Virginia Pregnancy Risk Assessment Monitoring System (PRAMS)
Data Sharing Policy and Data Request Guidelines

I. Overview of PRAMS

The Pregnancy Risk Assessment Monitoring System (PRAMS) is an ongoing, population-based surveillance system that is designed to collect information about maternal attitudes, experiences and behaviors around the time of pregnancy. The goal of PRAMS is to improve the health of mothers and infants by reducing adverse outcomes such as low birth weight, preterm birth, and infant mortality. The PRAMS project provides data for planning and assessing health programs and for describing maternal experiences that may contribute to maternal and infant health. The PRAMS project was initiated in 1987 by the Centers for Disease Control and Prevention (CDC). As of April 2006, 37 states, one tribal nation, and New York City participate in the project. All states follow the CDC PRAMS model protocol. In Virginia, data collection began in 2007.

II. Methodology

In Virginia, each month approximately 100 mothers who have recently given birth are randomly selected from birth certificate records to participate in PRAMS. In Virginia, the PRAMS project oversamples mothers of infants born with low birth weight. Non-residents and mothers who had a multiple birth of quadruplets or more are excluded from the sampling frame. Sampled mothers are contacted by mail with a survey packet. Telephone follow-up is initiated with mothers who have not responded by mail within 2 months of initial contact. The Virginia PRAMS questionnaire consists of approximately 56 core questions that are required by the CDC and asked by all projects. In addition, Virginia PRAMS includes 23 standard questions. The Virginia PRAMS questionnaire is currently administered in English and Spanish.

PRAMS data are weighted annually to adjust for nonresponse, noncoverage, and the sampling design. The questionnaire data contain mothers’ responses to the questionnaire. The birth certificate data contain information on selected maternal characteristics (e.g. race, ethnicity, age) and pregnancy outcomes (e.g. birth weight, gestational age). The operations data are generated by the PRAMS operational software and are used primarily for operational evaluations and analyses of survey methods. In addition, a comment data set, which consists of mothers’ comments to the questions or their comments about answering questions related to their pregnancies (either directly written on a mailed questionnaire or spoken during a telephone interview), is maintained separately from the weighted Virginia PRAMS data set.

Due to the complex survey design of the PRAMS survey, both the CDC and the Virginia PRAMS project recommend that analysts use SUDAAN (Survey Data Analysis, Research Triangle Institute, NC) software or another software product (SAS, SPSS, STATA) that accounts for complex sampling designs, when computing variance estimates and performing significance testing. Standard software products can be used to compute point estimates if analysis weights are incorporated into statistical procedures.
III. Review and Approval Process for Research Using PRAMS Data

To facilitate the planning and implementation of analyses, ensure scientific quality and appropriate use of the data, and avoid duplication of efforts, any individual or group who intends to analyze Virginia PRAMS data for the purposes of research must obtain approval from the Virginia PRAMS team, the Virginia Department of Health (VDH) Division of Health Statistics, and the VDH Institutional Review Board (IRB) for research involving human subjects.

The PRAMS dataset available for request is a restricted use de-identified dataset; there are very few operations data elements, and no data elements that might be considered identifiable. A list of the included topics can be found in Appendix A. Studies using the restricted use de-identified data should qualify for exempt status when submitting to the VDH IRB. Researchers who request variables that are not included in the restricted use de-identified dataset (e.g. additional birth certificate fields and/or PRAMS Comment Data) will need to include a detailed justification and obtain approval for those additional data elements in the standard request. It is likely the additional data elements will require the researcher to submit an expedited IRB request rather than an exempt one. Information regarding the VDH IRB can be found at: http://www.vdh.state.va.us/healthpolicy/policyanalysis/irb.htm

The following is a summary of the review and approval steps:

1. **The principal investigator will complete and submit a PRAMS research proposal. To streamline the data request process, all of the following documents must be submitted to the PRAMS Coordinator:**
   a. Completed Virginia PRAMS Data Request Form (Appendix B)
   b. Cover Letter to the Virginia Department of Health Institutional Review Board (VDH IRB) that briefly describes your project, team, and why you need Virginia PRAMS data.
   c. Study Protocol / Research description. Use the outline in Section V to construct your protocol.
   d. Completed VDH IRB submission form for **expedited** or **exempt** review.
   e. Resume or CV for the Principal Investigator

2. **The submitted PRAMS proposal will be distributed to members of the PRAMS team for input regarding the suitability of PRAMS data for the proposed analysis and the appropriateness of the analysis plan considering the PRAMS survey design.**

3. **Upon approval from the PRAMS team, the proposal will be submitted to the VDH Division of Health Statistics for approval.** Since PRAMS data include items from the birth certificate, the VDH Division of Health Statistics must approve the proposal before data can be released.

4. **Upon approval from VDH Division of Health Statistics, the proposal will be submitted to the VDH IRB for final approval.**
5. Upon IRB approval, all researchers listed on the proposal will be required to complete the PRAMS Data Sharing Agreement for External Researchers (Appendix C) and return the form to the Virginia PRAMS Coordinator. By signing, all researchers agree to the terms of use. Approval to analyze Virginia PRAMS data applies only to the research questions described in the research proposal. If a researcher desires to conduct additional analyses, a separate research proposal is required.

6. The PRAMS team will create a Virginia PRAMS data packet for the primary researcher on a CD-ROM. This packet will include:
   a. README file describing the contents of the CD-ROM
   b. The SAS restricted use de-identified analysis dataset and any additional approved variables.
   c. The codebook, describing variable names, labels, associated SAS formats, response codes, and source of the variable (questionnaire, birth certificate, operations, weights)
   d. Two SAS programs that create and attach the SAS formats to the variables.
   e. Copies of the mail questionnaire in English and Spanish

7. Upon receipt of the data, the researchers agree to secure the data in a password-protected environment. Only authorized users will have access to the data and password.

8. Upon completion of the approved project described in the research proposal, researchers must destroy their copy of the data (confirmed in writing to Virginia PRAMS) and return the data CD-ROM to Virginia PRAMS.

IV. Using PRAMS Data for Public Health Surveillance:

All requestors who are located within the Virginia Department of Health and are requesting PRAMS data for the purposes of public health surveillance should complete a Virginia PRAMS Data Request Form (Appendix B), stating that the intended use of PRAMS data is for Public Health Surveillance. Upon approval, the requestor will be required to sign a PRAMS Data Sharing Agreement for Public Health Surveillance (Appendix D). Should the requestor desire to use PRAMS data for a research study, he/she is required to complete the request and approval process for research studies using PRAMS data as outlined above.

V. Outline for Study Protocol / Research Description

Title page: A working study title; list study researchers who will use the PRAMS data, their institutional affiliations and contact information; and if appropriate the names of journal(s) where the findings will be sent.

Background: Provide literature review, cite strengths and limitations of any earlier research, and state the purpose for the proposed study. Provide a rationale for why PRAMS data are useful for the proposed project.
Methods: Provide a list of the specific variables you will use and the statistical methods you will use to conduct your analysis. Describe whether your analysis relies on any implicit assumptions. Describe any proposed data linkages.

Results: Although the analysis has not been initiated, researchers should provide sample table shells or figures for PRAMS staff review.

Discussion: While the results are not known, researchers should discuss the following: strengths and limitations of their project; how the findings will enhance the literature and public health practice in the topic area; and benefits to the Virginia Department of Health and how the knowledge can contribute to public health practice.

Experience with SAS, SUDAAN, or other statistical packages: Indicate the level of experience with SUDAAN software, or another software package that can be used to analyze complex survey data. Virginia PRAMS cannot provide technical assistance for statistical software for complex sampling designs.

Time frame: List a starting date and anticipated milestones for the project.

Anticipated products: Describe how you anticipate disseminating findings from analysis of PRAMS data (peer-reviewed publication, presentation at conferences or meetings, promotional materials, articles).

VI. PRAMS Research Proposal Submissions

Submissions should be sent to the PRAMS Coordinator, Christopher Hill:

Christopher Hill  
Virginia PRAMS Coordinator  
Office of Family Health Services / 10th Floor  
Virginia Department of Health  
109 Governor Street  
Richmond, Virginia 23219  
Email: Christopher.Hill@vdh.virginia.gov  
Phone: (804) 864-7765  
Fax: (804) 864-7380

VII. Authorship

The PRAMS project is a collaborative effort between the Virginia Department of Health and CDC’s Division of Reproductive Health; both Virginia PRAMS and CDC representatives should be acknowledged as follows:

Acknowledgments
Virginia Department of Health, Office of Family Health Services PRAMS Team, and Virginia Department of Health, Division of Health Statistics. The CDC PRAMS Team, Program Services and Development Branch, Division of Reproductive Health.
Authorship of all articles and journal submissions shall be negotiated based on the amount of time, consultation, collaboration, and technical support provided by Virginia PRAMS staff to the primary investigator(s).

VIII. Publications and Presentations

The Virginia PRAMS project requests that researchers giving an oral presentation or submitting a manuscript for publication using Virginia PRAMS data send a copy of their slides, abstract, or manuscript to the Virginia PRAMS team at the time of submission or presentation for the purpose of tracking utilization and dissemination of PRAMS findings. Please include the audience or journal to which the information has been distributed.

IX. Compliance and Penalties

By signing the Virginia PRAMS Data Sharing Agreement, all researchers agree to the terms of use of the PRAMS data. The Virginia PRAMS project reserves the right to request documentation of compliance with policies. Researchers are required to report any breach of the agreement to the Virginia PRAMS Coordinator immediately. Breaches of the Data Sharing Agreement may result in immediate revocation of access to Virginia PRAMS data, and may result in civil litigation and/or criminal prosecution.
APPENDIX A: VIRGINIA PRAMS TOPICS: RESTRICTED USE DE-IDENTIFIED DATASET

- Alcohol use before and during pregnancy
- Birth control before pregnancy
- Breastfeeding: initiation, reasons for not breastfeeding, duration, reasons for stopping, first food
- Delivery type
- Dental care during pregnancy
- Health during pregnancy
- Health Insurance: before pregnancy, for prenatal care, at delivery
- HIV testing
- Household income, source, people in household
- Infant Health: mortality, birthweight, preterm birth
- Infant sleep position and sleep location
- Infertility treatment
- Injury and safety during pregnancy and postpartum – car seats, seat belts, smoke detectors, loaded firearms in the home
- Marital status
- Maternal age
- Maternal education
- Maternal post-partum check-up
- Medical History from the birth certificate
- Neonatal intensive care
- Physical abuse before and during pregnancy
- Postpartum birth control
- Postpartum depression screening questions, provider talked about postpartum depression
- Preconception health: multivitamin use, BMI, diabetes, previous preterm and low birthweight births
- Pregnancy intention
- Prenatal care: entry, number of visits, barriers, content
- Race/ethnicity
- Resources for childbirth, parenting, food stamps, government assistance
- Services received during pregnancy
- Smoke exposure
- Smoking before and during pregnancy
- Smoking inside the home, smoking cessation
- Social support during pregnancy
- Stressful life events
- Well-baby check-up and location
APPENDIX B: Virginia Pregnancy Risk Assessment Monitoring System (PRAMS) Data Request Form

This form should be used to request raw data from the PRAMS project. If you are looking for results from the PRAMS project, please see the data tables posted on our website:
http://www.vahealth.org/prams/

Name:__________________________  Date Request Submitted:__/__/____

Organization:___________________________________________________

Address:_______________________________________________________

City:_______________ State:____________ ZipCode:____________

Email:_________________________

Telephone:_____________________ Fax (optional):__________________

Title of Study or Project:___________________________________________

Year(s) of data requested:

You must use a software package that is capable of handling complex sampling designs. Please indicate which software package you intend to use:
__SAS __SUDAAN __SPSS __STATA __Other (Please fill in):

In order to obtain data from PRAMS for research purposes, a submission to the Virginia Department of Health Institutional Review Board is necessary. To streamline the data request process, the following documents must be submitted to the PRAMS Coordinator:

1. Completed Virginia PRAMS Data Request Form (this form)
2. Cover Letter to the Virginia Department of Health Institutional Review Board (VDH IRB) that briefly describes your project, team, and why you need Virginia PRAMS data.
3. Study Protocol / Research description. Use the outline in the data release policy in constructing your protocol.
4. Completed VDH IRB submission form for expedited or exempt review.
5. Resume or CV for the Principal Investigator

The PRAMS project provides a standard set of variables for external researchers. Researchers who request variables that are not included in the restricted use de-identified dataset (additional birth certificate fields and/or PRAMS Comment Data) will need to include a detailed justification and obtain approval for those additional data elements in the standard request. It is likely the additional data elements will require the researcher to submit an expedited IRB request rather than an exempt one. Information regarding the VDH IRB can be found at:
http://www.vdh.state.va.us/healthpolicy/policyanalysis/irb.htm
APPENDIX C: VIRGINIA PRAMS DATA SHARING AGREEMENT WITH EXTERNAL RESEARCHERS

I, ______________________________, as principal investigator/research staff on this proposed analysis of Virginia Pregnancy Risk Assessment Monitoring System (PRAMS) data, agree to the following requirements for the use of Virginia PRAMS data, and assure compliance with the requirements.

1. I will not use nor permit others to use these data except for statistical analysis and reporting.

2. I will not use nor permit others to use these data to conduct analyses other than those described in the proposal, titled ____________________________________, which accompanies this statement.

3. I will not release nor permit others to release the data set or any part of it to any person other than those listed as collaborators in the attached proposal.

4. I will not attempt to link nor permit others to link the data set with individually identifiable records from other Virginia Department of Health (VDH) or non-VDH data sets.

5. I will not attempt nor permit others to attempt to use the data set to learn the identity of any participant. If the identity of a respondent should be inadvertently discovered, I will make no use of this knowledge, nor will I permit others to use the knowledge. I will inform the Virginia PRAMS staff of the discovery, so they can prevent future discoveries. I pledge that neither I nor other members of my team will inform anyone else of this knowledge.

6. I will adhere to the authorship agreement discussed with the Virginia PRAMS team. Additionally, all oral or written presentations of the results of the analyses will include an acknowledgment of the Virginia PRAMS team and the Centers for Disease Control and Prevention's PRAMS Team.

7. A copy of all oral or written presentations of the results of the analyses will be sent to the Virginia PRAMS Coordinator at the time of presentation or submission for the purpose of tracking utilization and dissemination of PRAMS findings.

8. When the proposed analyses are completed, all copies of these data will be destroyed or returned to Virginia PRAMS. Written confirmation that the data has been destroyed will be provided to the Virginia PRAMS Coordinator.

9. I understand that the sharing of this data does not imply, in whole or in part, that the proposed topic has not been investigated before, or will not be investigated now or in the future, by other investigators interested in this topic.

10. I agree that the data will be kept in a secure environment and will be password-protected in that environment and when transported to another environment. Only authorized users will have access to the data set and password.

11. I agree to allow VDH staff to disseminate any materials or products developed as a result of this research for the purpose of promoting the health and well being of all Virginians.

My signature indicates my agreement to comply with these requirements.

Name: ___________________________________________ Title: ___________________________________________
Organization: __________________________________________
Signature: ___________________________________________ Date: ____________________________
APPENDIX D: VIRGINIA PRAMS DATA SHARING AGREEMENT: PUBLIC HEALTH SURVEILLANCE

I, ______________________________, as principal requestor on this proposed analysis of Virginia Pregnancy Risk Assessment Monitoring System (PRAMS) data, agree to the following requirements for the use of Virginia PRAMS data, and assure compliance with the requirements.

1. I will not use nor permit others to use these data except for statistical analysis and reporting.

2. I will not use nor permit others to use these data to conduct analyses other than for public health surveillance activities.

3. I will not release nor permit others to release the data set or any part of it to any person other than those listed as collaborators in the data request form.

4. I will not attempt to link nor permit others to link the data set with individually identifiable records from other Virginia Department of Health (VDH) or non-VDH data sets.

5. I will not attempt nor permit others to attempt to use the data set to learn the identity of any participant. If the identity of a respondent should be inadvertently discovered, I will make no use of this knowledge, nor will I permit others to use the knowledge. I will inform the Virginia PRAMS staff of the discovery, so they can prevent future discoveries. I pledge that neither I nor other members of my team will inform anyone else of this knowledge.

6. I will adhere to the authorship agreement discussed with the Virginia PRAMS team. Additionally, all oral or written presentations of the results of the analyses will include an acknowledgment of the Virginia PRAMS team and the Centers for Disease Control and Prevention’s PRAMS Team.

7. A copy of all oral or written presentations of the results of the analyses will be sent to the Virginia PRAMS Coordinator at the time of submission or presentation for the purpose of tracking utilization and dissemination of PRAMS findings.

8. When the data are no longer needed for public health surveillance activities, all copies of these data will be destroyed or returned to Virginia PRAMS. Written confirmation that the data has been destroyed will be provided to the Virginia PRAMS Coordinator.

9. I agree that the data will be kept in a secure environment and will be password-protected in that environment and when transported to another environment. Only authorized users will have access to the data set and password.

10. I agree to allow VDH staff to disseminate any materials or products developed as a result of this research for the purpose of promoting the health and well being of all Virginians.

My signature indicates my agreement to comply with these requirements.

Name:  ___________________________________________ Title: ______________________________

Organization:  __________________________________________

Signature:      ___________________________________________ Date: ____________________________