**Required Documents for New Protocols Seeking FIRST Support**

The following is a list of documents required by the FIRST team to support Principal Investigators (PIs) requesting full regulatory and/or staffing support for new research projects:

* Protocol Title
* Background: 1-5 paragraphs describing previous research relevant to this project, please provide sources.
* Description of research protocol: a step by step description of the study procedures and methods. This should be detailed and, depending on the type of study, 1-10 pages. Please focus on the subjects’ experience and what will be required of them. The FIRST program also provides study design consultations if you need guidance.
* Statistical Analysis Plan: discuss how you plan to analyze the data, this can be general. The FIRST program also provides biostatistics consultations if you need guidance.
* Data Usage: list any people or groups with whom you plan to share the data. Please include how the data will be transferred and what data the external persons or groups will have access to ie identifiable or unidentifiable.
* Study inclusion and exclusion criteria (please be specific).
* Possible Risks: list all risks associated with the study related procedures that are NOT standard of care. (Risks should be categorized into the following groups: more common >5%, less common >1%-<5%, and rare <1%.)
* Data and safety monitoring plan: All expedited and full board protocols performed at BIDMC require a data and safety monitoring plan. The plan is typically unique to each protocol and is based on the risk level of the study.
* Funding Information (if applicable)
* Required Training: please consult the FIRST team if you are unsure of what training is required.
* Signed CV and medical license (electronic versions are fine).
* Research staff list: all people who will be participating in the study procedures and have access to identifiable study data.