Data Use and Access Sub-Committee Information and Requirements

The RAD-PD Publications/Data Use and Access Sub-Committee (Publications/DUAC) will begin accepting proposals for research one (1) year from the registry launch date (October 2018).

The RAD-PD Publications/DUAC will serve as the governing body that provides oversight to the access and use of de-identified RAD-PD data sets. The primary function of this committee will be to review and evaluate all requests for RAD-PD/OUR DBS data access for their scientific merit, analytic rigor, feasibility, clinical relevance, and for their potential conflicts of interest.

The RAD-PD Publications/DUAC will consider "preliminary" research proposals, should researchers wish to obtain feedback regarding potential merit, feasibility and lack of conflict with existing proposals prior to submission of their studies to local IRBs. These preliminary reviews are non-binding, and research can only proceed with full RAD-PD Publications/DUAC approval of "formal" research proposals (which should be accompanied by written evidence of IRB approval and signed data use agreements, as outlined below).

The RAD-PD Publications/DUAC will aim to prevent duplication of publication or conflicting publications from similar datasets, and ensure that only the variables necessary for the proposed analysis will be made available. In addition, the RAD-PD Publications/DUAC will ensure proper completion of all necessary documentation ensuring human subjects ethics and regulations, including confirmation of local IRB approval and completed Research Data Use Agreements from all members of the proposed research team. Proposals demonstrating scientific relevance, methodological validity, feasibility, and that contribute to prior or existing studies without infringing upon existing work in progress and planned studies, and without significant conflicts of interest will be given priority for access to de-identified RAD-PD/OUR DBS data. All sites are free to use their own site-specific data at any time based on their local IRB mandates. Only data sets that de-identify patients, surgeons, practice groups, and hospitals will be provided for research purposes.

The unique governance structure of the RAD-PD registry necessitates appropriate acknowledgment of all study partners for study design and implementation. The study partners are the Michael J. Fox Foundation, Parkinson Study Group, NeuroPoint Alliance, Inc., and Neurotargeting, LLC.

Formal proposals must include the following elements:

1. Background/theoretical framework
2. Statement of the problem ("Why does this research need to be conducted?")
3. Purpose of the study
4. Letter verifying local IRB approval
5. Specific scientific question(s) and/or hypotheses
6. Study design (with special attention to the specific analytic methods to be employed and the data required to conduct the research)
7. List the statistical analysis personnel (Contact the RAD-PD Project Manager directly for a list of available for providers, as needed)

8. Significance of the investigation ("How will the study extend existing knowledge?")
9. Funding source (if applicable)
10. Pertinent references (preferred by not required)
11. Estimated project timeline

Proposals will not be granted to sites for the following reasons:

- Sites without local IRB approval, prior to the submission of the RAD-PD Data Use and Access application
- Sites that have not fully executed the RAD-PD Research Data Use Agreement (each team member must execute a RAD-PD Research Data Use Agreement)

All proposal submissions must submit a Data Use and Access Application Cover Page.