Study Proposal Form SOCA

Purpose: To describe the design, methods, analysis plan, and resources of the proposed study.

When: Whenever a study is proposed that involves SOCA centers, SOCA participants, SOCA staff, or other SOCA resources.

Completed by: Investigator proposing a study.

Instructions: Please refer to the SOCA website for help in completing this form (http://www.lsoca.com). The study director should sign the completed SOCA Study Proposal form and send it, along with any supporting materials, to: SOCA Chairman's Office, Department of Ophthalmology, Mount Sinai School of Medicine, Box 1183, One Gustave L. Levy Place, New York, NY 10029-6574. After review, the Chairman's Office will notify the study director of the decision made and any changes necessary.

SOCA Chairman's Office use only:

Study ID: __ __ __ __ (Sequential numbering of all studies using leading zeros)
Date proposal received: _____
Date reviewed by Study Officers: _____
Recommendation: Approve ( ) Reject ( ) Approve with revisions ( )
Date reviewed by Steering Committee: _____
Decision: Approved ( ) Rejected ( ) Approved with revisions ( )
Date study director notified by SOCA Chairman's Office: _____
Date approved Study Proposal form sent to CC: _____

SOCA Coordinating Center use only:

Date approved Study Proposal form received at CC: _____
Date received copy of submission to study director's local IRB, including protocol and approved consent statement: _____
Date received letter of approval from study director's local IRB: _____

Please ensure that the CC receives a copy of this form and any subsequent revisions. The CC will maintain this form in the official SOCA file.

A. Administrative information

1. Proposed study director: _____

2. Proposed study investigators (name, affiliation/SOCA center): _____

_____

3. Address: _____

4. Phone: _____

5. Fax #: _____

6. Email: _____

7. Other collaborating institutions/SOCA centers? (yes) (no)

→ 8.

If yes:

a. List institutions/SOCA centers:

_____

b. Has written approval been obtained from all institutions/SOCA centers? (yes) (no)

→ Attach letters of agreement.

B. Study design

8. Proposed study title (and acronym): _____

_____ (_____)

9. Study objective: _____

_____

_____

10. Estimated duration of study: _____

11. ABSTRACT: Write a description of the research design and methods for achieving the study objectives. Append additional page(s), if needed.

12. Describe the proposed analysis including anticipated tables and graphs. Append additional page(s), if needed.

C. Overlap with other SOCA studies

13. To your knowledge, does the study overlap with any other SOCA studies or publication proposals? (yes) (no) → 14.

a. Which studies/publication proposals? _____

_____

b. Have you discussed the overlap with the investigator? (specify results of discussion): _____

_____

_____

c. How will you deal with the overlap? _____

_____

_____

D. SOCA resources

14. Does the study involve SOCA participants? (yes) (no) → 15.

a. Number of participants and SOCA study(s) involved: _____

_____

b. How will participants be selected for inclusion: _____

_____

c. Impact on participants' involvement in SOCA, if applicable: _____

_____

15. Does this study require access to previously collected SOCA data items? (yes) (no)

If yes, describe by specifying the relevant photographs, forms and items on the forms below or attach copies of the forms with the items circled. Indicate how these data will be obtained and how confidentiality will be assured.

_____

_____

_____

_____

_____

_____

16. Does the study require access to banked SOCA specimens? (yes) (no)

If yes, briefly summarize your specimen requirements (type of specimens, number of patients, number of specimens per patient, study population characteristics).

17. Does the study require new data to be collected from SOCA participants? (yes) (no)

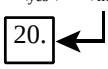
If yes, specify the type of data to be collected and the collection procedure. Specify impact for ongoing SOCA data collection.

18. Does this study require any other SOCA resources, including staff, equipment, space, or data or general analysis help from the SOCA Coordinating Center? (yes) (no)

If yes, please explain:

E. Funding and IRB

19. Is the project contingent upon additional funding? (yes) (no)

If yes, 

( ) Funding is available (list source and amount):

( ) Request for added funding pending (list agency approached for funding and amount requested):

20. Has this proposal been reviewed and approved by your IRB? (yes) (no)

20a. ← (yes) 20b. ← (no)

a. If yes, date approved (e.g., 01 Jan 03):

__ __ - __ __ __ - __ __
day month year

b. If no, Status of IRB approval:

( ) Pending

( ) Not submitted (specify why not) _____

_____

c. Will the study have a consent statement? (yes) (no)

Send a copy of your submission to and approval from the local IRB for this study, including the study protocol and approved consent statement to: SOCA Coordinating Center, Bloomberg School of Public Health, Room 5010, 615 North Wolfe Street, Baltimore, MD 21205.

F. Sign off

21. Attachments to this form:

( ) _____

( ) _____

( ) _____

22. Date this study proposal submitted to SOCA Chairman's Office:

__ __ - __ __ __ - __ __
day month year

- I understand that a summary of this study may be presented on the SOCA website, if approved.
- I understand that prior to submitting any publication related to this study, I may be required to submit a copy for review by the SOCA Study Officers.
- I understand that any presentations or publications from this study may be required to credit the SOCA Research Group.

23. Signature of study director: _____