

**THE CORONARY ARTERY RISK DEVELOPMENT IN YOUNG  
ADULTS (CARDIA) STUDY  
DATA ANALYSIS AND PUBLICATION POLICIES**

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**I. Overview**

The Coronary Artery Risk Development in Young Adults (CARDIA) Study is a longitudinal epidemiologic study of an initial cohort of 5115 participants from four clinical centers. As a multi-center study, it involves Investigators from each of the clinical centers, the National Heart, Lung, and Blood Institute (NHLBI) which is the funding agency, the CARDIA Coordinating Center, and several consultants to the study. Each of the clinical centers, the Coordinating Center, the NHLBI, and the chair of the CARDIA Steering Committee has complete copies of the CARDIA data set. The official CARDIA data set is maintained at the Coordinating Center.

CARDIA requests that individuals working on projects involving CARDIA data work closely with at least one of the CARDIA Investigators and follow the policies of the study. This is to ensure that you have access to all information pertinent to your analysis venture. This important information includes the documentation notebook which is distributed by the Coordinating Center with the data; this notebook gives detailed information on the data set including the edits which have been performed, any problems in the data set, and lists of calculated variables and their algorithms. This documentation also includes the distributed data forms that are used in the research process by the Investigators. We also encourage you to obtain access to the manual of operations that describes the data collection process and quality control procedures used by the study.

CARDIA has implemented policies involving the use of its data, (1) to ensure that Investigators know of ongoing research efforts and have the opportunity to participate in the efforts if they so desire; (2) to ensure that duplication of analyses is kept to a minimum; (3) to permit the Coordinating Center to maintain control of the official CARDIA data base includes being informed of any problem areas in the data base; (4) to ensure that publication or presentation of CARDIA data does not occur without the knowledge and approval of the Steering Committee; and (5) to maintain the integrity of study data longitudinally.

The CARDIA Steering Committee has final say over all CARDIA publications and presentations. In 1990 the CARDIA Steering Committee initiated a set of policies to encourage

the timely completion of manuscripts in the study and to recommend guidelines for the effective functioning of writing groups. In 1996, The Steering Committee empanelled a Publications Planning Committee to deal with long-range planning issues. Acknowledging the continued growth of the study and the increasing scope and complexity of the scientific collaborations that use CARDIA data, the CARDIA Publications and Presentations (P&P) Committee was created in October, 2003.

## **II. Publications and Presentations Committee**

The success of the CARDIA Study will be judged largely on the number and quality of its scientific publications and presentations. The purpose of the policies established herein is to encourage and facilitate important analyses while providing guidelines that assure appropriate use of the CARDIA data, timely completion of projects, and adherence to the principles of authorship.

### **Role of the Publications and Presentations (P&P) Committee**

The P&P Committee oversees all CARDIA publications and presentations activities, with final adjudication of decisions by the Steering Committee. The P&P committee approves the proposal of publications and the submission of abstracts; as well as all publications and presentations before they are submitted for publication or presented in a public forum. The P&P Committee submits its decisions to the Steering Committee for approval at the Steering Committee meeting that follows the P& P Committee meeting, usually within one week of the P&P Committee meeting. Appeals of P&P Committee decisions may be made to the Steering Committee. However, the expectation is that only occasionally will decisions made by the P&P committee be discussed at Steering Committee meetings in detail. Such occasions might be an appeal or another exceptional circumstance.

The P&P Committee may decide who assumes lead responsibility for a paper if there is more than one interested candidate. The P&P Committee also may re-assign lead responsibility if reasonable progress on completing an abstract or manuscript has not occurred.

### **Composition of P&P Committee**

The P&P Committee consists of one representative from each of the four CARDIA Field Centers, one representative from the Coordinating Center, one representative from the NHLBI Project Office, and the Chair of the Steering Committee. A Chair and Co-Chair for the P&P Committee will be designated from the P&P Committee membership by the Steering Committee. An additional member of the P&P Committee who is a CARDIA investigator and a

biostatistician will be added to the P&P Committee by the Steering Committee, if the seven members of the P&P Committee do not include at least one biostatistician.

### **P&P Committee Meetings**

The P&P Committee meets on a biweekly basis by conference call, preferably during weeks that alternate with standing Steering Committee calls. **Decisions requiring a vote will be made during these calls only by P&P Committee members.** However, all Steering Committee members are invited to attend. Lead authors of manuscripts, proposals, abstracts, or presentations that are to be discussed during a P&P Committee call are invited to either attend themselves or send a representative. Steering Committee members who are not designated members of the P&P committee are welcome to contribute to deliberations of the committee. It is expected that the great majority of discussion of papers will be during the P&P meeting, rather than the subsequent Steering Committee meeting. Thus, Steering Committee members with a special interest in a given paper should attend the corresponding P&P meeting. Coordinating Center staff (the Publications Coordinator or delegate) will arrange the calls and take minutes, to be forwarded to the Steering Committee.

### **III. Proposing Manuscripts and Abstracts**

Proposals for manuscripts and abstracts may be initiated by any CARDIA investigator, who should be listed as one of the authors on the proposal. CARDIA investigators include Principal Investigators and Co-Investigators at any field center and the Coordinating Center, participating NHLBI staff, and CARDIA subcontractors. CARDIA values collegiality and across center collaborations very highly. In this spirit, it is strongly recommended that co-authors from more than one center be included in each Abstract or paper proposal. We also encourage that the number of authors be kept at or below 4 at time of submission of a paper proposal to the P&P committee. The purpose of this is to allow additional CARDIA authors to join the writing group at the time of paper proposal approval by the P&P committee. We recognize that occasionally it is not possible to adhere to these recommendations. When this is the case, please include in the paper proposal an explanation of why there are more than 4 authors or why all authors are from the same Center.

After review by all initially named co-authors, paper proposals and abstracts should be submitted to the **P&P Committee** one week prior to the regular biweekly **P&P Committee** conference call. Abstracts should be submitted to the **P&P Committee** for approval to assure that the Committee can discuss it on a conference call at least two weeks prior to the deadline

for submission. Investigators are encouraged to conduct limited preliminary data analyses prior to making a formal paper proposal to test the feasibility of pursuing a given topic. Each abstract must include a CARDIA investigator, as designated by the Steering Committee. **The CARDIA Steering Committee requires that ancillary studies follow the same policies as the core study.**

#### **Abstract Format**

The CARDIA Steering Committee strongly encourages the use of a structured abstract format, even when this is not required by the meeting at which the Abstract is to be presented. We suggest that, at a minimum, each Abstract be written in four sections, with the headings of **Background/Objectives, Methods, Results, and Conclusions.**

We further suggest that, even if a journal does not require it, Abstracts for completed manuscripts also be presented in a structured format. In addition, we strongly recommend that Abstracts for completed manuscripts not exceed 250 words, because MedLine will cut off Abstracts for published papers at 250 words.

#### **Data Distribution Policy and Agreement**

After a manuscript proposal or abstract is approved, the investigator(s) collaborating with the CARDIA Study and/or investigators must review the CARDIA Data Distribution Policy and complete and sign the CARDIA Data Distribution Agreement. Upon receipt of the Data Distribution Agreement, the CARDIA Coordinating Center will prepare an analytic dataset that will be sent to requesting investigator(s) or data center(s).

#### **IV. Submission of Abstracts/Manuscripts**

Each Principal Investigator has the right to publish data from his/her own clinic population after approval of the Steering Committee and review by the Project Office of NHLBI. Usually, local data presentations and publications will be limited to those data already presented from study-wide results. **See Section “XV. Review of Abstracts and Presentations” for guidelines on P&P Committee review/approval of a presentation (page 16).**

#### **V. Authorship**

The initiator generally assumes first authorship of the proposed manuscript. The initiator is encouraged to contact other potentially interested individuals before the paper or abstract is proposed. At the time of proposal, individuals at each of the clinical centers, the

Coordinating Center and the Project Office are given the opportunity to be co-authors. The first author is encouraged to involve individuals with specific expertise or experience as necessary. Each manuscript must include a CARDIA investigator, as designated by the Steering Committee.

## **VI. Co-Authorship**

The criteria for authorship will be those of the International Committee of Medical Journal Editors (ICMJE, the "Vancouver Group"). [1] These criteria are similar to those of other major organizations concerned with authorship, especially those written recently. Excerpts of these criteria follow.

“All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take responsibility for the Integrity of the work as a whole, from inception to published article.

Authorship credit should be based only on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Conditions 1, 2, and 3 must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship.”

Co-authors should become involved in manuscript development as early as possible. The lead author should seek involvement by soliciting help early on, e.g., by circulating to co-authors a paper outline with some table shells and/or a request for suggestions of additional table and figure shells. Early drafts should be circulated to all co-authors, with a deadline for responses. Though the time allowed for co-author response will vary, it is suggested that two weeks is a reasonable interval. The lead author is expected to play a pro-active role in seeking co-author involvement and in taking action if this involvement is not forthcoming. If during the completion of the manuscript or presentation it becomes apparent that the contributions of one or more co-authors do not merit authorship, the lead author should discuss the possibility of removing the names of individuals from the paper. Failure to respond in a timely manner to a request for comments, especially if unexplained or repeated, should be grounds for considering the removal of a co-author. In addition, each co-author should critically examine his/her role in the process and volunteer to remove his/her name if warranted. The first author should attempt to reconcile divergent views of the co-authors with his/her own. However, sometimes a co-

author may elect to remove his/her name because of disagreements in the interpretation of the data or in the style of writing, even though substantial contributions were made. [1]

<http://www.icmje.org>

## **VII. Three Paper Limit for First Authors**

Investigators are limited to first authorship on no more than three papers in progress (prior to submission to a journal). Exemptions from this policy may be made by the Steering Committee in the case of demonstrated productivity of the investigator, invited papers, or other special circumstances.

## **VIII. Six-Author Rule**

Some medical journals, such as the Journal of the American Medical Association (JAMA), limit the number of authors on a manuscript to six, and The National Library of Medicine's online reference service includes only six names. Moreover, it is difficult to work on a writing project with more than six people. Thus, CARDIA has established the policy of attempting to limit the number of authors on a paper or presentation to no more than six. Exceptions to this rule are allowed in the case of papers that legitimately require additional expertise or mainstream results papers that require the input and acknowledgment of many Investigators. The New England Journal of Medicine allows 12 authors in a multi-center study, while Annals of Internal Medicine allows a maximum of 10 authors. Also note that in Item III we encourage paper proposals to have no more than 4 authors at the time of submission of the proposal to the P&P committee. Again, the purpose is to leave "room" for additional authors to join at the time of proposal approval, and thus promote across-site collaborations.

## **IX. Timeline for Paper Completion and High Priority Manuscripts**

As for other multi-center studies, important CARDIA papers must be written in a timely fashion, yet most CARDIA Investigators are over-extended, budgets do not allow for adequate time for manuscript preparation, and papers may not be completed in an expeditious manner. This part of the CARDIA publications policies represents an effort to address this issue. Its purpose is to establish procedures that will facilitate the timely completion of CARDIA papers, with special emphasis on high priority manuscripts.

**Timeline for paper completion.** A proposed timeline for completion is part of each CARDIA paper proposal (see Template, page 21). At time of proposal approval, the P&P committee

approves the paper proposal conditional on adherence to the timeline. It is the lead author's responsibility to oversee timeline adherence. Non-adherence to timeline has specific implications if a paper has been designated as High Priority.

Soon after the proposal is approved by P&P (we recommend no more than one month), the lead author should coordinate a conference call with all co-authors. At this time, the paper's timeline should be refined, and co-authorship expectations clarified. The goal for this call should be to provide the first set of shell tables to the analyst(s).

**Expectation from co-authors.** Frequently, a manuscript lingers because all co-authors do not respond to a draft in timely fashion. Co-authors are expected to respond to any request from the lead author regarding a paper in progress within one week, preferably less, either by providing feedback or declaring that they will be unable provide feedback at this time. Declaring one's inability to respond to a single request does not eliminate one from the co-authorship list. However, once the paper is ready to go to the P&P committee for approval, both lead and co-authors need to ensure that each listed author has satisfied scientific requirements for co-authorship, as outlined in "**X. Manuscript Completion Process**" on page 8. For example, if a co-author has never provided input, in spite of repeated requests from the lead author, then the lead author should drop the co-author from the authorship list before sending the final draft to P&P.

**Dormant and withdrawn papers.** The CARDIA Coordinating Center contacts the lead authors of all papers in progress at least twice a year, to request an update on the status of the paper. If a lead author does not respond to this request, he/she is re-contacted twice within a month, with a warning that lack of response will result in the paper being classified as "dormant". If the lead author of a "dormant" paper does not respond to the status update request at the next semi-annual contact, the P&P committee will review the authorship list and either reassigns lead authorship to another member of the writing group, who commits to getting the paper written, or declares the paper "withdrawn". Withdrawn status means that any other CARDIA investigator may propose to write this paper or another one that seriously overlaps with it.

**Designation of a manuscript as High Priority.** The P&P committee will review the list of all in progress manuscripts at least biannually with special attention to high priority classification. Criteria for classifying a paper as High Priority include (1) Scientific importance of potential findings; (2) Potential impact of publication on the future of CARDIA; (3) Potential for high

visibility in wide circulation scientific journals; (4) Urgency in making findings available to scientific community and/or public.

**High Priority Timelines.** High priority papers will be scrutinized closely at least biannually by the P&P committee regarding timeline adherence. If approval of the completed paper by the P&P committee is not obtained within three months of the initially approved timeline, the P&P committee will request a new timeline from the lead author, which will be subject to P&P approval. If the lead author and the P&P committee cannot agree on a new timeline, or if the new timeline is not adhered to either, the P&P committee will ask the lead author to select another lead author from the initial writing group, who will commit to an acceptable new timeline. Should no member of the initial writing group be willing to make this commitment, the P&P committee may select a new author to lead the paper to completion in a timely fashion.

**Operational implication of High Priority designation.** A High Priority paper will receive priority by the Coordinating Center in the preparation of analytic data-sets and data verification. High Priority papers will be scrutinized closely in terms of timeline adherence, as above.

## **X. Manuscript Completion Process**

In general, manuscripts are initiated and completed as described below:

1. Investigator submits a proposal (one to two pages) for review by the Steering Committee.

**The proposal should include:**

- A. Title and list of proposed collaborators.
- B. Scientific background and rationale.
- C. Research questions and hypotheses, when appropriate.
- D. Brief description of methods of analysis.

A template for a manuscript proposal is attached to these policies as Appendix A.

2. Once the proposal is approved by the P&P Committee, the initiating author, in conjunction with the selected co-authors, should agree upon assignments for research, analysis and writing, as appropriate. If not included in sufficient detail in the proposal, the first author should circulate a detailed plan for data analysis among the co-authors and solicit their input. A copy of this plan should be sent to the Publications Coordinator at the Coordinating Center.

3. Early in the process, there should be at least one communication (phone, E-mail or regular mail) between the lead author(s) and each co-author about research strategy; additional communications will be needed. Response to communications from any author should be as quick as possible, typically less than two weeks. Response the same day is desirable, given the critical nature of collaborative feedback in the paper writing process. Failure to participate collaboratively may be taken by the lead author(s) as a signal that the co-author no longer wishes to participate in the paper.
4. Each stage of the paper writing process is monitored by the P&P Committee Chair, Co-Chair and the Publications Coordinator. The first author is encouraged to keep the Publications Coordinator informed of the manuscripts' progress. Chronic failure to advance in the writing of a manuscript may result in the reassignment of the topic to another investigator.
5. In the cover memo accompanying a manuscript draft, first authors should provide a time line to co-authors for returning the draft. The first authors may clearly state that the coauthor will be removed from the manuscript if a response is not received by the specified date. Removal of a co-author will be at the discretion of the first author and not a requirement of the publication policies. However, the Steering Committee strongly encourages adherence to reasonable timelines.
6. The final version of the manuscript is submitted for review/approval by the P&P Committee and review of the NHLBI before the paper is submitted to a journal for publication. All co-authors must be willing to take public responsibility for the manuscript as submitted to the P&P Committee, as is implied by signing the Statement of Authors form. See next section on P&P Committee Review for Manuscripts.
7. Authors should keep the Publications Coordinator informed of journal submission(s) (dates and journal name), results of reviews (acceptance, rejection or request for revision) and final acceptance by journal.
8. **Copies of all Journal submissions**

Simultaneously with the submission of a manuscript to a journal (whether it be the first, second, third, etc. submittal), the first author will send a copy of the submitted version as well as a copy of the cover letter to the Publications Coordinator at the Coordinating Center. This will allow the Coordinating Center to have on file the final copy of all submissions whether accepted, rejected, or under revision and also to compile data on journal responses to CARDIA manuscripts.

9. If there are any substantial changes to an approved manuscript prior to publication, whether required by the journal or not, these changes must be discussed with the coauthors. Co-authors should receive proposed re-submissions at least one week prior to journal re-submission. Occasionally, a re-verification of the manuscript is needed. See “Re-verification of a manuscript”, Item 13, page 11.
10. Entities involved and the responsibilities of each entity in the publications and presentations approval process are summarized in Tables 1 and 2.

**Table 1. Entities involved in the publications and presentations approval process with timing of approval, CARDIA Study**

	<b>Paper Proposal</b>	<b>Abstract</b>	<b>Presentation</b>	<b>Manuscript</b>
Co-author	A	A	A	A
Chief reviewer	N/A	N/A	N/A	B
P&P Committee	B	B	B	B
NHLBI	N/A	C	N/A	C

A- Approval required prior to date of scheduled P&P Committee discussion.

B- Approval required at time of P&P Committee discussion or subsequently, but prior to manuscript or abstract submission to journal or meeting, and prior to presentation. P&P Committee rarely delegates approval to chief reviewer or an ad hoc committee.

C- Review required at time of P&P Committee discussion or subsequently, but prior to manuscript or abstract submission to journal or meeting and prior to presentation.

N/A- Not applicable

**NOTE:** Approval of a paper proposal is not required prior to approval of an abstract/presentation.

**Table 2. Responsibilities of entities involved in the publications and presentations process, CARDIA Study**

	<b>Paper Proposal</b>	<b>Abstract</b>	<b>Presentation</b>	<b>Manuscript</b>
First author	1,2	1,2	1,2	1,2
Co-author	3,4,5	3,4,5	3,4,5	3,4,5
Chief reviewer	N/A	N/A	N/A	6,7
P&P Committee	8,9	8,9	8,9	8,9
NHLBI	N/A	14	N/A	14
CoC pubs coordinator	12	12	12	11,12
PI of originating center	4	4	4	4
CoC analysts	N/A	N/A	N/A	13

- 1- Leads proposal/analyses/writing efforts, keeps co-authors informed and active as needed.
- 2- Assures required approvals obtained.
- 3- Participates significantly in all scientific efforts.
- 4- Approves before submission to P&P Committee.
- 5- Is informed of minor changes and approves major changes after P&P Committee decision.
- 6- Approves final version of manuscript before submission to journal.
- 7- Provides feedback to first author, summarizes all comments in writing, makes recommendations to P&P Committee.
- 8- Approves paper proposal. Approves manuscript prior to journal submission or delegates this authority to chief reviewer. Approves abstract prior to submission or presentation prior to meeting or delegate responsibility to an appointed ad hoc committee.
- 9- Gives feedback to first author and chief reviewer prior to P&P Committee discussion.
- 10- Assigns chief reviewer.
- 11- Assures that all co-authors have approved manuscript in writing prior to Steering Committee submission.
- 12- Maintains data base and filing system, communicates with first authors regarding status of all publication items.
- 13- Verify results presented in manuscript prior to submission to journal.
- 14- Approves manuscript prior to journal submission or delegates this authority to chief reviewer. Approves abstract prior to submission or presentation prior to meeting or delegate responsibility to an appointed ad hoc committee.

N/A- Not Applicable

11. **Verification Process**

When designing the distributed data analysis system, the Steering Committee recognized the need to ensure consistency in analyzing and publishing data. To do this, they instituted the verification process, in which the analyses for all submitted papers are duplicated at the Coordinating Center. During the process, staff verifies that the most recent version of the database was used, that all exclusions are described accurately in the manuscript, and that the results reported in the manuscript match those obtained from the submitted code. When appropriate, a suggestion may be made to use a different statistical method for analysis. Verifications are assigned to various Coordinating Center staff.

After all necessary materials are received at the Coordinating Center; it will take approximately three weeks to complete verification. This timeline is extended if further information is needed from the first author. When the verification is completed, the first author and the Chief Reviewer will be notified in writing of any discrepancies between reported findings and the Coordinating Center's analyses. If the first author disagrees, he/she may contact the Coordinating Center to resolve the discrepancy or work with the Chief Reviewer to adjudicate any discrepancies. Otherwise, the corrections should be made to the paper. CARDIA guidelines state that manuscripts cannot be submitted for publication until they are verified and resultant corrections applied.

At the time of proposal approval, first authors will receive a packet describing the materials needed for verification. These materials should be submitted to the Coordinating Center when the manuscript is submitted to the Steering Committee for approval.

**The following items are required for verification:**

- A. A copy of the manuscript submitted to the P&P Committee for review and approval, annotated to link with analysis files. For any figures, please note the values used to generate the figure on the figure or include a separate sheet listing the values.
- B. A completed Form DD-5 (Notification of Terminated Analyses).
- C. A signed checklist for all materials contained in the packet.

- D. Adequate documentation to replicate all analyses presented. This documentation should be on an MS-DOS formatted diskette in printable text files along with a text file describing the diskette's contents. Most CARDIA analyses are conducted using the statistical package SAS, but occasionally other software is used. All verifications will be done in SAS. Details of the documentation required are noted below for each of these circumstances.
1. All data set creation programs merging distributed CARDIA data, thoroughly documented. Be sure to include all code that makes exclusions. If SAS is not used, a list of variables used as a text file must be provided.
  2. All programs in which any variables are calculated, re-coded, coded for use as indicators, standardized, reformatted, or categorized from continuous variables, thoroughly documented. If SAS is not used, describe exactly (using the actual variable names) any of the conditions above.
  3. All programs that perform all analyses reported in paper. These programs should include any analyses reported in the text, as well as results reported in tables or figures. Include relevant materials for *all* analyses, claims, results, and figures, even if data are not shown. If SAS is not used, include programs, logs and/or outputs from relevant analysis sessions using the variables described above in #1 and #2. Since the Coordinating Center will be recreating your analysis with SAS, it is important to clearly indicate all model terms, exclusions, special circumstances, procedures, etc.
  4. Name and telephone number of the first author and programmer (if the programmer is different from the first author). Occasionally, questions arise during verification. Having this information expedites resolution of these questions.

12. **Data Set Verification**

In March 1997, the Steering Committee approved an **optional** step in the verification process. Prior to beginning analyses, authors may submit the materials used to create their data sets to the Coordinating Center for review of any problems. This allows problems with exclusions or

created variables to be detected before analyses are completed. The materials required for this type of verification are similar to those listed in Item #11. Analysis programs will not be included and only a draft of the Methods section of the manuscript is required.

13. **Re-Verification and Re-review of a Manuscript**

After a paper has been verified by the Coordinating Center, there often is occasion for revision. This may happen because of changes suggested by the P&P Committee or NHLBI or, perhaps most commonly, when a paper is resubmitted to a Journal. These revisions may entail re-analyses including additional use of data. The first author should request re-verification by the Coordinating Center when:

- A. The information contained in a table or figure is changed other than by (1) deletions, or (2) corrections of simple typographical errors.
- B. New statements in the text refer to analyses not previously verified.
- C. The first author or a co-author believes that a re-verification is in order.

In order to ensure that re-verifications may proceed as expeditiously as is desirable, re-verification materials should be submitted that conform to the specifications outlined for regular verification procedures. If the same data set was used for the new analyses, only the programs that contain the new analyses need be sent. If the revisions involve a new data set, (e.g., different exclusions, additional variables) all programs used for the paper should be submitted.

The Coordinating Center will confer high priority to re-verifications. Staff at the Coordinating Center should be notified of any deadlines associated with the re-verification to ensure the work can be done within that time frame.

In addition to re-verification, the need for re-review should also be considered. CARDIA investigators who are co-authors should decide whether the revised manuscript is sufficiently different from the originally approved version to require re-review by the P&P Committee. Examples of indications for re-review follow. This list is not exhaustive:

- 1. Any major change in the results, e.g., changes in the direction of an association, significant changes in the magnitude of an association, newly significant associations, or loss of statistical significance of previously found associations.

2. Potential new overlap with other CARDIA publications.
3. Use of new variables, not part of the dataset that yielded the original submission.

**NOTE:** Regardless of the need for re-verification by the Coordinating Center, each revision which is sent to a Journal should also be approved by each co-author. The form of this approval is up to the authors and may be verbal, if mutually agreed upon by the first author.

## **XI. P&P Committee Review of Manuscripts**

The purpose of manuscript review is to evaluate the scientific merit, the clarity of the writing, and the consistency with other CARDIA findings.

### **1. Assignment of Chief Reviewer**

Prior to submission of a manuscript to the P&P Committee, the first author should contact the P&P Committee Chair to arrange assignment of a Chief Reviewer. The lead author and the Chief Reviewer agree on a mutually convenient conference call date for the P&P Committee review of the manuscript. The lead author then circulates the manuscript to the entire Steering Committee, with a request that comments be sent to both the lead author and the Chief reviewer at least three days before the P&P Committee conference call date. The Chief Reviewer for the paper serves as the Steering Committee's representative in communicating with the first author and expediting the review.

- A. The Chief Reviewer assembles all the Steering Committee's comments and communicates them to the first author as well as to the P&P Committee.
- B. The Chief reviewer briefly summarizes his/her own major comments and those from the Steering Committee to the P&P Committee during the conference call. The Chief Reviewer then makes a recommendation to the P&P Committee, in one of three categories: (1) unconditional approval; (2) approval with revisions, conditional only on chief reviewer approval; (3) suggested major revisions with re-review by entire P&P Committee. The Chief reviewer is strongly encouraged to discuss his/her planned recommendation to the P&P Committee before the P&P Committee call, unless the recommendation falls into category (1).
- C. The Chief Reviewer adjudicates any differences in opinion between the writing group and the CARDIA Steering Committee.

- D. The Chief Reviewer receives the results of the manuscript verification performed at the Coordinating Center and ensures that all issues have been resolved with the first author prior to journal submission.
- E. By accepting Chief Reviewer status, the Chief Reviewer commits to timely execution of Chief Reviewer's tasks, including a rapid response to a revised manuscript conditionally approved by the P&P Committee and submitted to the Chief Reviewer for final approval. Typically, the last task should be carried out in less than two weeks.

## 2. **Statement of Authors Form**

The first author is responsible for having all co-authors sign-off on the Statement of Authors Form prior to the manuscript being sent to the P&P Committee. Each coauthor should state their involvement with the manuscript. The original of the Statement of Authors Form is kept by the first author and a copy is sent to the Publications Co- Chair c/o of the Publications Coordinator at the Coordinating Center. Completion of this form is **required** prior to manuscripts being approved by the P&P Committee. A copy may be obtained by contacting the Publications Coordinator at the Coordinating Center.

- 3. The first author sends the final version of a manuscript to each member of the Steering Committee after approval by the Principal Investigator of the responsible center. The manuscript should be accompanied by a memo stating the CARDIA manuscript number, the title of the manuscript, the name and telephone numbers of the first author and Chief Reviewer (as assigned by the Publications Co-Chair) and the date of the conference call when it will be reviewed by the Steering Committee.
- 4. Each member of the Steering Committee has an opportunity to review and communicate approval or disapproval to the Chief Reviewer and first author within two weeks of receipt (at least two working days prior to the conference call when the paper will be reviewed). If all P&P Committee members agree that the paper may be submitted for publication, the paper will be approved.

5. Approval of a manuscript is documented in the minutes of the P&P Committee conference call. The Principal Investigator of the originating center and the Chief Reviewer are required to ensure that any small but required changes not requiring another full cycle of review are made before the paper is submitted to a journal.

## **XII. NHLBI Review for Abstracts and Manuscripts**

As of July, 2008, NHLBI no longer routinely reviews manuscripts and abstracts that emanate from NHLBI-sponsored contracts and cooperative agreements and that do not include NHLBI staff as authors.

The NHLBI review will continue for manuscripts that include NHLBI staff as authors. The abstracts will undergo review within five (5) business days. Manuscripts that are not considered High Impact by the Project Officer will undergo expedited review within five (5) business days. Manuscripts that are considered High Impact will undergo a detailed review within 10 working days.

In order to minimize time delays, NHLBI review of CARDIA materials may take place simultaneously with CARDIA Publications and Presentations Committee review.

As a courtesy, the NHLBI Project Officer for CARDIA should receive copies of manuscripts at the time of journal acceptance or before, particularly for "high-profile" papers such as those published in high impact journals or those having potentially sensitive topics.

Manuscripts or abstracts which require NHLBI review **should** be submitted to NHLBI for approval @ [ebpdocs@nhlbi.nih.gov](mailto:ebpdocs@nhlbi.nih.gov). The lead author will receive the comments and the approval letter from NHLBI electronically. Please also provide your complete mailing address so that NHLBI can include it on the approval letter. A CARDIA manuscript **should** not be submitted to a journal until the NHLBI approval is received.

## **XIII. Acknowledgement of NHLBI Role and CARDIA Review**

All manuscripts using CARDIA's distributed data set need to acknowledge support. For example, this acknowledgment should read, "Work on this manuscript was supported (or partially supported) by contracts: University of Alabama at Birmingham, Coordinating Center, N01-HC-95095; University of Alabama at Birmingham, Field Center, N01-HC-48047; University of Minnesota, Field Center and Diet Reading Center (Year 20 Exam), N01-HC-48048; Northwestern University, Field Center, N01-HC-48049; Kaiser Foundation Research Institute, N01-HC-48050; University of California, Irvine, Echocardiography Reading Center

(Year 5 & 10), N01-HC-45134; Harbor-UCLA Research Education Institute, Computed Tomography Reading Center (Year 15 Exam), N01-HC-05187; Wake Forest University (Year 20 Exam), N01-HC-45205; New England Medical Center (Year 20 Exam), N01-HC-45204 from the National Heart, Lung and Blood Institute.”

In addition, some journals are requiring that the lead author describe the role of the sponsor. In this case, it should be reported that NHLBI had input into the overall design and conduct of the CARDIA study. If there is an NHLBI co-author on a manuscript, then this co-author will provide further guidance in describing NHLBI’s role in more detail.

#### **XIV. NIH Public Access Policy**

Because CARDIA publications are funded by NIH, the NIH Public Access Policy applies to this manuscript (please see <http://publicaccess.nih.gov/>). Authors should note that, depending on the journal, there may be costs involved in abiding by the NIH policy.

#### **XV. Other Publication Policies and Considerations**

1. **Causality Statement:** CARDIA is an observational study, with inherent limitations on any causal inferences to be made from CARDIA analyses. Authors should generally frame CARDIA findings and conclusions in terms of association rather than causation. However, hypotheses involving etiological pathways can and should be generated by CARDIA analyses, and causal inferences are an appropriate topic for the discussion section of the manuscript.
2. It is expected that some reference to CARDIA appear in the title of any mainstream paper. This helps in indexing and retrieval and in gaining recognition for the study.
3. When special databases are provided by the Coordinating Center to Investigators for special analyses, the Coordinating Center will keep copies of these. The Coordinating Center must maintain control of the master data file for each and all centers and not permit unauthorized changes to be incorporated in it.
4. Each clinical center will have a copy of the complete set of its own data, which may be explored as desired. However, all publications stemming from center-specific analyses must be reviewed and approved just as is done for all other CARDIA publications.

5. The P&P Committee will regularly review paper assignments to determine if they are sufficient. The questions to be answered are:
  - A. Are enough topics being covered?
  - B. Are selected topics of sufficient importance to justify continued support?
6. **Industry Funding:** The recipient agrees not to enter into any verbal or written agreement or contract with industry or private individuals that will provide funding for analyses of CARDIA data without prior review and written approval of the CARDIA Study Investigators.
7. **Graduate Student Dissertation:** The use of CARDIA data for doctoral or masters' levels theses is encouraged although some aspects of graduate student work with CARDIA data need special consideration. In particular, students are generally new investigators who are usually not familiar with CARDIA data. This section of the publication policies attempts to balance the opportunity to involve promising new investigators with preserving the opportunity for established CARDIA investigators to publish study findings.

Publications and presentations resulting from theses are subject to all CARDIA publication policies, including the requirement that the CARDIA P&P Committee approve all paper proposals, all completed papers before journal submission, and all presentations before they take place. This includes seminars open to the public that are part of a thesis defense.

The distinction between approval of a dissertation proposal and approval of specific manuscript proposals resulting from a thesis is important. A specific request for thesis approval should include not more than one paper proposal and the elements specified below, with additional proposals to be entertained by the CARDIA P&P Committee later, as the thesis matures. Although prompt submission of subsequent paper proposals is strongly encouraged, the student should note that approval of the thesis does not constitute approval of any manuscript proposal other than the one included in the thesis proposal.

**The request to use CARDIA data in a graduate dissertation should include the following elements:**

- A. The name of at least one CARDIA investigator who has agreed to serve on the student's dissertation committee and as a co-author of the first publication.
- B. Brief description of rationale, background, main hypotheses, analytic approach for the thesis.
- C. Proposal of one CARDIA manuscript to result from the thesis work, in the usual CARDIA paper proposal format. Like all other CARDIA paper proposals, this must include at least one CARDIA investigator as co-author.
- D. Acknowledgment of having read CARDIA publications policies and commitment to abide by them.
- E. Timeline for completion of analysis and proposed manuscript
- F. Formal involvement of the thesis advisor, in the form of an e-mail or letter that (1) endorses the thesis and paper proposal; (2) states willingness and availability to discuss the work with CARDIA investigators; (3) states commitment to abide by CARDIA publications policies.
- G. **Data Distribution Policy and Agreement in Relation to Student Dissertations:** After a thesis proposal is approved, both the student and the advisor must review the CARDIA Data Distribution Policy and complete and sign a CARDIA data distribution agreement, and only then will the CARDIA Coordinating Center prepare an analytic dataset that will be sent to the advisor, for both the advisor and the student's use for approved thesis work.

**XVI. Review Process for Abstracts and Presentations**

- 1. Verification of the analyses for an abstract is not performed by the Coordinating Center unless the data appear questionable.
- 2. Abstracts must be reviewed by both P&P and NHLBI prior to submission. See "NHLBI Review for Manuscripts and Abstracts".

3. If a poster presentation is not submitted to the P&P Committee at least two weeks prior to the presentation date, the poster may be required to be withdrawn. If an oral presentation is not submitted for review in sufficient time, the presenter may be asked to withdraw from the program.
4. Review by the P&P Committee is required for all presentations of CARDIA findings at meetings and conferences except:
  - a. Teaching conferences and classes for students and colleagues in a university setting, and that have no publicity involved, or
  - b. CARDIA findings, ALL of which have been previously published or approved for presentation.

## **XVII. Invited Papers and Presentations**

It is anticipated that Investigators associated with CARDIA will be invited as individuals to prepare papers or give oral presentations concerning findings or other aspects of CARDIA. When such invitations are received, the invitee should inform the inviter that acceptance will need to be approved by the P&P Committee. The Committee will decide whether such a paper or presentation is appropriate and who should give the presentation or take the lead in writing the paper. (Papers and the list of authors will need final approval as described above.) Among other factors, these decisions take into consideration possible conflicts with other planned data analyses or competition for use of other CARDIA resources within the time allowed for completion of the invited paper or talk.

If an inviter has special reasons for choosing the particular invitee, (e.g., special qualifications, previous or other involvements with the organization) these should be submitted by the inviter or invitee to the P&P Committee to assist it with the decision.

## **XVIII. Use of data documentation forms, CARDIA study**

FORM	WHEN	WHY
FORM DD-1	When any technical problems arise.	To notify Coordinating Center of problems with use of the data tape.
FORM DD-2	Prior to programs or analyses performed on any part of the data set.	To inform the Coordinating Center of all ongoing analysis and for assisting the Coordinating Center in communicating known problems with data sets back to clinical center.
FORM DD-3	When any questions concerning the data arises.	To allow the Coordinating Center to initiate the editing process for this variable.
FORM DD-4	To document any changes made to the SAS data sets by a clinical center.	To allow the Coordinating Center to update the CARDIA data files for later distribution
FORM DD-5	Upon closing out of analyses for a project whether or not it results in publication.	To allow the Coordinating Center to verify results of the analyses prior to publication and for final approval by Steering Committee.
FORM DD-11	When a person from outside the CARDIA study group wants to analyze data.	To request from Coordinating Center partial or complete copies of CARDIA data files. This documents and tracks all additional distributions of data.
FORM DD-13	When a person wants to submit a completed paper for NHLBI clearance.	To request NHLBI to begin the clearance process of the completed paper.

**XIX. APPENDIX A**

**Instructions for Completing Manuscript Proposal, CARDIA Study**

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1. Complete the form below; it may be returned via e-mail as an attachment.
  2. Provide complete contact information for the first author. If a CARDIA investigator will serve as the representative (contact person), state this on the proposal and include complete contact information for that person. Provide co-authors and e-mail addresses on separate lines. Do not include the e-mail address beside the co-author (i.e., Fred Watson, Jamie Hanes. On next line: [fwatson@ucsf.edu](mailto:fwatson@ucsf.edu), [jhanes@uab.edu](mailto:jhanes@uab.edu)). Co-authors and e-mail address to be typed from left to right, separate by a comma.
  3. **Indicate if “Core or Ancillary Study” Data. Include the “Ancillary Study title”, “Keywords” and a “Timeline.” All of this information is required, if it is not provided, the proposal will not be reviewed and will be returned to you for completion.**
  4. It is recommended that a paper proposal be limited to two (2) pages, if at all possible.
  5. The PI of the originating site or CARDIA investigator participating on the writing group must review and approve the proposal prior to submission to the **Publications and Presentations (P&P) Committee.**
  6. Submit the proposal to the **CARDIA P&P Committee** with a request for approval via e-mail.
  7. Provide the conference call date on which the proposal will be considered and any other information that may be related to the review of your proposal.
  8. E-mail proposal to Linda Sellers for distribution to the P&P Committee and the CARDIA investigators. [lsellers@dopm.uab.edu](mailto:lsellers@dopm.uab.edu).
  9. Questions? Contact the Coordinating Center at (205) 934-0786.
  10. **Please delete these instructions prior to submitting the manuscript proposal.**
- 

**Manuscript Proposal, CARDIA Study  
(Date of request)**

**I. Title:** \_\_\_\_\_

**II. Abbreviated Title:** \_\_\_\_\_

**III. Data:** Core:  Ancillary:  Both:  Ancillary Study Title: \_\_\_\_\_

**Keywords:** \_\_\_\_\_

**IV. Writing Group (list individual with lead responsibility first)**

Lead author: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_ E-mail: \_\_\_\_\_

Address: \_\_\_\_\_

Co-authors:

E-mail addresses:

**V. Background**

**VI. Main Study Questions and Hypotheses**

**VII. CARDIA data to be used (Required: CARDIA exam year(s);  
Recommended: variable types, names CARDIA source form)**

**VIII. Analytic Plan**

**IX. Timeline**

**References (if applicable)**