

1. PURPOSE

This document describes the top-level publication policy for the SESTOR Registry. The development of manuscripts and abstracts/presentation is based on Good Publication Practice (GPP2) Guidelines (BMJ 2009;339:b4330). The purpose of this policy is to facilitate the production of timely, high quality manuscripts, avoid inconsistencies and redundancies in the presentations, protect the scientific integrity of the data, and provide authorship guidelines such that all investigators have the opportunity to participate in and receive appropriate publication credit for the presentation of SESTOR Registry data.

2. SCOPE

This policy will cover all publications and presentations based on SESTOR Registry data. The SESTOR Registry Publication Committee will provide oversight for all presentations and publications of the data.

2. PROCEDURES

2.1 Publication Committee Composition

The Publication Committee will consist of the following individuals. Addition and removal of individuals from the Publication Committee will be in accordance of SESTOR bylaws.

Publication Committee Composition

Member
Raul G. Nogueira
David Liebeskind
Brijesh Mehta
Tareq Kass-Hout
Ashutosh Jadhav
Ameer Hassan
Thanh Nguyen
Fareed Suri
Johanna Fifi
Italo Linfante
Sunil A. Sheth
Diogo C. Haussen

2.2 Primary Paper

Papers based on primary objectives will be the first paper and/or presentation that presents data on the primary objectives. Secondary objectives may be included as deemed appropriate by the SESTOR Executive Committee. Additional pre-specified analyses, or *post-hoc* analyses of key outcome data made evident following the availability of datasets, may also be included.

Authorship of the primary results paper will be the members of the SESTOR Executive Committee, in addition to the site PIs from the top 3 enrolling sites (not already part of the Executive and Steering Committees).

All enrolling sites (i.e. sites that have enrolled at least one subject), together with each site's PI (and sub-investigators where journal policy allows), will be listed in the paper's appendix in order of highest enrollment.

2.3 Secondary Papers

1. New proposals for secondary papers or presentations not already covered by the primary results paper may be submitted by any SESTOR participant, using the attached proposal form. Proposals for data analysis and publication will include a hypothesis, a literature review supporting the validity of the hypothesis, an indication of the proposed statistical analysis, journal preference(s) for submission, information on conference presentation goals, and a proposed list of authors detailing the role of each author listed. Proposed authors may include those investigators affiliated with the SESTOR Registry and trainees at an enrolling site.

Proposals from non-SESTOR registry Investigators will also be considered. The inclusion of national experts who can contribute to the scientific design of the proposal and/or analysis of the data, but who were not SESTOR registry Investigators, will be considered in the circumstance that individuals with the required expertise are not available from within the SESTOR registry investigator ranks. Prior to submission of the proposal, it is suggested that the proposer work directly with a SESTOR registry investigator. In the case that the proposer is not acquainted with a SESTOR registry investigator, he/she may submit the proposal seeking recommendation to work with a designated member. If the proposal is approved, a SESTOR registry Investigator must be included as part of the Writing Committee and serve as a co-author on the manuscript. The assigned SESTOR registry investigator will be a representative who will review the manuscript to ensure correct use of SESTOR registry data and will make suggested revisions to the manuscript as deemed necessary. In order for non-SESTOR registry investigators to obtain access to study data (i.e. for the purposes of a pooled analysis), a confidentiality agreement must be executed and IRB approval must have been obtained.

2. The Publications Committee will establish separate Writing Committees for each proposal deemed addressable with study data. The Publications Committee will populate the roster of each Writing Committee based on investigator declared interest in the topic and known investigator expertise. The Publications Committee will designate a Chair for each Writing Group, selected from among the initial project proposers. When proposals overlap, as far as possible, all proposers will be included in the Writing Committee roster, with Chair selection guided by site productivity in the registry, known expertise of authors, and past author productivity in use of the SESTOR registry dataset.
3. Proposals will be received by the Publication Committee, and referred for in-depth review. Due to the large committee size, attendance/votes by six (6) members will constitute a quorum. A priority score will be assigned based on the perceived scientific importance and feasibility.
4. Upon approval of a proposed secondary paper, the Publication Committee will set a timeline for project completion that the proposing author is required to meet. This timeline will consist of a data request/initial analysis within 1 month of notification of acceptance of the proposal. A manuscript ready for publication submission will then be required within 6 months of receipt of the results of the first data analysis. If the original author and team is not able to meet the timeline, the Publication Committee may appoint a new author to complete the analysis and manuscript. The proposer of the initial submission is not required to remain an author on the subsequent manuscript.
5. All new proposals will be reviewed by the Publication Committee members for feasibility. If the data required for the analysis are not present in SESTOR nor could they be gathered in a feasible manner, the Publication Committee will work with the Proposer to modify the analysis and/or study design that is more suitable for SESTOR data. In the event that the study cannot be modified to be suitable to be addressed by SESTOR registry data, the proposal will be rejected and the Proposer encouraged to reapply if/when the data become available.

6. All data elements with summary statistics will be available to SESTOR registry members.
7. Regardless of the source of the funding or statistical analysis, all manuscripts of any proposed publication must be reviewed and approved by the Publication Committee prior to submission. All abstracts, posters and slide sets for national/international meetings must be submitted to the Chair of the Publication Committee a minimum of one week prior to the submission deadline for review and approval.
8. Authorship credit on the final manuscript shall be based on guidelines from the International Committee of Medical Journal Editors (ICMJE), dated October 2008. All final authorship decisions must be aligned with the Covidien Publication and Authorship Policy (GS50000190). Briefly, all authors must adhere to ICMJE criteria for authorship and any additional guidelines indicated by the specific journal/congress to which the manuscript/abstract is submitted. Co-authors should participate in discussions on the planning and execution of the project called by the lead author, and should contribute to the preparation and revision of manuscripts. The lead author will have the right to recommend exclusion of those investigators who signed up for, but did not contribute substantially to the analysis and development of the final manuscript as required to fulfill authorship criteria.