**SPAN STANDARD OPERATING PROCEDURE**

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| **#1** | **INFORMATION** |

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| **Procedure Title** | | **Publication policy** |
| **Originators** | | **SPAN Coordinating Center** |
| **Creation/Revision Date** | | **9/10/21** |
| |  |  | | --- | --- | | **SOP: 00**  **Version No: 1.1**  **Effective Date: 9/10/2019** | **Supersedes**  **Document: SOP 00 Version 1.0**  **Effective Date:** 8/1/2021 | | | |
| **#2** | **POLICY** | |
| 1. All data will be summarized and analyzed by the Biostatistics and Data Management Core. 2. Relevant commercial sponsors, if any, may use the clinical narrative for regulatory reporting; this narrative will include at least a description of the study methods, results, implications, and safety profile. 3. The Principal Investigators will prepare abstract submissions to appropriate research meetings and manuscripts for submission to a peer-reviewed journal. All investigators and the sponsor will review the draft manuscript. Authorship will be based on guidelines issued by the editors of medical scientific journals and will require active input into protocol design or manuscript preparation; subject recruitment alone is not considered sufficient (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>) . The order of authors will be determined by mutual agreement; if a dispute cannot be resolved by consensus, the lead author will make the final arbitration. 4. Negative publication bias is a significant problem in modern medical research; the results of this trial will be published, after manuscript review by all parties, including any commercial sponsors, the investigators, NINDS program staff. No Site PI will publish data individually without prior discussion with the Coordinating Center and the NINDS. 5. SPAN Site investigators may request data from the Coordinating Center for the purpose of additional analyses. Such requests will be submitted to the Coordinating Center in writing for discussion by the Steering Committee. To assure fairness across all sites, all requests will follow the same protocol:    1. Requests will be in writing. There should be a clearly defined question or hypothesis. Proposer should provide a rationale as to why SPAN is the appropriate database to answer the question.    2. There should be a clearly defined statistical analysis plan. What analyses will be done?    3. The proposer must specify exactly which variables and which study population e.g., per protocol vs. ITT, etc.    4. Ideally the proposer will provide ‘shell’ tables that illustrate how the data will be presented.    5. Authorship opportunity must be made available to all Sites using the same authorship rules as above.    6. Proposers will have 3 months to provide a draft manuscript after receipt of the data from the Coordinating Center. If the manuscript has not been drafted in 3 months, another investigator may request and be given primary responsibility for completing the analysis.    7. The Steering Committee will give final approval to all proposed data transfers before any data is provided. | | |
| 1. The Coordinating Center will track all publications as they are drafted and submitted. Authors are asked to keep the CC apprised of progress on all such manuscripts. | | |

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| **#3** | **REVIEWED AND APPROVED BY** |
| *Reviewed and Approved by Principal investigators at the SPAN Kickoff Meeting held in Los Angeles 9/09/19-9/10/2019.* | |