



VCU Human Research Protection Program

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<https://research.vcu.edu/human-research/>

## Research Participant Notice Changes in Definitions of Research Information

The VCU Human Research Protection Program (a program that oversees the ethical conduct of human research at VCU and VCU Health) would like to notify you of new information about how the information you provided to a research study is being protected.

When you agreed to be in a research study, the consent form you signed included a section about how your health information was considered to be “Protected Health Information” (PHI) that was protected under a regulation called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The consent form explained how PHI would be used and shared during the study (to learn more about HIPAA, visit <https://www.hhs.gov/hipaa>).

Effective 9/28/2020, the health information you provided to a research study is no longer protected by HIPAA regulations. This means your rights under HIPAA no longer apply.

VCU and VCU Health have narrowed the scope of what research data is considered to be “Protected Health Information” (PHI). Information is PHI if it is used for the provision of healthcare, healthcare operations or payment for healthcare services. The information you provided to researchers is solely used in a research study; therefore, it does not meet the new definition of PHI.

Instead, the health information you provided will now be considered “Research Health Information” (RHI) by VCU and VCU Health. RHI is still kept confidential and protected, and depending on the type of study, it may be regulated under various laws, regulations or contracts that offer other confidentiality protections.

All human research data at VCU and VCU Health is protected with the utmost diligence. The information you provided is still secure and is being protected in the same location and manner as it was before.

**Please contact the Principal Investigator or researcher(s) listed in your consent form if you have any questions or concerns about how your information is being protected or if you have changed your mind about continuing to participating.**

Thank you for your participation in research. Because of participants like you, VCU and VCU Health are able to enrich the human experience and advance human health and well-being.