**New function to enable the IRB to return studies to departmental review**	A new 'Return to Department Review" activity is available to IRB staff	Sometimes the wrong approver is selected or departmental review was not completed, so this change will enable studies to be sent back to the appropriate approver.

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Workflow	**Merged workflow for exempt and expedited submissions**	Exempt and expedited initial submissions will both follow the same workflow path instead of having separate pathways. See the diagram below of the review process.	This change provides more user-friendly state names for researchers and simplifies the overall workflow for initial submissions.
Workflow	**All external IRB studies will go through departmental review**	New external IRB studies will be routed to Departmental Review before reaching the HRPP	Department approvers should evaluate the feasibility and scientific merit of all research in their units and should be aware of all research that is happening.