Policy and Procedures Manual

Publication Policy

Policy Number: POL021.03
Version Date: 1/20/2020

1. **Purpose**

   The final step in research is the publication of results. In addition to conducting clinical trials investigations, the NSABP Foundation (the Foundation) aims to disseminate its research results to the scientific community in reports of primary study outcomes, secondary analyses, and ancillary studies. Peer-reviewed journals and national and international scientific meetings are the vehicles of choice for publishing and presenting the results of our research.

2. **Scope**

   This policy applies to any publications and presentations in which data from Foundation studies have been used.

3. **Policy Statement**

   The NSABP Foundation recognizes the importance of the accurate and timely publication of the results of our research.

4. **Responsibilities**

   The chairman and the board of directors are responsible for the following:
   - providing guidelines for publications,
   - monitoring the timeliness of the publication of study results,
   - assuring compliance with this publications policy, and
   - adjudicating disputes involving publication issues.

   The Foundation will maintain an up-to-date bibliography and repository of all publications resulting from NSABP studies. It is the responsibility of the primary author to provide the Department of Scientific Publications at the Foundation with the most up-to-date version of all publications.

   <u>Authority</u>
   The publication of NSABP data is not permitted without prior written consent from the chairman of the Foundation.

5. Procedures

5.1. PUBLICATION OF PRIMARY STUDY OUTCOMES

The Foundation will be the clearinghouse for all manuscripts reporting NSABP study results that are submitted for publication and for all NSABP abstracts submitted for publication and/or presentation.

5.1.1. Manuscript Process

- When the endpoints described in the protocol document have been reached, the biostatistician will begin an initial full analysis of results, leading to manuscript development. If early stopping of a study is recommended by the Data Monitoring Committee and approved by the Chairman, data analysis will commence at that point.

- The evaluation of protocol records necessary for final analysis will begin when 80% of the necessary protocol events have occurred. This review will be performed by the protocol chair, protocol officer, and other members of the Foundation scientific leadership, as required.

- The protocol committee, consisting of the protocol chair, the protocol officer, and the protocol statistician, will be responsible for assuring the production of the initial draft of the manuscript and for submitting it for review to the chairman, the director of the Biostatistical Center, and the appropriate senior scientist.

- The protocol committee will set a timetable for the production of the manuscript once they receive the final analysis of the data. Development of the primary manuscript is expected to proceed in a timely manner. If the manuscript is unable to be completed in a timely fashion, the protocol officer, with the agreement of the chairman, may delegate the responsibility for the manuscript to other investigators.

- Selection of the target journal will be made by the members of the protocol committee, in consultation with the director of the Department of Scientific Publications, if desired.

- The initial draft will be approved by the chairman or his designee, the director of the Biostatistical Center or his designee, and the senior scientist. The manuscript to be submitted will undergo review by these persons, by all co-authors, and, if desired, by the Director of the Department of Scientific Publications.

- After this review, the revised draft will be submitted to the Foundation's Department of Scientific Publications for distribution to all other authors. Following further revisions, the protocol chair will formally submit the final manuscript to the Director of the Department of Scientific Publications.

- Final manuscripts for some trials may necessitate review by a specific pharmaceutical company based on previous written agreements. It is the responsibility of the protocol chair to be aware of such arrangements and to comply with them. The Department of Scientific Publications will work with the Department of Regulatory Affairs to facilitate such review.

- Copies of journal reviewers' criticisms, authors' responses, and the final revised manuscript will be sent to all co-authors. Should revisions be required by journal reviewers or requested by company partners, these will be undertaken by the protocol committee and any additional authors they appoint.

- The Department of Scientific Publications will resubmit the revised manuscript to the original journal selected or to another journal as decided by the protocol committee.

- Final citations for all published articles will be recorded in the Publications Database, and copies of the published article will be maintained in the Foundation office, Department of Scientific Publications.

- NOTE: Editing of manuscripts, forms completion, graphics preparation, submission of manuscripts/abstracts/posters (noted below), and archiving are the responsibility of the Department of Scientific Publications unless other specific arrangements are made between the department and lead authors.

5.1.2. Authorship

- Authorship is granted to researchers who have contributed to the work in question and have fulfilled ICMJE authorship criteria (www.icmje.org). Authorship implies responsibility and accountability for the published/presented work.

- Principal authors of initial manuscripts of NSABP trials will include, but will not be restricted to, the protocol chair, the protocol officer, and the protocol statistician.

- Additional authors may be identified from given institutions based on contribution and involvement in the research projects, quality of data submitted, and other contributions. The principal investigator at an institution will ordinarily be an author, but he or she may defer to another investigator at the site. Additional authors may be named from the Foundation or the Biostatistical Center based on specific contributions. Each author is responsible for obtaining appropriate clearances at his/her institution.

- All NSABP manuscripts must acknowledge in the title, when the journal so permits, that this is a group effort of the Foundation. The manuscript cover page must acknowledge the source of financial support and include such other notices as are required by the sponsor as well as any disclaimers required by the sponsor or the Foundation.

5.2. PUBLICATION OF SECONDARY MANUSCRIPTS AND ANCILLARY OR CORRELATIVE STUDY RESULTS

5.2.1. Concept Development

Proposals for ancillary or correlative studies may be submitted by standing committees or by individual investigators. A concept proposal should be developed and submitted to the NSABP internal review committee. This committee is comprised of the chairman, the director of the Biostatistical Center, and senior staff personnel, who will review these concepts rapidly. Concepts that are approved will be returned for the development of a more detailed proposal. The detailed proposal may require review by a committee of scientists having expertise in the area under consideration. Appointment to this committee will be made by the chairman.

5.2.2. Concept Approval Process

Approval of ancillary or correlative projects will be determined on a case-by-case basis. When such projects have been proposed by non-NSABP investigators or institutions, the Foundation and the Biostatistical Center will be involved in the analysis and will assist in or, if deemed necessary by the director of the Biostatistical Center, may coordinate the conduct of such studies in accordance with Section 4. It is expected that the Foundation and Biostatistical Center personnel will share in the authorship of such manuscripts, as set forth in Section 5.2.3. A companion or ancillary study should not report on results of the primary study before the principal results of the primary study are published. Development of primary manuscripts is expected to proceed in a timely manner to avoid the loss of data access and to promote data access by authors of prospective secondary studies.

5.2.3. Authorship

Authorship of manuscripts from ancillary projects will be determined based on contributions to the work in question and on fulfillment of ICMJE criteria.

5.3. PUBLICATION OF SITE-SPECIFIC RESULTS

5.3.1. Site Specific

- After publication of the primary manuscript by the NSABP, an individual site may publish data related to a site-specific study conducted in connection with the protocol. Such publications will be sent to the chairman for review and comment at least 30 days before submission for publication.

- If the NSABP has not published the primary study within 18 months after the statistical analysis required in the protocol is completed, or within the timeframe required by a contract with a research partner, an individual site may publish data related to the site-specific study conducted in connection with the NSABP protocol. A copy of the manuscript

will be sent to the chairman for review and comment at least 30 days before submission for publication.

5.4. **INVITED PRESENTATIONS**

Invited presentations requiring the submission of a manuscript involving previously unpublished NSABP data must conform to NSABP publication guidelines, and the presenters must obtain permission from the chair and director of the Biostatistical Center at least 30 days before submission of the abstract or talk. These requirements should be considered before one accepts such an invitation.

5.5. **ABSTRACTS**

The protocol committee may initiate a proposal for the submission of an abstract. Abstracts may also be submitted by individual investigators. The concept and general content of the abstract must be approved by the chairman and director of Biostatistics or their designees before submission. Guidelines for abstracts will follow those established for manuscripts. Authors will generally include members of the protocol committee and others, based on the guidelines established for manuscripts.

Posters and slides developed from abstracts fall under any applicable NSABP Foundation publication requirements and finals of these should cite the Foundation, funding support, and any other notices required by an industry partner.

5.6. **NSABP FOUNDATION WEBSITE**

Information appearing on the Foundation's website in the Members' Section is confidential and not to be distributed or divulged other than to the membership. Postings to the website are under the jurisdiction of the Foundation's Marketing Team.

6. **Applicable Legislation and Regulations**

6.1. ICMJE authorship criteria. (www.icmje.org)

Signature Page

Reviewed and Approved by:

Joan Beyer Goldberg, Chief Executive Officer — 1/30/2020 Date

Effective Date 2/13/2020

Policy Version History:

Policy Version History			
Policy Version #	**Author**	**Version Date**	**Policy Revisions**
NA	Joan Beyer Goldberg	11/13/2015	
POL021.02	Barbara Good	2/23/2018	New format; Revised Purpose and Procedures
POL021.03	Barbara Good	1/20/2020	Moved and revised 5.1.3; revised 5.1.1 and 5.2.3