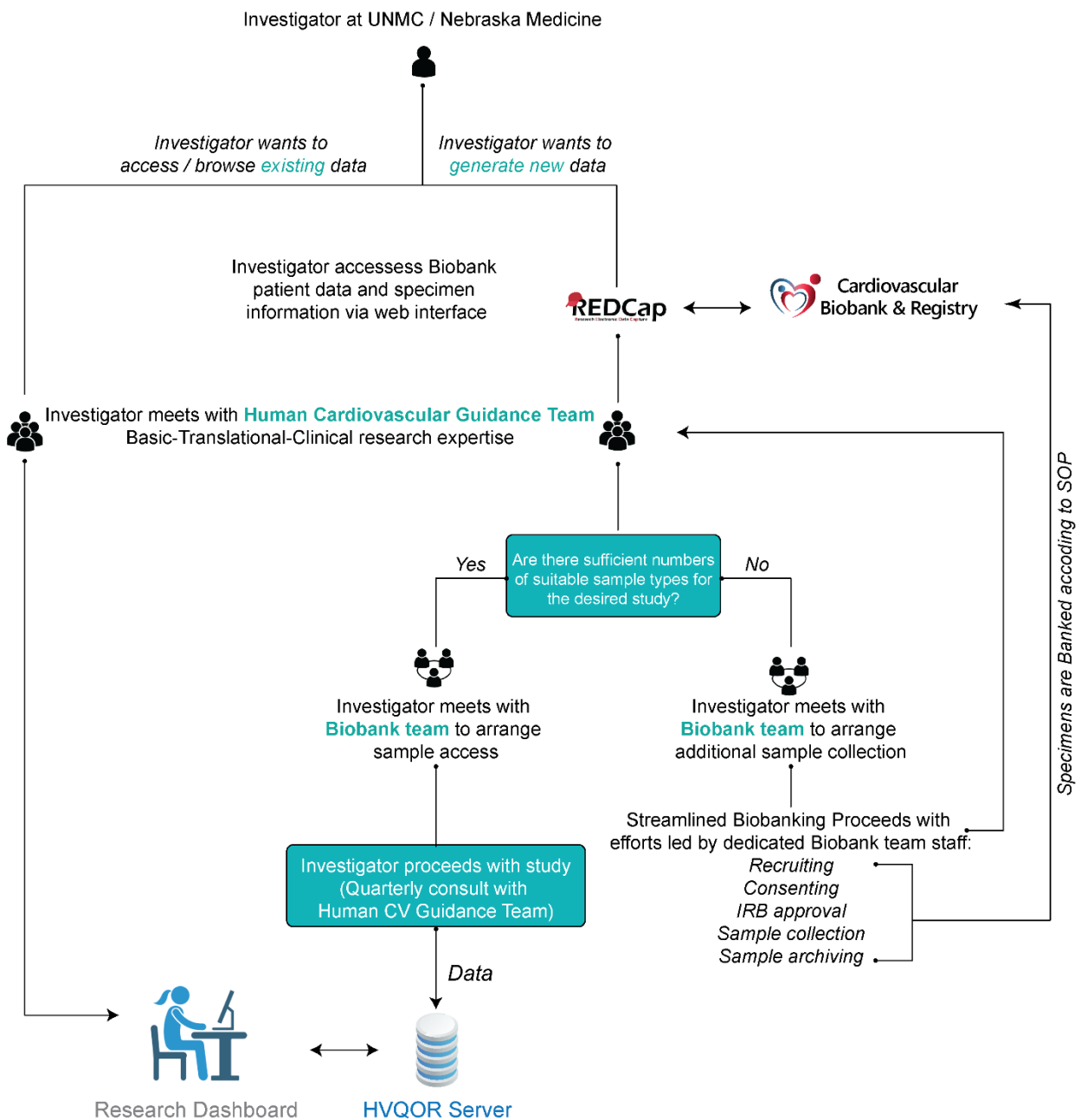




Cardiovascular Biobank & Registry

The UNMC Division of CV Medicine in collaboration with the Section of Rheumatology and Cardiothoracic and Vascular Surgery established the CV Biobank by collecting, preserving, and storing blood and tissue samples from CV patients since December of 2008. The CV Biobank was founded to facilitate basic, clinical, and translational research by acting as a repository for CV tissues and utilizing an honest broker to provide de-identified data and tissues for use in CV research. These samples and data are made available under a single IRB protocol and provided to investigators as either identified or de-identified samples through an honest broker.

Currently, the CV Biobank houses five -80°C freezers that contain >51,000 unique identified archived samples collected from 1,940 patients. These include samples from patients suffering from atherosclerotic disease, those treated and managed for chest pain, heart failure, heart transplant, arrhythmia, cardiomyopathy, and abdominal aortic aneurysms. >500 patient samples have been provided to researchers both locally and nationally.



The CV Biobank operates under a single IRB in which samples and clinical data from all enrolled CV patients can be collected. This system is a unique approach that removes many barriers normally encountered in studies employing human subjects, resulting in a simplified process that encourages the use of human specimens. Importantly, a separate IRB protocol is not required for every investigator that accesses specimens or data. Rather, the single IRB streamlines the deposition and use of specimens. All patients enrolled in the CV Biobank are consented using the same consent form, which allows for the use of the samples in CV research immediately or in the future. Patients are consented for genetic phenotyping, cell line generation, indefinite chart review, creation of a patient database and registry, permission to contact for future studies, and future tissue collection at follow-up visits (if agreed upon). Importantly, patients are able to opt out of specific aspects if they choose (e.g. cell line generation, genetic sequencing). Ultimately, these specimens are not tethered to a specific study and can be used in a broad range of investigations. Importantly, specimens are made available as de-identified samples to investigators through an honest broker. Use of de-identified specimens and clinical data are not considered human research; therefore, a separate IRB protocol is not required for the use of these samples. Instead, a brief letter or e-mail to the IRB detailing the specimens and data used by the researcher is sufficient for their affirmation of exemption.

For studies requiring new types of samples or from a different patient cohort than already available our Biobank team takes the lead on coordinating all consenting, IRB submissions, collection and archiving activities related to specimen procurement, requiring the investigators to provide only study-specific input. For studies where patient identification is required, investigators work with experts in the Biobank to prepare and submit a separate abbreviated IRB to gain access to all protected health information (PHI) that is needed for the study. These abbreviated IRBs need only address how the PHI is being used and leverages the already approved CV Biobank IRB for the consenting and archival/retrieval processes, thus streamlining these protocols for expedited review. This system provides investigators with efficient, effective access to identified data for their research protocols. This coordinated effort led by experienced CV Biobank team staff dramatically increases the speed and efficiency of initiating studies for investigators throughout UNMC and Nebraska Medicine. Importantly, all research data generated from specimens from the CV Biobank will be warehoused in a central repository, which can be accessed by any UNMC Investigator. These research data will be paired with clinical data, including future follow-up visits. This will directly promote cross-pollination of ideas among disciplines and dramatically reduce redundancies that can occur when investigators are unaware of existing resources.

Investigators interested in accessing the Cardiovascular Biobank and Registry should contact **Dr. Daniel Anderson**.