Clinical Research Core

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The Clinical Research Core (CRC) is comprised of the investigators and support staff operating clinical trials within the Comprehensive Transplant Center (CTC). Our stated objective is to enroll every willing transplant patient into a meaningful clinical study that will help to advance the field. In order to achieve this goal, we have developed this CTC core in order to facilitate the process of conducting clinical research for our investigators. Implicit in its design, the CRC is expected to achieve operational and fiscal sustainability. This means that studies carried out in the CRC must be supported by the necessary funding to support both the infrastructure and the operation of studies undertaken by the investigators. However, the CRC is also designed to provide seed support for studies that may receive funding in the future, but that may require initial funding for exploratory studies necessary to provide preliminary data.

There are critical elements that are needed for a CRC to successfully help investigators attract and execute clinical trials. These include, but are not limited to, experienced clinical research nurse coordinators, research associates, PharmDs, data managers, as well as regulatory, grants and administrative support. The structure of the CRC is based on functionality. Thus the research faculty and staff, together with support personnel, function as teams around specific studies. These are virtual teams that assemble and disassemble as needed in order to support a particular investigator. This model creates efficiencies and value. A weekly meeting serves as a clearing house for administrative issues related to the operation for the CRC. All personnel and activities occur on the 19th floor of the Arkes Pavilion, in immediate proximity to our outpatient clinic, phlebotomy facility and biopsy suite. This geographic advantage further facilitates the successful execution of clinical trials. Clinical trial requirements, such as clinic visits, lab draws, protocol biopsies, etc. are fully integrated into the standard of care provided by our clinical care delivery teams. Site visits by sponsoring and regulatory agencies are also conducted in the same space.

CTC investigators have been extremely successful in attracting and executing clinical trials in the field of transplantation, as well as in areas of study that border on transplantation, such as studies in patients with hepatocellular carcinoma or viral hepatitis. Notable transplant clinical trials include studies in both kidney and liver recipients of immune tolerance and proteogenomic biomarker discovery and validation, islet cell transplantation, and several clinical trials of novel immunosuppressive agents, particularly of calcineurin inhibitor sparing regimens. In addition, we are currently engaged in studies related to the prevention of infections, as well as other transplant complications. The CRC is flanked by translational research resources, including a state-of-the-art immune monitoring laboratory as well as a health services and outcomes research collaborative. Our Data Informatics group, which is now part of the Enterprise Data Warehouse, is also an integral partner to the CRC. An on-line biorepository will soon link samples in our freezer farm to clinical databases, and the newly acquired Aperio system will allow for digital review of all biopsy samples with the sole requirement of a laptop and access to the Internet.

The CRC currently employs 16 individuals and carries out an average of 45 clinical studies at any given time. Funding sources vary from the National Institute of Health to various industry sponsors and most of our studies are multi-center, although a few single center, investigator-initiated studies also exist. The current budget of the CRC is over $3 million. Dr. John Friedewald is the director of the CRC. Mr. Luke Preczewski, the executive director of the CTC supports the administrative, logistical and financial aspects of the CRC. Investigators interested in clinical studies related of any and all aspects of transplantation are encouraged to contact either Dr. Friedewald or Mr. Preczewski directly to inquire about the process for attracting or executing a clinical trial in transplantation. All clinical trials involving recipients of abdominal solid organs are vetted through the transplant center faculty at their bi-monthly meetings in order to obtain critical feedback and ensure that the trial meets the goals of the CTC. Once the project is approved in concept by the faculty, the CRC clinical and administrative staff will facilitate all regulatory and logistical aspects of the trial, including IRB submission and any regulatory agency filings, formulation of a budget, negotiations with sponsors, setting up the right accounts within the University, and making sure that successful enrolment and completion of the study occur.

It is the ultimate goal of the CTC to develop a full service Northwestern Medicine Academic Research Organization (ARO) for transplant clinical trials. We believe that through incremental growth and the through the continued pursuit of excellence in clinical research, we will achieve this objective.