

## IV. Consent Forms & Overview of Confidentiality Procedures

The Healthy Start program and its evaluation have developed stringent confidentiality procedures to protect the rights of participants and allow for the sharing of critical program and outcome information. Throughout the evaluation, *family privacy is protected*. The Healthy Start evaluation procedures for ensuring informed participant consent, confidentiality, and data security are reviewed annually by the Institutional Review Board (IRB) at Portland State University, to ensure protections are adequate and in compliance with Federal guidelines for research involving human participants.

At the time Healthy Start workers approach families to describe the Healthy Start program, parents are asked to sign a consent form on which they can indicate one of three levels of initial consent:

- “I agree to participate in Healthy Start and its program evaluation” – this indicates full consent for the Healthy Start screening and program services and for sharing of information with the evaluation.
- “I agree to participate in Healthy Start but not the program evaluation” – this indicates that the participant agrees to participate in Healthy Start (including completing the NBQ screen) but does NOT want information shared with the evaluation.
- “I am not interested in Healthy Start” – this indicates that the parent is declining Healthy Start services, including screening services. **Important:** IF the parent declines Healthy Start, this includes declining to complete the NBQ. If a parent completes the NBQ, but isn’t interested in other Healthy Start services or the evaluation, they should indicate consent level #2.

If families do not agree to participate in the evaluation, they still may choose to receive Healthy Start services, but are not included in the evaluation. Families also are informed that they are free at any time to decline to answer evaluation questions without affecting the services they are receiving.

Identification numbers for Healthy Start babies and their families are assigned to ensure privacy. Data files maintained at NPC Research (the contracted Healthy Start evaluators) do not include children’s names or the names of their parents or guardians. All information is transmitted to NPC Research by identification number only.

Healthy Start workers who obtain family consent should review the consent form in detail with the family. Typically, the consent form is reviewed in person with the parent. However, verbal consent may be granted (over the telephone) if the Healthy Start worker mails the consent form and HIPAA form to the parent, documents the date verbal consent was given, and documents the date they sent the forms in the mail. If the family accepts Healthy Start Intensive Services, the worker must obtain the signed consent form from the parent and maintain it in their records. On the following pages are suggested “talking points” to go over with the family to ensure that they understand the detailed consent language on the second page of this form.

## Talking Points for Home Visitors for the Healthy Start Consent Form “Welcome to Healthy Start”

As the family’s first contact with Healthy Start, it is important for you (the FSW or other staff) to help the parent understand the consent form (located on the back, or attached to, the “Welcome to Healthy Start” form). Below, we go through the “key points” to go over with families when they sign the consent forms. We suggest that you go over the consent form verbally with the parent, summarizing the key points below.

### About the Healthy Start Program

- This paragraph tells you that if you participate in Healthy Start, that you:
  - **Will be contacted** by phone or in person to learn about services, and
  - **Agree to fill out a short questionnaire**, called the New Baby Questionnaire, **which will tell us about whether you’re eligible for additional services.**
- **It also tells you that everything in Healthy Start is voluntary**, and you can skip any question that you don’t want to answer. Even if you sign the consent form, you can always change your mind later.

### About the Healthy Start Evaluation & Confidentiality

- This part tells you about our evaluation and how we keep your information confidential:
  - **The Healthy Start program has an evaluation** that helps us know whether the program is working for families.
  - **The evaluation is very important** for helping us improve the program and for our funding, *but* you can be in Healthy Start even if you don’t want to be in the evaluation
  - If you participate in the evaluation, all the information you provide will be kept **confidential** but shared with the researchers for evaluation purposes only.
  - This means your name and information about you or your family will **not be shared with** those outside of Healthy Start or the evaluation team without your permission.
  - I do need to tell you that the only exception to this is that Healthy Start workers are required by law to report child abuse or neglect if they witness it.

### Benefits of Healthy Start

- Here we are just saying that if you participate in Healthy Start, we hope you will get some valuable information and other services that can help you as a new parent. And, as I said before, participating in the evaluation helps the program to continue to improve our services.

## **HIPPA**

- This section is about a federal standard called HIPAA [Health Insurance Portability and Accountability Act] that protects your private health information and the health information of your child(ren). By checking off this box you are showing that you received our HIPAA form describing your rights and the protections of your personal information.

## **Questions**

- If you have any questions, this paragraph just tells you who to call to get more information.

After the parents read and understand the consent form, have them complete the “Welcome to Healthy Start” form with their level of consent and contact information. Copy the form and keep one for your program’s records.

On the next page is a copy of the Healthy Start consent form. Programs may make modifications to this form with the following exceptions:

1. Questions 1-10 (family information) must be included in the consent form.
2. Consent check boxes cannot be reworded or other options added
3. The detailed consent language on the back of the change may not be modified, as this language has been approved by the Portland State University Institutional Review Board for compliance with ethical treatment of participants in research projects.



# Important Information About Participating in Healthy Start

## About the Healthy Start Program

Healthy Start is a voluntary service for parents of newborn children. If you agree to be part of the Healthy Start program and sign this consent form, it means that **you agree to be:**

- Contacted by phone or in person by a member of the Healthy Start program to learn about services that might be available to you.
- Screened or assessed to determine your eligibility for Healthy Start services. Screening includes answering some questions about yourself and your family on a form called the “New Baby Questionnaire.” Assessment involves talking with a member of the Healthy Start team about issues or concerns you might be having as a new parent.

**Even if you sign this consent form**, you do not have to complete the screening or the assessment (they are voluntary). If you do participate, you may stop at any time, and you do not have to answer any questions you don’t want to.

## About the Healthy Start Evaluation

The Healthy Start program has an evaluation to measure how it benefits families and to help it improve the services it provides. All families who receive Healthy Start services are invited to take part in the program evaluation; however, you may still receive services even if you do not participate in the evaluation.

- **Participating in the evaluation includes:** Authorizing the Healthy Start program to provide information about you and your family to the Healthy Start evaluators to see if the program is helping families, and to help improve program services. (Evaluation reports, containing only information that does not use any names of people in the Healthy Start program, and that give only information that is summarized or grouped together, will be published and available to the public.)
- Authorizing the Oregon Departments of Education and Human Services to share health, education, employment, and child welfare information about you and your family with the Healthy Start evaluators to see if the program is making a difference for people who are in the Healthy Start program.

**Even if you agree to be part of the evaluation**, please remember that (1) you can stop being part of it at any time, (2) you do not have to be part of the evaluation in order to receive program services, and (3) you do not have to answer any questions that you do not want to answer.

## Confidentiality

All information that you give to the Healthy Start program or to the program’s evaluators will be kept **confidential**. Healthy Start and its evaluators take many steps to be sure that all of your information will remain confidential, such as:

- Keeping all written and electronic information in locked and password protected files accessible only by Healthy Start staff and contractors.
- Removing identifying information (such as names) from evaluation data.
- Being sure that all staff are well trained in ways to maintain confidentiality.

Even so, there is always a slight risk that your information could become known. The only exception to this protection of confidentiality is when there is a reasonable suspicion of child abuse or neglect, in which case Healthy Start program providers are required to report this information to the Oregon Department of Human Services, Child Welfare Division.

## Benefits

By participating in the Healthy Start program, you may receive some benefits, such as learning about services and resources for new parents that are available in your community. Participating in the evaluation may not benefit you directly, but may help the program by providing information that can be used to improve or expand services.

## HIPAA

By signing the consent form, you are agreeing that:

- The consent form was explained to you, and that you were given a copy of the program’s statement of understanding in regards to the Health Insurance Portability and Accountability Act (HIPAA).
- Any questions you had about the program or its evaluation have been answered.
- If consenting to the evaluation, you authorize Healthy Start’s evaluators to access your information for research and program evaluation purposes only.
- You understand that your consent expires 4 years following the completion of the study, and that all your information will be destroyed at that time.

## Questions?

If you have questions about the evaluation, please call Dr. Beth Green, NPC Research, (503) 243-2436. If you have questions about the statewide Healthy Start program, please contact Karen Van Tassell, (503) 373-1570. If you have any concerns or problems with your participation in this study, please contact the Human Subjects Research Review Committee; Portland State University; Office of Research and Sponsored Projects; 111 Cramer Hall; Portland, OR; (503) 725-4288.

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