

**Stony Brook University**  
**Office of Research Compliance/CORIHS**  
**Human Subjects Research Determination Form**  
**v. 2.4.19**

Principal Investigator: Annie Laurie Shroyer

Project Title/Description: TAA BAV Study

IRBNet #: IRB2021-00609

## **I. COMMON RULE DETERMINATION**

### **A. RESEARCH**

1. Indicate whether the activity meets the following criteria:

**Yes**  **No** The activity is a systematic investigation: *an activity that involves a prospective plan which incorporates data collection, either quantitative or qualitative, and data analysis to answer a question*

**Yes**  **No** The activity is designed to develop or contribute to generalizable knowledge: *designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population)*

2. Are **BOTH** of the criteria met?

**Yes.** The activity meets the definition of research in the Common Rule (OHRP).  
Go on to the next section.

**No.** The activity does not meet the definition of research in the Common Rule.  
Go to Section II – FDA Determination.

### **B. HUMAN SUBJECTS**

1. Indicate whether the research meets the following criteria:

**Yes**  **No** The research involves **living individuals**

**Yes**  **No** The investigator will obtain data or information **about** those  
Individuals

Will the investigator (whether professional or student) obtain **EITHER** of the following:

- Yes**  **No** Information or biospecimens through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens

***Intervention** includes both physical procedures by which information or biospecimens are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction** includes communication or interpersonal contact between investigator and subject.*

or

- Yes**  **No** **Identifiable private information or identifiable biospecimens.**

***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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record). A biospecimen or 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 biospecimen or information) in order for obtaining the biospecimen or information to constitute research involving human subjects*

**2. Are ALL of the criteria met?**

- Yes.** The activity involves human subjects research according to the Common Rule.
- No.** The activity does not involve human subjects research according to the Common Rule.

**Go on to the next Section**



## II. FDA DETERMINATION

### A. TEST ARTICLE

1. The activity involves a **DRUG/BIOLOGIC** (a chemical or biological substance – other than food – that achieves its primary intended purposes through chemical action within or on the body or which is dependent upon being metabolized for the achievement of any of its primary intended purposes) **or MEDICAL DEVICE** (an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory)

**that is one of the following:**

- The article is recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them
- The article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals
- The article is intended to affect the structure or any function of the body

2. **Are any of the criteria met?**

- Yes.** The activity involves an FDA test article. Go on to the next section.
- No.** The activity does not involve an FDA test article. Go to Section III – Determination.

### B. RESEARCH

1. Indicate whether the activity meets the following criteria:

- The activity is an experiment that involves a test article and one or more human subjects (as defined below)

***Note:** For drugs, an experiment includes any use of a drug other than the use of a marketed (approved) drug in the course of medical practice. For medical devices, it is limited to activities being conducted to determine the safety or effectiveness of a device.*

- Either of the following is true:
- The activity is subject to requirements for prior submission to the Food and Drug Administration; or
- The activity is intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit.

2. **Are BOTH of the criteria met?**

- Yes.** The activity meets the FDA definition of research. Go on to the next section.
- No.** The activity does not meet the FDA definition of research. Go to Section III (Determination).

### **C. HUMAN SUBJECTS**

1. Indicate whether the research meets either of the following criteria:
  - The research involves one or more individuals who become a subject in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.
  - For medical devices, an individual on whose specimen an investigational device is used
2. **Are either of the criteria met?**
  - Yes.** The research involves human subjects according to FDA regulations.
  - No.** The research does not involve human subjects according to FDA regulations.

### **III. DETERMINATION**

1. As a reviewer, are you an investigator, consultant, collaborator, or study personnel on the proposed study; do you have a financial interest in the study; or do you have any other conflict of interest with this study?
  - Yes:** An alternative reviewer must conduct review. Do not perform the review!
  - No**
2. Based on the information in the protocol, I have made the following determination:
  - The activity is not human subjects research under either the Common Rule or FDA regulations.
  - The activity is human subjects research under the Common Rule but not under FDA regulations.
  - The activity is human subjects research under FDA regulations but not under the Common Rule.
  - The activity is human subjects research under both FDA regulations and the Common Rule.

**Comments:**

**Thank you for your submission of New Project materials for this project. The Stony Brook University Office of Research Compliance reviewed your submission.**

**As confirmed in the uploaded protocol on 11/15/2021, they will be retaining de-identified information from the SPARCS database from 2005-2018 to seek to analyze New York State-based data regarding rates of newly diagnosed bicuspid aortic valve patients that have either an ongoing or new diagnosis of thoracic aortic aneurysm as well as surgical intervention rates. At no time will the Stony Brook study team be provided with any means to determine subject identity.**

**This activity does not involve use, study, or analysis of information or biospecimens obtained through intervention or interaction with subjects. This activity also does not involve obtaining, using, studying, analyzing, or generating identifiable private information or identifiable biospecimens. Therefore, it does not meet the definition of research involving human subjects according to the Common Rule (45 CFR 46 subpart A). The proposal does not require approval by the IRB or exemption by this office.**

**The Principal Investigator must obtain local departmental endorsement from an authorized representatives (i.e. Department Chair/Division Head/Dean, as applicable) and ensure that the activity complies with applicable regulations (i.e. FERPA, HIPAA, etc) prior to beginning this activity.**

**If the scope of this project changes, please resubmit to the Office of Research Compliance for review.**

**Reviewer:**

**Erin Augello  
IRB Assistant  
11/22/2021**