ANALYSIS AND PUBLICATION GUIDELINES
CENTERS FOR BIRTH DEFECTS RESEARCH AND PREVENTION (CBDRP)

DATA SHARING COMMITTEE

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ANALYSIS AND PUBLICATION GUIDELINES
CENTERS FOR BIRTH DEFECTS RESEARCH AND PREVENTION (CBDRP)

The Data Sharing Committee

I. GOALS and PURPOSE

The purpose of this committee is:

1. To assure and expedite orderly and timely presentation to the scientific community of all pertinent data resulting from the National Birth Defects Prevention Study (NBDPS) and the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS);

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

3. To assure that NBDPS/BD-STEPS investigators have the opportunity to be involved in data analysis and the preparation of NBDPS/BD-STEPS papers and presentations;

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

5. To establish guidelines for authorship, acknowledgements, and funding citations for any presentations and publications of the NBDPS and BD-STEPS; and

6. To maintain a record of proposed and published papers and presentations from the NBDPS and BD-STEPS studies.

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II. SCOPE OF THE GUIDELINES

This policy covers papers, abstracts, and presentations that involve unpublished data collected by the NBDPS and BD-STEPS and compiled at the Centers for Disease Control and Prevention (CDC) from the ten participating study sites [AR, CA, GA, IA, MA, NC, NJ, NY, TX, and UT]. The data covered by these guidelines include all interview, clinical, and biologic data associated with these studies. It does not apply to data collected as part of local NBDPS studies by each Center. These guidelines should be followed for any studies or writing projects involving data from two or more Centers this includes studies that include local biologic samples from two or more Centers. These policies will remain in force until the Data Sharing Committee is formally dissolved.

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III. MEMBERS OF THE DATA SHARING COMMITTEE

1. Members of the Data Sharing Committee will include two representatives from each of the Centers including CDC. The Center representatives may be the Principal Investigator and one additional representative, or the two Co-Principal Investigators. The Centers may allow substitute members to attend meetings or phone conferences. The substitute may vote on project approvals.

2. The Data Sharing Chair will serve as administrator of the committee and will be elected by the Coordinating Council. The Data Sharing Chair will serve a term of 12 months, January- December. CDC will coordinate the administrative aspects of the committee as well as represent the Georgia site. All correspondence to the committee, including letters of intent, proposals and abstracts, and manuscripts will be sent to CDC for distribution to committee members. The CDC coordinators will also be responsible for ensuring that all IRB requirements are met for any analyses resulting from the collaborative NBDPS/BD-STEPS. Committee members from each Center will be responsible for sharing documents submitted to the committee with their Center staff in order to inform them about proposed projects and to obtain their feedback. Each Center can submit 2 reviews to the Data Sharing committee for each proposal or manuscript being considered by the committee.

3. Only NBDPS investigators can submit reviews for submissions that include NBDPS data and only BD-STEPS investigators can submit reviews for submissions that include any BD-STEPS data.

4. The Data Sharing Editor will assign 2-3 reviewers according to area of interest or specialty and give final approval on all manuscripts involving the shared NBDPS data. The Data Sharing Editor will have a term of 6 months. If a conflict of interest arises, the "editor in waiting" will be asked oversee the review process for that particular manuscript.

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IV. APPROVAL OF THE NBDPS/BD-STEPS PROJECTS FOR ANALYSIS AND WRITING

A. Proposals and Letters of Intent

1. To initiate an analysis and writing project, a participating investigator must first complete the letter of intent template (Attachment A) and submit to the Data Sharing Committee. If any BD-STEPS data are used, then the project needs to be sponsored by a BD-STEPS PI; if NBDPS data are used, then the project needs to be sponsored by an NBDPS PI. The purpose of the letter of intent is to communicate research ideas and facilitate collaboration among Centers. The letter of intent template includes:

    a. the name of the lead investigator
    b. the name of the sponsoring PI
    c. the objective, aim or hypothesis to be tested
    d. collaborators involved in the research
    e. any issues related to conflicts with existing or proposed research.

    Letters of intent should be submitted to the Data Sharing Committee via the CDC Coordinator by the third Thursday of the month (Attachment B, Data Sharing Schedule). The sponsoring PI must review and approve the LOI before submission. The sponsoring PI has the responsibility to assure that all investigators and co-authors who will have access to any NBDPS/BD-STEPS data (clinical, interview or biologics) have signed the confidentiality and data use oath and that it is on file (Attachment C).The lead investigator must copy the sponsoring PI and all co-authors when submitting letters of intent to the Data Sharing Committee.

2. The CDC Coordinator will distribute the letter to all committee members for review on the day after the Data Sharing conference call. The committee members will review the letter to determine that the scope of the analysis is reasonable, and that there are no conflicts with existing or proposed analyses. The committee members may also make suggestions for collaboration with other Centers investigators.

3. Committee members will send their comments about the letter of intent using the email review form supplied when the letters of intent are distributed (Attachment D). Reviews are due three weeks after the letters are distributed to the committee. Comments will be compiled by the CDC Coordinator and distributed to the committee on the Monday before the next Data Sharing call. The compiled comments will include the name of each reviewer, along with his/her comments. During the Data Sharing call, the committee will discuss and informally vote on letters of intent. If the author or sponsoring PI is not on the call the CDC Coordinator will respond to investigators the following day with their decision and any comments, unless issues are raised that require further discussion. The Data Sharing Committee decision will also be entered in the Data Sharing Database and added to the Centers website.

4. Under very limited circumstances, the CDC administrators of the Data Sharing Committee may call for an expedited review of a letter of intent. Requests for an expedited review should be submitted to the committee with justification for the need to expedite the review.

5. After the committee approves the research proposed in the letter, the investigators must complete the proposal template (Attachment E) to prepare a 2-5 page study proposal before beginning analyses. The sponsoring PI must review and approve the research proposal before submission. If any new co-authors have been added, the sponsoring PI has the responsibility to assure that they have signed and have on file the confidentially and data use oath. Proposals should be submitted no sooner than 6 months before the time that it is expected that there will be enough cases or exposures of interest to do the study. The

lead investigator must copy the sponsoring PI and all co-authors when submitting the proposal to the Data Sharing Committee. The proposal should include:

1) investigators with lead investigator and sponsoring PI noted
2) contribution of each investigator
3) objectives, aim or hypothesis
4) background with relevant references
5) methods describing –
   a) specific outcomes of interest
   b) primary exposures of interest
   c) analysis plan with power calculations if relevant
   d) other data collection or record matching if relevant.

If particular expertise in, for example, molecular genetics, statistics, epidemiology or case classification will be required for the study, plans for obtaining this should be noted in the proposal. Proposals that include requests for biologic samples have additional requirements that are noted in Section C.

6. Committee members will send their comments about the proposal using the proposal review form supplied when the proposals are distributed (Attachment F). Reviews are due three weeks after the letters are distributed to the committee. Comments will be compiled by the CDC Coordinator and distributed to the committee on the Monday before the next Data Sharing call. The compiled comments will include the name of each reviewer, along with his/her comments. During the Data Sharing call, the committee will discuss and vote on each proposal. If the author or sponsoring PI is not on the call the CDC Coordinator will respond to investigators the following day with their decision and any comments, unless issues are raised that require further discussion. The Data Sharing Committee decision will also be entered in the Data Sharing Database and added to the Centers website.

7. If an earlier performed NBDPS and/or BD-STEPS analysis is re-done, an amended proposal is required. Updated proposals should use the proposal template (Attachment E) and include an updated methods section as well as an explanation of all elements that are new in the amended proposal.

   If an investigator with an existing approved NBDPS proposal wishes to add BD-STEPS data for analysis, then the investigator should indicate this intention in the DS updates, and when the first BD-STEPS data are available, he/she should submit an amended proposal to add BD-STEPS data for analyses and ensure the sponsorship or co-sponsorship of a BD-STEPS PI.

8. For proposals with biologics, the Biologics Committee will review the proposal for the first two weeks of the review period, and the CDC Coordinator will send the proposal to the Data Sharing Committee after the Biologics Committee review.

B. Policy on replication of NBDPS/BD-STEPS pooled data analyses

1. Analyses of NBDPS/BD-STEPS pooled data with the intention of publication in a peer-reviewed journal require replication of results. For this policy, replication is defined as:
   a. Confirmation of case and control counts for analyses
   b. Confirmation of all main exposure and covariate[1] distributions by case[2]-control status
   c. Confirmation of crude main effect analyses
   d. If the presence of interactions are to be reported, confirmation of interaction effects

2. Replication should take place no later than the time during manuscript review by the Data Sharing Committee. A check-box is added to the manuscript submission form (Attachment G) in which the lead author will indicate that the analysis has been or is currently undergoing replication, and by whom.

1 Covariates that are included in a “table 1” or if there is no such table of characteristics, covariates that are included in the multivariable analyses.
2 For spectrum analyses, confirmation of covariate distributions among all included case groups is not necessary. Confirmation of covariate distributions for all cases combined is sufficient.

3. The lead author may select the analyst to conduct the replication. This individual may be within the lead author's study center, or not, and may be an official project collaborator, or not. Depending on the level of effort undertaken, analysts who conduct replication who are not official project collaborators, may be officially acknowledged in the manuscript or offered co-authorship, although neither is required.

4. The lead author may petition the committee for a waiver of the replication requirement. This can be done by e-mail and it does not have to wait for a committee call.
   a. Justification for the waiver request should include:
      - Quality Control (specify what has been done to limit errors)
      - Short timeline
      - Qualitative Analysis (specify how questions were assessed and how errors are minimized)

5. Policies specific to new analysts:
   a. New analysts are required to conduct a study replication as part of their training.
   b. New analysts (or lead authors working with a new analyst) may not petition for a waiver of the replication requirement.
   c. Local Centers should suggest or require new analysts to attend/view yearly confidentiality webinar

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C. Proposals that include use of biologic material

If the proposed research includes use of biologic material, the following guidelines apply:

In addition to the proposal, the ***gene one-pager form*** for the CDC IRB must be completed for each gene to be studied. The genes from one candidate gene pathway may be grouped on one form if they are not clinically significant. Those genes that are clinically significant must be submitted as separate gene one-pagers. A single gene one pager form may be submitted for genome wide analyses. Examples of gene one pagers can be found on the CBDRP SharePoint site. The gene one-pager forms must accompany the proposal, and approval from the CDC IRB must be obtained before the central repository samples will be released. The CDC IRB review will be expedited and is expected to take 1-2 weeks.

I. Limited and Expanded SNP Projects

These guidelines should be followed for those studies that typically include a small number of candidate genes and a small number of SNPs chosen because of known functionality and previous studies (limited SNP projects) and studies that are an expansion of these currently approved and proposed NBDPS LOIs and proposals.

The proposed guidelines include:

1) Typically only a defect or defect group will be proposed for interrogation.

2) Priority should be given to questions of public health, clinical, and biologic significance. Priority should be given to projects with high likelihood of success based on power calculations.

3) Justification must be provided for the choice and prioritization of target genes and SNPs. A broad array of genes and SNPs may be chosen depending upon the hypothesis. The proposal should clearly articulate the criteria used to select the genes and SNPs, including but not limited to, as appropriate, allele frequencies, known associations, functionality of polymorphism, or LD structure of the gene.

4) Additional anonymous SNPs may be selected to define or tag haplotypes or bins of correlated SNPs. In addition, there should be a description of the approach used to select a minimal number of SNPs needed to define haplotypes including racial/ethnic-specific SNP selection methods if necessary.

5) *Proficiency Testing:* The proposal must include verification that the lab proposing to perform genotyping on NBDPS samples passed the required annual External Quality Assessment (EQA)

6) *Preliminary Data:* Proposals must include preliminary data from a new pilot study or a previously performed study. If from a previous study, the reference must be cited and a summary of the results included. Laboratories using high throughput platforms (e.g., Illumina, Affymetrix) and assays for the first time can include data from 12 subjects (instead of 90) following the same guidelines for gene variants, DNA, and genotyping platform listed below. Assays must be directed by lab staff who will be handling the samples for the proposed research. If the laboratory has genotyping results using NBDPS samples from a higher throughput assay (e.g., Infinium), they can include those data in a proposal that will include lower throughput assays (e.g., Golden Gate). Preliminary Data must include the following:
   - Type and Number of Gene Variants
     - Type of gene variant (SNP, indel, STR, etc) must be consistent with proposed research (for example, if proposed research includes analysis of multiple SNPs and a few deletions, preliminary data must include analysis of SNPs and deletions). Data for specific gene variants to be analyzed in proposed research is not required.
     - Number: minimum of 3 variants
   - Type of DNA: buccal; specify whole genome amplified and/or unamplified gDNA
     - If buccal DNA will be amplified in the proposed research, a description of the WGA method and preliminary data demonstrating the labs experience and proficiency must be provided including genotype concordance rates between paired amplified and unamplified buccal gDNAs.
   - Number of Subjects: minimum of 90
   - Genotyping Platform: must be consistent with proposed research

7) Samples with DNA concentrations < 0.1ng/ul (measured using human RNaseP real-time quantitative PCR) should be excluded from analyses

8) A proposal section on the methods to be used to determine and account for potential false positive associations should be included.

9) If genes are of interest to other researchers, research agendas should be coordinated among interested investigators. Proposals should specify others who were contacted regarding interest in the project. Priority should be given to those proposals that combine genotyping from multiple projects into a single effort.

10) *Sharing of results with the group and contribution of final data to the NBDPS data repository.* Within 6 months of publication of a manuscript or other final product, the primary research team should deposit study results into the NBDPS Genetic Analysis Database (GAD - Progeny) or provide data via SAMS for storage in a secure location if the GAD cannot hold those data. If the team is unable to meet the deadline, they should notify the Data Sharing or Biologics Coordinator of when to expect the transmission of results. If individual PIs from other Centers need data sooner, they should contact the lead project PI directly. Submission of results from studies using repository and local cytobrush-derived samples is required. Submission of results from studies using other local samples (e.g., saliva, bloodspots, etc) would enhance the data repository and is strongly encouraged.

11) Approved proposals may be resubmitted as amended/revised proposals including the expanded aims. The description of the new target genes and SNPs and related material should be incorporated into the approved original proposal with the new text demarcated.

12) All PIs contributing samples should be included as sponsors on the proposal with the lead project PI listed first.

Once proposals are submitted to the Data Sharing Committee (DSC), they will be reviewed by the Biologics coordinator or an alternate CDC reviewer and 2 members of the Genetic Analysis Working Group (GAWG) who are to serve for 6 months. The initial review will determine if all guidelines for biologics were followed, and if data analyses and interpretation of preliminary data were correct. The intent of the GAWG review is to make sure the methods are reviewed by those most knowledgeable about biologic studies. Within 2 weeks of submission to the DSC, GAWG reviewers will tell the DSC coordinator whether they approve the document. If approved, the coordinator will send the proposal to all DSC members so that approved documents will be reviewed by the Data Sharing deadline. If the

proposal does not fulfill the biologic requirements and/or accepted standards of genetic epidemiology and/or statistical genetics, it will be returned to the lead investigator, and the sponsoring PI will be copied, with a brief report listing the requirements that were not fulfilled and/or concerns about genetic epidemiology or statistical methods. Documents that are not approved can be revised where possible, and resubmitted to the DSC upon fulfillment of requirements and/or completion of revisions (for review by the GAWG and DSC members no sooner than the following month). The DSC will provide the final decision for approval based on their review.

II. Whole Genome Studies

Development of WGS projects are complex, requiring extensive planning for genotyping platforms, DNA quality, costs, data analysis, etc. Additional technical expertise, facilities, and major funding are required. Given that they are typically beyond the scope of usual NBDPS genetic projects these may be undertaken by a team of NBDPS investigators with relevant expertise representing multiple Centers and the CDC. Issues to be considered when planning and preparing LOIs and proposals involving whole genome scans include:

1) Typically only a defect or defect group will be proposed for interrogation.

2) Priority should be given to questions of public health, clinical, and biologic significance.

3) Other groups with potential overlap through ongoing or planned genetic studies of the same defect or defect group should be contacted. Proposals should specify others who were contacted regarding interest in the project.

4) *Sharing of results with the group and contribution of final data to the NBDPS data repository.* Within 6 months of publication of a manuscript or other final product, the primary research team should deposit study results into the NBDPS Genetic Analysis Database (GAD - Progeny) or provide data via SAMS for storage in a secure location if the GAD cannot hold those data. If the team is unable to meet this deadline they should notify the Data Sharing or Biologics Coordinator of when to expect the transmission of results. If individual PIs from other Centers need data sooner, they should contact the lead project PI directly. Submission of results from studies using repository and local cytobrush-derived samples is required. Submission of results from studies using other local samples (e.g., saliva, bloodspots, etc) would enhance the data repository and is strongly encouraged.

5) *Proficiency Testing:* The proposal must include verification that the lab proposing to perform genotyping on NBDPS samples passed the required annual External Quality Assessment (EQA)

6) *Preliminary Data:* The primary research team must provide information demonstrating that they are capable of conducting WGS studies with regard to: 1) performing the appropriate laboratory assays and 2) performing primary data analysis. This should be a general description of the laboratory's experience with the relevant WGS platform. It is expected that the laboratory, whether a Center's in-house facility, or a collaborating or contract lab, will provide this summary. Note that the laboratory should present preliminary data from a representative WGS genotyping experiment. The quantity of DNA necessary to perform whole genome amplification and genotyping assays should be included. Other data, as it applies to the specific WGS platform, should include data quality assessments. Where appropriate, specifics regarding the inclusion of negative and positive controls as well as QC replicates, duplicates of selected samples, or the repeat testing of 5-10% of samples should be included. Local NBDPS buccal samples should be used for all feasibility studies and pilot testing. Verification that WGA products were amplified with no allele bias using other sources of DNA should be included. The group's experience and expertise in the processing and analysis of WGS and similar high-dimensional gene data should be presented.

7) The authorship plan for the primary publications from the scan project and associated secondary papers should be defined in advance. These collaborative efforts will require a list of primary authors with The NBDPS listed last on the authorship line. The PI from the Center that will author the primary publication will be the lead project PI. All PIs contributing samples should be included as sponsors on the proposal with the lead project PI listed first.

8) Decisions may be made by an expanded research team including the PI and co-investigators

including those of the primary research team, others with ongoing or planned analyses of candidate genes of the defect(s) under study and those with additional expertise and interest.

Once proposals are submitted to the Data Sharing Committee (DSC), they will be reviewed by the Biologics coordinator or an alternate CDC reviewer and 2 members of the Genetic Analysis Working Group (GAWG) who are to serve for 6 months. The initial review will determine if all guidelines for biologics were followed, and if data analyses and interpretation of preliminary data were correct. The intent of the GAWG review is to make sure the methods are reviewed by those most knowledgeable about biologic studies. Within 2 weeks of submission to the DSC, GAWG reviewers will tell the DSC coordinator whether they approve the document. If approved, the coordinator will send the proposal to all DSC members so that approved documents will be reviewed by the Data Sharing deadline. If the proposal does not fulfill the biologic requirements and/or accepted standards of genetic epidemiology and/or statistical genetics, it will be returned to the lead investigator with a brief report listing the requirements that were not fulfilled and/or concerns about genetic epidemiology or statistical methods. Documents that are not approved can be revised where possible, and resubmitted to the DSC upon fulfillment of requirements and/or completion of revisions (for review by the GAWG and DSC members no sooner than the following month). The DSC will provide the final decision for approval based on their review.

III. DNA Methylation Projects

Development of DNA methylation projects are complex, requiring extensive planning for platforms, DNA quality, costs, data analysis, etc. Additional technical expertise, facilities, and major funding are required. Given that they are typically beyond the scope of usual NBDPS genetic projects these may be undertaken by a team of NBDPS investigators with relevant expertise representing multiple Centers and the CDC. Issues to be considered when planning and preparing LOIs and proposals involving methylation projects include:

1) Typically only a defect or defect group will be proposed for interrogation.

2) Priority should be given to questions of public health, clinical, and biologic significance. Priority should be given to projects with high likelihood of success based on power calculations.

3) Other groups with potential overlap through ongoing or planned genetic studies of the same defect or defect group should be contacted. Proposals should specify others who were contacted regarding interest in the project.

4) *Proficiency Testing:* The proposal must include verification that the lab proposing to perform methylation assays using NBDPS samples passed the required External Quality Assessment (EQA)

5) *Preliminary Data:* The primary research team must provide information demonstrating that they are capable of conducting methylation studies with regard to: 1) performing the appropriate laboratory assays and 2) performing primary data analysis. This should be a general description of the laboratory's experience with the relevant DNA methylation platform (i.e., the same platform as that in the proposed research). It is expected that the laboratory, whether a Center's in-house facility, or a collaborating or contract lab, will provide this summary. Note that the laboratory should present preliminary data from a representative DNA methylation experiment that includes data from a minimum of 12 subjects. The quantity of DNA necessary to perform methylation assays should be included. Bisulfite conversion rates, CpG site call rates, and concordance between technical controls should be included. Other data, as it applies to the specific methylation platform, should include data quality assessments (e.g., removal of samples or individual data points). Where appropriate, specifics regarding the inclusion of negative and positive controls as well as QC replicates, QC standards, or duplicates of selected samples should be included. Local NBDPS buccal samples should be used for all feasibility studies and pilot testing. The group's experience and expertise in the processing and analysis of DNA methylation data should be presented.

6) Samples with DNA concentrations < 0.1ng/ul (measured using human RNaseP real-time quantitative PCR) should be excluded from analyses

7) The authorship plan for the primary publications from the scan project and associated secondary

papers should be defined in advance. These collaborative efforts will require a list of primary authors with The NBDPS listed last on the authorship line. The PI from the Center that will author the primary publication will be the lead project PI. All PIs contributing samples should be included as sponsors on the proposal with the lead project PI listed first.

8) A proposal section on the methods to be used to determine and account for potential false positive associations should be included.

9) *Sharing of results with the group and contribution of final data to the NBDPS data repository.* Within 6 months of publication of a manuscript or other final product, the primary research team should deposit study results into the NBDPS Genetic Analysis Database (GAD - Progeny) or provide data via SAMS for storage in a secure location if the GAD cannot hold those data. If the team is unable to meet this deadline, they should notify the CDC Coordinator or Biologics Coordinator of when to expect the transmission of results. If individual PIs from other Centers need data sooner, they should contact the lead project PI directly. Submission of results from studies using repository and local cytobrush-derived samples is required. Submission of results from studies using other local samples (e.g., saliva, bloodspots, etc) would enhance the data repository and is strongly encouraged.

10) Approved proposals may be resubmitted as amended/revised proposals including the expanded aims. The description of the new target genes and methylation sties and related material should be incorporated into the approved original proposal with the new text demarcated.

Once proposals are submitted to the Data Sharing Committee (DSC), they will be reviewed by the Biologics coordinator or an alternate CDC reviewer and 2 members of the Genetic Analysis Working Group (GAWG) who are to serve for 6 months. The initial review will determine if all guidelines for biologics were followed, and if data analyses and interpretation of preliminary data were correct. The intent of the GAWG review is to make sure the methods are reviewed by those most knowledgeable about biologic studies. Within 2 weeks of submission to the DSC, GAWG reviewers will tell the DSC coordinator whether they approve the document. If approved, the coordinator will send the proposal to all DSC members so that approved documents will be reviewed by the Data Sharing deadline. If the proposal does not fulfill the biologic requirements and/or accepted standards of genetic epidemiology and/or statistical genetics, it will be returned to the lead investigator with a brief report listing the requirements that were not fulfilled and/or concerns about genetic epidemiology or statistical methods. Documents that are not approved can be revised where possible, and resubmitted to the DSC upon fulfillment of requirements and/or completion of revisions (for review by the GAWG and DSC members no sooner than the following month). The DSC will provide the final decision for approval based on their review.

IV. DNA Sequencing Projects

Development of sequencing projects are complex, requiring extensive planning for platforms, DNA quality, costs, data analysis, etc. Additional technical expertise, facilities, and major funding are required. Given that they are typically beyond the scope of usual NBDPS genetic projects these may be undertaken by a team of NBDPS investigators with relevant expertise representing multiple Centers and the CDC. Issues to be considered when planning and preparing LOIs and proposals involving DNA sequencing studies (targeted, exome, and whole genome) include:

The proposed guidelines include:

1) Typically only a defect or defect group will be proposed for interrogation.

2) Priority should be given to questions of public health, clinical, and biologic significance. Priority should be given to projects with high likelihood of success based on power calculations.

3) Other groups with potential overlap through ongoing or planned genetic studies of the same defect or defect group should be contacted. Proposals should specify others who were contacted regarding interest in the project.

4) *Proficiency Testing:* The proposal must include verification that the lab proposing to perform sequencing assays using NBDPS samples passed the required External Quality Assessment (EQA)

5) *Preliminary Data:* The primary research team must provide information demonstrating that they are capable of conducting sequencing studies with regard to: 1) performing the appropriate laboratory assays and 2) performing primary data analysis. This should be a general description of the laboratory's experience with the relevant DNA sequencing platform (i.e., the same platform as that in the proposed research). It is expected that the laboratory, whether a Center's in-house facility, or a collaborating or contract lab, will provide this summary. Note that the laboratory should present preliminary data from a representative DNA sequencing experiment that includes data from a minimum of 10 subjects for targeted sequencing, 4 subjects for exome sequencing, and 2 subjects for whole genome sequencing. The quantity of DNA necessary to perform sequencing assays should be included. Quality control data, such as concordance between technical controls or concordance with published third-party data, should be included. Other data, as it applies to the specific sequencing platform, should include data quality assessments (at a minimum: read depth, uniformity of coverage, and per base quality (Q) scores, and possibly GC content distribution, capture efficiency, transition/transversion (Ti/Tv) ratio, and number of non-synonymous SNPs). Additionally, the informatics pipeline and what thresholds or cutoffs were used (e.g., the minimum coverage for a region or the percent allele cutoffs to call a heterozygous or a homozygous variant). Where appropriate, specifics regarding the inclusion of negative and positive controls as well as QC replicates, QC standards, or duplicates of selected samples should be included. Local NBDPS buccal samples should be used for all feasibility studies and pilot testing. The group's experience and expertise in the processing and analysis of DNA sequencing data should be presented.

6) Samples with DNA concentrations < 0.1ng/ul (measured using human RNaseP real-time quantitative PCR) should be excluded from analyses

7) The authorship plan for the primary publications from the scan project and associated secondary papers should be defined in advance. These collaborative efforts will require a list of primary authors with The NBDPS listed last on the authorship line. The PI from the Center that will author the primary publication will be the lead project PI. All PIs contributing samples should be included as sponsors on the proposal with the lead project PI listed first.

8) A proposal section on the methods to be used to determine and account for potential false positive associations should be included.

9) *Sharing of results with the group and contribution of final data to the NBDPS data repository.* Within 6 months of publication of a manuscript or other final product, the primary research team should deposit study results into the NBDPS Genetic Analysis Database (GAD - Progeny) or provide data via SAMS for storage in a secure location if the GAD cannot hold those data. If the team is unable to meet this deadline, they should notify the Data Sharing or Biologics Coordinator of when to expect the transmission of results. If individual PIs from other Centers need data sooner, they should contact the lead project PI directly. Submission of results from studies using repository and local cytobrush-derived samples is required. Submission of results from studies using other local samples (e.g., saliva, bloodspots, etc) would enhance the data repository and is strongly encouraged.

10) Approved proposals may be resubmitted as amended/revised proposals including expanded aims. The description of the new target genes and sequencing sites and related material should be incorporated into the approved original proposal with the new text demarcated.

Once proposals are submitted to the Data Sharing Committee (DSC), they will be reviewed by the Biologics coordinator or an alternate CDC reviewer and 2 members of the Genetic Analysis Working Group (GAWG) who are to serve for 6 months. The initial review will determine if all guidelines for biologics were followed, and if data analyses and interpretation of preliminary data were correct. The intent of the GAWG review is to make sure the methods are reviewed by those most knowledgeable about biologic studies. Within 2 weeks of submission to the DSC, GAWG reviewers will tell the DSC coordinator whether they approve the document. If approved, the coordinator will send the proposal to all DSC members so that approved documents will be reviewed by the Data Sharing deadline. If the proposal does not fulfill the biologic requirements and/or accepted standards of genetic epidemiology and/or statistical genetics, it will be returned to the lead investigator with a brief report listing the requirements that were not fulfilled and/or concerns about genetic epidemiology or statistical methods. Documents that are not approved can be revised where possible, and resubmitted to the DSC upon

fulfillment of requirements and/or completion of revisions (for review by the GAWG and DSC members no sooner than the following month). The DSC will provide the final decision for approval based on their review.

Beginning with proposals submitted in September 2003, all proposals involving the use of biologic samples will be reviewed at CDC to ensure compliance with the above guidelines. All proposals that have not followed the guidelines will be returned to the submitting lead investigator with a brief note outlining criteria from the Data Sharing Guidelines that have not been addressed. For example, "Please provide information on the pilot testing of the proposed methods including results of pilot studies." The investigator will then be asked to resubmit the proposal with the next data sharing round.

For proposals approved prior to September 2003, the same review will occur when samples are requested from the repository. If the approved proposal does not address the criteria in the Data Sharing Guidelines, it will be necessary to submit an updated proposal that addresses these issues.

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D. Approval of NBDPS/BD-STEPS Abstracts

1. Abstracts must be sent to the CDC coordinator at least 5 working days before the deadline for submission; earlier is preferred.

2. An abstract will not have to go back through Data Sharing review if it is generally the same as a previously approved manuscript abstract or an approved abstract that was submitted to another conference, but it should be submitted to the CDC Coordinator as an "FYI" for the DSC. Whether an author judges changes significant enough for re-submission is at the discretion of the author.

3. Abstracts that have been submitted to a conference without any Data Sharing review have to be withdrawn from the conference.

4. Abstracts without data (only representing analysis plans, no results included, but planned for the presentation), will need to undergo the usual abstract review cycle. Abstracts that are opinion pieces will be sent by the CDC coordinator as an FYI to the Data Sharing Committee and asked for concerns within a 5 working day comment period. The author will wait to submit the abstract to the meeting until this period has passed.

5. The CDC coordinator will select three abstract reviewers from the list of abstract reviewers. This list is provided by each Center PI and updated each year.

6. The CDC coordinator will send the abstract, the review deadline (5 working days) and a review form (Attachment G) to three reviewers, asking them to determine if the abstract is accurate, scientifically sound, and does not compromise the collaborative study. The next two abstracts submitted to the CDC coordinator, if received within two weeks of the first abstract submission, will be sent to the same three reviewers. Reviewers will not receive more than three review requests in their two-week review period.If the abstract includes a CDC author, the CDC coordinator must ensure that the abstract is submitted to and approved through CDC clearance.

7. Reviewers will use the form in Attachment H and will send the form to the CDC coordinator by e-mail. They will respond within 5 working days. If there are no concerns or issues raised, the CDC coordinator will inform the investigator that the committee has approved their abstract. Any comments or suggestions on improving the document will be sent to the lead investigator as well. If there are minor issues raised by the reviewer(s), an attempt will be made to resolve these by e-mail discussions among the lead author and reviewers. If there are major areas of concern, the CDC coordinator will schedule a conference call for the lead author and reviewers to discuss the issue(s). Sometimes it may occur that all 3 reviews are not completed. In those situations, at least one completed review form must be sent back to the CDC coordinator for an abstract to be considered approved. The CDC coordinator will ask one additional reviewer for a one-day review if no reviews are received by the last day of the review period of one week. Under very limited circumstances, the lead author may request an expedited review of an abstract. Such requests should be submitted to the CDC coordinator with justification for the need to expedite the review.

The CDC coordinator can approve the abstract or if needed, consult with the Data Sharing Committee chair or send it out to three reviewers.

8. Abstracts that are disapproved may be revised and resubmitted if there is time left before the deadline.

9. The CDC coordinator will maintain a tracking form to ensure that all abstract reviews are received and forwarded to the author before the submission deadline. A copy of accepted abstracts should be sent to the CDC coordinator for record keeping purposes.

10. The CDC coordinator will create a list of abstracts submitted each month and attach this list to the monthly Data Sharing Committee meeting agenda.

11. The CDC coordinator will also maintain a list of the deadlines for submitting abstracts for review for some of the common conferences collaborators attend. The deadlines will be 5 working days before the conference abstract deadlines. This list will be available to NBDPS/BD-STEPS investigators, probably on the sharepoint site.

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E. Approval of Manuscripts

Manuscripts may be submitted to the CDC coordinator at any time. The lead investigator must submit a manuscript submission form (Attachment F) with his/her manuscript. The CDC coordinator will send the manuscript to the Data Sharing Editor and the Data Sharing Committee (as an FYI) at the same time. The DS Editor will assign 2-3 reviewers according to area of expertise. Review turnaround time will depend on the number/type of issues that arise during the review process. Reviews will be conducted anonymously using the manuscript review form (Attachment I), and compiled comments will be presented in electronic form to the author. Approval status will be communicated to the Data Sharing Committee as part of the "Manuscripts in the Pipeline" updates during the DS monthly calls.

It is the responsibility of the lead investigator to determine if a re-review of a manuscript by the Data Sharing Committee is necessary when peer review requires substantial revision of the manuscript.

If there are one or more CDC authors, one of the CDC authors must ensure that the manuscript undergoes CDC clearance. Manuscripts can be submitted for CDC Clearance and NBDPS/BD-STEPS Data Sharing review at the same time or sequentially. This is up to the author. When contradictory comments occur, there should be a negotiating process on an individual basis – where the author discusses the contradictory comments with both CDC clearance reviewers and Data Sharing.

For manuscripts without NBDPS/BD-STEPS data, including opinion pieces, the CDC coordinator will send the document as an FYI to the Data Sharing Committee and ask for concerns to be submitted to the author within a 5-working-day comment period. The author will wait on submission to journal until this period has passed. The DS editor will read FYI submissions.

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F. Guidelines for Presentations

Presentations do not need to be reviewed by the Data Sharing Committee.

G. Theses/Dissertations

The committee will not conduct formal review of dissertations. [This assumes a CBDRP investigator will be a member of the student's thesis/dissertation review committee]. The masters or doctoral candidate must submit an abstract of the dissertation as an FYI to the committee.

H. Sharing of Unpublished Data

The Data Sharing Committee (DSC) permits pooled NBDPS/ BD-STEPS data to be included in peer-reviewed manuscripts and to be presented at scientific meetings. These uses of the data are reviewed by established DSC procedures in either manuscript or meeting-abstract form. All other public use/public sharing of NBDPS/BD-STEPS data must be done with caution. All NBDPS/BD-STEPS investigators must consult the DSC editor before any data are publicly shared in any way. Decisions to permit the sharing of data will be

guided by the public health urgency and likely benefit, how well the confidential nature of the data is protected, and the probability that downstream use of the data does not jeopardize the integrity of the NBDPS/BD-STEPS.

V. AUTHORSHIP

1. Authors who participate in the writing of a manuscript from the collaborative CBDRP should do so in accordance with the International Committee of Medical Journal Editors guidelines (N Engl J Med 1997 Jan 23;336(4):309-15). These guidelines can be found in Attachment J.

2. All papers should include the words "The National Birth Defects Prevention Study" and/or "Birth Defects Study To Evaluate Pregnancy exposureS" or "Centers for Birth Defects Research and Prevention" in the authorship line (e.g. Smith JL, Jones KC, Williams ME, and The National Birth Defects Prevention Study). All papers should also include an "Acknowledgements" section that lists each Center unless journal policy prohibits publication of such a list.

3. Also in the "Acknowledgement" section, all papers should include the words "This study was supported by a cooperative agreement from the Centers for Disease Control and Prevention."
   a. General pooled data:
      This work was supported through cooperative agreements under PA 96043, PA 02081 and FOA DD09-001 from the Centers for Disease Control and Prevention to the Centers for Birth Defects Research and Prevention participating in the National Birth Defects Prevention Study.

   b. Occupational exposure assessment data:
      This work was supported by contract 200-2000-08018 from the Centers for Disease Control and Prevention and the National Institute for Occupational Safety and Health.

   c. Nutrient data:
      This work was supported by grant no. DK56350 from the Nutrition Epidemiology Core of the University of North Carolina Clinical Nutrition Research Center.

   d. Medication dictionary data:
      Coding of drug information in the National Birth Defects Prevention Study used the Slone Drug Dictionary under license from the Slone Epidemiology Center of Boston University.

4. First Authorship

   a. First authors will usually be NBDPS/BD-STEPS investigators. Other scientists may serve as first authors if at least one other NBDPS/BD-STEPS investigator serves as a co-author and "sponsor" of the project and the scientist has played a major role in the data analysis and writing for the paper.

   b. Conflicts about first authorship should be resolved, if at all possible, by members of the analysis/writing group. In case the group is unable to resolve a conflict among the Centers, the Data Sharing Committee will adjudicate and may assign first authorship.

   c. If progress on a given project is unduly slow, the Data Sharing Committee may request an explanation from the lead investigator. If timely progress is not likely to occur in the near future, the Data Sharing Committee may, at its discretion, assign a new lead investigator to the study.

5. Co-Authorship

   a. The first author should determine the order of authorship on a paper. In general, authors will appear in order of contribution to the writing and analysis of the paper. In some circumstances, the senior author will elect to list him/her-self last in author order.

   b. If conflicts among the Centers regarding the order of authorship cannot be resolved by the analysis/ writing group, the Data Sharing Committee will adjudicate and may assign order.

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VI. DATA SHARING WORKING GROUPS

1. Working Groups will be formed of interested scientists from the Centers for specific topics such as congenital heart defects, twinning, infant mortality, and environmental exposures. These groups will be formed on an ad hoc basis.

2. The primary role of the Working Groups will be to develop comprehensive research agendas, to be informed about the current state of knowledge in the specific topic area, and to discuss how the research activities might be shared among the interested collaborators. .

3. A minor role of these groups will be to discuss letters of intent or proposals that are in conflict or overlap for the specific topic area. The Working Group may help the investigators reach agreement as to how the research will be apportioned to the interested Centers. The Data Sharing Committee, however, has the ultimate responsibility for working out any conflicts between Centers investigators.

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VII. AVAILABILITY AND ANALYSIS OF DATA BY OUTSIDE INVESTIGATORS

1. Investigators outside the NBDPS/BD-STEPS who are interested in accessing the data must identify a collaborator and sponsoring PI from one of the participating NBDPS/BD-STEPS centers as appropriate. If outside investigators are unable to identify a potential collaborator their own, they may submit a brief letter describing their research interest (maximum of 2 pages) to the Data Sharing Committee in care of the CDC coordinator. The Data Sharing Committee will forward it to the appropriate NBDPS/BD-STEPS working group if applicable. All submissions will be considered in terms of potential for collaboration, priority for the current NBDPS/BD-STEPS research agenda, and scientific merit. Because of the limited amount of DNA currently available, proposals involving the use of biological specimens will be carefully evaluated to ensure that the study is an optimal use of the available material.

   A sample response to inquiries from outside investigators is located in Attachment K.

2. The Data Sharing Committee will remain active as long as CBDRP data are being analyzed. So long as the Data Sharing Committee remains active, the committee must still approve projects and review manuscripts prior to submission even if the analyses are done locally.

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VIII. CONFIDENTIALITY AND DATA USE OATH AND DATA TRACKING

1. Scientists, colleagues, and collaborators who are given access to clinical, interview and/or biologic data from the NBDPS/BD-STEPS must sign a confidentiality and data use oath that describes how the data should be used, stored and returned at the conclusion of a research project (Attachment C).

2. The Principal Investigator at each Center has full and direct responsibility for assuring that each person who has access to the data has read and signed the confidentiality and data use oath. The Principal Investigator also has the responsibility of tracking the use of the NBDPS/BD-STEPS data at their Center using the Data Tracking Sheet. Copies of the data tracking sheets will be kept on file at CDC. Oaths must be signed by study staff/collaborators and copies sent to CDC on a yearly basis.

3. Each Center should maintain files of the signed confidentiality and data use oaths. Signed oaths will also be kept on file at the CDC. Oaths should be signed annually.

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IX.PROJECT UPDATES

Project update forms must be completed at least annually for every active NBDPS/BD-STEPS project. Any project either actively terminated or not updated by the deadline will have the project status changed to “terminated.” New letters of intent may be submitted on these topics.

If a project is not terminated but taken over by a different group of investigators, a new LOI or proposal must be submitted to the Committee.

The project update form is located in Attachment L

Letter of Intent (LOI) Template

Date Submitted:

Title of LOI:

Lead Investigator:

Sponsoring PI:

Center:

Co-Authors:

Associated with existing project? __YES __NO
If yes, please list project #_____.

Objectives:

Background:

Methods:

Conflicts (Include Project #):

References:

2014 NBDPS Data Sharing Schedule			
Submission Deadline	**Date of Distribution**	**Review Due Date**	**Date of Call**
16-Jan-2014	**24-Jan-2014**	**20-Feb-2014**	**27-Feb-2014**
20-Feb-2014	**28-Feb-2014**	**20-Mar-2014**	**27-Mar-2014**
20-Mar-2014	**28-Mar-2014**	**17-Apr-2014**	**24-Apr-2014**
17-Apr-2014	**25-Apr-2014**	**15-May-2014**	**22-May-2014**
15-May-2014	**23-May-2014**	**19-Jun-2014**	**Meetings – No Call ***
19-Jun-2014	**27-Jun-2014**	**17-Jul-2014**	**24-Jul-2014**
17-Jul-2014	**25-Jul-2014**	**21-Aug-2014**	**28-Aug-2014**
21-Aug-2014	**29-Aug-2014**	**18-Sep-2014**	**25-Sep-2014**
18-Sep-2014	**26-Sep-2014**	**16-Oct-2014**	**23-Oct-2014**
16-Oct-2014	**24-Oct-2014**	**20-Nov-2014**	**Holiday – No Call ***
20-Nov-2014	**28-Nov-2014**	**18-Dec-2014**	**Holiday – No Call ***
18-Dec-2014	**26-Dec-2014**	**15-Jan-2015**	**22-Jan-2015**

Centers for Birth Defects Research and Prevention (CBDRP)
CONFIDENTIALITY AND DATA USE OATH

Each Center for Birth Defects Research and Prevention (Centers) has been awarded a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC) In accordance with Section 301(d) of the Public Health Service (PHS) Act (42 U.S.C. 241(d)), I, as a _____ (Centers employee, CDC employee, scientist, contractor, colleague), am permitted access to personally identifiable data. As a condition of this access and my participation in this project, I am required to comply with the following safeguards and policy commitments for individuals against invasions of privacy.

1. I agree to be bound by the following promise:

In accordance with Section 301(d) of the PHS Act (42 U.S.C. 241(d)), all respondents are assured that the confidentiality of their responses in this study will be maintained, and that the privacy of research subjects is protected by the withholding of, from all persons not connected with the study, any personally identifying characteristics of the research subjects.

2. I agree to maintain the following safeguards to assure that confidentiality is protected and to provide for the physical security of the records:

To preclude observation of confidential information by persons not authorized to have access to the information on this project, I shall maintain all records that identify individuals, or from which individuals could be identified, in locked containers or protected computer files, when not under immediate supervision by me or another authorized member of the project. The keys or means of access to these containers or files are not to be given to anyone other than CBDRP authorized staff. I further agree to abide by any additional requirements imposed by CDC for safeguarding the identity of individuals.

3. The CBDRP Data Sharing Committee must approve uses of the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS) and/or National Birth Defects Prevention Study (NBDPS) data. No analysis of data or dissemination of findings from BD-STEPS and/or NBDPS may occur without approval from the committee for a specific research purpose. Instructions for submission of research proposals are specified in the Data Sharing Guidelines document available from each Center.

4. The Principal Investigator from each Center is responsible for tracking the use of the BD-STEPS and NBDPS data at their Center and assuring that each person who has access to the data has read and signed this agreement.

5. I understand that the Data Sharing Committee must approve any manuscripts, abstracts, or public presentations based on the analyses before they can be submitted for consideration.

6. I agree not to attempt to identify any individual person whose information is contained in the BD-STEPS and/or NBDPS data unless required for BD-STEPS and/or NBDPS activities authorized by the Data Sharing Committee.

7. I agree not to distribute, copy, or share the data with any person(s) other than those designated by the Principal Investigator of the Center.

8. At the conclusion of the research covered by this agreement, I agree to promptly return to the Center from which the data were obtained, any documentation and manuals about the BD-STEPS and/or NBDPS, and to remove (delete) any electronic files containing data or output from any computer equipment which I have used to gain access to and/or to analyze BD-STEPS and/or NBDPS data.

My signature below indicates that I have carefully read and understand this agreement and the oath which pertains to the confidential nature of all records to be handled in regard to this project. As a _____ (Center employee, CDC employee, scientist, contractor, colleague), I understand that I am prohibited from disclosing any such confidential information that has been obtained under this project to anyone other than authorized CBDRP staff. I understand that any disclosure in violation of this Confidentiality Oath may lead to termination of my employment, as well as other penalties.

_____ _____
(Typed/Printed Name) (Signature)

_____
(Date)

_____ _____
(Center PI) (Date)

Review of CBDRP Letters of Intent (to be distributed in email form)

LOI Title:

DECISION [Approve/Needs Discussion]:
OUR CENTER WOULD LIKE TO DISCUSS COLLABORATION:
COMMENTS:

CBDRP Proposal Template

Date Submitted:

Title of Proposal:

Project ID#:

Lead Investigator:

Sponsoring PI:

Center:

Co-Authors and their contributions:

List plans for obtaining particular expertise in statistics, epidemiology, molecular genetics or case classification, if relevant:

All investigators and co-authors signed a confidentiality and data use oath? __YES __NO

Need additional IRB approval? __YES __NO
If yes, list specifics:

List biologics criteria:

List objectives, aim or hypothesis:

Background:

Methods:

***Exposures of Interest*:**

***Outcomes of Interest*:**

Analysis:

Power Calculations:

Conflicts (Include Project #):

Other:
References:

Proposal Review Form Attachment F

Review of NBDPS Proposals

Title of Proposal: _____

Lead Investigator: _____

Sponsoring PI: ___ Center: ___

Date reviewed: _____

Reviewed by: _____ Center: ___

1. Investigators with lead investigator noted ☐YES ☐NO ☐NA
   Comment: _____

2. Objectives, aim or hypothesis stated ☐YES ☐NO ☐NA
   Comment: _____

3. Background with relevant references ☐YES ☐NO ☐NA
   Comment: _____

4. Methods
   - specific outcomes of interest ☐YES ☐NO ☐NA
   - primary exposures of interest ☐YES ☐NO ☐NA
   - analysis plan with power calculations ☐YES ☐NO ☐NA
   - other data collection or record matching ☐YES ☐NO ☐NA
   Comment: _____

5. Scope of analysis is reasonable ☐YES ☐NO ☐NA
   Comment: _____

6. Plans for particular expertise in statistics, epidemiology, molecular genetics or case classification described ☐YES ☐NO ☐NA
   Comment: _____

6a. Biologics criteria have been addressed ☐YES ☐NO ☐NA
   Comment: _____

7. Conflicts with existing research ☐YES ☐NO ☐NA
   Comment: _____

8. Suggestions for collaboration ☐YES ☐NO ☐NA
   Comment: _____

9. Need for additional IRB approval ☐YES ☐NO ☐NA
   Comment: _____

10. Other Comments: _____

☐APPROVE ☐DISAPPROVE ☐RESUBMIT ☐ABSTAIN

☐NEEDS DISCUSSION: _____

AUTHOR MUST RESPOND TO THE FOLLOWING COMMENTS:

Manuscript Submission Form Attachment G

CBDRP Manuscript Submission Form

Title of Manuscript:
Lead Investigator:
Sponsoring PI: Center:

1. Data Sharing Committee documents that cover this manuscript (provide document numbers and titles):

LOI:
Proposal:
Comments (please note any discrepancies in what is in the manuscript versus what is in the proposal):

2. Manuscript acknowledges overlap with results using NBDPS data that have been published previously or are In Press and discusses potential explanations for substantial differences in findings.

YES
NO
N/A
If no, please comment on why previous results are not acknowledged:

3. Has analysis been replicated or currently undergoing replication?

YES
NO
N/A
If yes, by whom?

4. Author plans to submit manuscript to:

CBDRP Abstract Review Form

Title of Document: _____

Lead Investigator: _____

Sponsoring PI: ___ **Center:** ___

Date reviewed: _____

Reviewed by: _____ **Center:** ___

1. **Investigators with lead investigator noted** ☐**YES** ☐**NO** ☐**NA**
   Comment: _____

2. **Comments on scientific aspects of the document:** _____

3. **Comments on other issues (e.g. authorship, conflict with other NBDPS research, etc):** _____

Recommendation:

☐**APPROVE** ☐**DISAPPROVE** ☐**RESUBMIT**

CBDRP Manuscript Review Form

Title of Document: _____

Lead Investigator: _____

Sponsoring PI: ___ **Center:** ___

Reviewer No: _____ **Date reviewed:** _____

1. **Author list includes "and the NBDPS"** ☐YES ☐NO ☐NA
   Comment: _____

2. **Participating Centers and funding source acknowledged** ☐YES ☐NO ☐NA
   Comment: _____

3. **Slone Epidemiology Unit acknowledged for Drug Dictionary** ☐YES ☐NO ☐NA
   Comment: _____

4. **UNC Nutrition Epidemiology Core acknowledged for use of nutrient database. Comment:** _____ ☐YES ☐NO ☐NA

5. **Comments on other issues (e.g. authorship, conflict with other NBDPS research, etc):** _____

Recommendation:

☐**APPROVE AS IS**

☐**APPROVE WITH MINOR REVISIONS (requires final approval from DSC editor only)**

☐**REVISE AND RESUBMIT, REVIEWER REQUESTS TO SEE REVISED MANUSCRIPT**

☐**REVISE AND RESUBMIT, REVIEWER DOES NOT WISH TO SEE REVISED MANUSCRIPT**

☐**DISAPPROVE (*please explain*)** _____

Please provide comments on scientific aspects of the manuscript (*use as much space as necessary*): _____

Uniform requirements for manuscripts submitted to biomedical journals.
International Committee of Medical Journal Editors.

N Engl J Med 1997 Jan 23;336(4):309-15

Response to Inquiry from Outside Investigator
TO BE ADAPTED

Dear <name of person making inquiry>,

Thank you for your inquiry about access to the data from the National Birth Defects Prevention Study (NBPDS). This study is being conducted as part of a cooperative agreement between 9 sites (state health departments and universities) and the Centers for Disease Control and Prevention (CDC). We have just begun the analytic phase of this study, and there is currently no public use data set available.

Because of the collaborative nature of the study, we have established clear guidelines for data sharing among the investigators participating in the study. All research proposals must be sponsored by one of the collaborating Principal Investigators, and be submitted to NBDPS Data Sharing Committee for review and approval.

At this time, researchers outside the NBDPS centers who are interested in accessing the data must identify a collaborator and sponsoring PI from one of the participating centers. If you are unable to identify a potential collaborator on your own, you may submit a brief letter describing your research interest (maximum of 2 pages) to the Data Sharing Committee in care of Kim Newsome at kan3@cdc.gov. The Data Sharing Committee will forward it to the appropriate NBDPS working group. All submissions will be considered in terms of potential for collaboration, priority for the current NBDPS research agenda, and scientific merit. Because of the limited amount of DNA currently available, proposals involving the use of biological specimens will be carefully evaluated to ensure that the study is an optimal use of the available material. You will be notified of the status of your submission.

I have listed 2 references below which you may find helpful. Thank you for your interest in the NBDPS.

Sincerely,
<name of person responding>

1. Yoon P, et al. The National Birth Defects Prevention Study. *Public Health Reports*, 2001;116(Suppl 1):32-40.
2. Rasmussen SA, et al. Integration of DNA sample collection into a multi-site birth defects case-control study. *Teratology* 66(4):177-84, 2002

Example of CBDRP Project Update (Excel)- Attachment L

		project 1	project 2	project 3
	Project ID			
	associated project ID (if any)			
	title			
	date of update			
	was proposal submitted			
	Sponsoring PI			
	lead investigator			
	lead investigator not in drop down			
	intended data source			
	status			
if not yet begun	**proposal date**			
	date sufficient sample available			
	analysis start date			
if in progress	**expected publication date**			
	version used			
	progress to date			
if published	**citation**			
	high priority for center			
	main exposure			
	main outcome			
	genetics			
	date genetic data submitted to CDC			
	justification for genetic data not submitted to CDC			
	collaborator			
	collaborator			
	collaborator			
	collaborator			
	collaborator			
	collaborator			
	collaborator			
	collaborator			

	collaborator			
	collaborator			
	collaborator			
	collaborator			
	collaborator not in drop down			
	collaborator not in drop down			
	comments or additions			