

Institutional Review Board

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February 28, 2018

Cornelius Dyke, M.D.

Marc Basson, M.D., Ph.D., M.B.A., FACS

University of North Dakota Department of Surgery

Stop 9037

Dear Drs. Dyke and Basson:

Thank you for submitting your protocol, Pre-Procedural Clinical Predictors of Outcomes for Patients Undergoing Percutaneous Coronary Intervention, for review by the University of North Dakota Institutional Review Board (UND IRB). After reviewing your application, I have determined that UND IRB approval is not necessary for your project because it does not meet the definition of 'human subjects' in the federal regulations governing research with human participants.

According to the Code of Federal Regulations at 45 CFR 46.102(f), human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:


- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

As indicated in your protocol, you will be receiving a dataset from Sanford's bioinformatics department that has been stripped of all direct and indirect patient identifiers. You have no plans to intervene or interact with patients, nor will you receive or have access to identifiable private information in patient medical records for this study. Because you will have no involvement with patients or their identifiable private information, your research does not involve 'human subjects' as defined in federal regulations. This protocol does not require oversight by the UND IRB.

If you have any questions, just let me know.

Sincerely,



Michelle L. Bowles, M.P.A., CIP
IRB Manager