**HEALTH RESOURCES AND SERVICES ADMINISTRATION**

**MATERNAL AND CHILD HEALTH BUREAU**

**Participant Informed Consent**

**PRAMS Oversampling**

**Study Title: Evaluation of the National Healthy Start Program**

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**What you should know about this program and study:**

* You are being asked to take part in interviews to screen and refer you and, if relevant, your child[ren] to services and counseling.
* You are also being asked to join an evaluation study.
* This form explains the interview process, the study, and your part in the study.
* Please read it carefully and take as much time as you need.
* You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty if you decide to stop the interviews or quit the study. Your decision will not affect the services you are receiving or will receive.

**Purpose of the Healthy Start Program Evaluation (Study):**

The evaluation is being done by the federal government’s Maternal and Child Health Bureau (MCHB) in the Health Resources and Services Administration (HRSA). We are doing an evaluation study of the Healthy Start Program. What we wish to learn about the program:

* The experiences of women and children in the Healthy Start Program.
* What is the impact of the program on their health?
* What parts of the program help improve the health of participants?
* Why they are successful?
* How can we grow the most successful parts of the program?

**Why you are being asked to participate:**

You were asked because you [will] participate in a Healthy Start Program’s case management services. We ask you to join this study because you can provide information about your experiences with Healthy Start, your health and, if relevant, the health of your child[ren] up to age two. You do not have to participate. It is your choice. Your decision will not affect the services you are receiving or will receive.

**Length of participation:**

 The Healthy Start Program Evaluation began in August 2016 and is expected to end in March 2019. You are being asked to share personal information about you and, if relevant, your child[ren] up to age two during the evaluation study.

**Description of the process:**

If you say yes, we will ask you to share information about you and, if relevant, your child[ren] up to age two, the care you receive, and about your participation in Healthy Start. **Your information is private and will be kept in a secure place by the Healthy Start program**.

If you choose to participate, you will be interviewed today and during future Healthy Start visits. The interviews will range from 5 minutes to 60 minutes, depending on whether or not you are pregnant:

|  |  |  |
| --- | --- | --- |
| **Form** | **Which participants fill out this form?** | **About how long will this form take to complete?** |
| Demographic Form | All participants | 5 minutes |
| Pregnancy History Form | All participants | 10 minutes |
| Prenatal Form | Participants who are pregnant or become pregnant during the study | 60 minutes (1 hour) |
| Preconception Form | Participants who are not pregnant | 60 minutes (1 hour) |
| Postpartum Form | Participants who have delivered a baby within 4-6 weeks | 60 minutes (1 hour) |
| Interconception Form | Participants who have delivered a baby in the past6-12 months | 60 minutes (1 hour) |

Some of the information we will collect include the following:

* **Mother’s name**
* **Mother’s date of birth**
* Mother’s address at time of delivery
* Mother’s social security number
* Mother’s race
* Mother’s ethnicity
* Mother’s Medicaid status
* Number of pregnancies
* Number of live births
* Mother’s date of enrollment in HS
* **Mother’s Healthy Start Client ID #** (this will be provided by your Healthy Start program)
* **Infant date of birth (or expected month or date of delivery if known)**
* Infant birth hospital
* Infant sex
* Infant name
* Infant birthweight

The items in **bold** are those we must have to include you in the evaluation study.

This information about you and your child[ren] up to age two will be sent to your state’s Vital Records Office (VRO), where birth and death certificates are kept. From the VRO, information will be sent to your state’s PRAMS (Pregnancy Risk Assessment Monitoring System) program. PRAMS collects information from mothers about their feelings and experiences before, during, and up to 9 months after pregnancy.

Your state’s PRAMS program will contact you to complete a survey. The vital records and PRAMS survey information, without any of your identifying information, will then be sent to the Healthy Start office in MCHB/HRSA, where it will be studied to assess the effects of Healthy Start on the health of you and your child[ren].

**Risks and Benefits:**

There is minimal risk and no direct benefits related to participation in this study. Your participation is completely voluntary. There is no penalty for not participating. The information collected will help the Healthy Start program(s) understand and improve the health of mothers and children up to age two.

**Confidentiality:**

* Your personal information will be kept private
* Your information will be given a random number that will keep your information private.
* VRO’s will not keep your personal information after they have sent data to MCHB/HRSA, and the study has ended.

**Whom to contact if you have questions:**

You may have questions about your rights as a participant in this evaluation study. If so, please call the Research Ethics Review Board at the National Center for Health Statistics, toll-free at 1-800-223-8118. Please leave a brief message with your name and phone number. Say that you are calling about Protocol # 2016-11. Your call will be returned as soon as possible.

**Agreement:**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have read the process described above. I freely agree to participate in the evaluation of the Healthy Start Program. I understand that all data collected will be kept private and only shared with the Healthy Start program, my state’s VRO, and PRAMS.

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

Witness Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_