DIABETES PREVENTION PROGRAM OUTCOMES STUDY
DPPOS 4
MANUAL OF OPERATIONS
Chapter 7

7. Policies

7.1 Publications and Presentations Policy

7.1.1 Summary

The Publications and Presentations Subcommittee (PPS) will coordinate, monitor, review, and assume responsibility for arranging the preparation of all study-wide scientific communications (press releases, interviews, presentations, and publications). These policies apply to data derived from either the Diabetes Prevention Program (DPP) or the Diabetes Prevention Program Outcomes Study (DPPOS), which, in this chapter, will be jointly referred to as DPP/DPPOS. When the Research Group is identified in communications, it will be referred to as the "Diabetes Prevention Program Research Group" regardless of whether the data reported are from the DPP, DPPOS, or both. During the course of these studies, there will be no publications or presentations of study plans or results which have not been reviewed and approved by a majority of the PPS, and for some types of communications, a majority of the Steering Committee.

With respect to publications and presentations from the DPP/DPPOS, the goals of the PPS are to:

1. Ensure accurate, uniform, timely, and high quality reporting of the DPP/DPPOS activities and results;
2. Preserve the scientific integrity of the study;
3. Safeguard the rights and confidentiality of participants; and
4. Ensure that the timing of publications and presentations serves the right of the public to know the results of the program without jeopardizing its conduct.

The PPS will organize a writing group for each publication or presentation proposed by the members of the Diabetes Prevention Program Research Group. Members of writing groups will include volunteers from the members of the Diabetes Prevention Program Research Group at large, and will not be restricted to members of the PPS. The PPS will coordinate the efforts of the writing group, establish priorities for data analysis by the Coordinating Center, and help edit the manuscripts produced by the writing groups.

There will be several categories of publications and presentations, with different rules for authorship, ranging from publications of the main results of the study (with authorship by a group writing on behalf of the entire research group) to other types of publications with named authors. The authorship rules balance the need to recognize the contributions of all members of the Diabetes Prevention Program Research Group and staff with the need to recognize individuals for specific contributions to certain types of publications and presentations.

7.1.2 Introduction

The PPS will coordinate, monitor, review, and assume responsibility for arranging the preparation of all study-wide press releases, interviews, presentations, and publications relating to the scientific aspects of DPP/DPPOS. During the planning, conduct, and analysis of the DPP/DPPOS, there will be no communications of study plans or results that have not been reviewed and approved following procedures as described below.

7.1.3 Duties of the Publications and Presentations Subcommittee

1. Recommend policy and procedures for review and approval of all scientific communications regarding the DPP/DPPOS to outside groups.
2. Identify publications to be written, abstracts to be submitted, and presentations to be made during the course of the study, with target dates for each. The PPS will also review proposals for DPP/DPPOS-related publications or presentations.
3. Propose policy guidelines for authorship of DPP/DPPOS publications and appoint writing groups.
4. Monitor the writing of each paper to ensure publication in a timely fashion.
5. Suggest appropriate journals for DPP/DPPOS publications and monitor the process of publication.
6. Perform other writing, reviewing, or editing tasks assigned by the Steering Committee.
7. Assist writing groups in publishing papers of the highest quality and clarity. Review and edit all DPP/DPPOS publications and presentations prior to submission, enlisting the special assistance of other members of the Diabetes Prevention Program Research Group and subcommittees whenever appropriate. The activities of the PPS will be conducted pursuant to the goals outlined under Section 7.1.1 (Summary) regarding publications and presentations from the DPP/DPPOS.
8. The PPS will also review and suggest necessary revisions for any publications arising from approved ancillary studies prior to their submission for publication. In addition to the issues cited in the editorial policy above, proposed publications of ancillary studies will be scrutinized to ensure that their presentation will not threaten the viability of the DPP/DPPOS.

7.1.4 Definition of Communications

7.1.4.1 Types of Communications

Any communication from the DPP/DPPOS will be classified as a press release, interview, presentation, or publication.

1. **Press Releases and Interviews.** A press release is defined as a document given to radio, television, newspapers, popular periodicals, or scientific journals (including publications of pharmaceutical companies or professional organizations) not indexed in Index Medicus. An interview is any discussion with a member of the press, a science writer, or a radio or television commentator, who in turn provides information for public dissemination.
2. **Presentations.** A presentation is the delivery of information to scientific, professional, or public groups. A presentation may include an abstract to be published by the group to which the presentation is made.
3. **Publications.** A publication is any document (other than an abstract) submitted to a professional journal listed in the Index Medicus or any popular periodical with national circulation.

7.1.5 Classification of communications

Old or new information. A communication will be classified as containing old information if the content is limited to review of background material, substantive information available either in the final

Protocol, the Manual of Operations, previously published DPP/DPPOS results or other published data, with no added interpretations or inferences.

A communication will be classified as containing new information if it contains DPP/DPPOS material not previously published or presented. A communication containing both old and new material is considered new.

If an abstract is submitted to a national meeting, the abstract may be published before the meeting, and the presentation at the meeting is likely to occur before the full article on the same topic is published in a journal. This gives rise to the question of when the information changes from being "new" to "old". This transition occurs only for the precise information made public at each step. For example, data in a published abstract are public, and can be discussed or cited by anyone, including members of the Diabetes Prevention Program Research Group. However, no background data or interpretations which are still new and were not included in the abstract can be discussed or otherwise considered old information. Similarly, new information presented at a national meeting becomes old, and can be cited or discussed, but only to the extent that it was actually presented. Other details that will appear in a full article cannot be cited or discussed until that article is published. Copies of slides or other presentation materials (e.g. poster figures) used in meetings will be made available to other members of the Diabetes Prevention Program Research Group upon request by a Principal Investigator. Principal Investigators should not distribute the material outside their centers. Presentation materials may also be made available to other respected scientists if the request is approved by the PPS. This approval can be given by the PPS Chairperson unless he/she wants to refer the question to the full PPS. Approval will generally be given for legitimate academic purposes but not for commercial activities.

Invited or submitted communications. A communication is invited if it is made in response to an invitation from an entity outside the DPP/DPPOS, whether the invitation is to an individual member of the Diabetes Prevention Program Research Group or to the DPP/DPPOS as a group. A communication is submitted if it is initiated by the DPP/DPPOS and the DPP/DPPOS chooses the meeting (for a presentation) or journal (for a publication).

7.1.6 Categories of Communications and Authorship of Publications

The following categories of communications apply to all types of communications, i.e. press releases, interviews, presentations, and publications. Press releases, interviews, and presentations without published abstracts are not considered to have authors. When they are accompanied by published abstracts, the authorship rules for the abstracts are the same as for other types of publications, as described in this section. Responsibility for the category assignment for all publications and presentations rests with the PPS. Writing groups may be composed of two types of persons: regular members of the DPP Research Group are those who have been members (staff, investigators, and co-investigators) of a DPP clinic, coordinating center, or collaborating unit, independent of a paper in question. Outside collaborators are those who collaborate in a particular DPP study or paper(s) but are not regular members of the Research Group. For purposes of listing authors, both categories are considered members of the DPP Research Group. Outside collaborators may work at institutions that are DPP centers or at other institutions. For example, they may represent laboratories performing special tests for a DPP project, but that have no other role in the DPP. They will propose their studies through a regular member of the DPP Research Group or will be recruited by such a member. A person who was an active regular member of the DPP Research Group will still be considered a regular member even if no longer funded by or spending substantial time on DPP/DPPOS.

A. Primary DPP/DPPOS Communications: These communications address the principal goals and objectives of the program and use the database from all participating centers. A major feature of these communications is inclusion of study-wide data generated by the DPP/DPPOS. Examples of topics are: baseline data, protocol design, primary and secondary outcomes, recruitment, assessment of compliance, informed consent procedures, and relationships between study variables such as measures of adiposity, diet, physical activity, glucose, insulin, lipids, blood pressure, ethnicity, quality of life, and economic costs, either at baseline or in response to treatment. The writing group will almost always be composed entirely of regular members of the DPP Research Group.

Authors - The Diabetes Prevention Program Research Group, Prepared by A.B. Smith (Chairperson), C.D. Garcia, and E.F. Johnson.

There may be some variation of the format of this listing of authors according to the journal requirements, e.g., the writing group members may be listed on the authors' line or in a footnote on the title page.

Whenever possible, the complete list of members of the Diabetes Prevention Program Research Group will appear at the end of the paper.

B. **Secondary Communications:** These communications use the database from all participating centers, but address issues that are peripheral to the major objectives of the trial or involve measurements or analyses that were not specified in detail in the DPP or DPPOS protocols or manuals of operation. Examples of topics are: previously unanticipated relationships between variables, measures of substances in blood or urine samples that had not been previously planned (such as new diabetes or cardiovascular risk factors), or genotypes. The writing group will usually include regular members of the DPP Research Group who participate in planning and analysis of the study, but in many cases will also include outside collaborators for the paper in question.

Authors - A.B. Smith, C.D. Garcia, and E.F. Johnson for the Diabetes Prevention Program Research Group[+]

[+] Reference should be made to a category A paper in which all regular Research Group members are listed. The affiliation of outside collaborators may also be indicated in footnotes (according to the style of the journal). The acknowledgments may also list other members of the outside collaborators' institutions/laboratories who are not members of the writing group.

C. Ancillary Communications: These communications use only limited subgroups of DPP/DPPOS participants and/or a significant amount of non-DPP/DPPOS data: These communications either use data from certain subgroups of clinics or from one clinic and/or use significant amounts of non-DPP/DPPOS data. Protocols for obtaining such non-study wide DPP/DPPOS data would receive approval by the Ancillary Studies Subcommittee before activation. The writing group may include regular DPP Research Group members plus outside collaborators.

There are two types of ancillary communications:

C_1: These communications involve most or all centers in the Diabetes Prevention Program as well as additional clinic or participant burden. The Presentations and Publications Subcommittee will treat these communications as if they are Diabetes Prevention Program communications including, but not limited to, proposal approval, writing group volunteer solicitation and PPS and Steering Committee approval of resultant communication.

C_2: These communications involve only a select number of centers in the Diabetes Prevention Program and require no additional data collection or participant burden. The Publications and Presentations Subcommittee need only approve the communication. Approval of these proposals, solicitation of writing group volunteers, and Steering Committee approval is not required.

Authors - A.B. Smith, C.D. Garcia, and E.F. Johnson and the Diabetes Prevention Program Research Group[+]

[+] Acknowledge the Diabetes Prevention Program: a complete list of the members of the Diabetes Prevention Program Research Group can be found in (appropriate journal citation).

D. Miscellaneous Communications: Some communications, mostly concerned with methodological issues, will not deal with the DPP/DPPOS population or the DPP/DPPOS study directly but will be prompted by discussions during the development of the DPP/DPPOS study designs. Such a communication, prepared by a member of the DPP/DPPOS, should include an acknowledgment of its NIDDK/DPP/DPPOS support.

Authors - A.B. Smith, C.D. Garcia, and E.F. Johnson[*]

[*] This study was partially supported by the Diabetes Prevention Program (or the Diabetes Prevention Program Outcomes Study), NIDDK.

E. Reviews or Commentaries: Review or commentary presentations (papers or lectures) summarize and discuss DPP/DPPOS methods or results that have already been published or publicly presented elsewhere. They are typically written as book chapters or review articles in journals. This category will apply to presentations dealing primarily with the DPP/DPPOS, although reference to other studies of diabetes prevention will usually be included. On the other hand, review papers covering a broader field of diabetes prevention or risk factors in which the DPP/DPPOS is discussed but is not the major topic will not be considered DPP/DPPOS presentations and will not be reviewed by the PPS. Similarly, presentations made by non-DPP/DPPOS investigators are of necessity outside the purview of this policy.

Authors - A.B. Smith, C.D. Garcia, and E.F. Johnson for the Diabetes Prevention Program Research Group*

* Acknowledge DPP/DPPOS: a complete list of the members of the Diabetes Prevention Program Research Group can be found in (appropriate journal citation).

When authors' names are listed (for papers of any category), they will be those of the members of the writing group. Note that all references to the full Research Group will be to the Diabetes

Prevention Program Research Group whether the data in the communication were derived from the DPP, DPPOS, or both.

All professional members of the Diabetes Prevention Program Research Group who have the approval of the Principal Investigators and have served at least two years in a significant capacity with the study will be listed at the end of some category A papers and will be considered as authors. In addition, a Principal Investigator may provide justification in writing to the PPS to include individuals who have been with the DPP/DPPOS for less than two years for inclusion.

Whenever possible, a list of all participating centers will appear in the category A and B publications. Under each center, a roster of names, as described above, will appear, each followed by the academic degree(s), when allowed by the journal. For the purposes of this listing, the Coordinating Center, the central units and core facilities, and the NIDDK will be considered as special units and be listed as participating centers. Other organizations providing scientific input and funding, such as the NIA and the CDC, will be so listed. Those scientific, government, or commercial organizations only providing funding will also be listed. If the roster of credits is deemed too lengthy by a journal, the PPS may ask the NIDDK to pay a reasonable amount towards page costs to permit such a roster to be printed intact. If the list does not appear in the publication, reference will be made in that to publication to the most recent published article with the full list included.

The categories and authorship rules for abstracts accompanying presentations are as above except that a full list of members of the Diabetes Prevention Program Research Group will not be included.

7.1.7 Policies and Procedures

Proposals for presentations and publications should come from the members of the Diabetes Prevention Program Research Group at large, and are thus not the sole responsibility of the PPS. The PPS, through the Coordinating Center, will keep the Steering Committee informed of the status of all communications, from their inception through review and the final presentation or publication.

All communications from the DPP/DPPOS, including those of ancillary studies, will be prepared under the overall review of the PPS. Approval of publications or presentation of ancillary studies that may jeopardize the outcome of the DPP/DPPOS may be withheld until it is deemed appropriate by the PPS.

7.1.7.1 Press releases and interviews

Except for the purposes of recruitment, press releases and interviews will not be initiated by clinical centers. Press releases or interviews concerning old or new study information may not be made without the prior approval of the PPS. Centrally prepared press releases will be reviewed by the PPS and distributed to the centers. It is suggested that these prepared releases be given to the media when interviews are requested. This procedure will help ensure uniformity and accuracy of the information disseminated through the media. In this instance, such centrally prepared press releases need no prior approval from the PPS. Should a clinical center be solicited for information other than that detailed above, the Clinical Center should refer the soliciting party to the Chairperson of the PPS.

A press release or interview providing new information may be appropriate simultaneously with a presentation or publication announcing a study result of great public interest. Such a press release or interview needs to be approved in advance by the PPS and the Steering Committee (by majority vote of each), and the simultaneous presentation or publication must be approved as specified below.

7.1.7.2 Presentations

A presentation of old information to a regional or local meeting may be given without prior review and approval by the PPS, provided that the PPS Chairperson has been notified in writing beforehand, This notification should include an outline or description of topics to be covered. Any change of the old information, will need prior approval by the PPS. "Regional or local" refer to the scope of influence of the meeting, not to the location relative to the workplace of the presenter; i.e. a local meeting can take place at a great distance from the workplace of the presenter.

Any DPP/DPPOS presentation involving new data and any presentation to a national or international meeting, regardless of content, must be reviewed as follows:

1. Invited presentations (of old information): If a member of the DPP/DPPOS is personally invited to present old DPP/DPPOS information or represent the DPP/DPPOS at a national or international meeting, the invitation must be forwarded to the PPS as soon as possible. The PPS reserves the right to accept or decline the invitation and suggest a presenter other than the invited DPP/DPPOS member in order to distribute the opportunities for presentation widely among the members of the Diabetes Prevention Program Research Group.
2. Submitted presentations (of old or new information) or invited presentations of new information: The PPS will identify scientific and professional meetings where presentations about DPP/DPPOS should be made on behalf of the group. Suggestions for such meetings and topics for presentation will be made by the PPS or individual members of the Diabetes Prevention Program Research Group. The PPS will identify one or more members of the Diabetes Prevention Program Research Group (not necessarily PPS members) to prepare and present the material. These persons will be referred to as the presentation group, and the person designated to make the presentation as its Chairperson. If several proposals for similar presentations are made, the PPS will request the involved persons to resolve their differences, and if appropriate, join in a common presentation group.
3. Preparation and review of submitted presentations or invited presentations of new information: For any particular proposed presentation, a member of the PPS who is not a member of the presentation group will be designated by the PPS Chairperson to serve as the PPS primary reviewers. The PPS primary reviewers will assist the presentation group Chairperson in coordinating the efforts of the presentation group. For presentations including new data, the PPS will establish priorities for data analysis by the Coordinating Center. The Principal Investigator of the Coordinating Center will designate one of his/her staff to work with each presentation group in order to provide liaison and resource material for the presentation.
4. Abstracts of Category A,B, or C1: The presentation group must write an abstract of the proposed presentation. This will be the abstract submitted to the organization sponsoring the meeting, if one is required. If new data are to be presented and no abstract is required by the

meeting organization, an abstract or description must be prepared for DPP/DPPOS review. The presentation group will submit the abstract to the entire PPS (through the Coordinating Center) for approval. The PPS will appoint a primary reviewer(s) to review the manuscript, who may recommend changes to the abstract prior to its approval.

After approval by the PPS, the final abstract will be distributed to the Steering Committee. The abstract must be delivered to the Steering Committee at least 14 days prior to the deadline for submission to the organization holding the meeting. At least 7 days prior to the submission deadline, the Coordinating Center will conduct a vote of the Steering Committee (by telephone, fax, or e-mail, or in person if the Steering Committee is in session) for approval of the abstract of a category A or B presentation. In addition to voting, Steering Committee members may give suggestions for revision to the presentation group and the PPS primary reviewer(s). If the latter choose to revise the abstract in response, the revised abstract must again be approved by the PPS. If the revision alters the substance of the abstract (rather than merely improving style and clarity), it must be distributed to the Steering Committee for another vote. If the abstract is approved by a majority of the Steering Committee, it can be submitted by the Coordinating Center. If it is not approved, the presentation group can revise and resubmit to the PPS only if sufficient time for review remains, or they can resubmit it to the PPS for consideration for a different meeting with a later submission deadline. Non-votes by steering committee members will be considered as YES votes.

It is expected that the presentation group will submit a corresponding manuscript to the PPS by the time of their presentation. Usually the members of the presentation and writing groups will be the same. If, at the time a presentation is proposed, a corresponding publication has not already been proposed, such a proposal should be made by the presentation group as soon as possible after the presentation is approved so that the manuscript can be completed on time.

5. Abstracts of Category C2, D, E: Presentations will be distributed as above, and members of the Steering Committee may comment to the Chairperson of the presentation group and to the PPS, but a vote of the Steering Committee will not be taken. Submission of an abstract or agreement to a category C-E presentation requires approval of a majority of the PPS, but not of the Steering Committee.

   Slides, tables, and/or a presentation script must be sent to the PPS primary reviewer(s) at least four weeks prior to the scheduled presentation.

6. Publication associated with a presentation: Ordinarily, a DPP/DPPOS presentation should not be accompanied by a manuscript or other written material except for an abstract. If a manuscript is requested in conjunction with a presentation (e.g. a "proceedings" paper), such manuscript must be prepared and approved according to the rules and procedures for publications, and approval of the presentation does not constitute approval of the publication. A member of the Diabetes Prevention Program Research Group accepting an invitation to present DPP/DPPOS material must make the inviting organization aware of these requirements.

   If an abstract is included with a submitted presentation and the presentation is not accepted, then the presentation group should request that the abstract not be published.

A complete list of DPP/DPPOS publications will be posted on the DPP/DPPOS website, which will be updated regularly.

7.1.7.3 Publications

The following procedures apply to all publications (of any category) whether submitted or invited, and whether they consist of old or new information.

1. Writing group: Members of the Diabetes Prevention Program Research Group who propose and formulate topics for publication will be included to the extent practical. In order to provide equal access to volunteers from all DPP/DPPOS affiliated institutions, proposing groups should contain no more than two or three authors from the same institution unless the proposing group chair can demonstrate the writing group cannot find the same, necessary expertise anywhere else. The entire proposing group should include no more than 5 members to allow opportunity for other Research Group members to volunteer. The individuals proposing a new manuscript may also propose a writing group and identify its members. The PPS will review and approve the manuscript topic as well as the members, including Chairperson, of the newly formed writing group. It will then vote on a category and assign priority of the manuscript. Potential conflict with other proposals for publication will be evaluated. If several proposals for similar papers or data analyses are made, the PPS will request the involved persons to resolve their differences, and if appropriate, join in a common writing group. Any disagreements between a member of the Diabetes Prevention Program Research Group and the PPS may be appealed as discussed in Section 7.1.9(Grievances). Finally, the Coordinating Center will post the approved proposal, category, and priority on the web. The Coordinating Center will send a call for volunteers to the DPP Research Group at large. The PPS will review the volunteers including those originally proposing the paper. The PPS recommends a writing group of up to 12 individuals for each proposed publication (more individuals are allowed for genetics related papers and those involving collaboration with other projects). Members of the writing group will be drawn from the members of the Diabetes Prevention Program Research Group at large, and will not be restricted to members of the PPS. A writing group may also include non-DPP/DPPOS individuals. When there are more than 12 volunteers, the PPS, in consultation with the writing group chair (usually the person proposing the paper), will decide which ones to accept. This decision is based on consideration of potential contribution to the writing group, subject matter expertise, group diversity (with respect to centers and professional categories), and the volunteer's involvement in other writing groups. Although writing groups will usually be limited to 12 members, if more than 12 volunteer, the PPS may consider whether an exception to this limit should be made in this case.
2. IRB approval: Authors of DPP/DPPOS manuscript proposals and all members of writing groups must have IRB approval to work with DPP/DPPOS data or have an IRB waiver (e.g. be considered exempt) from their institution. For papers involving analysis of data generated by the DPP/DPPOS, at least one member of the writing group will be from the Coordinating Center. The PPS will designate one individual as Chairperson of the writing group, who will be responsible for ensuring that the first draft of the publication is written.

Refer to the resources on the Publications and Presentations Subcommittee webpage for additional information.

3. Journal identification: The PPS will endorse the recommendation of the writing group or occasionally suggest an appropriate journal for the submission of each proposed publication so that the manuscript can be prepared according to the guidelines of a specific journal and be directed towards its known readership.

4. Preparation and review: For each proposed publication, at least one member of the PPS who is not a member of the writing group will be designated by the PPS to serve as the PPS primary reviewer(s). The PPS primary reviewer(s) will serve as the most thorough reviewer for the manuscript, reviewing the manuscript in detail and then leading the discussion of the manuscript once under review by PPS. For publications including new data, the PPS will establish priorities for data analysis by the Coordinating Center. The Principal Investigator of the Coordinating Center will designate one of his/her staff to work with each writing group in order to provide liaison and resource material for the publication. The writing group chairperson and Coordinating Center statistician will formulate a working analysis plan for the manuscript. Additional PPS review may be needed if the analysis plan is changed dramatically from the original proposal. Upon the completion of analyses, tables, and results by the Coordinating Center, the chairperson of the writing group will prepare a manuscript draft to be submitted to the Coordinating Center. The Coordinating Center will post the manuscript draft for review by the PPS primary reviewer(s) and the other PPS members on the DPPOS website.

   Upon reviewing the draft manuscript, the PPS will make a determination to approve the manuscript or request revisions. Depending on the magnitude of the revisions, the manuscript may require re-review and approval from one of or a combination of the PPS chairperson, primary reviewer(s), or the PPS members. Once approved by a majority of the PPS, the manuscript will be distributed to the Steering Committee by the Coordinating Center.

   After distribution of the final draft to the Steering Committee, the Coordinating Center will conduct a vote (via the DPPOS website, or in person if the Steering Committee is in session) for approval of a category A or B paper. Non-votes (i.e., abstention or non-response) by a Steering Committee member will be counted as a "yes" vote. In addition to requesting Steering Committee review and vote, the draft manuscript will be posted on the website for the research group to review. Any member of the Diabetes Prevention Program Research Group who wishes to comment on the paper must communicate his/her concerns to the Coordinating Center PPS liaison who will compile the comments for the writing group. Comments should be made by the time the vote is taken. If the writing group Chairperson agrees that the comments warrant a further revision of the paper, the writing group will make such a revision, and depending on the magnitude of the revision the revised paper must again be approved by the PPS. Similarly, if the revision alters the substance of the paper (rather than merely improving style and clarity), it must be distributed to the Steering Committee for another vote.

   Manuscripts that are classified as category C-E will be distributed as above, and members of the Steering Committee may comment to the Chairperson of the writing group and to the PPS, but a vote of the Steering Committee will not be taken. Submission of a category C-E publication requires approval of a majority of the PPS, but not of the Steering Committee.

5. Submission of manuscript: If the Category A or B manuscript is approved by a majority of the Steering Committee, it will be submitted to the journal by the Coordinating Center. The Chairperson of the writing group, through the Coordinating Center, will serve as corresponding author.

   Papers of categories C-E will be submitted by the chairperson of the writing group who will also serve as the corresponding author.

   The corresponding author is responsible for reviewing the galleys and responding to the reviewer comments, which do not need PPS review.

   Page and reprint charges will be paid by the Coordinating Center (for category A and B publications) or by the Chairperson of the writing group (for category C-E publications).

   If the manuscript is rejected, the writing group will target another journal. For rejected manuscripts, or those where a journal requests a revision and resubmission, PPS review is required if substantial changes have been made.

   A complete list of the status of ongoing manuscripts can be found on the DPPOS website.

7.1.8 Standards of excellence

In addition to the review system established for the critique of publications and presentations as described in the previous section, the following guidelines are suggested for maintaining the highest standards of excellence for DPP/DPPOS publications and presentations.

If, in the opinion of the members of the PPS, no member of the Diabetes Prevention Program Research Group has sufficient scientific background to review the pertinent material, then outside (of DPP/DPPOS) expert consultants will be selected by the PPS and asked to critique the material.

For the major publications and presentations, the completeness and adequacy of the reports will be assured by consideration of the 32 steps described in "A Proposal for Structured Reporting of Randomized Controlled Trials", JAMA 272: 1926-1931, 1994. While these considerations should govern the design and conduct of the trial, not all points need to be mentioned in each publication or presentation.

7.1.9 Grievances

A member of the Diabetes Prevention Program Research Group may formally appeal in case of disagreement with the PPS concerning the following:

1. Classification of a communication,
2. Membership or chairmanship of a writing or presentation group,
3. Handling or approval of a communication,
4. Authorship inclusion and order,
5. Suitability of a presentation or publication, or
6. Any other action taken by the PPS.

To initiate an appeal, the claimant should initially discuss the issue with the Chairperson of the PPS to clarify why the disputed judgment was made. If this does not satisfactorily resolve the matter, the claimant should send a letter of appeal (supported by appropriate documentation) to the Coordinating Center for distribution to the entire PPS. The PPS will review the grievance and respond in writing within four weeks of receipt of the appeal. If the claimant still feels that the issue has not been satisfactorily resolved, copies of the letter of appeal and the response of the PPS will be sent to the Coordinating Center within two weeks for distribution to the entire Steering Committee for review. A decision of the Steering Committee regarding a grievance will be binding.

7.1.10 Ownership of Data

For purposes of publication and presentation policies, study data are defined as all data specified in the Manual of Operations pertaining to participants randomized in the clinical trial. Participants evaluated for eligibility but not randomized (for whatever reason) can be used by the individual Clinical Centers for other studies. Any DPP/DPPOS data obtained during the screening and eligibility process, however, can be presented or published only according to these policies.

Study data will be owned jointly by the individual Clinical Centers and the Coordinating Center, but will be kept at the Coordinating Center. The Coordinating Center and Clinical Centers will make no use of study data nor disclose them to any other parties except as specified in the Protocol or Manual of Operations, unless such use or disclosure is approved by a majority of the Steering Committee.

Approximately two years after the publication date of each DPP/DPPOS publication of category A or B which includes outcome data, the Coordinating Center will make the appropriately anonymized data available to the scientific community through the NIH data repository. The anonymized data will contain only the variables that are used in the publications. The repository will sign a data use agreement with the Coordinating Center, and will also require all future recipients of the data to sign a data use agreement. The Coordinating Center will release a fully documented copy of all DPP/DPPOS data to each Clinical Center when it ceases to function as an analytic resource to the DPP/DPPOS (i.e. when its DPP/DPPOS funding terminates). The full data set will be made public two years after this release. Decisions regarding disclosure of data to other parties, such as pharmaceutical companies or the FDA (beyond the required adverse events reports), shall be determined by the Steering Committee. Confidentiality of individual participants will be maintained with all releases of data.

7.1.11 Presentations to Volunteer Participants

Presentation or report of key results will be offered to the volunteer participants before they are presented to the public or to the professional communities and the public. Each Clinical Center can use their judgment to determine whether this should be done by in person or virtual presentations to participants at each Clinical Center or by a written report or letter. Typically, the Executive Committee will aid with drafting the written report or letter for participants.

7.2 Analysis Policy For Manuscripts

All manuscripts in the DPP/DPPOS will have an analysis plan, data tables and figures, manuscript drafts, correspondence to/from journals. All versions of documents will be posted to the DPP/DPPOS website. Writing Group proposals and final manuscripts are available for the research group.

Analysis proposals should state whether troglitazone patients are to be included. The CoC and PPS will advise on whether the addition of the troglitazone group would create too much complexity. See Table 7-1 for reference.

Table 7-1

Topic	Policy
Proposal	Proposals will include background with references, significance, specific aims, hypotheses, timeframe (DPP, Phase 1, Phase 2, Phase 3, or Phase 4), AD/ADRD project, outcomes, and target cohort. The Coordinating Center statistician may contribute to the proposal by adding a very brief description of the statistical methods and the availability of the data items required.
Analysis Plan	An analysis plan will be written for each paper proposal. Analysis will begin after the proposal has been approved by the PPS. The Coordinating Center staff will revise the plan, adding a description of the statistical methods and the availability of the data items required. Deviations from the original approved analysis plan will be added to the plan to create a new version of the analysis plan document. Significant changes to the original plan may have to be approved by the publications committee.
Analysis methods	Analysis will adhere to original design using methods appropriate for randomized clinical trials. All analyses comparing the DPP/DPPOS treatment groups will be conducted under the principle of intention-to-treat, with all patients included in their originally assigned DPP treatment group. Statistical methods that require deletion of subjects or visits are to be avoided as they break the randomization and introduce biases. However, some research designs may require the use of specific visits, for example, analyses based on OGTT results may be based on annual visits only. Analyses will either 1) be conducted separately by treatment group or 2) incorporate treatment effects. Analyses including more than one treatment group should initially include treatment group interactions with other factors because of the DPP's reported effects of both Metformin and ILS on most outcomes.
	Subgroups should be defined from baseline characteristics rather than outcomes. For example, those with or without metabolic syndrome at baseline, those with history of GDM, etc. For studies for which it is infeasible (for example, too expensive) to collect data on all participants, a case-cohort design will be used (Prentice 1986)
Data issues	Extra data collection. Papers are viable when based on the data collected prospectively during the study.

Topic	Policy
	Papers should acknowledge deficiencies in the data collected rather than requiring additional retrospective data collection.
Conventions	Data lock. DPP papers not specifically addressing the bridge period will use the July 2001 data lock.
	Data lock. DPPOS Phase 1 papers will use the August 2008 data lock.
	Data lock. DPPOS Phase 2 papers will use the January 2014 data lock.
	Significance. All results that are nominally significant at the 0.05 level will be indicated. Significance levels for tests including interactions will be stated in the analysis plan.
	Multiple testing. Hochberg's (1988) improved Bonferroni procedure will be used to adjust for multiple comparisons where appropriate. The adjusted p-value will be reported and will be significant at the 0.05 level.
Reporting	Cell size. In general, papers will not report data with sample sizes in cells ≤15.
	Tables. Groups will be presented in the order established in the primary manuscript. For example: Placebo, Metformin, Lifestyle.
	Categorization. Standard categorizations should be used whenever possible for the following variables at baseline:
	Race/ethnicity: Caucasian African American Hispanic American Indian Asian American
	Age groups: 25-44 45-59 ≥ 60
	BMI categories: 22 to <30 30 to <35 ≥ 35

REFER TO THE ANALYSIS POLICY ON THE PUBLICATIONS AND PRESENTATIONS SUBCOMMITTEE WEBPAGE FOR ADDITIONAL INFORMATION.

7.2.1 References

Hochberg, Y. (1988). A sharper Bonferroni procedure for multiple tests of significance. Biometrika, 75, 800-802.

Prentice, R.L. (1986). A case-cohort design for epidemiologic cohort studies and disease prevention trials. Biometrika 73 1-11.

7.3 Ancillary Studies Policy

7.3.1 Overall Principles

Ancillary studies offer the opportunity for maximizing the scientific impact and research benefits that can be derived from the resources developed during the course of the DPP and DPPOS. Investigators within and outside the DPPOS Study Group are encouraged to submit proposals for ancillary studies. Ancillary studies will be evaluated with careful consideration of their potential impact on the objectives and performance of the DPPOS. Ancillary studies that complement the objectives and thereby enhance the value of DPPOS are to be encouraged. Such studies should augment and promote the continued interest of both participants and investigators. To protect the integrity of the major DPPOS study, a proposal to conduct an ancillary study must be reviewed and approved by the Ancillary Studies Committee (ASC) and the Steering Committee before its initiation. No center will be required to participate in an ancillary study.

7.3.2 Definition of an Ancillary Study and a Substudy

An **ancillary study** is defined as research or data collection involving study sites, participants or specimens, using any technique, medication, procedure, questionnaire or observation other than those set forth in the Protocol, and ancillary studies must be supported entirely by funding external to the main study, including support for the Coordinating Center as appropriate.

The investigator responsible for the conduct of an ancillary study may or may not be a member of the DPPOS Research Group. If a proposal for an ancillary study is made by an individual who is not a member of the DPPOS Research Group, a member of the Study Group must be a co-investigator. The DPPOS Research Group member who serves as a co-investigator must be scientifically involved in the design, execution, and interpretation of the ancillary study. In addition, he/she shall be responsible for ensuring that DPPOS policies and procedures are observed during the conduct of the ancillary study.

A **sub-study** is a special category of an ancillary study that is conducted as a research initiative of the full DPPOS Research Group. Sub-study funding will generally be provided by sources beyond the core funding of the study, although in some cases supplemental funding may be added to the core funding to support a sub-study. A sub-study may arise from deliberations within the Research Group or be initiated by individual members of the Research Group or by collaborators. Sometimes the Ancillary Studies Committee, Executive Committee or Steering Committee may recommend an ancillary proposal to become a substudy, if the project warrants adoption into the main DPPOS trial. Such decisions are approved by the investigator and voted on by the Steering Committee. As sub-studies are incorporated into the main trial, they follow the same Publications and Presentations Committee requirements as all DPP/DPPOS publications and presentations.

Similarities and differences between ancillary studies and sub-studies are shown in Table 7-2.

Table 7-2 Similarities and Differences between DPP/DPPOS Ancillary and Sub-studies.

	Ancillary Study	Sub-study

Ancillary Studies Committee Approval	Required	Required
Funding	External to DPPOS	External to DPPOS, though may be supplemented with some internal funds
Steering Committee Approval	Required	Required
Involvement of CoC	Only to facilitate submission and tracking May be further supported with agreement of CoC investigators and external funding	Fully supported including data analysis. External funding may be required
DSMB approval	Ancillary studies that involve interaction with the DPPOS participants must be reviewed and approved	Sub-studies that involve interaction with the DPPOS participants must be reviewed and approved
Provision of data to the CoC	Ancillary studies must ensure that their protocol and consent allow for data to be shared back to the DPPOS Research Group and available for analysis, no longer than 2-years following the end of data collection	Substudy data will, by definition, be stored at the CoC and available to Research Group members for analysis
Submission to data repositories	Ancillary studies need to ensure that their protocol and consent allow for data to be provided to the NIDDK repository with all other DPPOS data by the CoC.	Sub-studies need to ensure that their protocol and consent allow for data to be provided to the NIDDK repository with all other DPPOS data by the CoC.
Study population	May be full DPP/DPPOS cohort or a sample of participants and visits, depending on costs and scientific requirements	May be full DPP/DPPOS cohort or a sample of participants and visits, depending on costs and scientific requirements
Ongoing Progress Reporting to the Ancillary Studies Committee	Submit to the ASC an annual update of progress	Not required

7.3.3 Obtaining Approval for Ancillary and Sub-Studies

For this section, ancillary and sub-studies are treated identically.

The Ancillary Studies Committee strongly encourages investigators submit preliminary concept proposals (maximum length 2 pages) before the submission of a full proposal. This preliminary proposal will be pre-reviewed by the Executive and Ancillary Studies Committees to evaluate scientific rigor and feasibility; suggestions will be provided to the investigator(s). Following receipt of the completed proposal, ancillary and sub-studies will receive a primary, secondary and statistical review. An outside reviewer may be used if there is no expertise within the study in a specific area. The Ancillary Studies Committee meets three times per year to consider new proposals and review the progress of approved studies, as described in the timeline below. The Ancillary Studies Committee will submit its recommendation to the Research Group for review and consideration and the Steering Committee will need to approve the study. Ancillary or sub-studies that involve interaction with the DPPOS participants must be reviewed and approved by the Data and Safety Monitoring Board (DSMB). The protocol or consent process may need to be amended to allow an ancillary study to proceed.

After approval by the Ancillary Studies Committee, the Steering Committee and the NIDDK, final approval is contingent upon the Steering Committee receiving a letter signed by the principal and all collaborating investigators in which they agree to abide by the policies for ancillary studies herein described including that regarding publication or presentation of results. Applicants whose proposals are denied by the Ancillary Studies Committee can appeal to the Steering Committee for reconsideration.

7.3.3.1 Reasons for Approval Requirement

Investigators and participants are entitled to prior assurance that all ancillary and sub-studies are of high scientific merit and that no study will:

1. Cause a deviation from the Protocol.
2. Confound interpretation of the DPP and/or DPPOS results.
3. Adversely affect participant cooperation.
4. Adversely affect participant safety.
5. Jeopardize the public image of the DPPOS.
6. Create a diversion of DPPOS resources, at the clinical sites or at the Coordinating Center or any other level.
7. In any way negatively influence the cooperative spirit of the collaborating investigators.
8. Otherwise compromise the scientific integrity of the DPP and/or DPPOS.

7.3.4 Submitting an Ancillary or Sub-Study

The request for approval of an ancillary or sub-study should be in narrative form. It should contain a brief description of the objectives, methods, significance of the study, plans for analysis and publications, and information regarding funding level and source. If a proposal is being submitted elsewhere for funding (e.g., a grant application), the source of funding should be identified and the application may be used as the basis for the request. Full details should be given concerning any procedures or tests to be carried out on a study participant including: any ophthalmologic, renal, cardiovascular, neurologic, psychological or other evaluation to be performed; any substances to be injected or otherwise administered to the participants; any observations to be made or procedures to

be conducted on participants outside of the clinic; any extra clinic visits required of the participant or any prolongation of the participant's usual clinic visits; any additional specimens (blood, urine, etc.) to be obtained or additional procedures to be done on specimens collected according to the DPP and DPPOS Protocol. The proposal should discuss the measures to be taken to ensure participant safety and confidentiality and an assessment by the investigator(s) of the potential impact of the ancillary study on DPPOS. Prior commitment by clinical centers and approval by the appropriate Human Subjects Review Committee should be demonstrated.

Investigators applying for use of biosamples will be required to first go to the NIDDK Repository and determine whether the samples available at the repository will be adequate and are available for the proposed study. The Repository samples should be used if at all possible, and the use of remaining DPP samples only requested if this is not possible. If investigators proceed with a request for remaining DPP samples they must explain in their application why the Repository samples will not satisfy the proposed study's needs.

The investigators should send their ancillary study proposal to the Coordinating Center, which will distribute it to all members of the Ancillary Studies Committee. The proposal should be written in sufficient detail so that the Ancillary Studies Committee can assess the study's scientific merit and potential impact on the DPP and DPPOS. This proposal should include a power calculation, and should generally follow the template provided with the DPPOS Ancillary Studies Application package.

Submission of completed DPPOS Ancillary Studies application forms is required. These forms are available on the password secured part of the DPPOS website and completed forms should be forwarded to the DPPOS Coordinating Center. If an external investigator is proposing a study, he/she can obtain the form through the DPPOS Steering Committee member who will be the Co-investigator for the study.

To ensure a thorough scientific review, the Chair of the Ancillary Studies Committee may elect to seek outside expert opinion in advance of the Committee meeting. In general, ancillary proposals will be reviewed by 2 investigators. A statistical review by the Coordinating Center will also be done. Upon completion of the scientific and statistical reviews, the Chair of the Ancillary Studies Committee will convene a meeting of the Ancillary Studies Committee to discuss these reviews and vote on the merits of the proposal under review. Approval or disapproval is based on a simple majority of the Ancillary Studies Committee. A copy of the Ancillary Studies Committee consensus statement will be sent to the submitting investigator(s).

The Ancillary Studies Committee consensus statement and approval will then be forwarded to the Steering Committee as well as the DPPOS Data and Safety Monitoring Board if required. Each Steering Committee member should respond to the Chair of the Ancillary Studies Committee within two weeks. A majority of the voting Steering Committee members must approve the proposal. The investigator may proceed with the ancillary study once it has been approved by the Steering Committee and the DSMB, as required, when funding is available.

In the event that the Ancillary Studies Committee fails to approve a proposed ancillary project, the investigator(s) can appeal to the Steering Committee, whose decision may override that of the Ancillary Studies Committee. If the Steering Committee also fails to approve the ancillary study, the proposed study will not be undertaken.

The Ancillary Studies Committee will maintain documentation of the final study design and any later modifications that are approved by the Steering Committee, including any DPPOS data or specimens that are approved to be released.

7.3.5 Funding of Ancillary Studies

The DPPOS will not provide funds for ancillary studies. In particular, no funds are provided for the conduct of the study or for Central Biochemistry Laboratory or Coordinating Center activities related to ancillary studies. The investigator must consult with CBL and CoC to determine the projected costs. The anticipated source of funds must always be identified in the submitted proposal.

Ancillary studies that require extensive data and/or specimen retrieval or related services by the coordinating center must make adequate provision for defraying the cost of personnel time and effort. The exact FTE shall be determined in consultation with the DPPOS Coordinating Center.

7.3.6 Policy on Data Generated by Ancillary Studies

7.3.6.1 Use of Ancillary Study Data by DPPOS Investigators

The data generated in ancillary studies belong to the investigator and the DPP Research Group. As a condition of approval to conduct the study through DPPOS, the investigators must agree that all data generated by the study will be forwarded to the DPPOS Coordinating Center to be treated like other DPPOS study data and that the DPPOS Research Group may use such data to conduct other analyses. Data and relevant documentation must be transmitted by the Ancillary Studies Investigators to the DPPOS CoC no later than 2-years after the final data collection or laboratory measurement.

7.3.6.2 Provision of Ancillary Study Data to an NIH Repository

The DPPOS Coordinating Center has an agreement with the funding agency to contribute biological specimens and data from the study to the NIDDK data repository for use by the broader investigative community. Appropriate wording should be included in the ancillary study protocol and consent documents to permit the sharing, storage, and use of ancillary study data with the DPPOS Coordinating Center and ultimately with the NIDDK or other appropriate repository. Ancillary study data will be provided by the CoC to the appropriate NIH repository along with other DPPOS data.

7.3.7 Policies on Sub-Studies

A sub-study may be developed as an extension of the core study by the DPPOS Research Group. The Principal Investigator for the sub-study will work closely with the Coordinating Center to develop the preliminary proposal and subsequently, if approved, the funding application. Sub-study planning is a core responsibility of the Coordinating Center and funding is provided for this activity.

The sub-study funding application budget will include additional Coordinating Center support staff, as needed, above and beyond that funded by the core project. The sub-study application may be submitted with GWU as the prime site, or with a clinical center investigator as the sub-study PI. Regardless, the application must include funding support for the Coordinating Center, clinical centers, labs, and other services, as needed to conduct the ancillary study.

All sub-studies will be considered part of the parent DPPOS project. In most cases, sub-study data will be collected, managed, and analyzed by the DPPOS Coordinating Center. In sub-studies where that is not the case, all data and relevant documentation generated by the sub-study will be forwarded to the DPPOS Coordinating Center. While a sub-study will generally be funded via an independent mechanism, as a condition of DPPOS authorization to conduct the study, the named investigators must agree that ownership of the data will vest with the DPPOS Research Group. The DPPOS Coordinating Center may then use the data to conduct other analyses.

The DPPOS Coordinating Center has an agreement with its funding agency to contribute biological specimens and data from the sub-study to the NIDDK data repository. Appropriate language wording to permitting the sharing, storage, and use of data with the DPPOS Coordinating Center and the NIDDK repository must be included in the sub-study protocol and consent documents.

7.3.8 Publication of Ancillary or Sub-Study Results

All manuscripts, abstracts or presentations for scientific meetings based on ancillary or sub-study data must follow the policies of the DPPOS Publications and Presentations Committee before publication or presentation.

Ancillary Study investigators are required to inform the PPS committee of all planned publications once the proposal has been approved and funding is available.

7.3.9 Protocol Changes

If the Ancillary Studies Committee feels that the proposed ancillary or sub-study requires a change in the DPPOS protocol or requires its own protocol, the Committee recommendation must be submitted to the Steering Committee and DSMB for final consideration and approval. The protocol must include language that allows data to be transferred to the DPPOS Coordinating Center and the NIDDK repository for storage and use, similar to that of the main DPPOS consent. The final protocol must be reviewed and approved by the Steering Committee.

7.3.10 Informed Consent Changes

If an additional informed consent is required, the consent must include language that allows data to be transferred to the DPPOS Coordinating Center and to the NIDDK repository for storage and use, similar to that of the main DPPOS consent.

7.3.11 Time Line for Ancillary and Sub-study submission and review

The Ancillary Studies Committee holds scheduled reviews of ancillary/sub-study applications three (3) times a year, timed roughly to anticipate NIH grant submission cycles. Additional ad hoc reviews are scheduled based on receipt of applications. Considering the limited number of biosamples available, selection of the most deserving studies to access biosamples is helped by performing head-to-head comparisons of submitted proposals (for scientific importance and quality). To accomplish this end, applications requesting use of scarce biosamples will be aggregated and reviewed in a group (similar to an NIH study section review). Applicants aiming to seek grant funding from the NIH or other agencies to support their ancillary study should submit their ancillary study application at least 10-12 weeks before the NIH or other grant submission deadline. Such timely submission would allow 6-8 weeks for ASC and Steering Committee review and addressing any questions raised, with sufficient time for the PI to finalize the grant submission. If a special RFA is issued that triggers DPP/DPPOS ancillary study proposals

at any time, the ASC would be flexible and would schedule an additional review session to accommodate submitted proposals.

The Ancillary Studies Committee will work expeditiously to minimize delay in approving meritorious proposals. However, prospective investigators should understand that the approval process by the Ancillary Studies Committee may take 60 days and that the approval by the Steering Committee may take another 30 days. Therefore, early submission is strongly recommended, especially if approval of an ancillary study proposal is deemed necessary to secure funding for the proposed research.

In general, studies requiring review and by all parties and approved, i.e., the Ancillary Studies Subcommittee, , the Steering Committee and the DPPOS Data and Safety Monitoring Board, require that the proposal be received at the Coordinating Center 10-12 weeks prior to the submission deadline to the funding agency.

To facilitate planning for these reviews and to prepare for a speedy response, it is recommended that the investigators notify the Ancillary Studies Committee in advance of their plan to submit an ancillary study proposal. This letter of intent is not required but highly recommended, and should include an outline of the study aims, the proposed use of the parent study data, and the anticipated date of submission to the funding agency. Without this type of advance notification it can be difficult to convene a timely review by the ancillary studies and steering committee.

7.3.12 Determination of Priority for Ancillary and Sub-studies

Ancillary and sub-study proposals will be considered based on their scientific merit, potential public health impact and impact on the objectives of the main study, while maximizing the yield/usage of the remaining valuable DPP specimens. Proposals with identical or closely related scientific objectives, submitted contemporaneously or within the same quarterly review period, will be reviewed and adjudicated on their scientific merits. For efficient use of available resources and to maximize their scientific value, investigators with similar interests are encouraged to submit broad collaborative applications.

7.3.13 Procedures for Requests of DPP/DPPOS Data and Specimens for Ancillary Studies

A list of specific items such as participant samples, variables, or other data and samples required should be submitted with the original ancillary study proposal. Once an ancillary study has been approved a Coordinating Center statistician will contact the principal investigator to confirm and review the materials requested.

In accordance with HIPAA regulations and the Privacy Act, all participant identifiers such as Participant ID, Nickname etc. will be removed from all samples that will be released to an ancillary study unless otherwise approved. In cases where identifiers are required, the investigator should submit a justification why participant identifiers are needed for the ancillary study.

After permission to use DPP/DPPOS stored samples for an ancillary study has been granted (by the Ancillary Studies Committee and subsequently by vote of the Steering Committee), the biosamples that are approved for an ancillary study are only reserved for the approved study for ~ 1 typical NIH review cycle (~ 9 months from time of approval and submission). The expectation is that investigators will submit their approved studies at the next possible NIH submission cycle (typically within 2 months) after study approval by the Steering Committee (see review schedule below). If the study is funded, the samples will be provided to the study. If not funded, the samples will go back into the “pool” of stored

samples available for other investigators to access for subsequently approved studies. If an investigator re-submits an ancillary project that has failed to garner funding support, the application, including the request for samples, will be re-considered by the Ancillary Studies Committee, in competition with other applications submitted during that cycle.

In order to keep track of data/samples requested and obtained, the Coordinating Center requires that investigators provide and maintain a status database. The Principal Investigator will also be required to send an annual report containing an account of data collected by the ancillary study, and specimens or data requested and obtained from CBL or the Coordinating Center.

7.3.14 IRB Requirements for Ancillary Studies

The following documents should be submitted to the Coordinating Center for each clinic that is going to be involved in an Ancillary Study.

1. Letter of agreement,
2. IRB approval letter,
3. Approved consent (any future consents and yearly stamped approved consents should also be sent to the Coordinating Center) and

7.3.15 Initiation and Progress Report for Ancillary Studies

The Principal Investigator of an approved ancillary study shall provide a brief (approximately 2-page length) status report on the progress of the study to the Ancillary Studies Committee annually.

The progress report should include the following information, in table format wherever possible.

1. Date of initiation of ancillary study,
4. Current or pending sources of funding,
5. Number of subjects enrolled,
6. Completion of ancillary data collection instruments, by visit
7. Completion of ancillary outcomes, by visit
8. Receipt of specimens from CBL by date of receipt and visit
9. Summary of results obtained during the project period, (means of notable variables)
10. Future goals and expected completion of ancillary study.
11. Expected time for data/sample/material transfer to the DPPOS Coordinating Center

Approval shall lapse, if the study has not been initiated after 1 year from the date of initial approval, in the absence of extenuating circumstances. Significant deviation from the research plan or scientific, ethical or procedural infringements will be grounds for termination of an ancillary study.

7.3.16 The Role of the DPPOS Coordinating Center with Respect to Ancillary Studies

The Coordinating Center's funded role for ancillary studies is limited to coordinating the Ancillary Studies Committee reviews, participating as a voting member of that committee, presenting studies approved by the Ancillary Studies Committee to the Steering Committee for voting. The CoC Principal Investigator has the same right as other DPPOS Principal Investigators to decline participation in any

ancillary study beyond distribution of approved data and specimens. The ancillary study must provide funding for all CoC activities related to the conduct of the ancillary studies which include may include sample identification, transferring data and/or samples as approved by the Steering Committee, statistical analyses or consult, and receipt of data upon ancillary study completion. Whenever possible, funds budgeted for the Coordinating Center by proposals in response to funding opportunity announcements will provide resources for delivering the approved data and samples to these studies, and for preparing data and sample use agreements.

7.3.17 Activities Excluded From the Funded Work Scope

The CoC cannot divert its DPPOS staff or other resources to assist ancillary studies, beyond what is covered in the funded work scope. The following activities are not included in the CoC's funded work scope, and are the responsibility of the ancillary study investigator: study design, sample size and power estimation, sample selection, training, coordinating study conduct, arranging or participating in conference calls, managing additional data or specimens collected especially for the ancillary study, conducting statistical analyses, or submitting ancillary study papers for publication.

7.3.18 Mechanism for CoC Direct Participation in Ancillary Studies

The CoC Principal Investigator or Co-investigators may join an ancillary study's consortium as an investigator with an expanded role by being part of the consortium's application for funding. In this case, the resources budgeted will be separate from the CoC's DPPOS award. The CoC Principal Investigator has the right, as do other DPPOS Principal Investigators, to decline participation in an ancillary study consortium.