**SHINE Trial Publications Policy**

1. **Overview**

These policies are intended to optimize and expedite accurate translation of trial results to the scientific medical community, and to enhance scholarly productivity of the trial. This document outlines the steps for reporting trial data from beginning to end. This process will be guided by the members of the SHINE publications committee (see below). For each project writing groups will be created that will be responsible for that project. A group leader will be appointed that will usually be the first or the senior author on the manuscript. Requests for data analysis will be thoughtfully reviewed and tabulated by the publications committee. Proposals will be prioritized based on feasibility, scientific validity, and significance among other factors. The trial data will become publically available as specified in the data sharing plan.

**2. SHINE publications committee members:**

● Askiel Bruno MD, MS (SHINE Protocol PI) and William Meurer, MD, MS (NETT Co-Investigator)(Co-Chairs)

● Karen Johnston, MD, MS (SHINE Administrative PI),

● Christiana Hall, MD, MS (SHINE Recruitment PI),

● Valerie Durkalski-Mauldin, PhD (SHINE SDMC PI),

● Robert Silbergleit, MD (NETT Co-Investigator)

● Scott Janis, PhD (NINDS Scientific Program Officer)

● Amy Fansler (SHINE Project Manager)

The publications committee will have the following key responsibilities:

1. Review project requests for SHINE data analysis and publication in chronological order.

2. Approve, request modifications, or disapprove the requests based on scientific merit, feasibility, and significance.

3. Prioritize the approved projects based mainly on scientific merit, significance, and availability of resources.

4. Manage the timely progress of the projects. The publications committee will have the authority to reassign a project to a different working group leader in the event that the specified time lines are not met.

**3. Types of manuscripts**

**3.1 Primary and pre-specified secondary manuscripts**

These analyses have been pre-specified in the SHINE NINDS grant Statistical Analysis Plan application. The publications committee will work with the SHINE PIs to optimize the timely and accurate preparation of these manuscripts for publications. The SHINE PIs will lead these writing groups. The pre-specified secondary manuscripts may be submitted for publication only after the primary manuscript has been accepted for publication.

**3.2 Subsequent manuscripts**

All other projects based on analyses not pre-specified in the SHINE NINDS grant Statistical Analysis Plan are considered as subsequent projects. These manuscripts may be submitted for publication only after the primary manuscript has been accepted for publication. The working group leadership of the subsequent manuscripts will be open to all those who have made contributions to the SHINE trial and other scientists who submit worthy proposals.

**3.3 Ancillary manuscripts**

The PIs of the ancillary studies will form the working groups that will prepare the primary analysis of those studies. Subsequent working groups including the ancillary study PI may be formed to propose, analyze, and report secondary findings from the ancillary studies. **At least one of the SHINE PIs will be a member of the ancillary study working groups.**

**3.4 Manuscripts not using SHINE subject data**

Members of the NETT CCC, SDMC and SHINE site PIs may wish to prepare manuscripts that describe the SHINE trial operations, network function, or other issues unrelated to SHINE subject data. These projects will not address the SHINE trial specific aims. These projects proposals will also be submitted for approval to the SHINE publications committee.

**3.5 Individual Site Investigator Publication Rights**

Individual site investigators will not present data gathered at their sites before the primary SHINE results are published. Individual site investigators who wish to prepare manuscripts using only data collected only at their institutions will seek approval from the publications committee (see Project proposals and data requests below).

**4. Authorship**

The appropriate authors and their order in the primary and pre-specified secondary manuscripts will be determined by the SHINE PIs. For subsequent manuscripts the authors and their order will be determined by the leaders of those writing groups, with final approval by the Publications committee. Final authorship will be guided by the International Committee of Medical Journal Editors’ rules for authorship. All SHINE publications must include at least one SHINE PI as a Co-author and the clause “on behalf of the SHINE investigators” if the manuscript contains data from all clinical sites. The primary authors will coordinate and consolidate all written contributions, and will communicate the manuscript developments with the relevant scientific journals and the NIH. The corresponding authors of each manuscript will comply with all NIH Public Access policies (see Compliance with NIH Public Access Policy below).

**5. Project proposals and data requests**

Prior to the public release of the SHINE dataset the SHINE investigators from all sites will be encouraged to submit proposals for research projects to the SHINE publications committee using a simple established form. These dated forms will be submitted to Dr. Bruno for distribution to the publications committee and filing. The committee may approve, request modifications, or deny the proposals.

Proposals will specify if statistical assistance is needed from the SDMC or if another source is available. When significant assistance from the SDMC is requested, the SDMC-PI will determine the timelines and capacity to provide analytic services for subsequent manuscripts.

When transfer of data is requested for independent analysis, standard data-use agreements, IRB approvals, and material transfer agreements will be expected. When data analysis is done external to the SHINE SDMC and prior to public data release, the publications committee may request to review the codes used in the analyses to ensure that the results are consistent and reproducible. After the dataset is released for public use, the working groups using resources other than the SDMC will be encouraged to save all codes and any final transformed analytic datasets to ensure others can reproduce the analyses.

**6. Research project progress**

 In general, the SHINE publications committee will respond within 30 days to proposals for research projects and to review manuscripts for publication submission. Approved proposals that request analytical services from the SDMC will be prioritized based mainly on scientific merit, significance, and availability of resources. Once the SDMC begins work on a project, reasonable timelines will be established with the working groups. In general, manuscripts should be ready for submission for publication within 6 months of availability of the initial data analysis results. Working groups will be expected to report progress on their projects to the publications committee at least monthly. If in the opinion of the publications committee a project progress has slowed significantly, the publications committee may re-assign the project leadership.

**7. Presentations of SHINE data at scientific meetings**

All original presentations at scientific meetings containing data from the SHINE trial require a prior approval by the publications committee. All abstracts presented in any form will be expected to be published as manuscripts in scientific journals. Manuscript drafts based on the abstract presentations should be submitted to the publications committee prior to the meetings where the abstracts will be presented. This manuscript draft should contain at least the following sections: Introduction, Methods, Results, Tables (with titles and headings even if not completely filled in), and Figures (with titles even if not in the final format).

**8. Acknowledgements**

Acknowledgements at a minimum should include the following statement: Research reported in this publication was supported by the National Institute of Neurological Disorders and Stroke of the National Institutes of Health under Award Numbers 1U01NS069498, NCT01369069, and U01NS059041. The content is the responsibility of the authors and does not necessarily represent the official views of the NIH or other supporting entities. Other acknowledgements will depend on the specific manuscript.

**9. Confidentiality and data release**

No SHINE data will be released to the public or non-SHINE entities unless prior approval is obtained from the SHINE publications committee. All data and correspondence regarding publications are considered confidential until approval for release. All data associated with SHINE, whether locally or centrally stored, will be de-identified prior to release, sharing, or publication. SHINE results should not be discussed with the media without authorization from the SHINE PIs. The trial PIs and their designees, Site PIs, and members of the NETT CCC and SDMC have collective data rights until one year after the publication of the primary results. Individual Institution shall retain ownership of all data that they have generated. Institutions shall grant to NETT/SHINE non-exclusive license to use data for educational and research purposes. Prior to the public data release, the SHINE publications committee will retain oversight and decision-making authority of the data.

**10. Compliance with NIH Public Access Policy**

Publications will comply with all relevant NIH and external policies and regulations. All peer reviewed manuscripts accepted for publication will be registered with NIH per the NIH Public Access Policy, generating an NIHMS ID Reference Number, and ultimately a PMC ID Number, for citing. The corresponding authors of each manuscript will have the responsibility to comply with all such regulations.