

## Mailed Informed Consent Document (English)

### **Important Information About PRAMS** ***Please Read Before Starting the Survey***

- The Pregnancy Risk Assessment Monitoring System (PRAMS) is a research project sponsored by the Centers for Disease Control and Prevention and the <NAME OF HEALTH DEPARTMENT>.
  - The purpose of the study is to find out why some babies are born healthy and others are not.
  - We are asking <NUMBER> women in <STATE> to answer the same questions. All of your names were picked by a computer from recent birth certificates.
  - It takes about 25-35 minutes to answer all questions. Some questions may be sensitive, such as questions about smoking or drinking during pregnancy.
  - You are free to do the survey or not. If you don't want to participate at all, or if you don't want to answer a particular question, that's okay. There is no penalty or loss of benefits for not participating or answering all questions.
  - Your survey may be combined with information the health department has from other sources.
  - If you choose to do the survey, your answers will be kept private and will be used only to answer questions related to the purpose of this study. This is so because this study has been given a Certificate of Confidentiality. This means that we may not share information that may identify you in legal suits or proceeding, even if a court orders us to do so, unless you say it's okay. <OPTIONAL STATE-SPECIFIC LANGUAGE BASED ON STATE REPORTING REQUIRMENTS SUCH AS child abuse, elder abuse, harm to self and others. For example: *But under the law, we must report to the state suspected cases of child abuse or elder abuse or if you tell us you are planning to cause serious harm to yourself or others.*>
  - If you are currently in jail, your participation in the study will have no effect on parole.
  - Your name will not be on any reports from PRAMS. The booklet has a number so we will know when it is returned.
  - Your answers will be grouped with those from other women. What we learn from PRAMS will be used to plan programs to help mothers and babies in <STATE>.
  - If you have any questions about your rights in the project, please call <NAME OF A PERSON AT YOUR LOCAL IRB OFFICE> at <PHONE NUMBER>.
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If you have questions about PRAMS, or if you want to answer the questions by telephone, please call <PROJECT COORDINATOR=S NAME>, <STATE> PRAMS Project Coordinator, at 1-800-<###-####>. The call is free.

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