# **DPBRN**

Data Analysis, Publications, and Presentation Policies October 4, 2011

# **TABLE OF CONTENTS**

I.	Overview	3
II.	P and P Committee	4
III.	General Publication Procedures	4
IV.	Review Process for Invited Papers and Presentations	5
V.	Review Process for Peer-Reviewed Abstracts	5
VI.	Proposing Manuscripts	6
VII.	Authorship Issues	6
/III.	Review Process for Manuscripts	9
IX.	Acknowledgement of NIDCR Support and DPBRN Review	10
X.	Other General Publication Policies	10
XI.	Appendices	
	<ul> <li>A. Overview of DPBRN Data Documentation Forms</li> <li>B. Manuscript Proposal Form</li> <li>C. Data Confidentiality Agreement</li> <li>D. Notice of Intent to Analyze (DD-2)</li> <li>E. Data Distribution Agreement (DDA)</li> <li>F. Notification of Completed Analyses (DD-5)</li> <li>G. Statement of Authors Form</li> <li>H. Presentation and Poster Templates</li> </ul>	

## **DPBRN Data Analysis, Publications, and Presentation Policies**

### I. Overview

The "Dental Practice-Based Research Network" (DPBRN), an international dental practice-based research network, includes the Office of the Network Chair, the Coordinating Center (CC), the National Institute of Dental and Craniofacial Research (NIDCR), and Regional Centers at HealthPartners, Minneapolis, MN; Kaiser Permanente Center for Health Research/Permanente Dental Associates, Portland, OR; University of Alabama at Birmingham; University of Copenhagen, Denmark; and the University of Florida, Gainesville, FL. The network, composed of practitioner-investigators from the US and Scandinavia, undertakes studies specifically relevant to the practice of dentistry. The network is one of three such networks funded by NIDCR currently in operation.

The success of DPBRN 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 DPBRN data, timely completion of manuscripts and abstracts, and adherence to the principles of authorship. It is recognized that some DPBRN publications and presentations will be based on data from a single study, others on data from more than one study within the network, and others will include data from the other networks. The policies and procedures described herein apply to all DPBRN publications.

DPBRN has implemented policies involving the use of its data to: (1) ensure that lead investigators for specific studies have adequate opportunity to participate in the publication and presentation process for those studies; (2) ensure that other investigators know of ongoing research efforts and have the opportunity to participate in these efforts; (3) ensure that duplication of analyses is kept to a minimum; (4) permit the CC to maintain control of the official DPBRN database, which includes being informed of any problem areas in the data base; (5) ensure that publication or presentation of DPBRN data does not occur without the knowledge and approval of the DPBRN Executive Committee; and (6) maintain the integrity of study data.

The DPBRN Executive Committee has final say over all DPBRN publications and presentations. The Executive Committee has empanelled a Publications and Presentations (P&P) Committee to facilitate the implementation of these policies and to deal with long-range planning issues.

DPBRN requests that individuals working on manuscripts involving DPBRN data, who are not DPBRN investigators themselves, work closely with at least one of the DPBRN Investigators and follow all policies. This is to ensure that they have access to all information pertinent to analyses. This important information includes the dataset documentation that is distributed by the CC, along with the data. This detailed information includes the edits which have been performed, any problems in the dataset, and lists of calculated variables and their algorithms. This documentation also includes the forms that were used in collecting the data. Such individuals are also encouraged to obtain access to the manual of operations that describes the data collection process and quality control procedures used by the study. This information is available on the DPBRN Operations Webpage (http://share1.dopm.uab.edu/sites/dentalpbrn/default.aspx; but accessible only via a password provided by DPBRN).

### II. P&P Committee

The P&P Committee oversees all DPBRN publications and presentations activities, with final adjudication of decisions by the Executive Committee. The Committee approves manuscript proposals and the submission of abstracts; as well as all publications and presentations before they are submitted for publication or presented in a public forum. Appeals of P&P Committee decisions may be made to the Executive Committee. However, the expectation is that only rarely will decisions made by the P&P committee be discussed at Executive Committee meetings in detail. Such occasions might be an appeal or other exceptional circumstances.

The P&P Committee decides 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 voting members of the P&P Committee will consist of at least one practitioner-investigator, representatives from two of the Regional Centers, one from the CC, and one from the Office of the Network Chair. A Chair for the P&P Committee will be designated by the Executive Committee from the P&P Committee membership.

# **P&P** Committee meetings

The P&P Committee will conduct its business either by conference call or email on an as-needed basis, depending upon the volume of proposals requiring review. The goal is to act on a request within two weeks of when it is made. Committee decisions will be based on a simple majority of the voting members; however, all Executive 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 to provide a representative. Staff of the Chair of the P&P Committee will arrange the calls and take minutes, to be forwarded to the Executive Committee. P&P Committee members may not vote on their own requests.

## **III. General Publication Procedures**

The phrase "Dental PBRN" must appear in the title of DPBRN manuscripts, peer-reviewed abstracts, and invited papers and presentations that report DPBRN studies. This helps in indexing and retrieval of publications and in gaining recognition for the study.

It is acknowledged that some manuscripts, peer-reviewed abstracts, and invited papers and presentations will have received DPBRN grant support, but are communicating broader topics and are not specifically reporting DPBRN studies. In these cases, the words "Dental PBRN" do not have to be included in the title, even though DPBRN grant support is to be acknowledged.

# Use of approved names and abbreviations for DPBRN regions

DPBRN comprises five regions, each of which has an approved name and abbreviation. Authors should use these

names and abbreviations in all DPBRN presentations and publications. They are: (1) the Alabama/Mississippi region (AL/MS); (2) the Florida/Georgia region (FL/GA); (3) the Minnesota region (MN), which comprises dentists employed by HealthPartners and dentists in private practice in Minnesota; (4) the Permanente Dental Associates region (PDA), which comprises dentists in Oregon and Washington in the PDA organization, in cooperation with the Kaiser Permanente Northwest Research Foundation's Center for Health Research; and (5) the Scandinavian region (SK), which comprises dentists in Denmark, Norway, and Sweden.

# Use of approved DPBRN slide template and poster template

For DPBRN slide presentations, presenters should use one of the two DPBRN slide templates that has the DPBRN logo at the bottom right-hand corner of the slide. This template is available at the DPBRN Operations website or by sending an email to Karen Stewart of the CC (KStewart@mail.dopm.uab.edu). One can easily incorporate this template into existing slides in Microsoft Powerpoint<sup>©</sup> by following the instructions available in appendix H.

DPBRN posters should also use the DPBRN logo. A Microsoft Powerpoint<sup>©</sup> template that has been used to print posters is available at the DPBRN Operations website or by sending an email to Karen Stewart of the CC (KStewart@mail.dopm.uab.edu).

# Other uses of logo

The logo may be used by any DPBRN enrolled practitioner-investigator to communicate his or her affiliation with DPBRN following approval by the P&P Committee. Permission to use the logo does not transfer ownership of the logo to the practitioner-investigators. Examples include personal letterhead, business cards, biographical summaries, brochures, web pages and telephone book listing, provided this is done in a dignified and professional manner. The logo shall not be used in the direct solicitation of patients or for strictly commercial purposes. A detailed description of the planned use should be sent to the P&P Committee for approval. Send communications to Brad Rindal, chair of the P&P Committee.

### Use of approved presentations by others

DPBRN presentations can be used by others in DPBRN or affiliated with DPBRN pending permission by the original author and the DPBRN P&P Committee. The requester should clarify the intended audience and the purpose for using the presentations. Send communications to the author and Brad Rindal, chair of the P&P Committee.

# IV. Review process for Invited Papers and Presentations

It is anticipated that investigators associated with DPBRN will be invited as individuals to prepare papers or give presentations concerning findings or other aspects of DPBRN. When such invitations are received, the invitee should inform the inviter that acceptance will need to be approved by the DPBRN P&P Committee.

Unlike the process for submitting a manuscript proposal, for invited papers and presentations all that is required initially is an email that describes the paper or presentation, with a request for approval and background information for the request. 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.

This email should be sent to the Chair of the P&P Committee. The Chair is Dr. Brad Rindal (d.brad.rindal@healthpartners.com). Please also copy Karen Stewart of the CC (KStewart@mail.dopm.uab.edu) on this email. The committee will aim to vote on the proposal within one week through an e-mail process and the results will be conveyed to the lead author.

The Committee will decide whether such an invited paper or presentation is appropriate. Among other factors, these decisions take into consideration possible conflicts with other planned data analyses or competition for use of other DPBRN resources within the time allowed for completion of the invited paper or talk.

Once approved, basic information about the invited papers and presentations will be logged on the DPBRN Operations website. Final approved versions to be logged should be sent to Karen Stewart of the CC (KStewart@mail.dopm.uab.edu). Content of these presentations may be of value to other members of the DPBRN in the future. Therefore, we encourage presenters at their discretion to provide an electronic copy of the presentation to be available to others.

#### V. Review Process for Peer-Reviewed Abstracts

Unlike the process for submitting a manuscript proposal, for peer-reviewed abstracts all that is required initially is an email that has the abstract attached, with a request for approval and background information for the request.

This email should be sent to the Chair of the P&P Committee. The Chair is Dr. Brad Rindal (d.brad.rindal@healthpartners.com). Please also copy Karen Stewart of the CC (KStewart@mail.dopm.uab.edu) on this email. The committee will aim to vote on the proposal within one week though an e-mail process and the results will be conveyed to the lead author.

For abstracts, verification of the analyses is not performed by the CC unless the data appear questionable. An abstract preferably should be submitted to the P&P Committee at least two weeks prior to the presentation date. This allows sufficient time for circulation to the committee. If the review can not be completed in time, it 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. Once approved, all abstracts will be logged on the DPBRN Operations website.

# The uniqueness of abstract submission software for some organizations

In accordance with DPBRN policy, it is important that the final author be "for The DPBRN Collaborative Group" when appropriate. The abstract submission systems of some organizations are not constructed with corporate authors in mind. For example, with the International and American Associations for Dental Research, entering "The DPBRN Collaborative Group" will appear as "and T. DPBRN Collaborative Group". The IADR/AADR was notified of this limitation in its system and responded with the following addition to their abstract submission guideline [http://www.iadr.org/files/public/10AAAbstInfo.pdf].

### GROUP-AUTHOR ABSTRACTS

"Some research collaborations with large numbers of investigators, operating under a single group name, request the inclusion of the group name as an author, distinct from the individual authors. Group authors may also be known as Collaborative-, Corporate-, or Collective-authors. Group-authors would include individuals who contributed to the research that led to the abstract, but are not named individually as authors. A common example in dental research would be a practice-based research network. Group-authorship is not meant to acknowledge the University, Institution, or Corporation under whose auspices the research was conducted. If your abstract does have a Group-author that includes individuals who contributed to the research that led to the abstract, but are not named individually as authors, the name of the Group-author must be added along with the City, State/Prov, and Country. The Group-author listings will be included in the Author/Co-author Index online, the Program Book, and the CD-ROM/USB of Abstracts".

It is also important that the DPBRN grant numbers be cited. Some abstract submission systems have separate entry windows for this information, but the grant numbers nonetheless do not show in the published or electronically-available versions. For this reason, it is best if authors place this information in the text of the abstract itself. Although a full version of a citation might read "This research was supported by grants U01-DE-16746 and U01-DE-16747 from the National Institute of Dental and Craniofacial Research, National Institutes of Health", if brevity is required, an acceptable abstract citation would be "Support: DE-16746, DE-16747".

# VI. Proposing Manuscripts

Proposals for manuscripts may be initiated by any DPBRN investigator, with the proviso that lead investigators, being practitioner-investigators or others, for a specific study are to be given appropriate priority and ample opportunity to propose manuscripts for that study. Other investigators for that study should also be given appropriate opportunity and priority for participation in the publication and presentation of results for that study.

The expectation is that manuscript proposals will be developed by the lead author with input from designated coauthors. After review by the co-authors, manuscript proposals should be submitted to the P&P Committee chair who
distributes the proposal for review by the committee through e-mail or at a committee meeting as deemed appropriate.

The committee will vote on the proposal within one week through an e-mail process and the results will be conveyed to
the lead author. 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 publication including DPBRN data must include a DPBRN
investigator as an author.

# **Data Distribution Policy and Agreement**

If the authors are not affiliated with a Regional Center, the Office of the Network Chair, or the CC, and thus do not have direct access to the full dataset that was distributed to those entities, they can receive the dataset required for their manuscript directly from the CC. This can be done after a manuscript proposal or abstract is approved; however, the lead author first needs to review the DPBRN Data Distribution Policy and complete and sign the DPBRN Data Distribution Agreement. Upon receipt of the Data Distribution Agreement, the CC will prepare an analytic dataset that will be sent to the requesting lead author. Lead authors can also request direct assistance from the CC to perform the

required analyses.

## VII. Authorship Issues

The initiator generally assumes first authorship of the proposed manuscript, invited paper or presentation, or peerreviewed abstract. The initiator is encouraged to contact other potentially interested individuals before the manuscript,
paper, presentation, or abstract is proposed. At the time of proposal, other members of the network 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 at least one DPBRN practitioner-investigator, as designated by the P&P
Committee. DPBRN makes a point of engaging practitioner-investigators at every step of the research process, and this
includes the publication process. For the purposes of this requirement, a practitioner-investigator is defined as a clinician
who treats patients on a regular basis and who collects primary data on patients in DPBRN studies. All regions involved
in data collection should be given the opportunity to have one author from the region. This is the expectation unless other
authorship issues are of greater priority. The final decision will rest with the Publications and Presentations Committee.
This means that at the minimum the typical DPBRN paper would have an author from each DPBRN region involved in
the study. These authors could be either practitioner-investigators or faculty investigators.

# **Suggested communication to potential authors**

A goal of DPBRN is to involve practitioner-investigators in the dissemination of results of studies. This includes involvement in writing and authoring manuscripts. The purpose of this communication is to inquire about your interest in being a part of this process.

*The expectations for authorship credit include the following:* 

- 1. substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- 2. drafting the article or revising it critically for important intellectual content
- 3. final approval of the version to be published

Generally the first author puts together a first draft which is circulated to the other authors. After receiving the first draft, you would be asked to provide thorough, thoughtful and timely feedback. Probably all communications will be by email and will include attachments that you will have to review. The lead author for each manuscript will articulate the expectations regarding writing and editing responsibilities, including timelines for each step.

If you choose not to commit to the authorship expectations, you can be involved in the writing group where your contribution would be acknowledged in the publication, but you would not be listed as a co-author.

# **Co-Authorship**

The criteria for named, non-corporate authorship will be those of the International Committee of Medical Journal Editors (ICMJE, the "Vancouver Group"; http://www.icmje.org). 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.

The lead author should contact individuals whose work was used during the study, such as the Principal Investigator of a DPBRN questionnaire study from which certain questionnaire items were taken for a subsequent DPBRN study. These individuals should be given the opportunity to be co-authors with the understanding that they will meet the criteria for authorship. If the individual declines authorship, his or her work should be referenced in the publication.

### **Seven-Author Guideline**

Some journals limit the number of authors on a manuscript. Moreover, it is difficult to work on a writing project with too many authors. Thus, DPBRN has established the policy of attempting to limit the number of named, non-corporate authors on a paper or presentation to no more than seven, with the eighth being the corporate author. Exceptions to this guideline 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. All practitioner-investigators, faculty investigators, and staff personnel involved with data collection or other significant aspects of the study, and who are not a named author, will be acknowledged collectively as the last author in corporate form as "for the DPBRN Collaborative Group", and will be listed at www.DentalPBRN.org accordingly. The use of

"collective author" or "corporate author" investigator groups is widely accepted. For example, a recent PubMed search for corporate authors that included the words "Collaborative Group" or "Investigator Group" or "Study Group" yielded more than 10,000 entries from a wide range of journals and scientific disciplines.

# A note of diligence for DPBRN authors regarding the DPBRN corporate author

Some dental journals, especially those that target dentists in daily clinical practice, have little experience with the use of corporate authors. Therefore, it is important that DPBRN authors remain diligent that the corporate author is maintained at each stage of the manuscript and publication process. For example, one DPBRN publication had completed its manuscript peer review and was then handed from the Editor to the Editor's staff. The staff then did some editing on the manuscript and at that point one staff member removed the corporate author due to lack of familiarity with this concept. Once the lead author pointed out to the Senior Editor of that publication what had happened, and that this was a very important part of the DPBRN publications policy, the corporate author was added back in the manuscript. However, this highlights the need for diligence among DPBRN authors so that the corporate author is not inadvertently removed.

# A note of diligence regarding use of the words "Dental PBRN" in the title

It is also important to be diligent that the words "Dental PBRN" remain in the title at each stage of the publication process. For example, one DPBRN publication had completed its manuscript peer review and the lead author was sent the final page proofs to review. The Editor had the correct title of the article (the title that had been used in all stages up to that point) in the email correspondence in which the page proofs were sent, but the editorial staff had removed the words "Dental PBRN" from the title in the page proofs themselves. It is important to ensure that these words are added back in to be in compliance with the DPBRN publications policy. Otherwise, they will not appear in the PubMed citations.

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

- 1. The lead author submits a proposal (one to two pages) for review by the P&P Committee that includes:
  - a. Title and list of proposed collaborators.
  - b. Scientific background and rationale
  - c. Research hypotheses
  - d. Data to be used
  - e. Brief description of methods of analysis

A template for a manuscript proposal is included as Appendix A.

- 2. The lead author and co-authors create a working group that prepares the manuscript
- 3. The P&P Committee monitors progress and chronic failure to advance the writing of a manuscript will result in the reassignment of the topic.
- 4. The final version of the manuscript is submitted to the P&P Committee for review/approval
- 5. The P&P Committee Chair assigns a Chief Reviewer and forwards the manuscript to the CC for statistical review and for verification.
- 6. The P&P Committee reviews the manuscript after considering the comments of the Chief Reviewer.
- 7. After the manuscript is approved, the lead author submits approved manuscript to journal, with copies to the CC.

# **Verification Process**

To ensure consistency and quality in analyzing and publishing data, DPBRN uses a verification process in which the analyses for all submitted papers are duplicated at the CC. During the process, staff will verify 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 by the CC. After all necessary materials are received at the CC, it can take two 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 CC's analyses. If the first author disagrees, he/she may contact the CC to resolve the discrepancy or work with the Chief Reviewer to adjudicate any discrepancies. Otherwise, the corrections should be made to the paper. DPBRN policies require that manuscripts be verified and resultant corrections applied before they are submitted for publication.

Lead authors should contact the CC for specifications as to what will be required to transmit to the CC so that the verification process can be completed.

# Re-Verification and Re-review of a Manuscript

After a paper has been verified by the CC, there often is occasion for revision. This may happen because of changes suggested by the P&P Committee 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 CC when:

- a. The information contained in a table or figure is changed other than by deletions or 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 believe that a re-verification is in order.

In order to ensure that re-verifications may proceed as expeditiously as possible, 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 CC will confer high priority to re-verifications. Staff at the CC 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. Investigators who are co-authors should decide whether the revised manuscript is sufficiently different from the originally approved version to require rereview by the P&P Committee. Examples of indications for re-review follow. This list is not exhaustive:

- a. 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.
- b. Potential new overlap with other DPBRN publications.
- c. Use of new variables, not part of the dataset that yielded the original submission.

NOTE: Regardless of the need for re-verification by the CC, 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.

## **VIII. Review Process for Manuscripts**

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

# **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 chair of the committee will assign a Chief Reviewer appropriate for the topic. The Chief Reviewer's role is to provide a thorough review of the manuscript prior to the P&P Committee review of the manuscript. The Chief Reviewer then circulates the manuscript to the full P&P Committee, The Chief Reviewer for the paper serves as the P&P Committee's representative in communicating with the first author and expediting the review. When the manuscript is ready for review by the P&P Committee, the Chief Reviewer will contact the committee chair to arrange for a committee call to review the manuscript if necessary, or to arrange a committee discussion by email.

## **Review Process**

- a. The Chief Reviewer provides the initial review of the manuscript.
- b. The Chief Reviewer briefly summarizes his/her own major comments to the P&P Committee during the conference call or email. 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.
- c. The Chief Reviewer receives the results of the manuscript verification performed at the CC and ensures that all issues have been resolved with the first author prior to final approval.
- d. Approval of a manuscript is documented in the minutes of the P&P Committee conference call and logged on the DPBRN Operations website.

# Statement of Authors Form

The first author is responsible for having all co-authors sign the Statement of Authors Form prior to the manuscript being sent to the P&P Committee. Co-authors 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 P&P Committee Chair c/o of the Publications Coordinator at the CC. Completion of this form is required prior to manuscripts being approved by the P&P Committee. A copy may be obtained by contacting the CC.

# IX. Acknowledgement of NIDCR Support and DPBRN Review

All DPBRN publications, invited papers and presentations, and peer-reviewed abstracts that use DBPRN data must acknowledge NIDCR support by listing the following grants: (1) U01-DE-16747, "Dental PBRN Network Chair"; (2) U01-DE-16746, "Dental PBRN Coordinating Center".

It is also recognized that some work does not use DPBRN data, but should have one or both of the DPBRN grant numbers cited. This might occur when a publication, paper, presentation, or abstract is done because of the DPBRN even though actual DPBRN data are not used. For example, if an author does a manuscript that discusses DPBRN or does analyses of practice-based research data because these analyses are preliminary to and/or supportive of current and/or planned DPBRN efforts, or time devoted to this activity is funded at least partially from one or both of the DPBRN grants, then the DPBRN grant(s) should be cited. NIH and most university personnel effort reporting guidelines would require such citations anyway.

# X. Other General Publication Policies

- 1. When special databases are provided by the CC to Investigators for special analyses, the CC will keep copies of these. The CC must maintain control of the master data file for each and all centers and not permit unauthorized changes to be incorporated in it.
- 2. 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?

# 3. <u>Industry Funding</u>

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 DPBRN data without prior review and written approval of the DPBRN Executive Committee.

### 4. Graduate Student Dissertations

The use of DPBRN data for doctoral or masters' level theses is encouraged, although some aspects of graduate student work with DPBRN data need special consideration. In particular, students are generally new investigators who are usually not familiar with DPBRN data. This section of the publication policies attempts to balance the opportunity to involve promising new investigators with preserving the opportunity for established DPBRN investigators to publish study findings.

Publications and presentations resulting from theses are subject to all DPBRN publication policies, including the requirement that the DPBRN 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 DPBRN 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 DPBRN data in a graduate dissertation should include the following elements:

- a. The name of at least one DPBRN investigator who has agreed to serve on the student's dissertation committee and as a co-author of the first publication.
- b. Communication from the thesis advisor which should include the following information: (1) endorsement of the thesis and paper proposal; (2) statement of willingness and availability to discuss the work with DPBRN investigators; (3) commitment to abide by DPBRN publications policies; (4) a timeline for completion of the thesis; and (5) a plan for manuscript submission of manuscript(s).
- c. Brief description of rationale, background, main hypotheses, analytic approach for the thesis.
- d. After a thesis proposal is approved, both the student and the advisor must review the DPBRN Data Distribution Policy and complete and sign a DPBRN data distribution agreement, and only then will the DPBRN CC prepare an analytic dataset that will be sent to the advisor, for both the advisor and the student's use for approved thesis work.

# 5. Adherence to NIH Public Access Policy

The NIH Public Access Policy implements a federal law that states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

### It is important that all DPBRN publications comply with this policy.

Frequently asked questions about this policy are available at http://publicaccess.nih.gov/FAQ.htm. These are some key elements: Authors own the original copyrights to materials they write. Consistent with individual arrangements with authors' employing institutions, authors often transfer some or all of these rights to the publisher when the journal agrees to publish their paper. Some publishers may ask authors to transfer these rights when the paper is first submitted to the journal. Authors should work with the publisher before any rights are transferred to ensure that all conditions of the NIH Public Access Policy can be met. Authors should avoid signing any agreements with publishers that do not allow the author to comply with the NIH Public Access Policy. As an example, the kind of language that an author or institution might add to a copyright agreement includes the following: "Journal acknowledges that Author retains the right to provide a copy of the final peer-reviewed manuscript to the NIH upon acceptance for Journal publication, for public archiving in PubMed Central as soon

as possible but no later than 12 months after publication by Journal."

# 6. Public-Domain Questionnaires

Questionnaires developed as a part of network projects provide an opportunity for future research collaborations. When the network receives inquiries about the use of these questionnaires, communication with the contact person should include a discussion of the proposed study and the potential value of collaboration. For example, results from the proposed study conducted in a different study population could be compared to those of the DPBRN study. If a collaborative project is not feasible, the contact person should be aware of the effort involved with gaining written permission required by journals if specific content is published. Examples might include the use of pictures or figures. It should be clear that DPBRN is not responsible for securing these permissions.

# **APPENDIX A**

# Overview of DPBRN data documentation forms

FORM	WHEN	WHY
Manuscript Proposal Form	Upon first proposing a writing project to the P and P Committee.	To initiate the approval process.
Data Confidentiality Agreement	After approval of a manuscript proposal and prior to programs or analyses performed on any part of the data set	To guarantee that confidentiality practices are understood and agreed to.
FORM DD-2 (Notice of Intent to Analyze)	After approval of a manuscript proposal and prior to programs or analyses performed on any part of the data set.	To inform the CC of all ongoing analysis and for assisting the CC in communicating known problems with data sets back to clinical center.
DDA (Data Distribution Agreement)	After approval of a manuscript proposal and prior to programs or analyses performed on any part of the data set <i>IF</i> the lead author is outside the DPBRN study group.	To request from CC partial or complete copies of DPBRN data files. This documents and tracks all additional distributions of data.
FORM DD-5 (Notification of Completed Analyses)	Upon closing out analyses for a project whether or not it results in publication.	To allow the CC to verify results of the analyses prior to publication and for final approval by Executive Committee
Statement of Authors Form	When submitting a completed manuscript to the P and P Committee.	To allow P and P committee to approve or amend authorship.

These forms are available as Microsoft Word documents that can be obtained by contacting Valerie Winston of the CC (vwinston@mail.dopm.uab.edu) or accessed at the DPBRN Operations web site.

These forms are also attached at the end of this policy document.

# APPENDIX B

VII.Analytic Plan

**References (if applicable)** 

VII.Timeline

# **Instructions for Completing Manuscript Proposal, DPBRN**

- 1. Follow the format on the form below.
- 2. Provide complete contact information for the first author. If a DPBRN investigator will serve as the representative (contact person), state this on the proposal and provide complete contact information for that person.
- 3. It is recommended that a paper proposal be limited to no more than two pages.
- 4. The PI of the originating site or DPBRN investigator participating in the writing group must review and approve the proposal prior to it being submitted to the DPBRN P&P Committee.
- 5. Submit the proposal to the Chair of the DPBRN P&P Committee with a request for approval. The Chair is Dr. Brad Rindal (D.Brad.Rindal@HealthPartners.Com). Please also copy Valerie Winston of the CC (vwinston@mail.dopm.uab.edu) on this email.
- 6. The Manuscript Proposal Form is available as a Microsoft Word document that can be obtained by contacting Valerie Winston of the CC (vwinston@mail.dopm.uab.edu) or accessed at the DPBRN Operations web site.

**Manuscript Proposal, DPBRN** 

# I. Full Title: II. Abbreviated Title: III. Writing Group (list individual with lead responsibility first) Lead author: Phone: Fax: E-mail: Address: Co-authors: IV. Background V. Main Study Questions VI. DPBRN data to be used (Required: Study(s); Recommended: variable types, names)

# APPENDIX C

# POLICY FOR COMPLETION OF DPBRN DATA CONFIDENTIALITY AGREEMENT

All individuals with **any** access to DPBRN data must sign a Confidentiality Agreement. This includes, but is not limited to, the following groups of individuals:

- Principal Investigators
- Investigators
- Coordinating Center staff, including data entry, data management, data analysis, and support staff
- Network Chair Office staff and support staff
- Regional Center staff and support staff
- Data analysts (on-site and off-site)
- Fellows and students
- Consultants

Each individual with access to DPBRN data must read, sign and date the Confidentiality Agreement. The Principal Investigator at that site must also sign the agreement and keep the original copy on file. A copy of the completed agreement should be forwarded to the Coordinating Center.

The Principal Investigators (Regional Centers, Coordinating Center and Network Chair) are responsible for ensuring that all individuals currently affiliated with the DPBRN Study through their site sign the Confidentiality Agreement. The Coordinating Center is specifically responsible for ensuring that all subcontractors and consultants to the DPBRN through the Coordinating Center contract, including the Steering Committee Chair, sign the Confidentiality Agreement. The Principal Investigators are responsible for ensuring that all individuals who become affiliated with the DPBRN through employment or consulting in the future sign the Confidentiality Agreement at the time he/she joins the DPBRN.

# DENTAL PRACTICE BASED RESEARCH NETWORK (DPBRN) CONFIDENTIALITY AGREEMENT

As an employee of, consultant to, or fellow/student involved with the Dental Practice-Based Research Network (DPBRN), I am aware of the confidential nature of data on research participants maintained by DPBRN, and of the necessity for maintaining that confidentiality. I agree not to **transfer** or **disclose** any confidential data, nor any information about individual DPBRN participants, except as necessary for data/safety monitoring or programmatic management, in the course of my responsibilities at work nor in private, either during or after my affiliation with DPBRN. I agree not to transfer **any** DPBRN data to individuals outside the DPBRN without the written permission of the DPBRN Steering Committee. Further, I agree to return all DPBRN data to the Principal Investigator or delete/destroy all DPBRN data upon termination of my affiliation with DPBRN.

I understand that as an employee of, consultant to, or fellow/student involved with a study funded by the United States Government, I am subject to the provisions of 5 U.S.C. 552a governing federally maintained records on individuals. 5 U.S.C. 552a(i)(1) imposes criminal penalties on any federal officer or employee "who by virtue of his employment or official position, has possession of, or access to, agency records which contain individually identifiable information the disclosure of which is prohibited by this section or by rules or regulations established thereunder, and who knowing that disclosure of the specific material is so prohibited, willfully discloses the material in any manner to any person or agency not entitled to receive it. Recipient may be found guilty of a misdemeanor under 5 U.S.C. 552a(i)(1) and fined not more than \$5,000 for improperly disclosing personal information contained in Study records."

Name (print):	
Signature:	
Date:	-
Regional Center:	
Principal Investigator's Signature:	
Date:	_

# APPENDIX D

# Distributed Data Form (DD-2) Version 2007.07.31

# **DPBRN**

# NOTICE OF INTENT TO ANALYZE

This form should be submitted to the Coordinating Center prior to analyzing any part of the data set for publication, presentation, planning purposes, grant submissions, etc. This form is used by the Coordinating Center to monitor use of DPBRN Study data and assist us in communicating any known problems to the clinical centers in an efficient manner. This form should not be used for abstract submission.

# **INSTRUCTIONS**

Most of the information required on this form is self-explanatory (title of project, brief description, purpose, key words, etc.). The following are additional comments on those areas which may not be as clear.

# **Investigators**

Please list the principal investigator of the proposed project first with additional investigators listed in any order. The Coordinating Center recognizes that additional investigators may be added to the project by the Steering Committee.

# **Regional Centers involved**

Please indicate whether the entire DPBRN is used in the analyses or whether the project is using data from one or more regional centers only.

# **Expected date of completion**

This is the anticipated date that the project will be completed.

# SAS data sets

List all data sets that will be used in the analysis. Refer to the data documentation for proper file names.

### Main variables of interest

List the main variables of interest for the project. YOU MUST USE THE SAS VARIABLE NAMES ASSIGNED BY THE COORDINATING CENTER IN REPORTING THESE VARIABLES. (Please refer to the documentation which was distributed with the data sets.) This assists the Coordinating Center in identifying which SAS data sets are being used. If a variable will be created using a new or existing algorithm, please name the variable and include a copy of the algorithm which will be used in its construction.

# FORM DD-2 Version 2007.07.31

# **DPBRN**

NOT	ICE OF INTEN	T TO ANALYZE FOR	М	
Submit completed form to:	University of	ordinating Center f Alabama at Birminghan ve South, MTB 403 AL 35205	1	
Telephone: (205) 934-0786		(205) 934-0777		
Date of Request:		Title of Project:		
Publications log #: (This number is assigned upon a contact the CC at 205-934-0786.)  Major hypotheses:	)			er, please
Purpose: Paper Plan Quality Control	ning for DPBRN /local monitorin	g	rant/contract submission	
Expected date of completion:	MM DD YY	YYY		
Study data to be used: Study Study 7 Study 8 Study Study 15 Study 16 Enrol	9 Study 10	Study 11 Study 12	Study 13 Study 14	
Version of data sets used in an	nalyses:			
Main variables of interest (SA	S names):	Additional rows may be	e added, if needed.	

<u>Statisti</u>	cal metho	ods to b	e usec	d (check	all that a	ipply):				
	Frequenc	cies and	sumr	nary stati	stics					
	Regression analyses (general)									
Logistic regression ANOVA (t-tests, etc.)										
	Categori	cal data	mode	eling						
	Other									
	Specify:									
							<u> </u>			
Key w	ords:									
· · · · · · · · · · · · · · · · · · ·										
		•				•			•	
Comn	nents:									
			CO	ORDIN	ATING	CENTER U	ISE ONL	V		
				JORDIN	AIIIO	CLIVILIC	DE OILE	1		
DDRRN	V Paper Nu	umber ·								
DEDKI	N Paper IN	umber .								
A malvai	~ Number									
Anarysi	s Number	•								
Cantaat	Danson /	CC C4-4	er.							
Contact	Person /	CC Stai	1:							
D . D		<u> </u>			1					
Data Re	eceived:	3.53.5								
		MM	DD	VVVV						

# **APPENDIX E**

# The Dental Practice-Based Research Network (DPBRN)

# **DATA DISTRIBUTION AGREEMENT**

Please review and complete the "Distribution Data Agreement" form which consists of six (6) pages and return to the Coordinating Center, Attention: Valerie Winston of the CC (vwinston@mail.dopm.uab.edu) or Linda Sellers (lsellers@dopm.uab.edu).

The Dental Practice Based Research Network, represented by

(Name of DPBRN Study Investigator: This is the

DPBRN Investigator who is collaborating with you on the writing project.), and

(Name of Recipient and Recipient

**Organization:** This is "your name and organization IF you are the individual who will receive the data. Generally, only the principal investigator (first author of the writing project) will request and receive the data.) hereby enter into this Distribution Agreement as of the date specified on the final page hereof.

# PRELIMINARY STATEMENT

The "Dental Practice-Based Research Network" (DPBRN), an international dental practice-based research network, includes the Office of the Network Chair, the Coordinating Center (CC), the National Institute of Dental and Craniofacial Research (NIDCR), and Regional Centers at HealthPartners, Minneapolis, MN; Kaiser Permanente Center for Health Research/Permanente Dental Associates, Portland, OR; University of Alabama at Birmingham; University of Copenhagen, Denmark; and the University of Florida, Gainesville, FL. The network, composed of practitioner-investigators from the US and Scandinavia, undertakes studies specifically relevant to the practice of dentistry. The network is one of three such networks funded by NIDCR currently in operation. Promoting optimal use on a national scale of the data generated by these efforts will require a large and concerted effort that may exceed the research capacity of currently available DPBRN investigators. The NIDCR and the researchers it supports have a responsibility to the public in general, and to the scientific community in particular, to encourage as rapid scientific progress as possible using these resources, subject to appropriate terms and conditions. In order to take full advantage of such resources and maximize their research value, it is important that data collected with public funds be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

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

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

## **DEFINITIONS**

For purposes of this agreement, "Data" refers to the following information, which has been collected and recorded from study participants through the any of the studies conducted in the DPBRN, at any time.

A "DPBRN Investigator" is defined as a research investigator with a current and active contract or consulting agreement with NIDCR or one of its contractors to work on a DPBRN Study.

<b>RECIPIENT ORGANIZATION:</b> (Select the appropriate organization and enter the State in which it is located.)
(check one)
A non-profit OR for-profit corporation organized under the laws of the State of OR a government agency governed under the laws of
Recipient Principal Investigator requests access to DPBRN data at its sole risk and at no expense to the DPBRN and NIDCR.
Recipient Principal Investigator: (This is your name and organization IF you are the individual who will receive the data. Generally, only the Principal Investigator (first author of the writing project) will request and receive the data. If this is a circumstance in which you are not the Principal Investigator, but the first author of the writing project, YOUR Principal Investigator's information would be entered and this individual would request the data.)
, with a principal
address at
("PI") requests access to DPBRN data at no expense to the DPBRN and NIDCR.

# AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

- 1. Research Project.
  - 1.1. These Data will be used by Recipient's Principal Investigator solely in connection with the following research project ("Research Project"), specifically described below or in an attached Exhibit A:
  - 1.2. The Research Project involves the following DPBRN Investigator(s) as co-investigator(s): The work they will perform is described below or in an attached Exhibit B:
  - 1.3. This Distribution Agreement covers only the above-described Research Project. Recipient will submit a completed Distribution Agreement (this document) for each research project for which Data are requested.
- 2. <u>Non-transferability</u>. This Distribution Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project described above, and/or appointment by Recipient of another Principal Investigator to complete the Research Project, require execution of a new Distribution Agreement in which the new Principal Investigator and/or new Research Project are designated.
- 3. <u>Publication</u>. Recipient agrees to comply with DPBRN Publications and Presentations Policies. Prompt publication or any public disclosure of the results of the Research Project is encouraged. Recipient agrees to provide to the DPBRN Coordinating Center a copy of any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to ensure compliance with the confidentiality requirements set forth in paragraphs 4,5,6,7, and 8 of this Agreement.

### APPENDIX E PG 2

- 4. <u>Acknowledgments</u>. Recipient agrees to acknowledge the contribution of the DPBRN Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data.
  - 4.1. <u>Collaborations/Acknowledgments</u>. Recipients will acknowledge DPBRN Investigators as coauthors, as appropriate, on any publication. In addition, the manuscript will be reviewed by NIDCR and the Recipient will use the following acknowledgment below.

"The Dental Practice-Based Research Network" is conducted and supported by the National Institute of Dental and Craniofacial Research (NIDCR), in collaboration with the DPBRN Investigators. This manuscript has been reviewed by NIDCR for scientific content and consistency of data interpretation with previous DPBRN publications and significant comments have been incorporated prior to submission for publication."

- 5. <u>Non-Identification</u>. Recipient agrees that Data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the participants from whom Data were obtained.
- 6. <u>Use Limited to Research Project</u>. Recipient agrees that Data will not be used in any research that is not disclosed and approved as part of the Research Project.
- 7. <u>No Distribution</u>. Recipient agrees to retain control over Data, and further agrees not to transfer Data, with or without charge, to any other entity or any individual. Recipient agrees that when the Research Project is completed, or three (3) years have elapsed from the effective date of this Distribution Agreement, whichever occurs first, the data will be either returned to the DPBRN Study Investigator or deleted/destroyed as mutually agreed upon, unless an extension of this Agreement is obtained.
- 8. <u>Non-Data</u>. Notwithstanding the definition of "Data" or the agreed Terms and Conditions of this Distribution Agreement, Recipient's obligations under this Distribution Agreement shall not extend to any information:
  - (a) that can be demonstrated to have been publicly known at the time of disclosure; or
  - (b) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source prior to the disclosure; or
  - (c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
  - (d) that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Data provided under this Agreement; or
  - (e) that is required to be disclosed by law, provided the Recipient takes responsible and lawful actions to avoid and/or minimize such disclosure.
- 9. Non-Endorsement, Indemnification. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 4. To the extent permitted by law, Recipient agrees to hold the United States Government, Study Investigators, and all other investigator(s) who generated Data and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose of Data.
- 10. <u>Industry Funding</u>. 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 these Data without prior review and written approval of the DPBRN Investigators.

**APPENDIX E PG 3** 

- 11. <u>Amendments</u>. Amendments to this Distribution Agreement must be made in writing and signed by authorized representatives of all parties.
- 12. <u>Termination</u>. DPBRN may terminate this Distribution Agreement if Recipient is in default of any condition of this Distribution Agreement and such default has not been remedied within 30 days after the date of written notice by DPBRN's Authorized Representative of such default. Upon termination of this Distribution Agreement, Recipient agrees to either return all the data to the DPBRN Investigator or delete/destroy all data as mutually agreed upon.
- 13. <u>Disqualification</u>, <u>Enforcement</u>. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Data. The United States Government shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this agreement, the limitations on the use of the data provided, or both. Proceedings may be initiated against the violating party, legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this agreement may subject recipient to legal action on the part of Study participants, their families, or both.
- 14. <u>Accurate Representations</u>. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

**APPENDIX E PG 4** 

# DPBRN Publications Policy (version approved by the DPBRN EC on October 4, 2011)

This Distribution Agreement is entered into as of:	(Enter the date that you are entering
into this agreement.)	
<b>RECIPIENT ORGANIZATION:</b> (This is "your organization" information grants and contracts officer, or someone from the business office at your Institution this form is governed by each individual Institution's policy.)	
Name of Recipient Organization:	
Name and Title of Recipient's Authorized Representative:	
Signature and Date of Recipient's Authorized Representative:	
RECIPIENT PRINCIPAL INVESTIGATOR: (This is the same as Recip	pient Principal Investigator on page 2.)
Recipient Principal Investigator's Name and Title:	
Recipient Principal Investigator's E-Mail Address:	
Recipient Principal Investigator's Telephone Number:	
Recipient Principal Investigator's Fax Number:	
Signature and Date: Recipient Principal Investigator:	
TITLE OF PROJECT / MANUSCRIPT: (This is the title of the manuscridata.)	
MANUSCRIPT NUMBER: (This is the manuscript number that the DPBRN	N Coordinating Center assigned.)
<b>DPBRN INVESTIGATOR:</b> (This is the DPBRN Investigator who is collaboration that you filled in on page 1 of the DDA.)	
Name and Title of DPBRN's Authorized Representative:	
Signature and Date: DPBRN's Authorized Representative:	

**APPENDIX E PG 5** 

# APPENDIX F

### DPBRN FORM DD-5 Version 2007.07.31

# NOTIFICATION OF COMPLETED DPBRN ANALYSIS

This form should be submitted to the Coordinating Center when the final analyses for a project (i.e., publication, presentation, grant submission, etc.) have been completed. It should be submitted both when the analyses resulted in a paper or presentation or when the analyses resulted in unimportant or no findings. Upon receiving this form, the Coordinating Center will terminate inquiries into the progress of the project and will verify results of analyses for publication or presentation, if appropriate. In addition, it also identifies areas of study which were abandoned and reasons for the termination of the project.

# **INSTRUCTIONS**

Most of the information required on this form is self-explanatory (first author, major conclusions, paper submitted to, etc.). The following are additional comments on those areas which may not be as clear.

# SAS data sets used in analysis

List the SAS data sets on the distributed data tape that were used for the analyses. IN REPORTING THESE NAMES, YOU MUST USE THE NAMES OF THE DATA SETS ASSIGNED BY THE COORDINATING CENTER. (Please refer to the tape documentation which was distributed with the tape data sets.) It is recognized that you may not have used these names for your SAS data sets in the analyses but these names assist the Coordinating Center in verification of your analyses and insuring that no existing problems with these data sets were known.

# Variables generated, rules and/or algorithms

Please identify any variables which were created for the analyses that were not originally part of the DPBRN data. Include the algorithms used in creating the variables. If necessary, use additional sheets of paper.

APPENDIX F Form DD5

# DPBRN COORDINATING CENTER NOTIFICATION OF TERMINATED ANALYSIS

Mail completed form to: DPRBN Coordinating Center

University of Alabama at Birmingham

1717 11th Ave South, MTB 505

Birmingham, AL 35205 Telephone: (205) 934-0786

FAX: (205) 934-0777

This form is to be used to document all final analyses conducted on DPBRN data for which a request for analysis has been approved. If this has resulted in a paper, verification will take place only after receipt of this form and attached materials. This form should be filled out even if a paper or final analysis does not occur. This will terminate our inquiries into your progress on all approved requests.

Paper number _	First Author	
	to (name of journal if applicable)	
	ns from analyses or reasons for early termination:	
		_
	sets used in analyses:	_
Main variables	of interest (SAS names):	

APPENDIX F PG 2

DPBRN Publications Policy (version approved by the DPBRN EC on October 4, 2011) State any problems found in analysis and solutions used Computing Procedures (\*\*\*ATTACH A LISTING OF ALL SAS CODES\*\*\*) (\*\*\*ATTACH A DISKETTE CONTAINING ALL SAS CODES) If only a subset of subjects are included in the analyses, indicate the criteria for inclusion and/or exclusion. (Use additional sheets if necessary). Variables Generated Rules and/or Algorithms

Rev. 2007.07.31

# APPENDIX G

# Statement of Authors upon Submission of a Manuscript to the DPBRN Publications and Presentations Committee Version 2007.07.31

	as made significant contributions noted below and that thes ufficiently substantive to merit authorship.	e contributions a
• First Author Signature	Date	
**Each co-author,	briefly state your contribution to this manuscript and sign. <sup>3</sup>	¢.%
Co-Author Signature	Date	
Contribution:		
Co-Author Signature	 Date	
Contribution:		
Co-Author Signature	Date	
Contribution:		
Co-Author Signature	Date	
Contribution:		
Co-Author Signature	Date	
Contribution:		
Co. Andrew Circust		
Co-Author Signature  Contribution:	Date	

For each additional author, attach statements as above, and have first author provide justification for the inclusion of more than eight authors. DPBRN policy attempts to limit the number of named, non-corporate authors on a paper or presentation to no more than seven, with the eighth being the corporate author. 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.

APPENDIX G

# **APPENDIX H**

To add your existing presentation to the template:

- 1. Open the DPBRN PowerPoint template
- 2. Click on the "insert" menu
- 3. Choose "slides from files"
- 4. Click on "browse" or type in the name of your existing presentation
- 5. Select the slides you want to insert or click on" insert all"
- 6. Edit the new presentation to make sure slides inserted correctly

Once you have inserted your slides, you can begin working in the new presentation and "save changes" when you close.

Or

To add the template to your existing presentation:

- 1. Open both the existing presentation and the DPBRN template and click on "normal view" in the task bar in the lower left corner of both
- 2. Click on "View" in the top menu bar of the template
- 3. Click on "master"
- 4. Click on "slide master"
- 5. Right click on the slide master in the template
- 6. Click on "copy"
- 7. Click on "View" in the top menu bar of the existing presentation
- 8. Click "paste"
- 9. Right click on old master slide
- 10. Click "cut"
- 11. Click "normal view" again

The new template should now appear on all your slides.

Now you can begin working in the presentation again. Be sure to save the changes when you close.