Summary of Changes for VCU IRB Written Policy and Procedure revisions, effective 4-15-2021

WPPs available at: https://research.vcu.edu/human-research/hrppirb/hrpp-policies-and-guidance/

WPP #	Section	Change
WPP #: II-5 State Law Applicability for Research Conducted In and Outside of Virginia	2.5 State-Mandated Reporting	Added links to the state requirements for reporting of diseases
WPP #: IV-2 IRB Member Responsibilities and Conflicts of Interest	2.1 IRB Membership	Added clarification that IRB membership may be ended at any time by the member or by the HRPP.
WPP #: VII-4Reporting to Regulatory Agencies	2.1 Report Preparation	Clarified who is responsible for preparing and reviewing reports to federal agencies.
WPP #: X-1 Conditions of Approval	2.4. Conditions of Approval for the Conduct of Research Determined to be Exempt by an External Institution and 2.5. Conditions of Approval for the Conduct of Research Determined to be Expedited or Full Board by an External Institution	New sections added for the conditions of approval for reviewed by external institutions. These conditions were already being provided in notification and are being formally added to the WPP.
WPP #: XI-2 Informed Consent Documentation, Waiver of Documentation, and Required Signatures	2.1 Documentation of Informed Consent	Moved a paragraph about the two general ways of documenting informed consent to this section.
	2.2 Electronic Consent Signatures	Revised references to REDCap to reflect that the e-consent module (i.e. use of the e-consent project templates, NOT the e-signature element in survey settings) is now an accepted method for obtaining electronic consent signatures
	5.2 Electronic Consent Signatures	New section added (duplicate of section 2.2) to reflect that electronic signatures are permitted for studies reviewed under Pre-2018 Common Rule regulations
WPP #: XV-2 Assent and Parental/Legal Guardian Permission	3.2 Documentation of Assent	Added clarification that documentation of child assent may not be obtained using an electronic signature platform because of the complexities of verifying children's identities.
	3.7 Children Who Reach the Age of Majority	Added a reference to a video offered by the HRPP: Re-consenting in research involving children
WPP #: XVI-3 Emergency Use of a Drug, Device, or Biologic	1. Policy Statement	Added clarification that obtaining an independent assessment by an uninvolved physician is a subject protection procedure for emergency use of a device only. It is not applicable to emergency uses of a drug.

WPP #	Section	Change
WPP #: XVII-2 Subject Recruitment and Compensation	3. Procedures and Guidance	Added references to the HRPP's supplemental guidance documents for investigators and IRB reviewers about cold calling recruitment methods and the use of social media
WPP #: XVII-9 Use of the Internet for Research Data Collection	2.1 Active Data Collection	Revised references to electronic consent signatures to remove a direct reference to REDCap and instead direct readers to WPP XI-2
WPP #: XVII-11 Involving Foreign Institutions/Sites in VCU Human Subjects Research	1. Policy Statement	Added an explicit statement about how the VCU IRB neither relies upon foreign IRBs or Ethics Committees nor provides IRB review for engaged foreign sites.
	2.1 General Requirements	Added clarification that foreign site IRBs/Ethics Committees, principal investigators, or other community groups that provide ethics reviews may also fill the role of a cultural consultant.
WPP #: XVII-17 Additional Department of Education (DoED) and National Institute on Disability and Rehabilitation Research (NIDRR) Requirements for Human Subject Protection	WPP Title and 1. Policy Statement	Removed references to National Institute on Disability and Rehabilitation Research (NIDRR)
	2.2 Research Involving Disabled Subjects [34 CFR 350.4(c)(1)]	Section removed. On May 11, 2016, HHS published final regulations for National Institute on Disability and Rehabilitation Research's (NIDILRR's) three programs, superseding 34 CFR parts 350, 356, and 359, and combined them into a single part, now codified at 45 CFR part 1330. 45 CFR 1330 contains no IRB requirements.[83 FR 1556]