Cardiovascular Cell Therapy Research Network

PET Core Lab Application- 2014

Network: We are a network of physicians, scientists, and support staff dedicated to studying stem cell therapy for treating heart disease. The goals of the Network are to complete research studies that will potentially lead to more effective treatments for patients with cardiovascular disease, and to share knowledge quickly with the healthcare community.

Purpose: The mission of the CCTRN is to achieve public health advances for the treatment of cardiovascular disease, through the conduct and dissemination of collaborative research leading to evidence-based treatment options and improved outcome for patients with heart disease.

Expectations for Core Labs: It is expected that Network core labs will:

1. Work closely with the Steering Committee to determine the analysis needs of proposed protocols, provide a corresponding scope of work and budget to address those needs, and provide procedures for the proper collection, shipment, analysis, and storage of study data.
2. Employ sufficient personnel to ensure the primary analysis (at least one individual and a back-up), timely data entry/data transmission, and timely invoicing.
3. Regularly review, update, and re-issue SOPs to clinical centers at established intervals and as warranted by changes to the protocol.
4. Provision of and inventory monitoring of supplies needed to provide data from the sites to the core (e.g., Fed Ex account, shipping boxes, package labels, checklists of materials to be included)
5. Submit appropriate applications and annual reports to their institutional review board for approval to conduct analysis on de-identified data.
6. Submit periodic progress reports to the Data Coordinating Center (DCC) and to attend and participate in regularly scheduled Steering Committee meetings.
7. Adhere to the NHLBI and CCTRN policies on 1) presentations/publications, 2) intellectual property rights, and 3) access to and sharing data.
8. Provide timely provision of data deliverables to the DCC.
9. Provide monthly invoicing to the DCC to receive payment which includes detail support (patient identification numbers, visit type, etc.).

Application and Review Process:

Applications (no more than 6 pages in length) will be reviewed by the CCTRN Executive Committee and an NHLBI-appointed review group. Selected core labs will be notified via email from the DCC within 60 days of the close of the application period.

Applications must include 1) a copy of the lab director's current CV and 2) an application addressing the core lab elements listed beginning on page 4. In support of the application, a listing of relevant publications of previous or ongoing work may also be provided. The application must include the following elements:

Section I. Laboratory Description

A. Name and address of Core Lab
B. List of key lab personnel (including the Director), their credentials, and experience in cellular therapy field
C. Brief description of the lab; including any off site facilities or personnel utilized (can include years of operation, previous projects or programs on which the lab has functioned as a core, accreditations, special awards, acknowledgments, etc.). Please specify clinical trial experience.
D. Indicate any accreditation that the lab has and provide current documentation (i.e. certificates).
E. Provide descriptions of the types of analysis provided by the lab with respect to the type and nature of Network protocols.

Section II. Training and Management Plan for Sample Collection and Shipment

A. Describe training to be conducted by your laboratory with the clinical center personnel prior to data collection (e.g., site training visits, development of SOPs, teleconferences, distribution of materials, qualification information)
B. Describe the qualification process that your lab conducts-(e.g., site equipment validation, number of qualification runs needed to meet assurance, etc)
C. List any ongoing education sessions available to clinical centers by your lab (e.g. refresher training on coordinator calls, emails to technicians at clinical centers, etc)
D. Describe management processes for maintaining inventory/shipment of collection supplies to centers.

Section III. Communication Strategies with Centers and Sponsor

A. Describe circumstances, frequency and method of communication with clinical centers
B. Describe circumstances, frequency and method of communication with Sponsor (DCC)
C. Describe how your lab resolves/reports communication failures with clinical center personnel

Section IV. Laboratory Quality Control Processes

A. Describe your process for receipt and tracking of data received from clinical centers (e.g. logging system including date of receipt, date of analysis, condition of the data, etc.)

B. Describe process for addressing data issues: missing labels, media, or paperwork from clinical centers
C. List equipment and/or software used by your lab for analysis of data in the CCTRN trials
D. Provide additional info on software validation (standard used, frequency of calibration, etc.)
E. Describe your system for managing blinded quality control review

Section V. Sample Storage and Data Submission

A. Provide information on data storage (under what conditions are the data kept, how long are they kept, destruction methods, any security measures that are in place)
B. Describe your data backup process for data processed by your lab; including any off-site data storage
C. Provide information on your data transmission capabilities (secure upload, database entry, submission of spreadsheets, etc.)

Section VI. Budget

The budget should include cost for carrying out the analysis procedures, any necessary (non-electronic) shipping, and storage (if appropriate) of study data. Cost should be reported on a "cost per patient" basis.

PET Elements

Perfusion- **REST/STRESS Perfusion PET/CT Imaging with Rb-82**

Viability **Viability PET/CT Imaging with 18F-FDG**

Deliverable products:

1. Images analyzed (stress supine vs. rest supine or attenuation corrected supine stress vs. rest supine, if protocol is modified by adding this technique)
2. Method of attenuation correction (if adopted as part of protocol)
3. HR and BP at rest and stress
4. ECG findings of ischemia (positive, non-diagnostic, negative)
5. Summed stress score
6. Summed rest score
7. Summed difference score
8. The extent/size of myocardium with fixed defect on post-stress image:
    - The number of Standard Deviations (SD) below lower limit of normal will be tabulated and assessed for all segments and a fraction (extent) of diseased myocardium will be reported
9. The extent/size of myocardium with reversible defect on post-stress image:
    - The number of Standard Deviations (SD) below lower limit of normal will be tabulated and assessed for all segments and a fraction (extent) of diseased myocardium will be reported
10. Total defect size on post-stress image (as measured by the number of abnormal segments):
    - The number of Standard Deviations (SD) below lower limit of normal will be tabulated and assessed for all segments and a fraction (extent) of diseased myocardium will be reported
11. Total defect size on rest image (as measured by the number of abnormal segments):
    - The number of Standard Deviations (SD) below lower limit of normal will be tabulated and assessed for all segments and a fraction (extent) of diseased myocardium will be reported.
12. Left ventricular ejection fraction on post-stress image
13. Regional left ventricular wall motion on gated post-stress images (graded on 1-5 scale of normal to akinetic/dyskinetic, with normal = 5, akinetic/dyskinetic = 0).

Given the inter-patient heterogeneity of the coronary artery tree, describe how the lab maps the perfused segments to specific coronary artery territories?