K. PROJECTION OF HUMAN SUBJECTS

This individual fellowship grant proposes to perform an ancillary study on an ongoing prospective study: the Emory Cardiovascular Biobank. The above study aims to create a cardiovascular database that can be used to address a wide-variety of research questions in cardiovascular disease. The parent study is approved by Emory University's Institutional Review Boards and complies with federal, state, and internal regulations, including HIPAA. Recruited participants are men and women.

K1. RISKS TO SUBJECTS

Subject Selection/Recruitment

Patients with and without active cardiovascular disease (Cardiovascular disease includes: Heart Failure and Cardiomyopathies, Ischemic Heart Disease, Peripheral Vascular Disease, Valve Disease, Adult Congenital Heart Disease, Electrophysiological Disorders and others generally accepted to be cardiac or vascular in origin) will be recruited. We will not attempt in any way to restrict the patient population in terms of gender, race or ethnicity. We expect that the patient population will be highly diverse.

Inclusion Criteria

1. All hospital and clinic patients aged 18 years and older
2. Patients with active cardiovascular disease including but not limited to
    a. Ischemic Heart Disease
    b. Heart Failure and Cardiomyopathies
    c. Peripheral Vascular Disease
    d. Valve disease
    e. Adult Congenital Heart disease
    f. Electrophysiological Disorders
3. Any Atlanta metropolitan area resident aged 18 and above in satisfactory physical health and able to tolerate a blood draw or buccal swab.

Exclusion Criteria

1. Significant Documented Anemia (Hemoglobin <8 g/dL)
2. Blood transfusions within past 3 weeks
3. Active Cancer (non-skin cancers)
4. Enrollment against doctor recommendation
5. Patient not able to provide consent including but not limited to:
    a. Intubated and critically unwell patients
    b. Dementia
    c. Alzheimer's disease
    d. Moderate to severe alcohol or drug abuse
    e. Against religious beliefs (e.g. Jehovah's witness)

The inclusion and exclusion criteria listed below pertain to both the parent study and this research study. We will also exclude patients admitted to the intensive care unit, patients with high burden of ectopic beats, atrial fibrillation, or those that are pacer dependent.

Source of Materials

The research material for the electrocardiographic measures used in all aims will include ECG signal (VivaLNK ECG Recorder) collected before, during, and after cardiac catherization. The applicant will assess data quality and process signal using the HRV Toolbox on the enrolled patients, including data adjudication, as described above. The remaining clinical information, including cardiac catherization, is collected as part of the parent study by research staff. This data will be reviewed to ensure appropriate clinical phenotyping for subgroup analysis.

Potential Risks

This ancillary study will involve minimal risk to patients in addition to that of the parent study. The risk is discomfort or pain with application/removal of ECG patches. The patients will have continuous telemetry monitoring as part of their clinical care, and thus any ECG findings will already be known to the attending physician. The markers of interest to this applicant (HRV) does not indicate any acute clinical conditions that require prompt referral to a medical physician.

K2. ADEQUACY OF PROTECTION AGAINST RISKS

Recruitment and Informed Consent

All subjects included in the parent studies provided informed consent. The consent forms used were approved by the Institutional Review Board (IRB). The consent forms were amended to include ECG patch data collection, and have been approved.

Protection against Risk

All appropriate safety procedures are followed by the parent studies. The procedures will be performed in adherence to the Study Protocol with approval by the IRB. The person obtaining the consent will explain the procedure to the subject. If any significant adverse effects are noted during the procedure, the entire procedure will be terminated and the nurse will start conventional treatment for the specific adverse effect. The supervising attending physician is available for consultation to evaluate the situation and decide how to proceed. Participants are instructed to contact the study principal investigator if they have any questions regarding the risks, adverse reactions, or otherwise.

K3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE SUBJECTS AND OTHERS

This research is not specifically designed to provide a benefit to participants of the parent studies. The potential benefit lies in the identification of potential mechanisms for autonomic dysfunction and will be used in the future to develop preventative and intervention strategies to improve cardiovascular mortality.

K4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

By gaining a better understanding of the relationship between depression and coronary artery disease, this research will enhance our understanding potential autonomic mechanisms and lead to more targeted therapies.

K5. DATA AND SAFETY MONITORING PLAN

The parent study from which data will be derived for this grant are observational studies that involve minimal risk to study participants. Furthermore, the data to be used in this analysis is collected through a security system (REDCap) and poses no risk to the participants from whom the data will be derived. The Emory Cardiovascular Biobank has its own Data Safety Monitoring Plans which have been used to report adverse events to the IRB and, if needed, stop the study in the event of an adverse reaction. There are no expected adverse events that will occur by collection of ECG data. Should any unforeseen adverse events develop, they will be carefully evaluated by the Principal Investigator and reported according to IRB protocol. Additionally, the applicant will only use de-identified data that will be housed at Emory University. Therefore, the analyses proposed in this grant and the data to be used, will pose virtually no risk to the participants of the parent study.