

REGARDS

REasons for GEographic ANd RAcial DIfferences in STroke



PUBLICATIONS and PRESENTATIONS (P&P)
Policies and Procedures

Version 4.0
March 1, 2010

Outline

REGARDS Publications and Presentations (P&P) Policies and Procedures

Version 4.0, March 1, 2010

Key Points of P&P Policies and Procedures

Introduction and Types of Manuscripts

I Objectives

II Procedures

A. Basic Elements and Procedures for Submission of a Manuscript Proposal

B. Types of Studies: Main vs. Ancillary

C. Location of Analyses: Central vs. Local

D. Formation of Writing Group

E. Assigning Priorities for Analyses

F. Writing Group Responsibilities

G. Schedule for Manuscript Preparation

H. Guidelines for Investigators Using UAB Statistical and Data Coordinating Center for Analyses

I. Preparation and Submission of Abstracts Based on Approved Manuscript Proposals

III Appendices

A. Manuscript Proposal Form (available as msword document upon request)

B. Data Distribution and Use Agreement

C. Checklist for Requesting Dataset for Local Analyses

D. Required Acknowledgements Section for all Manuscripts

Key Points of REGARDS Publications and Presentations (P&P)
Policies and Procedures
Version 4.0, March 1, 2010

- Manuscripts and papers based on the REGARDS data are welcomed.
- Manuscript proposals are required for all papers and abstracts that use REGARDS data, including ancillary studies. For proposals requesting use of longitudinal or event data, please contact the REGARDS Administrator at regards_admin@uab.edu for further instructions.
- Please review all sections of these P&P Policies and Procedures prior to submission of a manuscript proposal.
- A Manuscript Proposal Form (see Appendix) must be submitted to and reviewed by the Executive Committee (EC).
 - The lead author must send an email confirmation to the REGARDS Administrator stating that the manuscript proposal has been approved by all co-authors and a copy of the final proposal should be attached.
 - Approval status and comments (if any) will be returned to the lead author.
 - If proposal is not approved, the revised proposal should be re-submitted to the EC with point-by-point responses to major comments.
- Abstracts, manuscripts, and presentations:
 - Must be based on active manuscript proposals or submitted papers.
 - Must not be submitted to any organization or journal for consideration without approval of the REGARDS EC and sign-off from all co-authors.
 - While exceptions can be made, it is strongly advised that the EC be provided at least two weeks for review, permitting time for questions to be addressed in the most constructive environment.
 - Please let the REGARDS administrator know whether or not the abstract/paper was accepted.
 - If the abstract is accepted, a copy of presentation materials (power point slides or poster) must be submitted to the EC for review at least two weeks prior to production or presentation. The lead author must send an email confirmation to the REGARDS Administrator stating that the poster/slide presentation has been approved by all co-authors and a copy of the final poster/slides should be attached. An exception to this is for a presentation that is based on a manuscript that has already been reviewed and approved by the EC.
 - Previously approved abstracts/manuscripts may be re-submitted or “recycled” to a second meeting/journal without undergoing a second EC Review process. The lead author should send an email informational note to the REGARDS Administrator. A copy of the abstract /manuscript/ presentation/ poster should be included if it was revised. While no additional review is required by the EC, it is expected that co-authors will have approved any major re-writes.

- All presentations (slides and posters) and manuscripts must include the acknowledgement of NINDS support (see Appendix for wording.)
 - A copy or PDF of the published or web-access abstract or manuscript with reference citation should be provided to the study through the REGARDS administrator at regards_admin@uab.edu.
 - Ancillary study abstracts, presentations, and manuscripts may have additional requirements for review and approval by ancillary study investigators.
- Additional policies related to manuscripts:
 - If new hypotheses or research questions arise during preparation of an approved manuscript, an amended manuscript proposal must be submitted to the EC. In some cases, a new manuscript proposal should be considered.
 - The Writing Group will have 6 months to prepare first draft of manuscript.
 - For completed manuscripts, the penultimate draft should be sent to the Executive Committee with a cover letter stating that this penultimate draft is ready for review, that it has been reviewed and approved by all co-authors, and indication of what journal is intended for submission.
 - If a manuscript is not approved by the Executive Committee, comments will be returned to the lead author indicating the necessary revisions before resubmission. The revised manuscript should be re-submitted to the Executive Committee with point-by-point responses to major comments, similar to what is done for standard re-submission to a journal after initial review.
 - When the manuscript is accepted, the EC asks that a copy of the accepted manuscript be submitted to the REGARDS Administrator. This will be forwarded confidentially to the NINDS project officer for consideration of preparation of media coverage.
 - A copy or link to the published PDF of the manuscript should be emailed to regards_admin@uab.edu.
 - Writing group chair must comply with the NIH Public Access Policy. Contact the REGARDS Administrator if assistance is needed.
- Location of Data Analyses:
 - Data analyses can be conducted at either the UAB REGARDS Statistical and Data Coordinating Center (SDCC) (centrally) or off-site (locally) according to P&P Policies and Procedures described herein. Currently, **local (off-site) analyses are restricted to REGARDS investigators or investigators from approved and funded ancillary studies.**
 - For local, non-UAB analyses, after the manuscript proposal is approved, a limited use dataset will be provided upon submission of a signed data use agreement and documentation of local IRB review.
 - Graduate students at UAB may request a dataset for analyses according to P&P Policies and Procedures described herein.

All correspondence for manuscript proposals, abstracts or manuscripts should be submitted to regards_admin@uab.edu

REGARDS Publications and Presentations Policies

Version 4.0, March 1, 2010

Introduction and Types of Manuscripts

The purpose of the policies established herein is to encourage and facilitate important analyses, while providing guidelines that ensure appropriate use of the data from the REasons for Geographic and Racial Differences in Stroke (REGARDS) study, timely completion of projects, and adherence to the principles of authorship. Note that manuscript proposals are required for all papers and abstracts that use REGARDS data, including ancillary studies.

Because of the relatively small number of REGARDS investigators in the parent study, these policies are currently under the direction of the Executive Committee rather than a separate “Publications and Presentations Committee” as is normally found in national cardiovascular epidemiology studies; however, this is subject to change.

The REGARDS investigators consider potential publications as falling into four broad categories:

- 1) *Methodological Papers*: Methodological papers will describe the approaches used to assemble and evaluate the cohort. Methodological papers also include manuscripts that develop new statistical methodology.
- 2) *Cross-sectional Papers*: Cross-sectional papers will focus on reporting data collected as part of the baseline evaluation. Within this category, papers will focus on the description of the distribution of risk factors, differences between groups (including races) in the distribution of risk factors, and the association between risk factors. An individual manuscript may include only “complete participants,” i.e., participants who completed both the CATI baseline as well as the in-person exam (for whom we have signed informed consent) or “partial participants,” participants who gave verbal consent over the telephone but in-person exams were not completed (for various reasons.) This will depend on the hypotheses and variables being investigated.
- 3) *Longitudinal Papers*: Longitudinal papers will focus on the association of baseline characteristics with data collected during follow-up of the REGARDS cohort. This includes such data as stroke symptoms, hospitalizations, cognitive assessment, for example.
- 4) *Event data* – These data include adjudicated stroke events, MI events, other vascular events, all-cause mortality and adjudicated causes of death. For further information on use of these data, please contact the REGARDS administrator through regards_admin@uab.edu.

I. Objectives

- To stimulate the scientific abstracts, presentations and manuscripts from REGARDS and other investigators;
- To ensure and expedite orderly and timely reports to the scientific community of all pertinent information resulting from REGARDS;
- To ensure that abstracts, presentations, and publications based on REGARDS material are accurate and objective, and do not compromise the scientific integrity of this collective study;
- To ensure that all investigators within REGARDS, particularly those of junior rank, have the opportunity to participate and be recognized in the study-wide REGARDS papers;
- To establish procedures that allow the REGARDS Executive Committee to exercise review responsibility in a timely fashion for REGARDS publications and presentations;
- To encourage manuscripts based on the information collected from all REGARDS participating institutions and organizations; and
- To prevent overlap of published material and duplication of analyses.

II. Procedures

A. Basic Elements and Procedures for Submission of a Manuscript Proposal for a Paper or Abstract

Manuscript proposals are required for all papers that use REGARDS data, including data from ancillary studies. Abstracts and presentations must be based on active manuscript proposals or submitted papers.

A formal manuscript proposal must be submitted to the Executive Committee through the REGARDS Administrator via email (regards_admin@uab.edu), using the “Manuscript Proposal Form Template.” This form (found in Appendix) has several parts. The proposal must include the following “Summary Information” in Part I:

- Date submitted to the Executive Committee
- Proposal title
- Abbreviated Title
- Authors (including REGARDS sponsor/mentor/investigator if first author is not either a REGARDS investigator or a REGARDS ancillary-study PI)
- Complete contact information for lead author and email addresses of all co-authors
- Potential overlap with other REGARDS manuscript(s)
- Type of Data (events, longitudinal, cross-sectional, methods)
- Type of Study (Main or Ancillary Study, Title & PI if Ancillary study)
- Data Analysis location (UAB Statistical and Data Coordinating Center (SDCC) centrally or off-site, i.e., locally) *Note: If plans are for a non-*

- Use of Genetic Information (if applicable)
- Keywords
- Conflict of interest disclosure

Part II, the scientific “Proposal Details” should be summarized in the proposal template. Proposal Details should include the following in 2-3 pages:

- Introduction (Rationale and background, brief)
- Research Hypothesis (Clearly state scientific questions to be addressed)
- Data (List variables to be used, sample inclusions/exclusions)
- Analysis plan and methods (Give detailed description of proposed statistical analyses)
 - o If plans are for a local (off-site) vs. central (UAB SDCC) statistician to perform the statistical analyses, additional details are required (see below Section II.C. Location of Analyses – Central vs. Local.)
- Summary and conclusions
- References

The proposed co-authors as identified on the Manuscript Proposal Form **must** have reviewed and approved the proposal prior to it being submitted to the Executive Committee. Although not required, it is recommended that a REGARDS investigator be among the co-authors.

For the first manuscript proposal submitted by a non-REGARDS investigator, a brief paragraph/letter of introduction must be provided, indicating background and credentials, and the name of the REGARDS investigator who is the sponsor.

It is recommended that the writing group chair have conversations with someone at the REGARDS SDCC or other study site in the development of the manuscript proposal, to include potential for overlap with other proposals, availability of data variables and detailed analysis plans. Contact regards_admin@uab.edu for assistance. A listing of submitted or pending manuscript proposals is maintained at the SDCC and can be checked in advance to help investigators determine overlap. In cases of potential overlap, a REGARDS investigator will contact the lead author for further discussion and resolution.

Upon receipt of the manuscript proposal by the REGARDS administrative assistant, the proposal will be assigned a number and entered in the Manuscript Proposal Tracking Log. The administrative assistant will review the proposal to verify that the proposal format has been followed and confirm potential overlap with any other papers or abstracts, proposed or in progress, has been addressed. The administrative assistant will also notify the co-authors that a manuscript proposal has been submitted with their name as a co-author.

Depending on date of submission, the Executive Committee review usually takes less than 2 weeks. The results of the Executive Committee review will be summarized and reported back to the lead author. If the proposal is not approved but significant changes could be made to address the Committee's comments, a revised proposal with point by point responses to the review concerns will need to be submitted to the REGARDS Administrator (regards_admin@uab.edu) for re-review by the Executive Committee. If the proposal receives conditional approval, a revised proposal with point by point responses to the Committee's concerns should be submitted to the REGARDS Administrator for tracking purposes. These instructions will be included in the email notification from the Executive Committee. Approved manuscript proposals will be tracked centrally for progress.

If the proposal is approved, the Executive Committee, in consultation with the SDCC, will determine priorities for data analyses to be performed centrally, as well as priorities for distribution of a dataset for local analyses. Individuals wishing to conduct analyses locally (at home institution) who are not funded by the parent REGARDS study will need to sign a data use agreement to obtain data (see below Section II.C. Location of Analyses – Central vs. Local for additional requirements for these manuscript proposals.) Currently, **local (off-site) analyses are restricted to REGARDS investigators or investigators from approved and funded ancillary studies.**

B. Types of Studies: Main vs. Ancillary -- Definitions

There are two study types: Main and Ancillary, which are defined below. Analyses for these may be done either centrally (at the SDCC) or locally.

Main Study Manuscripts:

A Main Study manuscript analyzes data collected as part of the original-funded REGARDS study.

Ancillary Study Manuscripts

Ancillary studies involve the collection of new data that were not a part of the original study protocol or the modified study protocol as approved and funded by NINDS (for example, the addition of cognitive evaluation component is not considered ancillary). These new data may have been obtained directly from participants or from previously collected samples, images, or other sources (e.g., medical records). An ancillary study derives funding from other sources than REGARDS. Examples include studies funded by investigator-initiated NIH research awards (R01s), grants from academic institutions, private sources (e.g., drug companies), or those performed at no cost (generally because of the special interest or a researcher). Ancillary study manuscript proposals will also be tracked centrally for progress; however, they will not be required to adhere to the timeline described herein.

Ancillary study manuscript proposals follow the same procedures with submission to the Executive Committee for approval; coauthor nominations are restricted to those with special expertise in the area of the proposal. Additional review and approval processes may be established by ancillary study groups and require an additional acknowledgement section for the manuscript.

Ancillary study analyses may be done either centrally (at the SDCC, provided funding for this has been provided for within the ancillary study) or locally.

C. Location of Analyses – Central vs. Local -- Definitions

1. Central – by SDCC at UAB. Data for these papers are analyzed by personnel affiliated with the SDCC. Priority for these analyses will be assigned by the REGARDS Executive Committee. Assignment of specific statisticians will be done by the Statistical Team Leader (STL) at the SDCC. The STL will contact the writing group chair and introduce him/her to the statistician conducting the analyses for the paper and will work with the statistician and writing group chair to develop a timeline for analyses. The writing group chair will be encouraged to prepare draft table shells to facilitate communications with the statistician.
2. Local – by non-REGARDS investigators. Data for these papers are analyzed by individuals not affiliated with the SDCC. **Currently, local (off-site) analyses are restricted to REGARDS investigators or investigators from approved and funded ancillary studies.**

The writing group chair must include in the manuscript proposal a brief paragraph describing the credentials of the data analyst indicating their ability to conduct the analyses locally, and a detailed description of the analyses proposed. During this time, access to the REGARDS data dictionary will be provided.

Following approval of the manuscript proposal (that includes a listing of variables needed), the writing group chair will be sent the Data Use Agreement (see Appendix) for the proposed analyses. Only the writing chair needs to sign the data use agreement. This will constitute an understanding that the writing group chair has responsibility for the appropriate use of the data. (It is acceptable to have a statistician or student perform the data analysis with appropriate IRB review from the writing group chair's home institution.)

The UAB IRB has determined that the de-identified data that are shared with members of research communities outside of UAB for the purposes of manuscript preparation does not constitute data involving human subjects under the definition of the Office for Human Research Protections (OHRP) *Guidance on Research Involving Coded Private Information or Biological*

Specimens, October 16, 2008. The IRB suggests that researchers who receive these data as described above contact their local institutions for guidance regarding institution policies and procedures for review and approval of data.

A dataset containing the variables requested will be sent upon receipt of the signed data use agreement, and documentation from local IRB indicating approval or waiver of review for the approved manuscript proposal. If not already provided during the manuscript development period, the data dictionary and other database documentation will be provided with the dataset.

Upon completion of the manuscript, the writing group chair should send all accompanying analytic code via regards_admin@uab.edu at the same time as the submission of the final manuscript for Executive Committee review.

3. Graduate students at UAB with appropriate credentials and REGARDS sponsorship may request a dataset to perform their own analyses, following the policies and procedures described herein and summarized in the steps below:
 - Prepare manuscript proposal with REGARDS sponsor. (Access to the REGARDS data dictionary will be provided through the sponsor) Include in the manuscript proposal a brief paragraph describing credentials to conduct the analyses.
 - Submit manuscript proposal to regards_admin@uab.edu (after all co-authors have approved.)
 - When manuscript proposal has been approved, submit materials to IRB. (**Important:** contact regards_admin@uab.edu for assistance with required paperwork to be submitted to the UAB IRB.)
 - Submit documentation of IRB review/approval and list of data variables to be included in dataset to regards_admin@uab.edu

D. Formation of Writing Group

In order to ensure that all investigators have the opportunity to participate and be recognized in the main study papers, writing groups usually include investigators from several REGARDS organizational units. Writing group members for both main and ancillary study papers may be nominated by the first author and by the Executive Committee, although nomination is no guarantee of co-authorship.

Final approval of the writing group for main study manuscripts is by the Executive Committee. For both main study and ancillary study manuscripts, the Executive Committee will review the nominees to ascertain if any investigator able to significantly enhance the Writing Group should be added, or, when it is in the best interest of publication, a smaller Writing Group may also be recommended. In general, the Executive Committee expects there will be no more than eight in each writing group.

Although not required, it is recommended that at least one REGARDS investigator be among the co-authors.

Usually the manuscript proposer will be designated as the Writing Group Chairperson and first author of the paper. He/she will receive written notification and comments from Executive Committee review of the manuscript proposal including recommendations for additional Writing Group members and his/her responsibilities as chair (see below). In general, an investigator should have no more than two approved and active manuscripts in which he/she is the Writing Group Chairperson. For papers using the SDCC for analyses, a second manuscript will be eligible to start after the penultimate draft of the first manuscript is approved by the Executive Committee.

If needed, the Executive Committee will provide recommendations on standardized text to be included in manuscripts and abstracts, especially in the basic description of REGARDS, e.g., study design features, cooperation rate, etc. For manuscripts, this can be expanded to include a generic paragraph on inclusion/exclusion criteria, sampling frame, processes of the telephone/in person component, response rates, and NINDS grant acknowledgment. Contact the REGARDS Administrator (regards_admin@uab.edu) for assistance.

E. Assigning Priorities for Analyses

The REGARDS Executive Committee will determine priorities for scheduling start dates for centrally-analyzed manuscripts. Priority assignment ranges from 1 (high) to 3 (low). Manuscripts will be scheduled to start (be activated), according to their assigned priority rating, when:

- The writing group chair is available and is not chairing a writing group for any more than one other active, centrally-analyzed manuscript, and
- Necessary SDCC staff/investigators at UAB are available.

Because locally analyzed manuscript proposals require effort on the part of the SDCC in preparation of datasets and documentation, the REGARDS Executive Committee will assist in determining priorities for scheduling start dates of these manuscripts.

F. Writing Group Responsibilities

The Writing Group Chairperson is responsible for all phases of manuscript preparation, from conception through publication. These responsibilities include:

- Preparation of outlines, identification of data analyses needed, and submission of interim status reports to the Executive Committee;
- Assignment of tasks to Writing Group members with clear deadlines for completion of these tasks and determination that the tasks are completed on schedule;

- Preparation and circulation of drafts for approval by each member of the Writing Group before submission of a penultimate draft to the Executive Committee and before submission to a journal;
- Determination of the order of authorship on the manuscript. A major criterion will be the effort and contribution made by each member of the Writing Group in the preparation of the manuscript;
- Choice of a journal to which the manuscript will be submitted;
- Correspondence with co-authors, communication with the SDCC and the Executive Committee, and responses to journal editors.
- Upon acceptance/publication:
 - notification of REGARDS Administrator at regards_admin@uab.edu
 - the Executive Committee asks that a copy of the final accepted manuscript (prior to availability of galley proofs) be submitted to the REGARDS Administrator. This will be forwarded confidentially to the NINDS project officer for consideration of preparation of media coverage. (This would be in conjunction with the lead author and his/her institutional media contact.)
 - Complying with the NIH Public Access Policy and providing the PubMed Central (PMC) reference number to the REGARDS Administrative Assistant when the number is available or the NIH Manuscript Submission reference number (pending publication), or by indicating that the journal submits articles directly to PMC on behalf of authors.
- In general, following the REGARDS publications and presentations policies and procedures.

Members of the Writing Group are responsible for performance of tasks assigned by the Chairperson within the allotted time period. Each member is expected to actively participate in the preparation of the manuscript.

If a Writing Group member does not accomplish the tasks assigned to him/her and has not contributed to the manuscript, he/she may be removed from the Writing Group. The chairperson should send a letter to the Executive Committee requesting the removal of non-contributing member(s). Upon receipt of a manuscript or abstract for review by the Executive Committee, the P&P Administrative Assistant will check the co-author listing as provided on the original manuscript proposal and additional recommendations from the Executive Committee. Any discrepancies will be queried.

If the initial results lead to a split of the original paper into more than one manuscript, a brief description/explanation on this **must** be submitted to the Executive Committee. The same writing group members are usually retained on the second paper. In addition, when in the process of analysis or preparing the manuscript, newly recognized aspects of the question broaden the scope of the proposal as it was originally approved, an amended manuscript proposal **must** be submitted to the Executive Committee. Contact the REGARDS Administrator at regards_admin@uab.edu for assistance.

G. Schedule for Manuscript/Abstract Preparation

The expected schedule for the development of a manuscript is described below. Deviation from this schedule must be approved by the Executive Committee. Failure to adhere to this schedule will prompt a review of circumstances. If it is determined that a manuscript is delinquent, this could be the basis for replacing member(s) of the Writing Group responsible for the delay, or for disbanding the Writing Group.

Draft. After notification by the Executive Committee of manuscript approval and the availability of statistical analyses personnel effort for central papers, the Writing Group will have four (4) months to prepare a first draft. A first draft will consist, at a minimum, of an Introduction, Methods and Results Sections. This draft should be sent to the members of the Writing Group. It is recommended that a response deadline of 4 (four) weeks be given to Writing Group members to prevent unnecessary delays.

Penultimate Draft. The penultimate draft becomes due three (3) to six (6) months after the first draft is distributed to the Writing Group. A penultimate draft should be sufficiently developed for subsequent submission to a journal. After review and approval of the penultimate draft by Writing Group members, the penultimate draft should be sent to the Executive Committee (via regards_admin@uab.edu) with a cover letter stating that this penultimate draft is ready for review, that it has been reviewed and approved by all co-authors, and the journal it is initially being submitted to. Include the manuscript proposal number in this correspondence.

All manuscripts – whether locally or centrally analyzed—are subject to automatic withdrawal if there is no reported progress within 3 years of proposal approval.

Acknowledgments. An acknowledgement section has been prepared by the REGARDS Executive Committee to acknowledge the funding source of NINDS and the REGARDS investigators. (See Appendix) This wording is to be included in all manuscript submissions and also included in poster and PowerPoint slide presentations. If journal policy/restrictions require editing of this approved text, please contact the REGARDS administrator at regards_admin@uab.edu for guidance and consultation with a representative from the Executive Committee. For ancillary study manuscripts, Contact the PI of the ancillary study for confirmation and further information. For investigators using laboratory information from the REGARDS Renal Ancillary study (cystatin C, urinary albumin/creatinine, complete blood count, serum albumin, blood urea nitrogen), the REGARDS Renal Ancillary Study must be acknowledged (see Appendix).

Review. The Executive Committee review usually takes two weeks. The Executive Committee will review each manuscript followed by a discussion during a conference call. Afterward, the writing group chairperson will be sent a

summary of any pertinent committee comments. If a manuscript is not approved by the Executive Committee, comments will be returned to the lead author indicating the necessary revisions before resubmission to the Committee.

Journal. It is recommended that within thirty (30) days of receiving Executive Committee comments, the revised manuscript be circulated by the writing group chair to the other members of the Writing Group for final sign-off.

The Writing Group Chairperson must keep the Executive Committee and the co-authors informed as to the manuscript's progress through journal review. As soon as possible after a manuscript is accepted, please notify the REGARDS P&P Administrative Assistant so that the master listing of all REGARDS publications in press or published can be kept up to date. Upon publication of the manuscript, the Writing Group Chairperson must provide either a PDF or link to the final publication to the REGARDS Administrator (regards_admin@uab.edu).

Previously approved manuscripts may be re-submitted or "recycled" to a second meeting/journal without undergoing a second Executive Committee Review process. The lead author should send an email informational note about this to the REGARDS Administrator. No additional review is required by the EC but it is expected that co-authors will have approved any major re-writes. **If there are substantive changes made in the manuscript during journal review (major findings or conclusions, alterations of the sample, exclusion/inclusion of major covariates), the revised manuscript should be submitted to the Executive Committee for re-review following co-author re-review and approval.**

The Writing Group Chairperson must comply with the NIH Public Access Policy and provide the PubMed Central (PMC) reference number to the REGARDS Administrator when the number is available or the NIH Manuscript Submission reference number (pending publication), or indicating that the journal submits articles directly to PMC on behalf of authors. If assistance is needed in complying with the NIH Public Access Policy, please contact the REGARDS Administrator at regards_admin@uab.edu

Online sessions and Press Releases. Press releases and lay summaries for the media need not undergo Executive Committee review, but must be sent as soon as possible to the REGARDS Administrator (regards_admin@uab.edu) for notification to NINDS. Lay summaries for any audience other than the media (e.g., for participant newsletters, internal institutional newsletters, etc.) must undergo review by the Executive Committee.

H. Guidelines for investigators using UAB SDCC for data analyses.

- Plan systematically for analyses of your data;

- Communicate with the assigned SDCC representative on the Writing Group for all requests and questions on analyses;
- Be sure that data requests are made in a timely fashion; interactive analyses will be allowed within the time window before and after the first draft;
- If the SDCC falls behind on the analyses, the Chairperson of the Writing Group should inform the Executive Committee via regards_admin@uab.edu ; if there is a problem, deadlines can be changed.

I. Preparation and Submission of Abstracts Based on Approved Manuscript Proposals

No abstract shall be submitted to any national or international organization for consideration prior to review by the REGARDS Executive Committee, approval by the Committee, and sign-off from all co-authors. Any abstract submitted without these approvals may be asked to be withdrawn.

Abstracts and presentations must be based on active manuscript proposals or submitted papers. An abstract or presentation based on an existing penultimate draft or submitted paper should be submitted to the Executive Committee for review no less than two weeks before the abstract submission deadline. If it is submitted too late for review, there is a risk of it not being approved in time to submit or withdrawal if the abstract is not approved. Information should include the meeting name and deadline.

If the abstract is accepted, a copy of presentation materials (including tables and graphs, PowerPoint slides or poster) **must** be submitted to the Executive Committee no less than two weeks before the presentation deadline. Co-authors must have first reviewed and approved the materials prior to submission to the Executive Committee.

For approval by the Executive Committee, abstracts should be e-mailed directly to the REGARDS Administrator (regards_admin@uab.edu) for circulation to the Executive Committee. Abstracts can be pasted in the document or included as an attachment, preferably in MSWord format. A response will be e-mailed back to the sender within two weeks.

Previously approved abstracts may be re-submitted or “recycled” to a second meeting without undergoing a second Executive Committee Review process. (It is expected that co-authors will have approved any major re-writes.) The Writing Group chair need only provide the REGARDS P&P Administrator with the same details (i.e., meeting name, acceptance status, etc.) as these are required for reporting purposes.

Appendices of REGARDS Publications and Presentations (P&P)
Policies and Procedures
March 1, 2010

- A. Manuscript Proposal Form (available as msword document upon request)**
- B. Data Distribution and Use Agreement**
- C. Checklist for Requesting Dataset for Local Analyses**
- D. Required Acknowledgements Section for all Manuscripts**

APPENDIX A

REGARDS MANUSCRIPT PROPOSAL FORM

Please read REGARDS P&P Policies, available from regards_admin@uab.edu before completing this form.

Date of submission: _____

WRITING CHAIR NAME: _____

Contact information: _____ (Please include e-mail address and phone number.)

(If this is your first REGARDS proposal, please include a letter of introduction from a REGARDS investigator.)

REGARDS Investigator/Sponsor: _____

PROPOSAL TITLE: _____

Abbreviated title: _____

Co-authors: (The REGARDS Executive Committee may nominate additional authors if special expertise for interpreting REGARDS data is needed. For all locally analyzed papers, please justify use of each co-author; if the paper is from a multisite ancillary study, co-authors from contributing units of REGARDS should be involved.)

Proposed co-authors and their email addresses: _____

Have all co-authors reviewed and approved this document? _____ Yes (required)

Has lead author checked for overlap with other REGARDS manuscripts? _____ Yes (required)

Please confirm that this manuscript has been checked for overlap. Check with the REGARDS administrator at regards_admin@uab.edu.

If possible overlap exists, please explain and describe resolution here:

1. Type of study: _____ Main _____ Ancillary (select only one)

If Ancillary Study, please list Study Title & PI: _____

2. Type of data (select one): [_____ Events] [_____ Longitudinal] [_____ Cross-sectional]
[_____ Methods]

2a. If cross-sectional: Complete participants only: _____
Partial participants included also: _____
(Partial participants are those who only completed baseline but did not have in-person exam component.)

3. Location of analysis: _____ Central (by UAB Statistical and Data Coordinating Center staff)
_____ Local (Site) – additional details are required – see P&P Policies and Procedures for instructions and supplemental information to be provided.

4. Key words: _____

5. Genetic Information:

Do you propose use of data from participants' DNA? _____ No _____ Yes

If yes, is the paper addressing vascular-related conditions? _____ No _____ Yes

If no, REGARDS participants did not provide consent for uses of DNA for diseases unrelated to vascular problems. Please refer to the Coordinating Center for guidance.

6. Conflict of Interest:

a. Are these analyses to involve a for-profit corporation? _____ No _____ Yes

b. Do you or any member of your Writing Group intend to patent any process, aspect or outcome of these analyses? _____ No _____ Yes

c. If the answer to a or b is yes, the involvement includes (check one):

____ An unrestricted educational or research grant

____ Hypothesis development and/or data analysis (results require verification by the Coordinating Center)

PART I (The following should produce no more than approximately 2-3 pages):

Introduction [Rationale and background]:

Research Hypothesis:

Data [Variables to be used, sample inclusions/exclusions]:

Brief analysis plan and methods:

Summary/conclusion:

References:

APPENDIX B

DATA DISTRIBUTION AGREEMENT FOR

The REasons for Geographic and Racial Differences in Stroke (REGARDS) Study (PI – George Howard, DrPH)

The Board of Trustees of The University of Alabama for The University of Alabama at Birmingham (UAB) and _____
(Name of Recipient Organization) hereby enter into this Distribution Agreement as documented by the signatures of authorized representatives of the above parties below.

INTRODUCTION

The National Institute of Neurological Disorders and Stroke (NINDS), NIH supported collection of data from participants in the REGARDS study, hereafter referred to as the “Study.” The Study participants are a well-characterized population that provides a rare and valuable scientific resource. The NINDS and the researchers it supports have a responsibility to assure that that data collected with public funds be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Data collected by the Study have been stripped of all personal identifiers but the wealth of data available on them might make possible the individual identification of some subjects. To protect the confidentiality and privacy of these participants, the Recipient who is granted access to these data must adhere to the requirements of this Distribution Agreement. Failure to comply with this Distribution Agreement could result in denial of further access to Study Data. Violation of the confidentiality requirements of this agreement is considered a breach of confidentiality and requesting investigators may be liable to legal action on the part of Study participants, their families, or the U. S. Government.

The Study Investigators have made a substantial long-term contribution in establishing and maintaining the database. UAB seeks to encourage appropriate collaborative relationships by outside investigators with the Study Investigators and to ensure that the contribution of the Study Investigators is appropriately acknowledged.

DEFINITIONS

For purposes of this agreement, "Data" refers to the information that have been collected and recorded from participants in REGARDS. Data from Study participants were collected through the periodic examinations and follow-up contacts conducted specified in the Study protocol and Investigators' grants with NINDS.

A “REGARDS Study Investigator” is defined as a research investigator who was listed as an Investigator on the REGARDS study grant.

The "Recipient" and his/her Organization may be a non-profit or for-profit organization or corporation. The Recipient requests access to REGARDS data at its sole risk and at no expense to REGARDS and NINDS. ['Recipient' refers to a REGARDS study investigator, ancillary study PI and/or lead author if this data request is for an approved manuscript and/or ancillary study proposal.]

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Research Project. These Data will be used by Recipient Principal Investigator solely in connection with the "Research Project", specifically described in Exhibit A: Title of Manuscript and/or Ancillary Study Proposal.
2. Non-transferability of Agreement. This Distribution Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project, and/or appointment by Recipient of another investigator to complete the Research Project, require execution of a new Distribution Agreement in which the new investigator and/or new Research Project are designated.
3. Non-Identification of Subjects. Recipient agrees that Data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom Data were obtained.
4. Use Limited to Research Project. Recipient agrees that Data will not be used in any research that is not disclosed and approved as part of the Research Project.
5. No Distribution of Data. Recipient agrees to retain control over Data, and further agrees not to transfer Data, with or without charge, to any other entity or any individual.
6. Study Personnel, Agents and Contractors. Recipient assumes the responsibility that any personnel, agents and contractors who will use or will have access to the Data, agree to be bound by the same restrictions and conditions that apply to the Recipient with respect to the Data.
7. Notification of Publication to UAB. Prompt publication or any public disclosure of the results of the Research Project is encouraged. Recipient agrees to read and abide by the REGARDS Publications and Presentations Policies and Procedures, and if applicable, the Ancillary Studies Policies and Procedures. This includes notification of the REGARDS Coordinating Center in advance as to when and where a publication (or other public disclosure) of a report from the Research Project will appear. This also includes agreeing to provide to the REGARDS Coordinating Center, in advance of its appearance, a copy of any manuscript or other public disclosure document.
8. Acknowledgments. Recipient agrees to acknowledge the contribution of the REGARDS Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data, whether or not Recipient is collaborating with

REGARDS investigators. The manuscript should include the standard acknowledgement of REGARDS investigators and funding source that is available from the REGARDS administrator (email). If the Research Project involves a collaboration with REGARDS investigators then recipients will acknowledge REGARDS investigators as co-authors, as appropriate, on any publication.

9. Non-Data. Notwithstanding the definition of “Data” or the agreed Terms and Conditions of this Distribution Agreement, Recipient’s obligations under this Distribution Agreement shall not extend to any information:

- a. that can be demonstrated to have been publicly known at the time of disclosure; or
- b. that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source (with no duty to any party to keep the information confidential) prior to the disclosure; or
- c. that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
- d. that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Data provided under this Agreement; or
- e. that is required to be disclosed by law, provided the Recipient takes responsible and lawful actions to avoid and/or minimize such disclosure.

10. Non-Endorsement Liability. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 8, “Acknowledgements.” UAB, a division of The Board of Trustees of The University of Alabama, a state agency, cannot waive immunity conferred by Ala. Const, Article 1 § 14. The exclusive forum in which a claim can be asserted against UAB is the State of Alabama Board of Adjustment. UAB maintains self-insurance coverage applicable to the negligent acts and omissions of its officers and employees, which occur within the scope of their employment by UAB. UAB has no insurance coverage applicable to third-party acts, omissions or claims, and can undertake no obligation that might create a debt of the State Treasury.

11. Recipient's Compliance with IRB Requirements. Recipient acknowledges that the conditions for use of these Data must comply with the policies and procedures of the Recipient's Institutional Review Board (IRB) operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46 (or equivalent if Recipient is outside the U.S.) Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the REGARDS Executive Committee any proposed change in the Research Project and any unanticipated problems involving risks to subjects or others to the extent required by applicable law. This Agreement is made in addition to, and does not supersede, any of Recipient’s institutional policies or any local, State, and/or Federal laws and regulations which provide

additional protections for human subjects. Recipient must attach as Exhibit B a copy of the approval or exemption documentation from his/her institution's IRB.

12. Amendments. Amendments to the substantive terms of this Distribution Agreement must be made in writing and signed by authorized representatives of all parties. However, additional Exhibit As may be added to the agreement by UAB upon approval from the REGARDS Executive Committee.

13. Termination. UAB may terminate this Distribution Agreement if Recipient is in default of any condition of this Distribution Agreement and such default has not been remedied within 30 days after the date of written notice by UAB's Authorized Representative of such default.

14. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Data from this study and from other studies.

15. Accurate Representations. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

Signatures

Authorized representative of Recipient Organization:

Name and Title: _____

Organization: _____

Mailing Address: _____

Email address: _____

Telephone number: _____ Fax number: _____

Signature: _____

Date:

Recipient Investigator Information:

Name and Title: _____

Mailing Address: _____

E-Mail Address: _____

Telephone Number: _____ Fax Number: _____

Signature: _____

Date:

UAB:

Name and Title: Lynn Stedman, Interim Director, Grants and Contracts Administration

Organization: The Board of Trustees of the University of Alabama for the University of Alabama at Birmingham

Address: 1530 3rd Ave. S., AB 1170, Birmingham, AL 35294-0111

Email address: ogca@uab.edu

Telephone number: 205-934-5266 Fax number: 205-975-5977

Signature: _____

Date:

EXHIBIT A

Manuscript Proposal and Approval from REGARDS Executive Committee
And/or
Ancillary Study Proposal and Approval from REGARDS Executive Committee

EXHIBIT B

IRB Approval or Exemption from Recipient Organization



APPENDIX C – Checklist for Requesting Dataset for Local Analyses

Instructions: This checklist should be used as a guide to complete the steps for release of REGARDS data according to the Publications and Presentations Policies and Procedures.

Name of Manuscript Proposal _____

REGARDS Assigned Manuscript Proposal # _____

Lead Author _____

Institutional Affiliation: _____

-
- | Prepare and submit manuscript proposal and listing of variables requested to regards_admin@uab.edu
 - | After approval of manuscript proposal by the REGARDS Executive Committee, submit materials to local IRB for review/approval
 - | REGARDS P&P Administrator will notify UAB Office of Grants and Contracts (OGCA) of Executive Committee manuscript proposal approval and provide contact information of lead author
 - | OGCA point person will complete the appropriate portions of the Data Use Agreement (DUA) and send it electronically to the lead author with instructions for his/her institutional review and sign-off. A copy of the institutional IRB approval or exemption must be returned with the signed DUA .
 - | When the DUA is fully executed, the UAB Office of Grants and Contracts will notify the REGARDS P&P Administrator so that preparations on the dataset can begin.
 - | The REGARDS P&P Administrator will notify the Statistical Team Leader at UAB to prepare, document and release the dataset to the lead author.
 - | The Statistical Team Leader will provide dataset via the website.

APPENDIX D

Acknowledgements Section for All REGARDS Manuscripts

Approved by the REGARDS Executive Committee January 2010

Instructions for lead authors: This text has been prepared by the REGARDS Executive Committee to acknowledge the funding source of NINDS and the REGARDS investigators. Please include this wording in all manuscript submissions. (For ancillary study manuscripts, see suggested guidance below for additional text. It is also suggested that ancillary study principal investigator be consulted for appropriate acknowledgement of funding source.)

=====
This research project is supported by a cooperative agreement U01 NS041588 from the National Institute of Neurological Disorders and Stroke, National Institutes of Health, Department of Health and Human Service. *The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institute of Neurological Disorders and Stroke or the National Institutes of Health. Representatives of the funding agency have been involved in the review of the manuscript but not directly involved in the collection, management, analysis or interpretation of the data.*² The authors thank the other investigators, the staff, and the participants of the REGARDS study for their valuable contributions. A full list of participating REGARDS investigators and institutions can be found at <http://www.regardsstudy.org>

² This sentence should be removed when any representative of NIH is a coauthor.

Something similar to the following generic wording is suggested to be added to the acknowledgement section for ancillary study manuscripts.

Additional funding was provided by an investigator-initiated grant-in-aid from XXXXX. Representatives from XXXX did not have any role in the design and conduct of the study, the collection, management, analysis, and interpretation of the data, or the preparation or approval of the manuscript. The manuscript was sent to XXX for review prior to submission for publication.