

Human Subjects Rationale - Study STUDY00023526

3-dimensional virtual histology is a new and rapidly expanding field of research aimed at generating whole biopsy images for the volumetric analysis of tissue and cellular morphology[1]. The purpose of this study is to determine the 3-dimensional structure and spatial arrangement of prostate tissue architecture and glands in order to assess whether micro-CT is a viable tool for the 3-dimensional histological analysis of prostatic samples. All human tissue samples used in this study will be archival tissue already in tissue blocks. We are not collecting any new or additional biopsies from patients

Samples will be identified by Dr. Warrick within the EHR at HMC using a natural language search in Pathnet, the pathology informatics system. All samples will be prostate needle biopsies that were taken for pathologic diagnosis and formalin-fixed and paraffin-embedded (FFPE). All samples will be from men who subsequently underwent radical prostatectomy, yielding large amounts of tissue for any required testing. Prostate biopsies will be assigned an arbitrary identifier and provided to the Cheng Lab by Dr. Warrick. Dr. Warrick will keep a key that connects the arbitrary identifier to the pathology accession number, a unique identifier assigned to the specimen in Pathnet.

Subjects cannot be injured by this protocol. There are two theoretical risks conferred by a study as we describe here. First, the patient may need his tissue to undergo molecular testing, but the study protocol has exhausted the tissue, necessitating another biopsy. Second, protected health information could be accidentally disclosed.

Our design prevents both of these risks with a high degree of certainty. First, we will only image prostate needle biopsies on men who subsequently had a radical prostatectomy. This larger specimen will contain much more information than was present on the needle biopsy, allowing for molecular testing. Second, no protected health information on any patient will be stored as part of this study. Dr. Warrick will identify patients in Pathnet, and record their pathology accession number (which is not considered PHI). The patient's name and other identifying information will never be recorded. To add an additional layer of protection, Dr. Warrick will assign each tissue block an arbitrary identifier. This identifier will be connected to the pathology accession number in a key, which only Dr. Warrick will have access to. The specimens collected in this study will be FFPE prostate core needle biopsies after they have been analyzed by a pathologist and read for diagnosis. These samples will be stored at HMC within the Cheng or Warrick Labs until they are brought on person with Andrew Sugarman for imaging at LBNL in Berkeley, CA. After imaging, they will be brought by Andrew Sugarman back to the Cheng/Warrick Labs at HMC.

Imaging data will be stored on a Cheng Lab workstation and the HMC high-performance computing cluster. Specimens will be returned to Dr. Warrick following completion of analysis.