Data & Coordinating Center

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The first aim of the DBCC is to structure an efficient and effective communication and data system for the network. The structure of the DBCC will include the principle and sub investigators, an Internal Advisory Committee, and the project management team. The Clinical Research Informatics Core of the DBCC has experience in with multiple technologies including ENGAGE, Velos, and the Honest Broker. The database will be designed with the input of the Steering Committee and the Research Advisory Committee of the CMREF.

The second aim is to ensure that every collected lung is eligible. Given the effort required to harvest and prepare explanted lungs, it is crucial that the diagnosis of IPAH be fully validated. Based on these guidelines, we propose the following criteria for initial screening:

1. Doppler Echocardiogram with no significant mitral valve, aortic valve, or left heart disease.
2. Ventilation-perfusion scan demonstrating the absence of thromboembolic disease (normal perfusion). If the ventilation-perfusion scan is abnormal, further testing such as pulmonary angiography to demonstrate the absence of thromboembolic disease will be required.
3. Pulmonary Function Tests demonstrating the absence of significant obstructive or restrictive lung disease. If the FEV1/FVC is less than 70%, or the TLC is less than 70% of predicted, further documentation, such as a high resolution chest CT, must be submitted.
4. Right Heart Catheterization demonstrating a mean pulmonary artery pressure greater than 25 mmHg, a pulmonary capillary wedge pressure or left ventricular end diastolic pressure less than or equal to 15 mmHg, and a pulmonary vascular resistance greater than 3 Wood Units.

While these are minimum criteria, additional data (e.g. ANA and HIV serology, contrast or transesophageal echo, shunt run) may be required to further classify associated PAH conditions. The DCC will work closely with the Steering Committee to refine the entry criteria. Cases will be reviewed by the DBCC for confirmation of diagnosis.

The third goal of the DBCC is to ensure that every eligible lung is collected. With so few eligible candidates undergoing transplantation each year, the network cannot afford to miss opportunities. The DBCC will develop a training program that strikes a balance between

standardization and flexibility to accommodate unique site challenges.

The Project Monitor will schedule visits to each participating site to develop a site-specific plan for organ harvesting, codify these site plans into a written manual of procedures, and initiate phone-based training of new personnel as needed. In some cases, the needs of the Scientific Centers may require highly specialized preparation and shipping of tissue. The DBCC can consolidate these special needs into a single training program, increasing efficiency. Procedures for ongoing outreach to center staff and to participants will be implemented.

Lastly, the DBCC will provide a state-of-the-art infrastructure that meets the needs of the network. Data will be managed with Velos, a commercially available clinical trials data system available under contract to the University of Michigan. Velos allows data to be acquired either centrally or remotely through a secure, HIPAA and GCP-compliant, Web-based system. The informatics infrastructure must accomplish the following:

Sample Tracking, Clinical Data Collection, promoting Cross-Cutting Research and Collaboration, and maintaining Data Security. Specific capabilities that will be made available through Velos for this project will include sample tracking, inventory management, parent-child relationship management, barcoding and label printing with the specific goal of supporting the workflow associated with harvesting, processing and analyzing of tissue samples among the many Centers supporting this project. The clinical data will be collected in two phases. First, clinical data will be collected during screening, to confirm eligibility.

Second, persons who ultimately donate an explanted lung will undergo a second round of data collection to obtain more detailed medical information that may be useful to future analyses of banked tissues. Epidemiological data (e.g. age, gender, family history), historical data (e.g. onset of symptoms, medication exposure), and relevant serial clinical data (six minute walk tests, hemodynamics) will be collected.

Preserving confidentiality of participants is a crucial component of the DBCC plan and will be accomplished by a variety of methods including:

The informed consent process, use of de-identified data, and use of a standard Data Use Agreement for each participating Scientific Center investigator. Data will be captured electronically and a quality assurance system will be established.