Terms and Conditions

For Releasing Family Blood Pressure Program (FBPP) Data and/or Materials

By requesting FBPP Data and/or Materials, the requestor(s) agree to the following terms and conditions. These terms and conditions are subject to change without advance notice. All investigators and recipients affected by such changes will be notified of these changes in writing. It is mutually agreed as follows:

1. Terms used throughout this document are defined as follows: “Form” refers to either the Public Access Data Request Form or the Collaboration Request Form as appropriate. “Recipient” is defined as the person(s) requesting the data/materials. “Research team” is a group physically situated in the same physical location and using the same resources.

2. The FBPP Investigators agree to release to the Recipient(s) the Data/ Materials for use as described in the Form.

3. Research Project.
   3.1. These data will be used by the Recipient solely in connection with the research project specifically described in the Form.
   3.2. This agreement covers only the research described on the Form submitted. The Recipient will submit a separate completed Form for each research project for which data are requested.

4. Non-transferability. The rights conferred by this agreement are not transferable. The FBPP data and/or materials received are not to be transferred to others who are not members of the Recipient’s immediate research team. Recipient agrees that substantive changes made to the Research Project described in the Form, and/or appointment by the Recipient of another Project Director to complete the Research Project, require execution of a new agreement in which the new Project Director and/or new Research Project are designated.

5. Publication. Publication of the results of the Research Project is encouraged. Recipient agrees to provide a copy of any abstract ten (10) days in advance of submission for publication and any manuscript thirty (30) days in advance of submission for publication to the FBPP Program Data Center (fbpp-pdc@wubios.wustl.edu), in order to permit review and comment, and ensure compliance with the confidentiality requirements of this agreement.

6. Acknowledgments. Recipient agrees to acknowledge the contribution of FBPP Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of the data.
   6.1. Collaborations/Acknowledgments. If the Research Project involves collaboration with one or more FBPP Investigators (see Request for Collaboration), then Recipients will acknowledge those FBPP Investigators as co-authors, as appropriate, on any publication. In addition, the Recipient will use the following acknowledgment:

"FBPP is supported by the National Heart, Lung, and Blood Institute (NHLBI). This manuscript has been reviewed by FBPP Investigators for scientific content and
consistency of data interpretation with previous FBPP publications and significant
comments have been incorporated prior to submission for publication."

6.2. Other Studies/Acknowledgments. If the Research Project does not involve collaboration
with any FBPP Investigators (see Request for Collaboration), then the manuscripts, upon
submission pursuant to paragraph 5 above, will be reviewed by FBPP Investigators for
scientific content and consistency of data interpretation with previous FBPP
publications. If Recipient agrees to incorporate significant comments from the review,
Recipient will use the acknowledgment printed below.

"FBPP is supported by the National Heart, Lung, and Blood Institute (NHLBI). This
manuscript has been reviewed by FBPP Investigators for scientific content and
consistency of data interpretation with previous FBPP publications and significant
comments have been incorporated prior to submission for publication."

If Recipient does not agree to incorporate significant comments from the review,
Recipient will use the acknowledgment:

"The FBPP is supported by the National Heart, Lung, and Blood Institute (NHLBI). This
manuscript was not prepared in collaboration with investigators of the FBPP and does
not necessarily reflect the opinions or views of the FBPP, the NHLBI, or the institutions
participating in the FBPP."

7. Non-Identification. The Data/ Materials being provided have been de-identified as defined
by The Health Insurance Portability and Accountability Act (HIPAA). Recipient agrees that
the Data/ Materials 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 study
participants from whom the data were obtained. Recipient agrees to comply with all
requirements of HIPAA at 45 CFR Parts 160 and 165.

8. FBPP Rights are Unconditional: The Recipient recognizes and acknowledges the
unconditional rights the FBPP Investigators and their collaborators have to these Data/
Materials. In particular, the Recipient acknowledges that (s)he is prohibited from obtaining a
patent on any variation of the FBPP data and/or materials in whole or in part, in a manner
that will in turn prohibit or limit the access of the FBPP investigators and their collaborators
to the data and/or materials.

9. Use Limited to Research Project. Recipient agrees that the Data and/or materials, their
progeny, and unmodified or modified derivatives thereof will not be used in any experiments
or procedures that are not disclosed and approved as part of the Research Project.

10. Compliance with Subjects’ Informed Consent. Recipient agrees that the Data/ Materials,
their progeny, and unmodified or modified derivatives thereof will not be used for any
purpose contrary to the subjects’ applicable signed informed consent document(s). It is the
responsibility of the Recipient to consult with the FBPP Investigators to ascertain,
especially and in detail, the terms and conditions of applicable FBPP informed consent
documents. Recipient shall be responsible for advancing sufficient funds to cover the costs,
or its cost-share, of having the FBPP Investigators obtain re-consent documents from their
subjects, if determined to be necessary for Recipient’s use of the Data. In any event, Recipient agrees to indemnify, and to hold the FBPP investigators (and their agents, representatives, employees, contractors, nominees, and NIH or the U.S. government) harmless against any claims, liabilities, and/or costs, including any legal costs of defending against such claims, made by any subjects or by any third parties arising out of Recipient’s access and use of the Data.

11. No Distribution, Return of Materials. Recipient agrees to retain control over the Data/ Materials, their progeny, and unmodified or modified derivatives thereof, and further agrees not to transfer the Data/ Materials, their progeny, and unmodified or modified derivatives thereof, with or without charge, to any other entity or any individual. When the Research Project is completed, or three (3) years have elapsed from the effective date of this agreement, whichever occurs first, the Data/ Materials will be either returned to the FBPP Program Data Center (fbpp-pdc@wubios.wustl.edu), or disposed of as mutually agreed upon by FBPP Investigators and Recipient, unless an extension of this agreement is obtained in writing.

12. Recipient's Resulting Genetic Analysis Data to be Provided to the FBPP Investigators.

12.1. The Recipient agrees to provide the FBPP with a report every twelve (12) months during the term of this agreement.

12.2. The Recipient further agrees to provide new data and newly developed derived variables to the FBPP Program Data Center (fbpp-pdc@wubios.wustl.edu) one year after generation or after publication, whichever comes first.

12.3. Such report will cover all Genetic Analysis Data derived by Recipient since the previous reporting date. In addition, any Molecular Genetic Data derived by the Recipient during the twelve months prior to the reporting date shall be electronically transmitted to the FBPP with each annual report.

12.4. The Recipient agrees that the FBPP may distribute all data it receives from the Recipient to qualified scientific investigators requesting access through established NHLBI procedures and completing a signed agreement comparable to this agreement.

12.5. The Recipient will provide Genetic Analysis Data, indexed by the FBPP subject ID number in the precise electronic format specified by FBPP. When genotyping has been conducted, DNA marker names and allele sizes in numbers of base pairs or detailed polymorphism descriptions will be provided for each individual subject as indexed by the FBPP subject ID number; descriptive information about each typed marker that includes marker name, allele sizes in numbers of base pairs and corresponding frequencies, relative distances in megabases and in centimorgans, marker heterozygosity, and the source of information used to determine map location, sequence data, SNP primers, conditions, and probes will also be provided.

12.6. The Recipient also agrees to submit to the FBPP all data relevant to the establishment of paternity at the time such determinations are made.

13. Non-Endorsement, Indemnification. The Recipient agrees not to claim, infer, or imply endorsement by the United States Government of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 8. To the extent permitted by law, Recipient agrees to hold the FBPP, the United States Government, and all other investigator(s) who generated Genetic Analysis
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 the Data/ Materials, their byproducts, or modified or unmodified derivatives thereof.

14. **Accuracy of Data.** Recipient agrees that the FBPP, the United States Government, and the other investigator(s) who generated Genetic Analysis Data, are not responsible for the accuracy of Genetic Analysis Data provided by other Recipients. The FBPP and the United States Government are not responsible for the accuracy of the data provided.

15. **Recipient's Compliance with IRB Requirements.** Recipient acknowledges that the conditions for use of these Data and/or Materials have been approved by the Recipient's Institutional Review Board (IRB) in accordance with the Department of Health and Human Services regulations as contained in 45 CFR Part 46. A copy of the up-to-date IRB approval must be provided to the FBPP Program Data Center. Recipient agrees to comply fully with all such conditions and with the subjects' informed consent documents, on record with the FBPP. It is intended that the Recipient's agreements herein shall inure to the benefit of the research subjects, as well as to the parties to this agreement. Recipient agrees to report promptly to the FBPP any proposed change in the research project and any unanticipated problems involving risks to subjects or others. Recipient is subject to applicable State and local laws and regulations and institutional policies which provide additional protections for human subjects.

16. **Conflict of Interest.** The Recipient agrees to promptly disclose direct and indirect conflicts of interest, such as affiliation(s) with any organization with an explicit or indirect financial interest in the subject matter of the proposed research employing the data from the FBPP. Examples of (but not limited to) such affiliations are employment consultancies, expert testimony, honoraria, stock, or retainers that may affect the work being considered.

17. **Amendments.** Amendments to this agreement must be made in writing and signed by authorized representatives of both parties.

18. **Termination.** The FBPP may terminate this agreement if Recipient is in default of any condition of this agreement and such default has not been remedied within 30 days after the date of written notice by the FBPP of such default. Upon termination of this agreement, Recipient agrees to return all Data and/or Materials to the FBPP within 30 days.

19. **Disqualification, Enforcement.** Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Data/ Materials from the FBPP. The FBPP 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, and/or the limitations on the use of the Data and/or Materials provided. Proceedings may be initiated against the violating party, its legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding at law or in 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 the Recipient to legal action on the part of FBPP participants and their families, or the institutions participating in the FBPP.
20. **Accurate Representations.** Recipient expressly certifies that the contents of any statements made or reflected in this agreement are truthful and accurate.

21. **Prior Agreements.** The following two paragraphs apply only to Recipients who have entered into a previous agreement:

   21.1. Execution of this agreement is contingent upon Recipient's compliance with all terms and conditions of existing agreements with the FBPP and NHLBI.

   21.2. If Recipient has executed a previous agreement, and the effective date of such previous agreement was more than twelve (12) months before the time of the current request for Data and/or Materials, and Recipient has not provided to the FBPP Genetic Analysis Data derived from any Data/ Materials previously received from the FBPP, Recipient agrees that providing the FBPP with such Genetic Analysis Data is a precondition for consideration of the current agreement.