Appendix U
ANALYSIS AND PUBLICATION GUIDELINES FOR CADDRE

CADDRE Data Sharing Committee

I. GOALS and PURPOSE

The purpose of these guidelines is:

1. To assure and expedite orderly and timely presentation to the scientific community of all pertinent data resulting from the collaborative National CADDRE Study: Child Development and Autism;

2. To promote accurate and scientifically sound presentations and papers from CADDRE and its collaborating investigators;

3. To promote collaboration between CADDRE and to assure that all participating investigators have the opportunity to be involved in data analysis and the preparation of CADDRE papers and presentations;

4. To assure that press releases, presentations, and publications related to CADDRE are accurate and objective, and do not compromise the collaborative study and the acceptance of its results;

5. To establish guidelines for authorship, acknowledgments, and funding citations for any presentations and publications of CADDRE; and

6. To maintain a record of proposed and published papers and presentations from the CADDRE study.

II. SCOPE OF THE GUIDELINES

1. This policy covers analyses and publications, including abstracts, presentations, press releases, and papers/manuscripts, that involve unpublished study data collected by CADDRE and compiled through funding by the Centers for Disease Control and Prevention (CDC) to the participating CADDRE Sites.

2. The data covered by these guidelines include all data elements collected and maintained by CADDRE projects as part of the CADDRE Cooperative Agreement program, including CADDRE methodology, data, and results. There are specifications for data collected and maintained by individual study sites as part of local studies by each site and for initial releases of unpublished site data as well (refer to Section IV of this document for specific reference to CADDRE policies on individual site data). For the purpose of these guidelines, CADDRE data are distinguished as being either:

    a. **Multi-site Data** – data elements collected using CDC funding that are part of the CADDRE pooled dataset or that combine data from more than one CADDRE Study Site or that are biological specimens.

    b. **Single-site Data** – data elements collected using CDC funding for a CADDRE Study Site that are from one study site. Single-site data also include additional data collected or analyzed by the site or data elements provided via linkages that are not part of CADDRE data, or collection of elements not included in the CADDRE Information System Database. Biological specimens collected as part of CADDRE are not considered single-site data.

3. Multi-site analyses and publications include any reports or publications concerning CADDRE study methodology, data collection, and analysis; collaborative reports; and all collaborative analyses, presentations (including posters), reports, abstracts, press releases, and papers/ manuscripts that utilize the pooled multi-site dataset or that combine data from more than one CADDRE site. Any collaboration on analyses or writing involving more than one CADDRE site, or any analysis involving biological specimens, is subject to approval by the CADDRE Data Sharing Committee. Site-specific analyses and publications are those prepared by individual study sites based on their own data (other than biological specimens) alone. Single-site analyses may not address any principal or primary CADDRE study aims (as defined below), which will be addressed solely through multi-site analyses. Site-specific papers do not require approval by the Data Sharing Committee but do require Committee notification prior to commencement with a letter of intent (Section IV.B.1.) and prior to release of any single-site data (Section V.C.1.). In addition to the two main types of publications, there may be related studies prompted directly by CADDRE but not using CADDRE data. These studies do not have to be approved by the CADDRE Data Sharing Committee but the Committee should be given a copy for information.

   The types of analyses/publications are as follows:

   a. Principal Multi-Site Analyses, involving multi-site data on primary study aims that have been prioritized by the CADDRE Principal Investigators.
   b. Primary Multi-Site Analyses, involving multi-site data on other (non-prioritized) primary study aims, as defined by the CADDRE Principal Investigators.
   c. Secondary Multi-Site Analyses, involving multi-site data, not on a primary aim. This could include papers related to statistical, methodological, or laboratory issues.
   d. Single-Site Analyses, involving single-site data, not on a primary study aim. Multi-site papers are encouraged when feasible. Single-site analyses on principal or primary study aims are not permitted.

4. The CADDRE Principal Multi-Site Analysis papers should be accepted for publication, and the estimated publication date announced, before any papers are submitted for publication that use data (whether multi-site or single-site) that are to be reported in the Principal Multi-Site Analysis papers, or that reveal the findings of the Principal Multi-Site Analyses. However, such papers can be in preparation and submitted for clearance prior to publication of the Principal Multi-Site Analysis paper. They may be approved but are considered "embargoed" until cleared for submission. Other papers (i.e., those reporting Primary or Secondary Multi-Site Analyses, Single-Site Analyses, or preliminary results of Principal Multi-Site Analyses) may be written and circulated to the CADDRE Data Sharing Committee. The Data Sharing Committee will determine whether or not the paper reveals Principal Multi-Site Analysis findings. Manuscript submission and publication will be subject to the approval of the Data Sharing Committee (see V.B.1. and V.C.1).

5. These policies will remain in force until the CADDRE Data Sharing Committee representing the current CADDRE grantees funded through September 2011 is formally dissolved.

6. CDC is required to make data generated using CDC funding available for interested researchers as a public use dataset (PUD) or restricted access dataset within one year following evaluation of the data for quality and sharing in conjunction with partners involved in data collections. A project-specific data release plan will be developed and approved by the CADDRE Data Sharing Committee (also see Section VIII.5).

III. THE CADDRE DATA SHARING COMMITTEE

1. The CADDRE Data Sharing Committee is responsible for insuring that all the foregoing goals and purposes of the Guidelines are met.

2. Members of the CADDRE Data Sharing Committee will include two representatives from each of the CADDRE sites. Each CADDRE site will have one vote on project approvals. CADDRE representatives may be the Principal Investigator(s) or his/her designee(s) if the PI assigns this designee(s) to act on behalf of their project site for the Committee's purposes.

3. Committee Member Responsibilities.
    a. Each Committee member, or their designee, must attend (by telephone or in-person) monthly meetings of the Data Sharing Committee. It is anticipated that most meetings will be held as conference calls.
    b. Each Committee member, or their designee, must respond to requests for reviews of letters of intent and proposals within a three-week time frame.
    c. Each Committee member, or their designee, must respond to requests for expedited review within a one-week time frame.
    d. Each CADDRE Site will be responsible for sharing documents submitted to the Committee with their Project staff as necessary to inform them about proposed projects or to obtain their feedback.

4. The Data Coordinating Center (DCC) is funded under a separate cooperative agreement and the Central Laboratory is funded as a separate activity under a single CADDRE site. The PI's from the DCC project and Central Laboratory will participate in the Data Sharing Committee as "technical partners" and are considered non-voting members for the CADDRE Data Sharing Committee. As technical partners, the DCC and Central Laboratory PI's may review proposals submitted to the CADDRE Data Sharing Committee for approval, and may provide technical comments to the Committee concerning the proposal, within the specified approval timelines.

5. The Committee will elect a Chair-person who will be responsible for setting meeting agendas and presiding over meetings. The Chair-person will also serve as a mediator for the group to work towards consensus on areas of disagreement. The Chair-person will be elected annually. The Chair-person may serve multiple terms.

6. The Committee may vote to change elements of the Analysis and Publication Guidelines as needed. Each CADDRE Site will be responsible for sharing information about changes to these guidelines with their Project staff.

7. A quorum for voting on proposed analyses (including letters of intent and proposals, Section IV) shall consist of 75% of the sites, i.e., 75% of the sites must be represented at the meeting. For a vote to pass, at least 75% of the sites voting (i.e., 75% of the sites represented at the meeting) must vote for approval.

8. The CDC will designate an individual to serve as the administrator/coordinator of the committee. All correspondence to the Committee, including project proposals, abstracts, and manuscripts, will be sent to CDC for distribution to the Committee members. The CDC administrator will also be responsible for documenting that all CDC IRB requirements are met for any analyses resulting from the collaboration of CADDRE cooperative agreement recipients. All PIs are responsible for their local IRB requirements for any project proposals, abstracts, or manuscripts in which they are involved.

IV. PROCESS FOR ANALYSIS OF STUDY DATA

A. Initial Approval for CADDRE Project Proposals for Multi-Site Analyses

1. To initiate an analysis and/or papers/manuscripts (descriptive, conceptual, policy, analytic, review, etc.) using CADDRE data or information (as defined in Section II.2.c.), a

participating CADDRE investigator, or affiliated investigator (i.e., colleagues, students, or collaborators sponsored by the PI), must submit a letter of intent to the CADDRE Data Sharing Committee. The purpose of the letter of intent is to communicate research ideas and facilitate collaboration among CADDRE sites. Letters of intent should be submitted no earlier than 12 months before the time that it is expected that there will be enough cases or exposures of interest to do the study. The letter of intent should include:

a. the name of the lead investigator
b. the name of the sponsoring PI (if applicable)
c. the hypothesis to be tested
d. the type of analysis (principal, primary, or secondary), and its relationship, if any, to the principal multi-site analyses
e. data to be used: the pooled data set or other multi-site data (if the latter, specifying which sites are to be included)
f. collaborators involved in the research
g. any issues related to conflict with existing or proposed research conducted by other CADDRE sites.

2. Letters of intent should be submitted to the Data Sharing Committee via the CDC administrator. The lead investigator must copy the sponsoring PI (if applicable) and all co-authors when submitting letters of intent to the Committee.

3. On the day following the next scheduled Data Sharing Committee conference call, the CDC administrator will distribute the letter to all committee members for review. For example, if the letter is received on January 14 and the next meeting is February 1, it will be distributed on February 2. The Committee members will review the letter to determine that the scope of the analysis is reasonable, that the type of analysis is correctly defined, and that there are no conflicts with existing analyses being conducted by other CADDRE investigators. The committee members may also make suggestions for collaboration with other CADDRE investigators. Other CADDRE investigators have 1 week to indicate to the lead investigator that they would like to participate in the project. It is the responsibility of each Committee member to share information about the letter of intent to other investigators at their site to solicit possible collaborators. Investigators should contact the lead investigator to indicate their desire to participate and the role they wish to play in the project. The lead investigator for the project will determine the final investigative team for the project. The lead investigator must inform the CADDRE Data Sharing Committee of any changes in investigator status or roles prior to final approval of the project. If the proposed project includes the use of biologic specimens, a copy will also be sent to the *Biologic Monitoring Committee* (see Section IV.A.8.h. below).

4. Committee members will email their comments about the letter of intent to the CDC administrator using the email review form supplied when the letters of intent are distributed (Attachment X). Reviews are due three weeks after the letter is distributed by the administrator. The CDC Administrator will compile the comments, including the name of each reviewer along with his/her comments.

5. If any member of the Data Sharing Committee does not agree with the type of analysis (i.e., principal, primary, secondary) designated by the lead investigator, the letter of intent will be submitted first to the CADDRE Principal Investigators Committee for review. The PI Committee will make the final decision as to designation prior to further consideration of the proposal.

6. The compiled comments will be distributed to the committee at least 3 days before the next Data Sharing Committee meeting. During the Data Sharing Committee meeting, the committee will discuss and vote on each letter of intent. If the author or sponsoring PI is not on the call the Committee will respond to investigators within one week with their decision and any comments, unless issues are raised that require further discussion or clarification. The Data Sharing Committee decision will also be entered in the Data

Sharing Database and added to the CADDRE website.

7. Under unusual circumstances, investigators may submit a request for an expedited review of a letter of intent, with justification for the need to expedite the review, to the CDC administrator of the Data Sharing Committee. Such requests will be forwarded to the Committee chair. The Chair shall decide whether to approve the request for expedited review. If approved for expedited review, the letter will be forwarded immediately to the Committee members, and members will return review comments within 1 week. The CDC Administrator will schedule a conference call for the day after the review comments are due, at which time a vote will be taken for approval of the letter.

8. After the committee approves the research proposed in the letter of intent, the investigators should prepare a 2-5 page study proposal. Proposals should be submitted no earlier than 6 months before the time that it is expected that there will be enough cases or exposures of interest to do the study. The proposal should include:
    a. investigators with lead investigator and sponsoring PI noted
    b. contribution of/justification for each investigator
    c. objectives, aim or hypothesis
    d. background with relevant references
    e. methods describing –
        1. specific outcomes of interest
        2. primary exposures of interest
        3. data to be used: the pooled data set or other multi-site data (if the latter, specifying which sites are to be included)
        4. other data collection or record matching if relevant
    f. analysis plan with power calculations if relevant
    g. if particular expertise in, for example, molecular genetics, statistics, epidemiology or case classification will be required for the study, plans for obtaining this should be described in the proposal.
    h. if the proposed research includes use of biologic material, the following additional guidelines apply:
        1. The proposal should address the volume of the specimen to be committed for the study and the volume of the specimen that would remain. Pilot studies using other (non-CADDRE) specimen samples will help determine this amount. Investigators should document their discussion with the Central Laboratory.
        2. Methodology should be pilot-tested on local or volunteer samples, or based on previous published work. Information on the results of pilot testing should be included in the proposal.
        3. Methods utilizing the smallest possible amounts of the specimen should be used.
        4. If a particular biologic marker/analyte/polymorphism may be of interest to other researchers, the proposal should specify how research agendas will be coordinated among interested investigators.
        5. The proposal will be sent for an initial review by the CADDRE *Biologic Monitoring Committee*. The membership of this Committee will include representation from each site and may also include ex officio members with expertise relevant to particular proposals. Sign-off from this Committee will be required before review by the Data Sharing Committee begins. The *Biologic Monitoring Committee* Guidelines will specify their review process.
            a) Priority will be given to questions of public health significance and to studies that are hypothesis-driven.
            b) Evidence of previous assay pilot testing in other populations or with other samples to establish reliability and validity will strengthen proposals.
            c) Priority will be given to projects likely to have adequate statistical precision based on study size calculations. These calculations should be based on baseline biomarker prevalence and anticipated

effect size estimates drawn from existing literature or pilot work in other sample sets.

d) In some instances the *Biologic Monitoring Committee* may recommend sequential analysis procedures (i.e., sequential analysis of subsamples until sufficient evidence exists to rule hypothesis in or out) in order to preserve sample. These approaches involve the analysis of sample in small sets until there is sufficient evidence to either accept or reject a null hypothesis.

6. Once returned to the Data Sharing Committee with Biologic Monitoring Committee sign-off, the proposal will be distributed for the Data Sharing Committee to review as specified in step 9, below.

9. On the day following the next scheduled Data Sharing Committee conference call, the CDC 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 CADDRE investigators or comment if there are conflicts with existing analyses being conducted by other CADDRE investigators. [The committee expects that issues dealing with collaboration and conflicts with other CADDRE research will be dealt with when the letter of intent is reviewed. The review of research proposals will deal mainly with scientific content.] Committee members will review the proposals using the form in Attachment X and will return the form to the CDC administrator via e-mail. Reviews are due three weeks after the proposal is distributed to the committee.

10. Two Committee members will be assigned to prepare and present comprehensive reviews for discussion on the Data Sharing call. The CDC administrator will assign the reviews, rotating reviewers each time. The comprehensive reviewers must not be from the same site as the assigned proposal.

11. The comprehensive reviews and comments from other reviewers will be compiled by the CDC Administrator and distributed to the committee at least 3 days before the next Data Sharing call. The compiled comments will show the name of each reviewer, along with his/her comments. During the Data Sharing call, the committee will discuss and vote on proposals.

12. If the lead investigator or sponsoring PI is not on the call, the Committee will respond to investigators within one week with their decision and any comments, unless issues are raised that require further discussion or clarification. The Data Sharing Committee decision will also be entered in the Data Sharing Database and added to the CADDRE website. The Data Sharing Committee will notify the DCC of the approval and authorize release of multi-site data.

13. Under unusual circumstances, investigators may submit a request for an expedited review of a proposal, with justification for the need to expedite the review, to the CDC administrator of the Data Sharing Committee. Such requests will be forwarded to the Committee chair. The Chair shall decide whether to approve the request for expedited review. If approved for expedited review, the letter will be forwarded immediately to the Committee members. The review process will be identical to that used for non-expedited reviews, but members will return review comments within 1 week. The CDC Administrator will schedule a conference call for the day after the review comments are due, at which time a vote will be taken for approval of the proposal.

14. Letters of intent and proposals that are disapproved may be revised and resubmitted to the Committee. For letters of intent, resubmission must occur within one month after disapproval. For proposals, resubmission must occur within two months after disapproval. If the investigator does not resubmit by the deadline, the hypothesis for analysis will become available to other investigators.

15. Each lead investigator is limited to three active projects (i.e., any combination of letters of intent or proposals) at one time. An investigator with three such projects may not submit a new letter of intent until one of his or her projects is completed, so as to maintain no more than three currently active projects. A project shall be deemed to be completed when a manuscript addressing the objectives, aim or hypothesis described in the proposal has been submitted for publication.

16. Each CADDRE site is limited to nine active projects (i.e., any combination of letters of intent or proposals) at one time. No investigator from a site with nine such projects may submit a new letter of intent until one of the site's existing projects is completed, so as to maintain no more than nine currently active projects. A project shall be deemed to be completed when a manuscript addressing the objectives, aim or hypothesis described in the proposal has been submitted for publication.

B. Notification for CADDRE Single-Site Analyses

1. To notify the Data Sharing Committee of proposed analyses and/or papers/manuscripts (descriptive, conceptual, policy, analytic, review, etc.) using CADDRE single-site data or information (as defined in Section II.2.c.), a participating CADDRE investigator, or affiliated investigator (i.e., colleagues, students, or collaborators sponsored by the PI), must submit a letter of intent to the CADDRE Data Sharing Committee. The purpose of the letter of intent is to communicate research ideas and facilitate collaboration among CADDRE sites. The letter of intent should include:

   a. the name of the lead investigator
   b. the name of the sponsoring PI
   c. the hypothesis to be tested, and its relationship (if any) to principal multi-site analyses
   d. data to be used: specify single site
   e. collaborators involved in the research
   f. any issues related to conflict with existing or proposed research conducted by other CADDRE sites.

2. Letters of intent should be submitted to the Data Sharing Committee via the CDC administrator. The lead investigator must copy the sponsoring PI and all co-authors when submitting letters of intent to the Committee.

3. The Data Sharing Committee will notify the DCC of the receipt of the letters of intent and authorize release of single-site data.

V. <u>RELEASE OF CADDRE STUDY DATA</u>

A. General Information for Data Release

1. For all data or information that has been collected or analyzed as part of the CADDRE Cooperative Agreement program, including CADDRE methodology, tools, data, and results, references to the funding source(s), including CDC, and the collaboration of CADDRE must be made. Publications, journal articles, etc. produced under a CDC grant support project must bear an acknowledgment and disclaimer, as appropriate, such as: This publication (journal article, etc.) was supported by Grant/Cooperative Agreement Number xxxxx from the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and not necessarily represent the official views of the Centers for Disease Control and Prevention.

2. Completed presentations and published manuscripts should be made available to post on the internal CADDRE Web Board. Any other site or investigator that wishes to reproduce any aspect of a posted presentation from another site, including CDC, must request permission from and properly acknowledge the original author(s).

3. Any use of the "CDC" or "HHS" logo must first be approved through official CDC and HHS clearance processes.

B. Multi-Site Data Release

1. Any data release, press release, abstract, presentation, report, or manuscript concerning CADDRE multi-site data or CADDRE methodology (see section II.2.a. and II.3.c. for a description) is subject to approval by the CADDRE Data Sharing Committee.

2. Abstracts for presentations at scientific meetings, press releases, and manuscripts of collaborative CADDRE results will be sent to the CADDRE Data Sharing Committee for approval prior to submission to an outside organization. The CDC Administrator will distribute the document to the Committee upon receipt.

3. The Committee members will review the abstracts, press releases, and manuscripts to determine that they are scientifically sound and that they meet the guidelines for authorship.

    a. If all sites are not included in the document, other CADDRE investigators may request to participate to the submitting investigator. The submitting investigator may determine if collaboration is merited based on the requesting investigator's contribution to the project.
    b. Committee members will have <u>one week</u> to respond with comments and a vote for approval or disapproval of abstracts and press releases and <u>three weeks</u> to respond with comments and a vote for approval or disapproval of manuscripts. If a Project Site does not respond within the specified time frame, no vote will be recorded for that Site.

4. A quorum for voting on any data release (including abstracts, manuscripts, or other submissions) shall consist of 75% of the sites, i.e., 75% of the sites must return a vote. For a vote to pass, at least 75% of the voting sites (i.e., 75% of the sites who respond with a vote) must vote for approval. In all cases the authors will strive to obtain consensus through discussions with Project Sites who disapprove. If a quorum is not attained, the document will be presented for a vote at the next occurring regular meeting of the Data Sharing Committee.

5. The CADDRE Data Sharing Committee will review the comments and votes and respond in writing to the lead investigator <u>within two weeks</u> of submission for <u>abstracts or press releases</u> and within <u>four weeks</u> of submission for <u>manuscripts</u>. If necessary, a monthly review date will be established so that manuscripts received by the first of the month will be reviewed and responded to by the end of the month.

6. Under unusual circumstances, investigators may submit a request for an expedited review of an abstract, manuscript, or other data release, with justification for the need to expedite the review, to the CDC administrator of the Data Sharing Committee. Such requests will be forwarded immediately to the Committee chair. The Chair shall decide whether to approve the request for expedited review. If approved for expedited review, the letter will be forwarded immediately to the Committee members, and members will return review comments and votes on abstracts and press releases within 3 days, and comments on manuscripts within 1 week. The CADDRE Data Sharing Committee will review the comments and votes and respond in writing to the lead investigator <u>within one week</u> of submission for <u>abstracts or press releases</u> and within <u>two weeks</u> of submission for

manuscripts.

7. Any submissions that are disapproved may be revised and resubmitted to the Committee.

8. It is the responsibility of the lead investigator/sponsoring PI to determine if a re-review of a manuscript by the CADDRE Data Sharing Committee is necessary because of substantial revision of a manuscript in response to peer review.

9. A copy of each accepted abstract and manuscript will be sent to the CADDRE Data Sharing Committee for the record.

10. Any manuscript ready for submission that includes CDC personnel as an author or that represents CADDRE Group Authorship (II.2.a.) must go through the CDC Scientific Clearance after approval by the CADDRE Data Sharing Committee prior to submission. CDC Scientific Clearance is not required if the manuscript does not include CDC personnel as an author or does not represent CADDRE Group Authorship.

C. Single-Site Data Release

1. Prior to the release of any single-site data (see section II.2.b. for a description) obtained through CADDRE Study Projects, CDC and the Data Sharing Committee will be notified of the Title, Authors, Platform for Presentation or Publication, Audience, and any anticipated Press Releases. It is recommended, but not required, that all written results and reports be shared with CADDRE Data Sharing Committee prior to public release. The authoring entity may request comments from the Committee, if desired.

VI. AUTHORSHIP

1. Authors who participate in the preparation of a manuscript from the collaboration of a CADDRE site will do so in accordance with the International Committee of Medical Journal Editors guidelines -- JAMA 1997; 277(11): 927-934.

2. All multi-site papers that address a principal or primary study aim will include the words “National CADDRE Study” in the title line and, if allowed by the journal, the words “National CADDRE Study Group*” in the authorship line. The ‘*’ will note the names and affiliations of the National CADDRE Study Group members. Each CADDRE Project Site will determine the Study Group members from that site to be included in this list, consistent with authorship guidelines. All papers will also include an "Acknowledgments" section that will include a list of individuals and their affiliations submitted by each CADDRE Project Site, unless journal policy prohibits publication of such a list. Other CADDRE project staff and the DCC will be acknowledged or included as authors as allowable and appropriate, consistent with authorship guidelines.

3. First Authorship

   a. For publications of multi-site analyses, first authors will usually be CADDRE investigators (i.e., Principal Investigators and other investigators designated as such by CADDRE Project Sites). Another scientist may serve as first author on a multi-site analysis paper if at least one other CADDRE investigator serves as a co-author and "sponsor" of the project and the scientist has played a major role in the data analysis and interpretation and in writing of the paper.

   b. Conflicts about first authorship will be resolved, if at all possible, by members of the analysis/writing group. In case the group is unable to resolve a conflict among CADDRE sites, the CADDRE Data Sharing

Committee will adjudicate and may assign first authorship.

5. Co-Authorship

   a. The first author will determine who is specifically named as an author and the order of authorship on a paper. In general, authors will appear in order of contribution to the analysis and writing of the paper. Individuals to be listed as co-authors as part of the National CADDRE Study Group will be determined by the individual CADDRE Project Sites.

VII. STATUTE OF LIMITATIONS ON ANALYSIS AND REPORTING

1. If an investigator does not submit a proposal for analysis within 1 year after submitting an approved letter of intent, other CADDRE sites and/or the DCC or Central Laboratory with a CADDRE PI Co-sponsor may submit a proposal to utilize those data.

2. Any approved analyses, abstracts/presentations, or manuscripts should be completed in a timely manner. If the approved project is not initiated within a reasonable amount of time (a first draft with preliminary results or a progress report demonstrating satisfactory progress submitted to the CADDRE Data Sharing Committee within 1 year or less after approval of the full proposal), other CADDRE investigators may submit an application to the CADDRE Data Sharing Committee to allow other investigators access to those data.

3. If a manuscript from a completed project is not prepared within a reasonable amount of time (i.e., the final draft completed within 12 months after submission of the first draft with preliminary results [VII.2, above]), the CADDRE Data Sharing Committee may request an explanation from the lead investigator. If timely progress is not likely to occur in the near future, the CADDRE Data Sharing Committee may, at its discretion, assign a new lead author to the project.

4. In the case of a dispute over use and reporting of data in a timely manner, the issue will be brought to the Data Sharing Committee for a vote. A quorum for voting shall consist of 75% of the sites. A vote to allow other investigators access to data, or to assign a new lead author, will require approval by 75% of those sites voting.

VIII. AVAILABILITY AND ANALYSIS OF DATA BY OUTSIDE INVESTIGATORS, THE DATA COORDINATING CENTER (DCC), AND THE CENTRAL LABORATORY

1. The use of the collaborative CADDRE pooled data will initially be limited to CADDRE investigators. If CADDRE PIs wish to collaborate on a project with non-CADDRE investigators ("outside investigators"), they may submit a proposal to the Data Sharing Committee and allow other CADDRE PIs and the DCC or the Central Laboratory the first opportunity to serve as collaborators on the particular project.

2. The Data Coordinating Center (DCC) and the Central Laboratory are considered "technical partners" and will assist with data analysis. The DCC will maintain the study pooled datasets as described in detail in the DCC-Site MOU and provide expertise on data quality, storage, and analysis to the CADDRE Study sites, as is reasonable in their scope of work, cooperative agreement with CDC, and based on appropriate Institutional Review Board (IRB) guidelines.

3. A CADDRE PI may request collaboration with the DCC or the Central Laboratory on a project and submit this proposal to the CADDRE Data Sharing Committee. If the

proposal is accepted, authorship and acknowledgement based on contribution to the project should be determined by the involved investigators in an equitable way in accordance with the JAMA 1997 guidelines. The DCC and Central Laboratory resources will be focused primarily on multi-site data and analyses. Collaboration between the DCC or the Central Laboratory and individual sites on projects involving single-site data or specimens will be negotiated between the DCC or the Central Laboratory and the site, with input required from the CDC Project Officer concerning any use of CDC-funded CADDRE resources for single-site analyses or projects.

4. Following the same procedures and format for letters of intent as described under Section V.A. above, the DCC or the Central Laboratory may submit a letter of intent for methodological studies related to their respective areas of expertise, or for analysis or reporting of CADDRE data, by obtaining a CADDRE PI to serve as CADDRE Co-Sponsor for the project. The DCC or the Central Laboratory may alternatively submit a letter of intent to the Data Sharing Committee with an open invitation for other CADDRE site PIs to join the analysis or reporting project. Other CADDRE investigators have 1 week to indicate to the DCC or the Central Laboratory and PI lead investigators that they would like to participate in the project. They should contact the lead investigators and provide their intent to participate and the role they will play in the project. The DCC or the Central Laboratory and PI lead investigators for the project will determine the final investigative team for the project. The lead investigators must inform the CADDRE Data Sharing Committee of any changes in investigator status or roles prior to final approval of the project. Final authorship or acknowledgement status of an investigator will be determined in accordance with the International Committee of Medical Journal Editors guidelines -- JAMA 1997; 277(11): 927-934. Any proposals submitted to the CADDRE Data Sharing Committee by the DCC or the Central Laboratory will follow the same voting procedures as noted in Section V.A. and Section V.B. above.

5. At a point to be determined by CDC Guidelines and the CADDRE Data Sharing Committee, the pooled data will become available to outside researchers in the form of a public use dataset. The availability of this dataset to outside investigators will be in accordance with CDC policies on public use datasets and data sharing. The CADDRE Data Sharing Committee will determine the format of any future public use of data tapes and will specify the variables which are to be included in the database in accordance with CDC policies.

Proposal for Analysis and/or Publication of
CADDRE Study Data

E-mail to dschendel@cdc.gov (cc: jwojcik@cdc.gov) marked:

"IMPORTANT – ABSTRACT FOR REVIEW FOR CADDRE DATASHARING"

Submitted by: _____ Date: _____

Research Question(s):

Does the proposal involve the use of biologic material? Yes ☐ No ☐

If yes, please answer the following questions:

From which sites will material be needed?_____

Volume of the specimen to be committed? _____

Volume of the specimen that would remain? _____

Proposed Authors and Affiliations (attach explanation of all authors who are not CADDRE investigators):

1. Lead Investigator:

2.

3.

4.

Will the Data Coordinating Center (DCC) or the Central Laboratory be involved?

____Yes* ___No*

*Please explain scope of DCC or the Central Laboratory involvement.

If a DCC or Central Laboratory -initiated proposal, who is CADDRE PI or Co-Sponsor?

Proposed Audience/Journal:

Proposed Research Plan, including Sample, Subjects, Data Variables, and Analytic Strategy: Attach 2-4 page summary (please do not exceed maximum page limit)

_____

Date Circulated to CADDRE Data Sharing Committee:_____

Steering Committee Clearance: [ ] Yes [ ] No, Date_____

CDC Clearance Required: [ ] Yes [ ] No Project Officer: _____

Approved/Amended By: [ ] CDC for Access to Pooled Study Data_____

[ ] Cross Clearance Approvals if Needed _____

Approved by Investigators: Date _____