Appendix R

Guidelines for Collaborative Studies Using PRAMS Data
Examples of Data Sharing Agreements

There are numerous opportunities for PRAMS states to conduct collaborative analyses with other PRAMS states and CDC. To facilitate these collaborative efforts, various data sharing agreements have been created (refer to accompanying pages). These agreements were written to protect the integrity of state data and to promote opportunities for states to comment upon analyses performed by others (e.g., other states, CDC) prior to their publication or presentation. In order for CDC to routinely incorporate a state's data with a multi-state analysis, the **Data Sharing Between CDC and Participating PRAMS States** form must be signed and submitted to CDC on an annual basis. States may elect to provide permission for analyses on a case-by-case basis; however, this may result in a state's data not being included in some analyses if permission cannot be sought and obtained in a timely manner.

PRAMS data offer researchers from a variety of health and social science disciplines the opportunity to investigate research questions. As such, researchers who work in a state agency, but are not members of a state's PRAMS Working Group, or researchers who are not aligned with a state agency may request access to PRAMS data. Providing access to PRAMS data to external researchers offers several benefits: data analysis efforts extend beyond persons directly involved with PRAMS, state PRAMS staff gain insight from an external perspective, and dissemination activities are expanded.

Because PRAMS data contain confidential and sensitive information regarding behaviors before, during, and after pregnancy, states are advised to develop a policy for how their PRAMS data will be shared with external researchers, should such a request arise. To streamline the process, a staff person may be designated to handle such requests and to monitor adherence to security and confidentiality requirements. The state may also want to keep a log of all data requests and releases.

A state policy addressing external researcher requests should describe the following elements:

- The documentation of the proposed research that is required. It should address how the data will be used, any proposed data linkages, the variables to be included, the person responsible for compliance with the agreement, and all collaborators on the project.

- Any limitations on use of data, including prohibition on identifying individuals and linkages without prior permission.

- Procedures for releasing data to other collaborators and ban on releasing data to other parties.

- A signed agreement from the researcher that protects the state against breaches of confidentiality and prevents any potential misuse of the data.

- How the data will be given to the researcher.

- How the state will monitor access given to external researchers and any penalties for breaches in the agreement.

- Security procedures during and after the analysis has been completed.

- What the researcher should do with the data once the analysis has been completed.

States may wish to request that the researcher draft a proposal that summarizes the project. The proposal can be reviewed by state PRAMS staff prior to granting approval for access, and PRAMS staff can provide comments and suggestions given their familiarity of the strengths and limitations of PRAMS data.

States may decide to use the data sharing agreement titled **Agreement For Sharing State PRAMS Data With External Researchers** or develop an agreement that better suits their needs. The agreement should include:

- Limitations on the use of the data.

- Limitations on data access and a promise not to release it to others.

- An agreement not to try to identify anyone, not to link the data to other datasets without permission, and to notify the state of any inadvertent identification of individuals.

- Requirements for appropriate acknowledgements and review.

- A statement of return or destruction after analysis is completed.

- Procedures for monitoring compliance and penalties for failing to comply.

Protocol Development Task

Develop a policy for granting external researchers access to PRAMS data. This policy should delineate what documentation about the proposed research is necessary, the mechanism for reviewing external data requests, the type(s) of data sharing agreement(s) required, other information needed to deliver the data, the time frame to grant access to the data, and the medium by which the data will be given.

Identify an individual who will be responsible for obtaining completed data sharing agreements from external researchers and monitoring adherence to the agreements.

DATA SHARING BETWEEN CDC AND PARTICIPATING PRAMS STATES

I, _____, as a representative of the PRAMS project in the state of _____agree to allow staff of the Centers for Disease Control and Prevention (CDC) access to the PRAMS data of this state for analytic purposes for a one year period.

I understand that CDC PRAMS staff will continue to provide a summary of proposed analyses that are submitted by either CDC staff members and outside researchers, whenever possible, to the PRAMS states for review by a representative of the state of_____PRAMS project. If time is insufficient to allow for a review of a proposed analysis such as for a presentation, this agreement gives CDC staff access to the state of_____PRAMS data.

I understand that CDC staff members and external researchers who are given access to the data will provide draft copies of all publications for review by a representative of the state of_____PRAMS project prior to submission of the publication. The CDC staff members will also provide states with a copy of any submitted abstracts for their review. The PRAMS authorship guidelines will continue to be followed.

Signature:_____ Date: _____

☐The above agreement also applies to the release of the county code variable for the state of _____when requested by researchers.

☐The above agreement DOES NOT apply to the release of the county code variable for the state of _____ when requested by researchers; requests for the county code variable will need to be reviewed on a case by case basis.

☐The state of _____ chooses not to release the county code variable to researchers.

I,_____as a representative of the PRAMS project in the state of _____prefer to give approval to CDC for analytic use of _____PRAMS data on a case-by-case basis.

Signature:_____ Date: _____

AGREEMENT FOR SHARING <STATE> PRAMS DATA WITH EXTERNAL RESEARCHERS

I, _____, as principal investigator on this proposed analysis of <STATE> Pregnancy Risk Assessment Monitoring System (PRAMS) data, agree to the following requirements for the use of <STATE> 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 others than those listed as collaborators in the attached proposal.

4. I will not attempt or permit others to use the data set to attempt 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 <STATE> 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.

5. All oral or written presentations of the results of the analyses will include an acknowledgment of the <STATE> PRAMS and the Centers for Disease Control and Prevention.

6. All oral or written presentations of the results of the analyses will be submitted to the <STATE> PRAMS staff for review.

7. When the proposed analyses are completed, all copies of these data will be destroyed (confirmed in writing) or returned to <STATE> PRAMS.

My signature indicates my agreement to comply with these requirements.

Name: _____

Title: _____

Organization: _____

Signature: _____

Date: _____

AGREEMENT FOR SHARING DATA WITH NON-CDC RESEARCHERS

I, _____, as principal investigator on this proposed analysis of Pregnancy Risk Assessment Monitoring System (PRAMS) data, agree to the following requirements for the use of 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 others than those listed as collaborators in the attached proposal.

4. I will not attempt or permit others to use the data set to attempt 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 CDC-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.

5. All oral or written presentations of the results of the analyses will include an acknowledgment of the PRAMS Working Group and the Centers for Disease Control and Prevention.

6. All oral or written presentations of the results of the analyses will be submitted to the PRAMS participating states and the Centers for Disease Control for review.

7. When the proposed analyses are completed, all copies of these data will be destroyed (confirmed in writing) or returned to CDC.

My signature indicates my agreement to comply with these requirements.

Name: _____

Title: _____

Organization: _____

Signature: _____

Date: _____