**nPOD Tissue Prioritization Committee (TPC)**

**Outline of Review Process for Applicants**

**November 14, 2019**

This document outlines the steps of the review process for nPOD project applications (both new applications and addendum applications to existing projects. Addendum applications are typically used to update the TPC on progress of a previously approved project, including having met a project milestone previously agreed to with the TPC, to support continuation of the study, a request for additional samples, the pursuit of follow-up studies related to the original question, the addition of a new investigator and other administrative matters (moving to a different institution, transfer of samples, etc.).

Investigators are welcome and encouraged to contact nPOD with pre-submission inquiries, so that we can provide initial guidance.

Each application undergoes an administrative review followed by a scientific review by the TPC.

Deadlines for submission and dates of TPC review meetings are posted on the nPOD website.

**Administrative Review**

An administrative review precedes the scientific review, aiming at identifying problems that can be addressed before the scientific review. This process involves the 4 steps outlined below:

**Step 1: Required Documents**

* Ensure that all documents required from the applicant are in place, including IRB, MTA, etc. Lack of documentation does not preclude review but will prevent approval.
* IRB documentation. This is usually a letter of exemption since most IRBs do not consider organ donors as human subjects.

**Step 2: Feasibility Review**

* Determine the feasibility of providing the requested samples:
  + Ensure that requested donor types and cases are available.
  + Ensure that the study donor selection criteria can be implemented
  + Ensure that number of samples being requested and quantities are consistent with nPOD policies and inventory.

**Step 3: Scientific Pre-Review**

* Following administrative and feasibility review, a scientific pre-review is conducted with the TPC Chair to identify any major scientific shortcomings or issues with the application, which would likely prevent approval, and could potentially be addressed before the TPC review.
* Verify that the application is submitted as a full project or addendum, according to the guidelines.

**TPC Scientific Review**

* The TPC will review full project applications and addendum applications to existing projects.
* Currently the TPC consists of 11 reviewers and the TPC Chair. The meeting can take place if there is quorum, which exists when at least 6 reviewers, including the Chair, participate in the meeting or, if unable to attend, have provided a written opinion and recommendation.
* For each application, the TPC member to whom the application was assigned, is asked to discuss it during the TPC meeting; he/she will outline strengths and weaknesses of the application. The application is then discussed by the whole committee and aconsensus recommendation is achieved; if consensus is not possible, a decision will be determined by the majority. Given that there are 13 total votes with the 12 TPC reviewers and the TPC chair, then quorum will be met with 7 total votes which includes 6 TPC reviewers and the TPC chair.
* Outcomes:
* **Revisions Requested**
* **Application Declined**
* **Application Approved**
* **Application Approved with Contingencies** (step-wise approval)

Following initial review, an applicant who has been asked for revisions/clarifications will submit a revised proposal and a cover letter that addresses the original comments from the TPC Chair. At the discretion of the TPC Chair, a revised application can then be:

* Reviewed by the TPC.
* Approved by the Chair (this would occur for applicants that have clearly addressed the original criticism, especially if they had replied rapidly after the initial review, to avoid delaying approval until the next scheduled meeting). The reviewers will be notified at the upcoming TPC meeting if an application was approved by the Chair.
* Approved or declined via email vote (when there may be need to expedite a decision but the TPC Chair requires input from the TPC). If any one reviewer requests to have the application brought to the TPC for discussion instead of an email vote, the application will be brought to the TPC for discussion.

The above options are intended to expedite the review process and reduce burden on TPC members.

Addendum applications are reviewed according to the same guidelines described above for full projects. Similarly, attempts will be made to expedite the review process, reduce TPC burden, and ensure that the TPC is informed of the progress of approved projects.

**Funding by the Helmsley Charitable Trust George Eisenbarth nPOD Award for Team Science**

Applicants may request funding support using the dedicated pages in the application form. If the project is approved to receive nPOD specimens, the application may receive funding if the TPC recommends funding and the Helmsley Charitable Trust agrees with the recommendation and finds that the project is within the scope of the parent grant.