

HMHB - Form 001 – SCONS – Screening Study Consent

HAPPY MOTHER, HEALTHY BABY STUDY

Screening Consent for Participation in the Study Eligibility Screening

(This consent statement must be read (prior to Eligibility Screening) to those women who are pregnant and are interested in being screened for eligibility to participate in the trial)

Introduction: *As-salaam-u-alaikum.* My name is [XXXX], we are part of Rawalpindi Medical University and with the Obstetric Department at the Holy Family Hospital. Since 2004, we have been working in different parts of Pakistan to help improve maternal and child health. This research is funded by the National Institute of Health in the USA. In the past we have also partnered include the Lady Health Worker (LHW) Program, the Health Services Academy in Islamabad, and international organizations. We are doing research to learn if a new program that we developed for pregnant women, “Happy Mother, Health Baby” (HMHB), can reduce distress in pregnancy.

The purpose of the Happy Mother Healthy Baby Research Project: Many mothers feel stressed, nervous, or anxious during pregnancy. This can effect mother’s health and can cause problems for her growing baby. The purpose of the research is to learn if our HMHB program can reduce this anxiety and improved their wellbeing.

Why are we requesting your participation in this screening?: We want to include about 1200 pregnant mothers like you from Rawalpindi who are over 18 years old and have some signs of being anxious. We will only include in our study pregnant women who have certain stress related problems. Therefore, to see if you can be in our study, we would like your permission to ask you some questions and collect information.

What data will we collect?: If you agree, I will ask your age and education, and about how you are feeling today. I would also look at your medical records, including your antenatal card, to see if you have had any health conditions that would make it not possible to take part.

Do I have to take part?: No, you do not have to take part in this screening, participation is voluntary. You have a right to withdraw at any time without giving any reason, without penalty or loss of benefits to which you are otherwise entitled. Refusing to take part will not result in any penalty or loss of benefits.

What are the possible benefits of taking part?: By participating in this screening, we will determine if you are eligible to take part in the HMHB study. The purpose of the HMHB study is to help mothers \ to lower their level of anxiety. The HMHB program will also help mothers notice feeling nervous and deal with it so that it is less likely to harm her or her infant.

What are the possible disadvantages and risks of taking part?: We will be asking you questions that may take about 5 to 15 minutes of your time, and answering may make you tired. Also, talking about your feelings can sometimes be difficult and might make you upset. If you feel stressed, you will be offered to speak to a counselor. You can refuse to answer any questions that you are not comfortable answering. You also have the right to stop the interview at any time if you feel unhappy.

Payment for participation: You will not receive any payment for participation in this screening.

Will my information be kept confidential?: All information that we collect from you will be kept confidential and safe. This includes the information you tell us and any information about you or your baby that we copy from your medical records. Although the information from the screening is confidential, if you are at risk of hurting yourself or your child, it is the legal and ethical responsibility of the research team to share that information with others. If we learn that you are very stressed or

