National Institute of Neurological Disorders and Stroke

NINDS Standard Operating Procedure

NINDS SOP 16

SOP Title: Office of Biostatistics, Clinical Trials Unit

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Approval Signature: A. Nath Digitally signed by Nath, Avindra (NIH/NINDS) [E] Date: 2021.09.22 23:52:52 -04'00'

NINDS Clinical Director

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Table of Contents

1. PURPOSE

This standard operating procedure describes the roles and responsibilities of the Office of Biostatistics (OB) within the Clinical Trials Unit (CTU), Office of the Clinical Director (OCD) at the National Institute of Neurological Disorders and Stroke (NINDS).

The mission of NINDS is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease. The OB contributes to the NINDS mission by providing objective, high-quality statistical solutions through proper implementation of statistical methods and by promoting the use of rigorous quantitative methods. The scope of the work may include:

- Providing statistical expertise and advice to investigators at NINDS;
- Engaging in collaborative research with NINDS investigators;
- Providing education on statistical methods and various analytical techniques through lecture series and/or seminars;
- Mentoring students and fellows who are pursuing a career in biomedical or biostatistical research;
- Conducting research in statistical methodology related to NINDS research;
- Participating in Protocol Development Meetings (PDM) at CTU providing statistical input on the study protocols;
- Participating in Data Management Meetings for recently approved protocols to oversee the quality and management of key outcome measures and other analytical endpoints; and
- Serving on the NINDS Scientific Review Committee (SRC), intramural Institutional Review Boards (IRB), and attending advisory committee meetings.

2. POLICY

2.1 Requests for Statistical support

Projects supported by the NINDS Intramural Research Program may request statistical support. It is required that consultation or collaboration for any other projects (e.g., non-NINDS funded projects, non- NINDS investigators, etc.) must be approved by the CTU Director.

The scope of statistical support falls broadly into two categories: consultation and collaboration.

2.2 Consultation

The OB provides a one-hour consultation service to investigators. Statisticians may be able to provide some ideas and advice during the meeting. The topics discussed in consultation must be completed in the designated timeframe. If additional consultation is needed beyond the one-hour timeframe, follow-up consultation appointments can be made.

2.2.1 Scope of the work

The scope of the OB consultation includes:

- Providing advice and resources on the statistical approaches and data analysis;
- Giving advice on how to formulate research problems in statistical terms;
- Assisting in interpreting the statistical results; and
- Providing guidance and feedback on potential research projects to be developed.

The following requests may be beyond the scope of the consultation services although general comments, guidance, and recommendations can be provided:

- Reviewing and assisting with posters, abstracts, manuscripts, or responses to the editors/reviewers which are not results of a collaborative project with OB;
- Time-intensive, basic or advanced statistical training beyond the education program offered by the OB; Fellows and investigators are encouraged to take statistical courses offered by NIH or other institutions, which are the primary learning resources. The OB members may, however, provide input and materials for more advanced statistical methods during the consultation session.
- Reviewing the analysis results requiring the verification of statistical outputs derived from a particular software package (e.g., SAS, STATA, R, MATLAB).

2.3 Collaboration

If a project requires multiple meetings and interactions with investigators, active data analyses, or any other substantial contribution to the research project, investigators may request a collaboration regardless of the complexity of the project.

2.3.1. Scope of the work

The scope of the OB collaboration includes:

- Participating in the protocol as a member of the study team (e.g., study statistician, co- investigator, etc.). The name of the statistician should be listed on the protocol. The responsibilities may include:
    - Working closely with PI(s) to develop and design the study from the early stages of clinical research protocols;
    - Taking a primary role in writing statistical sections of the protocol such as sample size calculations and statistical analysis plans;
    - Analyzing the data, generation of figures, and reporting the results;
    - Participating in manuscript writing; or
    - Assisting in follow-up activities including protocol amendments, manuscript revisions, and addressing reviewers' comments; and
- Conducting data analysis, interpreting results, and participating in manuscript writing when the dataset is available;
- Supervising and directing statistical analysts (e.g., investigators, fellows, or other members of the study team) in appropriate statistical approaches and analyses, reviewing the results, and participating in manuscript writing.

We encourage investigators to collaborate with a statistician as soon as they begin to plan their study. Collaborating with OB members in the early stages of a research project ensures objective, high-quality, and statistically sound results. The OB primary goal is to build long-term collaborative relationships with investigators.

2.4 Authorship Policies

OB statisticians who collaborate as part of the research team should be entitled to authorship by conducting the work listed in Section 2.3.1.

- Per NIH Guidelines for Authorship Contributions[1], when providing substantial contributions to a research project (as defined in Section 2.3.1), OB biostatisticians should be listed on all study-related outcomes including posters, abstracts, results presented at meetings (e.g., conferences, seminars, lectures), and manuscripts. The authorship should be agreed upon at the beginning of collaborative relationships.

3. PROCEDURES

3.1 Initial Meeting

Similar to statistical consultations, the first meeting of the collaboration comprises a one-hour meeting, with all further appointments determined by the outcome of the initial meeting.

- To request statistical support (both consultation and collaboration), investigators should submit a Statistical Support Request Form (see Appendix B) to the NINDS OB.

Once the form has been returned, an OB member will contact an investigator to arrange for an initial meeting. The specific OB member (or contract statistician) to be involved with the project will be chosen based on either the preference of the investigator as noted in the form, the expertise of the OB members, or the availability of the OB members in relation to the study timeline or deadlines. Alterations in OB involvement may be made at any point after reassessing scope and need.

- During the initial meeting, consultation described in Section 2.2 can be provided.

- Alternatively, the meeting can be used for discussing potential collaboration with OB members. At this time, OB biostatisticians aim to get an overview of the research project and relevant background and discuss needs and timelines.

- Questions of authorship should be discussed at the beginning of collaboration, but final agreement may need further discussion.

3.2 Collaboration

- Following an initial one-hour consultation, OB members may participate in the projects of the investigators as a study statistician (see section 2.3.1).

- OB members will meet with investigators on a regular basis to discuss progress and results until the project is completed.

- Submission of the Statistical Support Request Form is required only for the first meeting. No additional forms need to be submitted unless the project is extended to address new aims and purposes.

[1]https://oir.nih.gov/sites/default/files/uploads/sourcebook/documents/ethical_conduct/guidelines-authorship_contributions.pdf

4. APPENDICES

A. APPENDIX A: STATISTICAL SUPPORT REQUEST FORM

Please review the Office of Biostatistics (OB) SOP before completing this form. To schedule an appointment, please complete the following form online at: https://share.ninds.nih.gov/sites/CTU/SitePages/Statistical%20Support%20Request.aspx

It is often helpful to send us any documents or papers, which might help familiarize a statistician with your work, in addition to the statistical support request form.

B. General Information

Requester (Name)	
Unit/Section/Lab/Branch	
E-mail Address	
Principal Investigator or Lead Associate Investigator	
Protocol Number/Protocol name *(if under development)*	
Title of specific project	
Project objectives and aims	

C. Service Requested

Please indicate whether you are looking mainly for statisticians to provide:

≠ Consultation (refer to OB SOP 2.2)

≠ Collaboration (refer to OB SOP 2.3)

If you are primarily seeking consultation, mark statistical problems you want to discuss:

Study design	Advice on statistical methodology for the analysis of data
Interpretation of statistical results	Others (specify):

Description of problem *(Give a concise description of the particular problem you are requesting statistical help for and what you expect from the OB):*

Preferred Statistician: _____