

Office of the Vice President for Research and Innovation Human Research Protection Program BioTechnology Research Park 800 East Leigh Street, Suite 3000 Box 980568

(804) 828-0868

TO: Richard Sterling
Nikki Duong
CC: Richard Sterling

FROM: VCU IRB Panel A

RE: Richard Sterling; IRB HM20022488 Clinical and predictive factors associated with need for TIPS revision

On 7/26/2021 the referenced research study qualified for exemption according to 45 CFR 46 under exempt category

Category Secondary research for which consent is not required when information is recorded in such a manner that the identity of the subjects cannot readily be ascertained, the investigator does not contact the subjects, and will not re-identify subjects

In order for VCUHS to meet HIPAA regulations for our patients regarding accounting of disclosures, data retention, and data destruction requirements for PHI data obtained without patient authorization, members of the study team (including principal investigators) are directed to consult with VCU Informatics or other approved method by the VCUHS Privacy Office to obtain data. This does not include obtaining data for which the study team has patient authorization. [VCU Health System Authority and Affiliates Policy COMP-014]

For data requests, including preparatory to research, contact informatics@vcu.edu to request the desired PHI or for a consultation on alternate methods to obtain the data. VCU Informatics will maintain and provide requested Accounting of Disclosures for research purposes to VCUHS as patient requested. See <a href="https://informatics.vcu.edu">https://informatics.vcu.edu</a> for more information.

The information found in the electronic version of this study's smart form and uploaded documents now represents the currently approved study, documents, and HIPAA pathway (if applicable). You may access this information by clicking the Study Number above.