The Evolution of an Academic Research Organization within the CTC

Members of the Comprehensive Transplant Center (CTC) are serving in a new role, as an Academic Research Organization or ARO. When Transplant Genomics, Inc. (TGI) decided to fund a biomarker study at the University of California at Davis (UC Davis), they looked to the clinical research core at the CTC to provide the administrative oversight and expertise to run the trial, and assume the duties of a traditional contract research organization (CRO).

Performing the functions of an ARO necessitated bringing together the efforts of our clinical research core, grants management core, and the biorepository core. The objectives of this trial with UC Davis and TGI include using peripheral blood genomic biomarkers in kidney transplant recipients to diagnose acute rejection and other important clinical problems in a non-invasive fashion.

From protocol development, to regulatory approval, to online clinical case report form creation and management, members of our team developed some entirely new skills to expand their research capabilities.

Beyond the clinical research core, the biorepository core was called upon to store and catalog a variety of biologic samples for the team at UC Davis. This furthers the mission of the biorepository core to enable and encourage future collaborations based on stored biologic specimens that have been linked to clinical outcomes and phenotypes. Along with the biologic samples, pathology slides are being stored in cataloged on the digital slide scanner in the CTC. Having the source information, in this case the original clinical kidney biopsies, available for future review adds a layer of authenticity and accuracy to future studies utilizing paired samples.

The efforts of Jane Charette, RN, Susan Brietigam, Emma Hoffman, Jaquelene Peysakhovich, Taylor Coffee and Taylor Graham need to be highlighted, as they demonstrated tremendous effort and creativity in forming the new ARO core in the CTC, and they continue to oversee the trial.

The hope is to build upon this experience and seek future opportunities to serve as an ARO. The process has been a tremendous way to learn and hone our own clinical research skills, as the adage states, we have seen one, done one, and now are in the role of teaching other centers about clinical research.

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