**HEALTH RESOURCES AND SERVICES ADMINISTRATION**

**MATERNAL AND CHILD HEALTH BUREAU**

**Participant Informed Consent**

**PRAMS Oversampling**

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

**Principal Investigator: Jamelle Banks, MPH**

**Chief Evaluation Officer**

**Division of Epidemiology | Office of Epidemiology and Research
Maternal and Child Health Bureau | Health Resources and Services Administration**

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**IRB No.: IRB NCHS – 00000187**

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

* You are being asked to join an evaluation study.
* This form explains 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 quit the study. Your decision will not affect the services you are receiving or will receive.

**Purpose of the Healthy Start Program Evaluation:**

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. We want to understand the experiences of women and children up to age two in the Healthy Start Program and the impact of the program on their health. This study will help us understand what parts of the program help improve the health of participants and why they are successful, so that we can 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 confidential 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. Every participant will be asked to complete the **Demographic Form**, which takes about **5 minutes** to complete and the **Pregnancy History Form**, which takes about **10 minutes** to complete. If you are pregnant or become pregnant during the evaluation study, you will be asked to complete the **Prenatal Form**, which takes about **60 minutes** to complete. If you are not pregnant you will be asked to complete the **Preconception Form**, which takes about **60 minutes** to complete. Once you have delivered a baby, you will be asked to complete the **Postpartum Form**, which takes about **60 minutes** to complete, four to six weeks after you deliver your baby. Finally, six month to one year after delivering your baby, you will be asked to complete the **Interconception Form**, which takes about **60 minutes** to complete.

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). Your state’s VRO will link this information to your child[ren]’s vital records (birth certificate and death certificate, if any) and forward the information to your state’s PRAMS (Pregnancy Risk Assessment Monitoring System) program. PRAMS collects information from mothers 2-9 months after they have delivered a baby about their attitudes and experiences before, during, and shortly after pregnancy.

Your state’s PRAMS program will contact you to complete the PRAMS survey. Your completed PRAMS survey will be sent to your state’s PRAMS program. 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] up to age two.

**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 identity will be kept confidential to the extent allowed by law. Your information will be given a code number that will keep your identity unknown to those other than your Healthy Start program, your state’s VRO, and your state’s PRAMS program. No other personal information will be shared. Vital records will not keep your personal information after they have sent your linked data to MCHB/HRSA and the project 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 voluntarily agree to participate in the evaluation of the Healthy Start Program. I understand that all data collected will be kept confidential to the extent allowed by law and only shared with the Healthy Start program, my state’s Vital Records Office, and PRAMS, and that no identifiable data will be shared with the Healthy Start office in MCHB/HRSA.

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

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