



## Informed Consent

### INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN PROJECT

Baby Steps for Health  
2018-0901

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**Subtitle:** Consent for Services

Project Chair: Jan Blalock

The overall goal of the Baby Steps for Health service is to help you make healthy choices and support you during pregnancy and in the first few months after the birth of your baby. The following services are recommended based on your responses to the assessment questions, and you have the option of receiving any or all of the services being offered to you. *Only the selected services will be presented.*

If you agree to receive these services now, but later change your mind, you can contact the project staff, and all services and/or app messages will be stopped.

You may choose not to participate in this part of the survey without any penalty or loss of benefits that you receive at this site.

#### Texting Service

SmokefreeMOM is a texting service offered by the National Cancer Institute's (NCI) Smokefree.gov and is designed to help women who are pregnant and use tobacco products with cutting back and/or quitting if that is their goal.

If you chose to sign this consent document, a member of the Baby Steps for Health team will send you information on how to sign up for SmokefreeMOM using a special keyword, created specifically for this program. After you are enrolled in the program, you will receive daily support text messages for 6-8 weeks. The National Cancer Institute will use your telephone number to link your usage data and may share this information about your enrollment and use of the program with the study team.

Participation in this texting program is entirely voluntary. You can choose to stop receiving text messages at any time by texting STOP. You can also text HELP at any time for information on the program.

## **Wellness App**

The Wellness app is available to pregnant women who are interested in topics specific to pregnancy and life after their baby is born. Topics may include information on cutting back or quitting smoking, benefits of quitting smoking and having a smoke-free home, and other wellness topics such as reducing stress, sleep, exercise, childcare resources and tips for breastfeeding.

If you agree to download the Wellness app on your smart phone, you will be sent a link to install the app on your phone.

Throughout your pregnancy and the first 4 months the baby is born, the app will provide you with contact information to learn more about additional Baby Steps for Health services. The program staff will be collecting data through the app on your use of the app, including the date and time that modules are accessed and which modules are viewed. This information will be stored and monitored (watched). The purpose of collecting this information is to understand your engagement, identify any usability problems, and general system performance measures.

Around the 8th month of your pregnancy and then about 4 months after your baby is born, you will receive a text message with a link to a survey. This will help the project staff better understand whether these new services are helping pregnant smokers and/or helping with establishing not smoking inside your home. These surveys will take about 5 minutes to complete.

## **Services for Women Who Currently Smoke or Who Quit for Their Pregnancy**

### **Supportive Phone Counseling**

Supportive telephone sessions will be provided to give you chance to talk about any changes you want to make with your smoking habits, staying quit after your baby is born, coping strategies, as well as other things that may get in the way of changing these behaviors, like stress. If you agree to provide your phone number and mailing address, the project staff will call you in 1 to 2 working days to complete your first information intake session. Before or during this first session, you may be asked questions about your mood to measure any level of distress. You will also be asked questions about your current smoking behavior, social support, and any stressors you may have. Women from participating clinics may be compensated with a \$20 gift card for completing this first intake session. If eligible for this compensation, you must provide your mailing address to receive the gift card.

You will receive a minimum of 6 phone counseling sessions during your pregnancy. Each session may be about 30-45 minutes long, as your schedule allows.

During the first 4 months after your baby is born, you will receive an additional 4-6 telephone sessions. For women who begin counseling after birth, we will provide up to 6-8 telephone sessions for up to 4 months.

You may choose to decline or stop these sessions at any time.

As a part of the counseling service, we will also provide you with mailed materials that provide additional support for decisions about smoking before and after your baby is born.

### **Additional Service Information**

If you are feeling distressed and the study staff or doctor thinks it is needed, you will receive recommendations for additional health support in your area.

Around the 8th month of your pregnancy and then about 4 months after your baby is born, you will receive a text message with a link to a survey. This will help the project staff better understand whether these new services are helping pregnant smokers and/or helping with establishing not smoking inside your home, as well as how helpful you think your counselor was in helping you meet your goals if you're receiving counseling. These surveys will take about 5 minutes to complete. If the study staff does not receive your completed survey, you may receive up to 4 reminders (1 text message a week) to take the survey.

### **Self-Help Materials**

If you agree to provide your mailing address, the project staff will mail you self-help materials which will help you make decisions that you feel are best for you about smoking before and after your baby is born. They offer ideas and help with challenges such as how to manage withdrawal, saying "no" to a cigarette when stressed, what to do if you have urges even though you haven't smoked in months, or dealing with sleep loss after you've had your baby.

Around the 8th month of your pregnancy and then about 4 months after your baby is born, you will receive a text message with a link to a survey. This will help the project staff better understand whether these new services are helping pregnant smokers. These surveys will take about 5 minutes to complete. If the study staff does not receive your completed survey, you may receive up to 4 reminders (1 text message a week) to take the survey.

### **Services Available For Women Who Are Exposed to Household Smoke**

Smoke-Free Homes Kit – Take It Outside is a tested program that walks you through how to talk with household members and visitors about not smoking inside the home. This kit includes tips for the discussion, door stickers, and other materials to keep your home smoke-free. A brief coaching call helps you work through any problems you may run into.

If you agree to provide your phone number and mailing address, you will receive 3 separate Smoke-Free Homes mailings over 6 weeks. You will also receive a coaching call from a Baby Steps for Health team member to discuss the steps described in the mailed materials.

Around the 8th month of your pregnancy and then about 4 months after your baby is born, you will receive a text message with a link to a survey along with reminders to take the survey. This will help the project staff better understand whether these new services are helping with establishing not smoking inside your home. These surveys

will take about 5 minutes to complete. If the study staff does not receive your completed survey, you may receive up to 4 reminders (1 text message a week) to take the survey.

### **Other Information**

For the Baby Steps for Health staff to be able to contact you for the services you choose and to contact you for the surveys at 8th month gestation and 4 months postpartum, they may ask this clinic or office for updated contact information.

You may ask the project chair (Dr. Jan Blalock, at 713-745-1728) any questions you have about this project.

The file linking project identification numbers with participant names will be destroyed at the conclusion of the project. Paper records will be kept in a locked file room. Names will not be identified in any reports resulting from the Project, and no individual information will be released to anyone outside of the Project. Data will be secured in password-protected computer files and reported at the group level. Data will not be destroyed and will be archived per institutional standards.

### **Authorization for Use and Disclosure of Protected Health Information (PHI):**

- A. PHI may include, for example, your name, telephone number, address, other health information about you, as well as information about depression or anxiety (if you receive phone counseling). During the project, MD Anderson may be collecting and using your PHI. For legal, ethical, and safety-related reasons, the project team may share your PHI with:
- Cancer Prevention & Research Institute of Texas, who is a sponsor or supporter of this project, and/or any future sponsors/supporters of the project.
  - Monitors and auditors who check the accuracy of the information

Project sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in project records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

- B. Providing your consent by providing your contact information is optional but you cannot take part in the services if you do not provide your contact information.
- C. MD Anderson will keep your PHI confidential when possible according to state and federal law.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

- D. The permission to use your PHI will continue for as long as needed unless you withdraw your authorization (permission) in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer of MD Anderson at 713-745-6636. If you

withdraw your authorization, you will be removed from the project and the data collected about you up to that point can be used and included in the studying of the data. However, no further information about you will be collected.

**CONSENT/AUTHORIZATION**

I understand the information in this consent form. I have had a chance to read the consent form for this service project. By providing my contact information, I am agreeing to provide my personal health information and receive the services above.

[REDCap: place agree or disagree option]

**[If agree, then a request for electronic signature appears]**