Summary of Changes for VCU IRB Written Policy and Procedure revisions, effective 9-28-2020

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

WPP #	Section	Change
All revised WPPs		Updated the WPP Effective date and Revision history, formatting and page layout revisions
WPP #: V-2 IRB Member and Staff Education and Training	Revised section 2.1 IRB Member Education	Added new requirement for IRB members to complete PRIM&R EROC training
WPP #: VII-2 Activities of the Full Board	Revised section 2.2 Meeting Scheduling	Clarified that the IRB Panel is generally scheduled to meet one to two times per week instead of only once.
	Revised section 2.5 Requirements for Quorum & section 2.8 Subcommittees	Revised terminology to better distinguish between the regularly convened IRB committee and the specially convened subcommittees that review particular types or categories of research when needed.
WPP #: VIII-1 Initial Review – Exempt **and** **WPP #: VIII-2 Initial Review - Expedited**	**Revised section 2.1 Qualification for Exempt Initial Review** **Revised section 2.2 Minimal Risk Determination**	New content: VCU applies SACHRP's recommendations that the IRB's evaluation of the harms and discomforts of the research should consider the nature of the study procedures, other study characteristics, subject characteristics, and steps taken to minimize risk. The IRB should carefully consider the characteristics of subjects to be enrolled in the research including an evaluation of subject susceptibility, vulnerability, resilience and experience in relation to the anticipated harms and discomforts of research involvement. (January 31, 2008 SACHRP letter to HHS Secretary) While the harms and discomforts ordinarily encountered differ widely among individuals and individual populations, an ethically meaningful notion of "harms and discomforts ordinarily encountered" should reflect "background risks" that are familiar and part of the routine experience of life for "the average person" in the "general population." It should not be based on those ordinarily encountered in the daily lives of the proposed subjects of the research or any specific population. For case examples, refer to SACHRP Appendix: Understanding Minimal Risk
WPP #: VIII-1 Initial Review – Exempt	**Revised description of exempt category 2**	New content for category 2: *VCU's Interpretation of the applicability of this category to Decisionally Impaired Adults:* The research participation of adults who would be unable to provide consent for themselves should generally be reviewed in an expedited manner. As explained in the Supplemental Information to the 2018 Common Rule, "The exemption of this type of activity rests in large part on the idea that all individuals, regardless of the setting or context in which the activity will take place, are generally familiar with common forms of educational tests and survey and interview procedures that they experience in their daily lives, and do not

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		need additional measures to protect themselves and their privacy from investigators who seek their involvement in research activities involving these procedures. They can decline to participate, or to answer some questions." (82 FR 7189). Decisionally impaired adults are less likely to understand the informational risks of research participation and be able to protect their own privacy. Expedited review enables the IRB to put additional measures in place to minimize risk and protect them and their privacy.
	Revised description of exempt category 3	Added clarification that sensors and wearable technology (e.g. Fitbit) do not collect audiovisual recordings and do not fit under this category.
	Revised description of exempt category 4(ii)	Added clarification that anonymous specimens may be used under this category.
WPP #: VIII-2 Initial Review - Expedited	**Revision to the Applicability paragraph of category 1**	New content for category 1: **Applicability:** IND exempt drugs, IDE exempt devices, and mobile medical apps under enforcement discretion may qualify. Devices that have been determined by the full board to be Non-Significant Risk (NSR) hold an abbreviated IDE application, making this category not applicable. Per personal communication from the FDA (rec'd 9/1/2020), "The IRB may not conduct an expedited review (either for an initial review or for the continuing review) of any clinical study that is subject to the IDE regulation, 21 CFR 812 (i.e., an SR or an NSR study)."
	Revision to description of category 2	New content for category 2: *VCU's Interpretation of Applicability to Indwelling Catheters:* At VCU, our interpretation is that collection of blood via an indwelling catheter (an existing catheter placed for clinical purposes or a catheter placed for research purposes) is not a "venipuncture" and should be reviewed by the full board.
	Revision to the Conditions paragraph of category 9	Added clarification that studies holding an IND or IDE (SR and NSR device studies) are excluded from this category.
	New references added	January 31, 2008 SACHRP letter to HHS Secretary: Recommendations related to waiver of informed consent and interpretation of "minimal risk" SACHRP Appendix: Understanding Minimal Risk
WPP VIII-3 Initial Review – Full Board	No changes	WPP was missing from the previous PDF file of all WPPs
WPP #: IV-4 Responsibilities of IRB Chairperson and Vice Chairpersons	Revised header in section 2	Revised heading for Responsibilities of the Panel Chairperson <u>after</u> each meeting
WPP #: X-1 Conditions of Approval	**Revised section 2.1 Conditions of Approval for Exempt Studies**	Added new condition that an amendment must be submitted for new sources of funding.

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WPP #: XI-2 Informed Consent Documentation, Waiver of Documentation, and Required Signatures	**New section 2.2 Electronic Consent Signatures**	New content: **2.2 Electronic Consent Signatures** When obtaining electronic signatures, the platform to be used must meet the applicable state requirements for the signature to be considered legally valid (e.g. Uniform Electronic Transactions Act; consult VCU Technology Services with questions). VCU offers DocuSign for obtaining electronic signatures, and a Part 11 DocuSign platform is available for FDA regulated studies. Other platforms (including REDCap) are not recommended as the security procedures to authenticate the signer's identity and attribute the signature to the individual are unconfirmed at this time. It is important to plan both how the consent discussion will occur (via telephone, Zoom, etc.) as well as how signatures can be obtained. If it is possible to have a consent discussion with the participant, then one should be held. There are different options for how to remotely obtain consent signatures, depending upon the study's risk level and whether the study is FDA regulated or not. FDA-regulated studies must follow 21 CFR 11 requirements for electronic records. • Minimal risk studies can request a waiver of documentation of consent (the consent signature) • DocuSign is available to all non-FDA regulated studies (no waivers needed). • DocuSign Part 11 is available to FDA regulated studies (no waivers needed). • COVID MyStudies App for FDA regulated COVID-19 studies only • Studies proposing to use REDCap's e-signature feature must have an approved waiver of documentation of consent in place. See the following resources to learn more: Q10 of this FDA Guidance on Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency VCU's Guidance on Informed Consent
WPP #: XII-2 Certificates of Confidentiality	**Revised section 2.3 Applying for a Certificate of Confidentiality**	Updated the process for applying for a CoC – for NIH CoC applications, the name and address of the Authorized Institutional Official for NIH applications can be found on the IRB's Forms webpage. If non-NIH CoC applications require an assurance letter, it is still available on the IRB's Forms webpage.

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WPP #: XII-3 Health Insurance Portability and Accountability Act (HIPAA) Information and the Conduct of Research	**Revised section 3 Definitions**	New header to create a definition of "Individual Identifiable" from current content New definitions for "Protected Health Information" and "Research Health Information" **Protected Health Information (PHI):** Individually identifiable health information held or transmitted by a covered entity or its business associate, in any form or media, whether electronic, paper, or oral. Health information by itself without any of the 18 identifiers is not considered to be PHI. The Privacy Rule excludes from protected health information: employment records that a covered entity maintains in its capacity as an employer and education and certain other records subject to, or defined in, the Family Educational Rights and Privacy Act (FERPA). ***Effective 9/28/2020 for all new research and all ongoing research with active participant interactions:*** **Research Health Information (RHI):** Individually identifiable health-related information that is <u>not</u> associated with or derived from a healthcare service event (e.g. treatment, payment, operations, medical records, etc.) and that is <u>not</u> entered into the medical records. Identifiable health information is considered RHI when it is self-reported or generated through research procedures and is kept only in the researcher's records or when secondary data is obtained from a source other than a covered entity. *Examples of research using only RHI and thus NOT subject to HIPAA include: use of identifiable research health information from another research study; diagnostic tests from which results are not entered into the medical record and are not disclosed to the subject; and identifiable health information reported in a research survey or interview. Some basic genetic research can be RHI, such as the search for potential genetic markers, promoter control elements, and other exploratory genetic research. In contrast, genetic testing for a known disease, as part of diagnosis, treatment, and health care, would be considered a use of PHI and therefore subject to HIPAA regulations*
	Revised section 4.1 How Does HIPAA Affect Research at VCU?	Paragraph 2 about creation of new PHI clarified to note that research-related, individually identifiable health information (RHI) that is not associated or derived from the provision of care or payment for care is not PHI (e.g., a health history questionnaire).
	Revised section 4.2.2 Waiver of Authorization	Deleted an inaccurate sentence that a waiver of authorization is generally approvable if a waiver of informed consent is approvable.

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WPP #: XVI-1 Review of Medical Devices	**Revised section 3.2 Abbreviated IDE Requirements (Non-Significant Risk Devices)**	Removed sentence about VCU's previous interpretation that NSR devices qualified for Expedited review under category 1(b)
	Revised section 3.3 Investigational Device Exemption (IDE) Requirements (Significant Risk Devices)	Added clarification that investigators who need an IDE for an SR device and submit to the IRB before submitting to the FDA will be asked to withdraw their IRB submission and resubmit after the IDE has been obtained.
WPP #: XVI-6 Review of Drugs and Articles Used as Drugs	**Revised section 3.1 Studies that Hold INDs**	Added clarification that investigators who need an IND and submit to the IRB before submitting to the FDA will be asked to withdraw their IRB submission and resubmit after the IND has been obtained.
	New section 3.4 In Vitro Drug Testing IND Exemption	New content: A drug intended solely for tests in vitro is exempt from the requirements of 21 CFR 312 if shipped in accordance with §312.160.
WPP #: XIII-1 Pregnant Women, Human Fetuses, and Neonates (Special Protections)	Revised section 2.5.2 Neonates of Certain Viability	Added clarification that when neonates are research participants, parental or guardian permission for the neonate must be sought after birth because upon delivery the fetus becomes a neonate/newborn and meets the definition of a 'child.'
WPP #: XIV-1 Prisoners as Research Participants (Special Protections)	Revised section 2.6 Types of Review by the VCU IRB and Special Considerations	Added clarification to the first bullet under Expedited Review that this situation refers to justifications for the continuation of research where an enrolled participant has become incarcerated
WPP #: XV-2 Assent and Parental/Legal Guardian Permission	**Revised section 3 Procedures and Guidance**	Added that a process for assent should be described for children who turn age 7 and become capable of assenting.
	Revised section 3.4 Parental/Legal Guardian Permission Process	Added that when neonates are research participants, parental or guardian permission for the neonate must be sought after birth because upon delivery, a fetus becomes a neonate/newborn and meets the definition of a 'child.'
WPP #: XVII-7 Evaluating Consent/Persons with Limited Decision-Making Capacity	Revised section 1 Policy Statement	Added sentence that to respect autonomy, assent should be obtained whenever possible to emphasize that assent is an expectation, not optional.
WPP #: XVII-12 Additional Department of Defense (DoD)-Department of the Navy (DoN) Requirements for Human Subject Protection	Revised section 3.5 Consent Requirements, Waivers and Exceptions from Informed Consent	Revised an incomplete sentence.
	Revised section 3.6 Inclusion of Decisionally Impaired Subjects	Added clarification that this section applies when research involves individuals that meet the definition of "experimental subject" and not to all participants of DoD/DoN research.

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WPP #: XVII-16 Planned Emergency Research, Exception from Informed Consent, and Waiver of Applicability of Informed Consent	**Revised section 1 Policy Statement**	New policy and procedure information for single IRB EFIC studies: When federally funded research involving exception from informed consent requires review by a single IRB, investigators are instructed to contact IRB Reliance (irbreliance@vcu.edu) prior to beginning the IRB submission. Requests for deferral to another IRB will be considered by the IRB Director on a case-by-case basis. If the decision is made to allow deferral, the VCU IRB (i.e. the full board committee) will conduct an institutional review of the community consultation and pre-study-initiation public disclosure plans and materials. This institutional review will focus on local context and will assess whether the community consultation plans adequately provide for reaching the community from which subjects will be drawn. Changes may be required to those consultation and disclosure plans or materials during institutional review, and the external IRB will be informed of what changes were requested and the rationale for those changes. If permitted by the reviewing IRB, a non-affiliated member of the VCU IRB may attend reviewing IRB Panel meetings in order to provide additional local context and consultation.