

## **ANALYSIS AND PUBLICATION GUIDELINES FOR THE CARES (CARDIAC ARREST REGISTRY TO ENHANCE SURVIVAL) PROGRAM**

### **The Data Sharing Committee**

#### **I. GOALS and PURPOSE**

The purpose of this committee is:

1. To assure and expedite orderly and timely presentation to the scientific community of all pertinent data resulting from the collaborative CARES Program;
2. To promote accurate and scientifically sound presentations and papers from the collaborative CARES Program and its collaborating investigators;
3. To assure that all participating investigators have the opportunity to be involved in the preparation of collaborative CARES papers and presentations;
4. To assure that press releases, interviews, presentations, and publications are accurate and objective, and do not compromise the collaborative registry and the acceptance of its results;
5. To establish guidelines for authorship, acknowledgements, and funding citations for any presentations and publications of the collaborative CARES Program; and
6. To maintain a record of proposed and published papers and presentations from the CARES Program.

#### **II. SCOPE OF THE GUIDELINES**

This policy covers papers, abstracts, and presentations that involve unpublished data collected by the CARES Program and compiled at the Department of Emergency Medicine at the Emory University School of Medicine (Atlanta, Georgia). Participating sites vary depending on the year of initial data collection. The data covered by these guidelines include all registry data associated with the collaborative CARES Program. These guidelines should be followed for any analyses or writing projects involving combined data from two or more sites. Analysis projects that involve data from only one site may be shared among the committee members for informational purposes but will not require approval. These policies will remain in effect until the Data Sharing Committee is formally dissolved.

#### **III. MEMBERS OF THE DATA SHARING COMMITTEE**

1. Members of the Data Sharing Committee will include 5 representatives from the pool of participating sites and 1 representative from Emory University. Membership of the Data Sharing Committee may vary depending on the data being analyzed.

2. The Emory representative to the Data Sharing Committee will serve as the administrator/coordinator of the committee. All correspondence to the committee, including project proposals, abstracts, and manuscripts will be sent to Emory for distribution to the Committee members. Committee members from each site will be responsible for sharing documents submitted to the committee with their site staff in order to inform them about proposed projects and to obtain their feedback.

#### **IV. APPROVAL OF PROJECTS FOR ANALYSIS AND PUBLICATION**

##### **A. Approval of Collaborative Project Proposals for Analysis and Writing**

1. To initiate an analysis and writing project, the investigators should prepare a 2-5 page proposal. The proposal should include: 1) investigators with lead investigator noted; 2) objectives, aim or hypothesis; 3) background with relevant references; 4) methods describing - a) specific outcomes of interest, b) explanatory variables of interest, c) analysis plan with power calculations if relevant, and d) other data collection or record matching if relevant. If particular expertise (i.e. statistics, epidemiology or cardiology) will be required for the analysis, plans for obtaining this should be noted in the proposal. The proposal should be submitted to the Data Sharing Committee via the Emory administrator.

The Emory administrator will distribute the proposal to all committee members for review. The Committee members will review the proposal to determine that it is scientifically sound and that the scope of the analysis is reasonable. The committee members may also make suggestions for collaboration with other sites' investigators or comment if there are conflicts with existing analyses being conducted by other sites' investigators. The review of proposals will deal mainly with scientific content.

2. Committee members will review the proposals using the form in Appendix A and will send the form to the Emory administrator by e-mail. If there are no concerns or issues raised, the Emory administrator will inform the investigator that the committee has approved their proposal. Any comments or suggestions for improving the analyses will be sent to the lead investigator as well. If there are minor issues raised by the committee members, an attempt will be made to resolve these by e-mail discussions among the committee members. If there are major areas of concern, the Emory administrator will schedule a conference call for the committee to discuss the issues. If the proposal is approved, lead authors must obtain IRB approval from their institutions within 4 months of Emory providing the dataset for analysis. A copy of the IRB approval must be shared with the CARES Data Sharing Coordinator. The committee will respond to the investigators within four weeks of the submission of the proposal unless issues are raised that require further discussion.
3. After approval of the proposal by the Data Sharing Committee, the CARES Data Sharing Coordinator will provide the requested de-identified dataset specific to the study proposal. The Data Sharing Coordinator will schedule a webinar with the study investigators and affiliated statistical staff to review the dataset and answer questions about interpretation of the CARES elements. Prior to receipt of the CARES dataset, information recipients must sign and return the CARES Non-Disclosure Agreement.
4. Proposals that are disapproved may be revised and resubmitted to the Committee.

## **B. Approval of Collaborative CARES Abstracts and Manuscripts**

1. Abstracts for presentations at scientific meetings and manuscripts of collaborative CARES Program results should be sent to the Data Sharing Committee for approval prior to submission. The abstract or manuscript should be submitted to the Data Sharing Committee via the Emory administrator. The committee will respond to the investigators within two weeks of submission for abstracts and within four weeks of submission for manuscripts unless issues are raised that require further discussion.
2. The Emory administrator will distribute the abstract or manuscript to all committee members for review. The Committee members will review the abstracts or manuscripts to determine that they are accurate, scientifically sound, and do not compromise the collaborative registry.
3. Committee members will review the abstracts or manuscripts using the form in Appendix B and will send the form to the Emory administrator by e-mail. If there are no concerns or issues raised, the Emory administrator will inform the investigator that the committee has approved their abstract or manuscript. Any comments or suggestions for improving the document will be sent to the lead investigator as well. If there are minor issues raised by the committee members, an attempt will be made to resolve these by e-mail discussions among the committee members. If there are major areas of concern, the Emory administrator will schedule a conference call for the committee to discuss the issues.
4. Under very limited circumstances, the Emory administrators of the Data Sharing Committee may call for an expedited review of an abstract or manuscript. Requests for an expedited review should be submitted to the committee with justification for the need to expedite the review.
5. Abstract or presentation proposals should be followed up with a submission within three months of the date that the dataset is provided. Papers should be submitted for review within nine months of the date that the dataset is provided. Proposals that are not followed by a submission within this time frame must be resubmitted. The CARES Data Sharing Coordinator will send reminder emails at one, three, and six months from the date the dataset is provided.
6. Abstracts or manuscripts that are disapproved may be revised and resubmitted to the Committee.
7. It is the responsibility of the lead investigator to determine if a re-review of a manuscript by the Data Sharing Committee is necessary when peer review requires substantial revision of the manuscript.
8. A copy of accepted abstracts and manuscripts should be sent to the Data Sharing Committee for the record.

## **V. AUTHORSHIP**

1. Authors who participate in the writing of a manuscript from the collaborative CARES Program should do so in accordance with the International Committee of Medical Journal Editors guidelines (JAMA 1997; 277(11): 927-934).
2. All manuscripts written using collaborative CARES data will use the following format to list authorship:
  - a. Individual authors of the manuscript will be listed first.
  - b. All manuscripts should include the words “and the CARES Surveillance Group” in the authorship line following the individual authors (e.g. Schwamm L, George M, Matters M, and the CARES Surveillance Group).
  - c. All papers in the "Acknowledgement" section should reference the CARES participating sites by providing the web link <https://mycares.net/sitepages/map.jsp>.
3. First Authorship
  - a. First authors will usually be CARES investigators. Other scientists may serve as first authors if at least one other CARES investigator serves as a co-author and "sponsor" of the project and the scientist has played a major role in the data analysis and writing for the paper.
  - b. Conflicts about first authorship should be resolved, if at all possible, by members of the analysis/writing group. In case the group is unable to resolve a conflict among the states, the Data Sharing Committee will adjudicate and may assign first authorship.
  - c. If progress on a given project is unduly slow, the Data Sharing Committee may request an explanation from the lead investigator. If timely progress is not likely to occur in the near future, the Data Sharing Committee may, at its discretion, assign a new lead investigator to the project.
4. Co-Authorship
  - a. The first author should determine the order of authorship on a paper. In general, authors will appear in order of contribution to the writing and analysis of the paper.
  - b. If conflicts regarding the order of authorship cannot be resolved by the analysis/writing group, the Data Sharing Committee will adjudicate and may assign order.

## **VI. DATA SHARING WORKING GROUPS**

1. Working Groups will be formed of interested medical directors from the sites for specific

topics. These groups will be formed on an ad hoc basis.

2. The primary role of the Working Groups will be to develop comprehensive analysis plans, to be informed about the current state of knowledge in the specific topic area, and to discuss how the activities might be shared among the interested collaborators. The Working Groups will meet regularly by phone and occasionally in-person and will create reports to keep the rest of the sites' collaborators informed about findings and progress in the specific topic area.
3. A minor role of these groups will be to discuss proposals that are in conflict or overlap for the specific topic area. The Working Group may help the investigators reach agreement as to how the projects will be apportioned to the interested sites. The Data Sharing Committee, however, has the ultimate responsibility for working out any conflicts between sites' investigators.

## **VII. AVAILABILITY AND ANALYSIS OF DATA BY OUTSIDE RESEARCHERS**

1. The availability of the data to outside investigators will be contingent on approval from the Data Sharing Committee. Requests for CARES data and their analyses will be submitted to the Data Sharing Committee as described in the guidelines.
2. The Data Sharing Committee will determine the format of the public use dataset and will specify the variables which are to be included in the database.





Review of CARES Abstracts or Manuscripts

Title of Document: \_\_\_\_\_

Lead Author: \_\_\_\_\_

Site: \_\_\_\_\_

Date reviewed: \_\_\_\_\_

Reviewed by: \_\_\_\_\_

Site: \_\_\_\_\_

1. Investigators with lead investigator noted      yes\_\_\_      no\_\_\_      NA\_\_\_  
Comment:

2. Comments on scientific aspects of the document:

3. Comments on other issues (e.g. authorship, conflict with other CARES analyses, etc):

APPROVE   

DISAPPROVE   

RESUBMIT