



PUBLICATIONS COMMITTEE CHARTER

The International Spontaneous Coronary Artery Dissection Registry

Version 2.0


23 April 2019

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Signature Page

Steering Committee



 Esther S.H. Kim, M.D.
 Steering Committee Chair

5/13/2019

 Date

Steering Committee

 Malissa Wood, M.D.
 Steering Committee Member

 Date

Steering Committee

 Sahar Naderi, M.D.
 Steering Committee Member

 Date

Steering Committee

 Katherine Leon
 Steering Committee Member

 Date

Coordinating Center

 C. Michael Gibson, M.S., M.D.
 Coordinating Center Representative

 Date

Signature Page

Steering Committee

Esther S.H. Kim, M.D.
Steering Committee Chair

Date

Steering Committee

Malissa Wood
Malissa Wood, M.D.
Steering Committee Member

5/15/19
Date

Steering Committee

Sahar Naderi, M.D.
Steering Committee Member

Date

Steering Committee

Katherine Leon
Steering Committee Member

Date

Coordinating Center

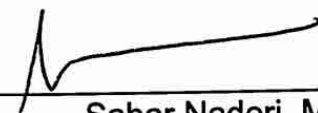
C. Michael Gibson, M.S., M.D.
Coordinating Center Representative

Date

Signature Page

Steering Committee	_____	_____
	Esther S.H. Kim, M.D. Steering Committee Chair	Date

Steering Committee	_____	_____
	Malissa Wood, M.D. Steering Committee Member	Date

Steering Committee	_____	7/2/19
	 Sahar Naderi, M.D. Steering Committee Member	Date

Steering Committee	_____	_____
	Katherine Leon Steering Committee Member	Date

Coordinating Center	_____	_____
	C. Michael Gibson, M.S., M.D. Coordinating Center Representative	Date

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Steering Committee	<hr/> Sahar Naderi, M.D. Steering Committee Member	<hr/> Date
Steering Committee	<hr/>  Katherine Leon Steering Committee Member	<hr/> 5/27/2019 Date
Coordinating Center	<hr/> C. Michael Gibson, M.S., M.D. Coordinating Center Representative	<hr/> Date

Signature Page

Steering Committee	_____ Esther S.H. Kim, M.D. Steering Committee Chair	_____ Date
Steering Committee	_____ Malissa Wood, M.D. Steering Committee Member	_____ Date
Steering Committee	_____ Sahar Naderi, M.D. Steering Committee Member	_____ Date
Steering Committee	_____ Katherine Leon Steering Committee Member	_____ Date
Coordinating Center	_____  C. Michael Gibson, M.S., M.D. Coordinating Center Representative	<u>5/29/19</u> Date

Document Administration

Document Name

Document Name	Publications Committee Charter
Protocol Name	The International Spontaneous Coronary Artery Dissection Registry

Version History

Date	Version
10 December 2018	1.0
23 April 2019	2.0

1. Overview

The purpose of this Publications Committee Charter is to outline and describe the roles and responsibilities of the Publications Committee and to identify the members of the committee who will provide academic leadership regarding publications associated with the iSCAD Registry.

2. Publications Committee

2.1 Purpose, Roles, and Responsibilities

The purpose of the Publications Committee is to develop and to oversee publications to support the registry's academic mission to advance the science of SCAD.

The roles and responsibilities of the Publications Committee are:

- To develop and to recommend strategic direction regarding publications associated with the registry
- To ensure that publications meet the appropriate level of quality assurance and preserve the scientific integrity of the registry
- To provide peer review of abstracts, presentations, and manuscripts for national and international scientific meetings
- To facilitate and monitor publication timelines, ensuring Sponsor disclosure rules are applied prior to publication
- To adjudicate authorship when necessary
- To hold regularly scheduled meetings either in-person or by teleconference to achieve Committee objectives

2.2 Committee Membership and Selection

The Publications Committee consists of Chairpersons, Committee Members and representatives of the Sponsor. Total membership should not exceed nine Committee members.

The iSCAD Registry Steering Committee members qualify for participation in the Publications Committee. Publications Committee members and their institutional affiliations are found in Table 1.

Table 1: Publications Committee Members

Name	Institutional Affiliation
Esther S.H. Kim, M.D., M.P.H	Vanderbilt University Medical Center
Malissa Wood, M.D.	Massachusetts General Hospital
Sahar Naderi, M.D.	Kaiser Permanente
Katherine Leon	SCAD Alliance
C. Michael Gibson, M.S., M.D.	PERFUSE Study Group/Beth Israel Deaconess Medical Center, Harvard Medical School
Ad Hoc Member (Working Group Chair)	By invitation based on proposal topic

3. Specific Committee Operations

SCAD Alliance, the Sponsor, and PERFUSE Study Group, the data coordinating center, are committed to the widespread dissemination of all primary, secondary, and tertiary analyses. As such, a top priority at the conclusion of the registry will be a multicenter abstract reporting the primary results of the registry that will be prepared by the Steering Committee. This will be the first scientific disclosure of the registry results.

3.1 Project Proposals

The Steering Committee has compiled a list of topics for manuscripts for the Registry. Authorship of these manuscripts will include all Steering Committee members with first and senior author positions taken by members of the Steering Committee. Remaining authorship spots will be occupied by the Principal Investigators (PIs) of the highest enrolling sites, up to the limit of authors set by the journal.

Project proposals may be proposed by all active site investigators at any time during the development and conduct of the registry. Active sites are those that have enrolled at least five patients over the previous year. Project proposals will be submitted to the Publications Committee Chairperson, who will review and disseminate the proposal to

Publications Committee Members. If the proposed project topic has not been addressed by iSCAD's previously published manuscripts, ongoing projects, and previous proposals, the proposing investigator will be asked to submit the following in the proposal:

- Name and institutional affiliation
- Anticipated collaborators external to the Publications Committee
- The hypothesis of the proposal
- The background and methods related to the hypothesis
- Proposed journal and/or medical/scientific meeting for presentation of results (if applicable)
- The scope of work related to the proposal including an analysis plan that describes the data to be analyzed, statistical methodology, and any corresponding key tables or figures to be prepared by statisticians
- References
- It is at the discretion of the lead author to include any other supporting materials in the proposal.

The Publications Committee members will vote to approve, to provisionally approve pending modification, or to reject the proposal. With approval, the author will move forward with the Committee recommendation and continue to develop the publication.

3.2 Data Analysis and Oversight

Once approved, the analyses described above will be completed by the PERFUSE Study Group statisticians in conjunction with the lead author or delegate, as appropriate. Any discrepancies will be resolved by consensus between the Publications Committee and the lead author.

The dataset does not leave the coordinating center. Authors will receive aggregate data, analyzed per the approved project proposal. The Publications Committee will oversee communication of analysis findings and/or publication in order to protect the integrity of the registry.

3.3 Manuscript Preparation

A first draft will be prepared and circulated by the author to the Publications Committee members. This shall be sent at least 30 calendar days in advance of the submission date to the journal and at least 20 days in advance for abstracts. Publications Committee Members will provide feedback within 14 days of receipt of the draft manuscript or abstract for the first author to review and incorporate as necessary. All publications will also be reviewed by co-authors assigned by the Publications Committee prior to submission.

Priorities in selecting journals and forums for publication will be given to peer-reviewed scientific journals. Presentations and publications for national and international scientific meetings will also take precedence.

3.4 Manuscript Submission

Abstracts and manuscripts will be submitted by the first or senior author. Manuscripts are expected to be submitted within 60 calendar days of analyzed data receipt. The Publications Committee may re-assign first or senior/corresponding authorship for manuscripts not submitted by this deadline.

3.5 Authorship

The iSCAD Publications Committee will make every effort to recognize the effort of site principal investigators and co-investigators.

The Steering Committee has compiled a list of topics for manuscripts for the Registry. Authorship of these manuscripts will include all Steering Committee members with first and senior author positions taken by members of the Steering Committee. Remaining authorship spots will be occupied by the PIs of the highest enrolling sites, up to the limit of authors set by the journal.

For manuscripts covering original topics not originally formulated by the Steering Committee, first authorship is given to the proposing author, as long as the proposing author is an investigator in an actively enrolling site (a site is considered active if it has enrolled at least 5 patients over the previous year), or unless other arrangements are agreed upon by the proposing author and Publications Committee. The senior author will be a highly active iSCAD Registry Member, often a current Steering Committee member or a Working Group member with expertise on the topic. Authorship decisions will be within the purview of the publications committee and will be based on substantive contributions to the iSCAD Registry.

Up to 15-16 authors will be assigned to an abstract or manuscript, as limited by the conference or journal. Founding members of the iSCAD Registry will be listed on all iSCAD publications. Working group chairs will be listed on all topic group-specific publications. Statistical support provided by the PERFUSE Study Group will also be recognized through authorship. For the remaining authorship spots, each site will be ordered based a score which takes into account enrollment, data completion, and follow-up data completion. Sites with the highest scores will be given remaining authorship spots. Outcomes manuscripts will weigh follow-up data completion with a higher factor to recognize sites completing follow-up data. Site Principal Investigators may allocate their authorship spot to another active investigator at their center. The decision to include

more than one author from a site will be at the discretion of the publications committee and will generally be considered if the proposed second author is a significant contributor to the work of the Registry or is a significant enroller of patients.

Authorship may also be granted to investigators based on additional expertise or contributions not recognized by the scoring system. For example, study methodology manuscripts will include members of the coordinating center.

If the proposal for a manuscript is truly a collaborative effort, the Publications Committee will vet who should be the lead author and senior author on the publication, taking into consideration registry contribution, writing experience, and the relevant analyses.

Publication or presentation of registry data without adhering to publication policies as described in this charter is not permitted without written consent from the Publications Committee.