SESTOR

SVIN Endovascular Stroke Therapy Outcome Registry

Research Consortium

Consortium Bylaws, August 1, 2016

1. DEFINITIONS.

"Central Database" means the database developed and managed by the SESTOR Consortium that contain the Data. Central Databases consist of the Patient Database and (in the future) the Imaging Database.

"**Central organizing centers**" means the 11 Consortium centers as of November 27, 2017. These centers have voting rights. The centers will be reappointed in annual basis based on (1) attendance of >2/3 conference calls, (2) full adoption of the prospective database, (3) fulfillment of the tasks assigned during the conference calls.

"**Collaborative Centers**" means centers that apply and qualify for membership after August 1, 2016. These centers do not have voting rights. These centers could be upgraded to an organizing center if there were vacancies or if Central Organizing Centers in agreement or during annual assessment of participation in SESTOR.

"**Observers**" means centers that are interested in the work of the Consortium. Observers may attend 1-2 meetings to get a sense for the Consortium, but then must apply for membership as a collaborative center in order to continue to attend meetings.

"Consortium Member" means any institution that has signed a Data Consortium Agreement and intends to deposit Data in the Central Database.

"Consortium Data" means all patient data that has been de-identified according to and deposited in the Central Database by a Consortium Member/Institution.

"Data" means all patient data that has been de-identified and deposited in one of the Central Database.

"Executive Committee" means the committee comprising of the founding members of the SESTOR research consortium. Executive Committee members will be reappointed in annual basis based on (1) attendance of >2/3 conference calls, (2) full adoption of the prospective database, (3) fulfillment of the tasks assigned during the conference calls.

"Consortium Member Investigator" means the member of the Central Organizing Center or Collaborative Center that is responsible for regularly depositing data into the Central Database. One per Institution.

"Non-standard Data" means data that is not part of the data regularly collected and available in the Consortium Data, which would require additional data extraction

by Central Organizing or Collaborative Centers that agree to participate in individual projects.

2. CONTRIBUTING DATA TO THE CENTRAL DATABASE
    a. Only Consortium members may contribute data to the central databases.

    b. Database Infrastructure- The data will be stored in RedCap servers.

    c. Database Access - Data will be entered into the SESTOR RedCap via The Institution P.I.

3. PUBLICATION.

    a. **Pre-Publication Review.**

    (i) All parties agree that any proposed publication reporting the results of research using the Data will be submitted to the Executive Committee for review and comment at least fifteen (15) days prior to submission for publication or for Meetings. The Executive Committee shall provide a copy of each proposed publication to each Consortium Member Investigator (one per institution) to review. All parties agree that any Confidential Information will be deleted from the manuscript prior to submission for publication.

    (ii) No one will be permitted to use the name of the SESTOR Consortium or to make any statement implying the Consortium's involvement or endorsement of any particular research result or publication without the prior, written permission of the Executive Committee.

    b. **Authorship.**

    (i) Authorship on publications and/or disclosure will follow the guidelines set forth by the New England Journal of Medicine statement on Authorship and Acknowledgements (Volume 325, Number 21, November 21, 1991) and be reviewed by the Executive Committee. In order to qualify for authorship, individuals must have made substantial contributions to: conception and design of the Protocol or analysis and interpretation of the generated data; *and* writing the publication or revising it critically.

    (ii) In addition, individuals who are named as authors on publications generated from the use of the Data must review and provide written comments regarding the final version of the manuscript. Determination by the Executive Committee that an individual has failed to meet these requirements will result in the individual's name being removed from the author list.

    (iii) For the sake of clarification, merely depositing Data to the Central Databases without meeting the requirements of Section 3.b.(i) and (ii) above shall not form sufficient basis for authorship.

    (iv) In case of a dispute, the Executive Committee will make the decision regarding authorship on such publications, including the order of authors. All

publications will include a list of named authors. In addition, a list of Consortium Member Investigators and their designated sub-investigators (maximum of 10 per Consortium Member) will be included in the acknowledgments as contributors to the SESTOR Consortium. Those named in this listing must meet the guidelines for acknowledgment as discussed in the aforementioned New England Journal of Medicine article.

(v) Each proposed research project will have a principal investigator (first author) defined upon the pre-submission review.

(vi) The author list order will follow a meritocratic approach. The absolute data contribution of each center will play a major role. Other aspects, such as personal additional data for non-standard projects, may influence author order and allow Sub-Investigators to be added to the publication author list.

4. ADDITION OF NEW CONSORTIUM MEMBERS: Any institution and their respective investigator(s) may apply to be a Consortium Member. All such requests shall be considered by the Executive Committee. All centers must possess the following attributes and be approved by a 2/3 majority of the Executive Committee:

    a. A program that passes Executive Committee approval after a trial period.

    b. The ability to obtain IRB approval.

    c. Successful execution of the Data Consortium Agreement

5. REVISION OF CONSORTIUM BY LAWS.

    a. Any amendment or revision of the Consortium By Laws requires approval by 2/3 majority of the Executive Committee.

    b. Any revision or amendment to section 3 pertaining to Publication requires revision of the Data Consortium Agreement in addition to approval by 2/3 majority of the Executive Committee.

NOTES:

- Quarterly performance reports that can be used for hospitals feedback on areas of improvement, recertification purposes, etc.
- How to include authors and define order of authorship:
    - Number of authors per center according to participation
    - Number of patients as a criteria to number and order of authors.
    - Quality of data – all the mandatory data must be entered!

- Monitoring of sites for the inclusion of all consecutive cases. Must be audited.
- Raul to send the IRB
- Authorship Criteria Committee:
    - Fareed
    - Sunil
    - David
    - Raul
    - Diogo