

Spinal Injury Foundation-IRB Main Application

Please answer the following questions concerning your research:

- The title of the study with appropriate version dates?**
- The purpose of the study, including any benefit(s)?**
- Results/references of previous related research?**
- Subject selection – inclusion/exclusion criteria?**
- Study design, including a discussion of the research methods?**
- Description of any/all procedures to be performed and any treatments to be administered and/or a copy of all surveys to be administered (if applicable)?**
- Provisions for managing adverse reactions?**
- Explanation of how the data collected will be monitored to ensure the safety of subjects?**
- Documentation of how the privacy of subjects will be protected?**
- Documentation of how the confidentiality of data will be maintained?**
- Informed consent documents(s) with appropriate version dates?**
- The investigator’s clinical brochure for any investigational drugs or devices, package inserts and advertisements when applicable?**
- Signed statement from the investigator defining and attesting to their competency in investigational practices.**
- HDE submissions need only include the FDA approval letter, instructions for use and pages 3-6 of this packet.**