10 Human Subjects

10.1 Institutional Review Board (IRB) Protocol Submission and On-going Adherence

Protection of human subjects is an essential component of PRAMS surveillance. CDC obtains approval for the overall project from the CDC Institutional Review Board (IRB). The CDC IRB reviews and approves the project on an annual basis. PRAMS states must apply to a federally assured IRB for approval of their surveillance methodology. All materials including the questionnaire, protocol, cover letter, etc., must be presented to the local IRB. No physical risks will occur to mothers through PRAMS. However, the PRAMS questionnaire will obtain sensitive and individually identifiable data on mothers. States must ensure that their local IRB has a Federal-wide Assurance (FWA) number that is current and not expired. All states must have the local IRB review completed prior to data collection (e.g., drawing the first sample from vital records and importing the sample into PRAMTrac). As part of ongoing adherence, states must submit their protocol for IRB review on an annual basis, after initial approval is granted.

All adverse events must be documented and reported to the CDC and the state's local IRB. An adverse event is defined by the CDC IRB as an incident in which the protection of the respondent may have been violated. CDC is required to report all adverse events to the CDC IRB as they occur.

Protocol Development Task

Provide a thorough description of your state's local IRB review process here. Describe the procedures followed for the IRB review process. Notify CDC of the status of project review.

States must also provide written documentation of local IRB continuation to CDC. CDC requests a copy of the updated letter when the project is reviewed each year. The annual IRB approval letter should also be sent as part of your continuation application for PRAMS funding.

10.2 Informed Consent

Each questionnaire mailing packet includes a cover letter as well as an informed consent document that includes all required elements of informed consent. A signed, written consent form is not required for participation. Instead, the mother's informed consent is inferred when she returns a completed questionnaire.

When a questionnaire is administered by telephone, the interviewer first reads an introduction to the mother that includes all elements of informed consent. After the introduction is read, the mother is asked explicitly whether she wishes to participate, and her consent is obtained verbally.

Because these materials provide the information necessary for the mother to provide informed consent, they should **not** be modified by the state. (See **Appendix I** for the mailed informed consent document; see **Appendix F** for the letters; see **Appendix G** for the telephone introductory script.) If modifications are required (for example, to explain abuse reporting laws), the state should send any proposed modifications to its local IRB and to its CDC program manager. This also applies to any additional materials that may be sent to the mother (e.g., question-and-answer brochure, resource list, preletter, or reminder letter). (See **Appendixes F and J-L** for examples of other letters and materials that are mailed to the mother.)

The PRAMS informed consent document and telephone introductory script include the following ***required*** elements of informed consent:

1. A statement that PRAMS involves research and that CDC provides support for the research.

2. An explanation of the purposes of the research.

3. The expected duration of the subject's participation.

4. A description of the procedures to be followed.

    a. For PRAMS, this includes a notification that data may be linked to other sources.

5. A description of any reasonably foreseeable risks or discomforts to the subject, including a statement that some questions may be sensitive.

6. A description of any benefits to the subject or to others which may reasonably be expected from the research.

    a. For PRAMS, indirect benefits to society may include health improvements for women and infants.

7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

    a. For PRAMS, confidentiality is protected “to the extent permitted by law.”

b. For states whose child abuse reporting laws include self-reported abuse to minors on the PRAMS survey, the requirement for reporting must be explicitly stated in the cover letter or the physical abuse questions must be removed from surveys sent to minors. (See **Section 10.3** for more information.)

8. An explanation of whom to contact for answers to pertinent questions about the research.

9. An explanation of whom to contact for answers to pertinent questions about the participant's rights in the project.

10. A statement that participation is voluntary.

11. A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

12. A statement that the subject may discontinue participation at any time or choose not to answer certain questions without penalty or loss of benefits to which the subject is otherwise entitled.

13. An explanation of how the mother was chosen, the approximate number of people chosen for the study, and the reason for the identification number on the questionnaire.

14. For telephone interviews, the telephone introductory script must include an explicit prompt for permission to conduct the interview.

The list above includes only those elements of informed consent that apply to PRAMS. A comprehensive list of elements of informed consent can be found online at http://www.hhs.gov/ohrp/humansubjects/assurance/consentckls.htm. The regulatory code 45 CFR 46 governs human subjects protections and is available online at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.

Protocol Development Task

The informed consent document is located in **Appendix I**. Add your state-specific information (state health department name, telephone number, incentive, etc.) to the document.

The model letters are located in **Appendix F.** Add your state-specific information (state health department name, telephone number, etc.) to the introduction.

The model telephone introduction is located in **Appendix G.** Add your state-specific information (state health department name, telephone number, incentive, etc.) to the

introduction. The text of the script is programmed into the CATI system, and the telephone interviewer will read the script exactly how it appears on the computer screen. If there are any minor changes to the state specific information notify your CDC Program Manager.

If any modifications to the documents are required (for example, to explain the abuse reporting laws or to inform a telephone participant the call may be recorded and any changes required by your local IRB), send any proposed modifications to your CDC program manager. ***Any changes to informed consent documents must have prior written approval from the CDC IRB and the local IRB.***

The CDC contractor providing support for WebCATI is not authorized to make changes to any state's telephone script without prior written approval from CDC.

10.3 Special Considerations

10.3a Physical Abuse to Minors: Determining Whether PRAMS Staff Is Subject to Reporting Laws. In some states, a minor's self-disclosure of physical abuse on the PRAMS survey is considered to be a reportable event. The PRAMS survey specifically asks whether the mother was physically abused during the 12 months before her pregnancy or during the pregnancy, and some of the women in the PRAMS sample are minors.

Reporting laws vary from state to state. Some of the issues to consider in determining the applicability of the law to your state's staff include:

1. Who is required to report child abuse?

    a. In some states, research staff is exempt from the reporting requirements. Only those providing services to clients are required to report child abuse.

    b. In some states, all health department staff, including research staff, is required to report.

2. What constitutes a reportable event?

    a. In some states, only abuse by the parent or guardian is reportable. The PRAMS survey asks whether the husband or partner abused the respondent and whether "anyone else" abused the respondent. The survey does not specifically ask about the parent or guardian (although a respondent may volunteer that information).

b. In some states, only current abuse is reportable. The PRAMS survey collects information about events that have occurred from two months to two years in the past.

3. How is a “minor” defined?

   a. Until what age is a person considered to be a minor?

   b. Are married, pregnant, or parenting minors considered to be emancipated (and thus exempt from the reporting laws)?

10.3b Physical Abuse to Minors: Actions Available If PRAMS Staff Is Required to Report. If it is determined that the state’s reporting laws apply to PRAMS staff, there are two options available to deal with the collection of abuse information on the survey.

i. Remove the Questions From the Survey. The state PRAMS staff may decide to avoid the reporting issue by not asking minors any questions about physical abuse. The questions about physical abuse will remain on the surveys that are mailed to adults.

ii. Inform Minors About Reporting Requirements. The state PRAMS staff may decide to ask the minors these questions in spite of the reporting requirements. In this case, the informed consent document and telephone script will contain a statement informing minors about the reporting requirements. This statement will only appear on documents sent to minors and telephone scripts read to minors. See **Appendix I (Mailed Informed Consent Document)** for an example of this document; see **Appendix G (Standardized Telephone Introduction)** for an example of the telephone introductory script.)

Protocol Development Task

Determine whether your state is subject to the child abuse reporting laws. This may involve input from your department’s legal counsel.

If state law does require that PRAMS staff report child abuse, decide which action above you will take and document that decision here.

10.3c Prisoner Subjects: Actions Required Since PRAMS Research May Involve Prisoners As Subjects. Due to the population-based design of the PRAMS methodology at the state level, prisoner subjects can not be prospectively

identified nor identified retrospectively in a systematic manner. Since the PRAMS sample includes women who may be incarcerated, the PRAMS protocol was evaluated under federal regulations concerning prisoner subjects and reviewed by an IRB with a prisoner representative. The IRB voted to allow the inclusion of prisoners as subjects in the PRAMS protocol. However, when prisoners are used as subjects, each prisoner must be clearly informed in advance that participation in the research will have no effect on his or her parole. The informed consent documents were revised to include language regarding prisoner subjects. (See **Appendix U (Waiver for Prisoner Subjects)**) for more information about the inclusion of prisoners in PRAMS research.

Protocol Development Task

Some states have a law, statute, or regulation that prohibits inclusion of incarcerated mothers in PRAMS. In this case, states are prohibited from conducting active follow-up on any woman who is later identified as being incarcerated (e.g. they can not send the incarcerated mother mailings or forward her to phone phase). If this is the case for your state, please indicate as such here and provide documentation to your CDC Program Manager.

10.4 Protecting the Privacy of PRAMS Data

To minimize unauthorized disclosure of individually identifiable data, states must adopt the following policies:

- All information collected shall be held in confidence to the extent allowed by law. All state staff and contractors involved in PRAMS shall be trained concerning procedures and practices to ensure privacy of data and shall sign a confidentiality pledge.
    - All new hires will be trained concerning these procedures and practices when they begin work.
    - Most state health departments and contract agencies require all staff to sign a confidentiality pledge. If your state or contract staff have signed a confidentiality agreement for the agency, then that will be sufficient for PRAMS purposes. If your state or your contracting agency does not have its own confidentiality pledge, contact your CDC program manager about developing one for PRAMS staff.

- All state PRAMS staff will participate in supplemental training regarding human subjects and adherence to the PRAMS protocol. Modules cover 1) human subjects protections, 2) adverse events, 3) human subjects considerations in mail and telephone surveys, and 4) maintaining confidentiality. New staff will complete Module 1 of the training upon being hired.

- No individually identifiable information will be provided to persons other than state PRAMS staff, contractors working on the PRAMS state project, or CATI system administrators as they maintain the Web-based CATI system for all states. In special circumstances where it is required to debug software, it may be necessary for states to share this information with technical support staff to correct the problem. States should verify that these staff have signed a confidentiality pledge before releasing any identifiable information.

- No information, including the fact that the woman recently gave birth, will be released to a woman's friends or family (e.g., when speaking to a woman's household members or when leaving answering machine messages). Individually identifiable information may be released ***only if authorization is explicitly granted by the affected individual or legal guardian.***

- No individually identifiable information will be presented in any reports arising from analysis of data collected as part of PRAMS.

- Completed questionnaires and any files with personal identifiers must be kept in a locked file cabinet or a locked room; access to these files must be limited to authorized personnel.

- All electronic files will have restricted access; the PRAMTrac database will be password-protected. Backup files of PRAMS data must also be secured.

- Only a few individuals from CDC and the CDC contractor may have access to identified data. In all other cases, data sent to CDC will be de-identified.

- States must decide on a policy regarding the archival and destruction of PRAMS questionnaires.

- States must ensure that any contractors who may be responsible for any portion of the PRAMS operations also follow all policies described above.

Protocol Development Task

Specify what measures your state will take to assure the security of PRAMS questionnaires and other identifying materials. See **Section 6.4** for more information on protection of computer files.

State what your policy will be for archiving and destroying PRAMS questionnaires and other related materials. CDC PRAMS recommends you keep hard copies of your questionnaires until you receive the weighted data set and have had an opportunity to review the contents. State policy may dictate the length of time that these materials must be kept.