INSTITUTIONAL REVIEW BOARD (IRB)
SHAIKH ZAYED MEDICAL COMPLEX, LAHORE
SHAIKH ZAYED FEDERAL POSTGRADUTE MEDICAL INSTITUTE, SHAIKH ZAYED HOSPITAL, NATIONAL INSTITUTE OF KIDNEY DISEASES, SHAIKHA FATIMA INSTITUTE OF NURSING & HEALTH SCIENCES, NATIONAL HEALTH RESEARCH COMPLEX AND SHAIKH KHALIFA BIN ZAYED AL-NAHYAN MEDICAL & DENTAL COLLEGE, LAHORE-54600 PAKISTAN
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Ref. No. SZMC/IRB/External/0048/2020 Dated: 13.03.2020

IRB APPPROVAL LETTER

IRB ID:	SZMC / IRB / External / Ph.D / 210 / 2020
Project:	**EFFECTIVENESS OF THINKING HEALTHY PROGRAM FOR PREVENTION OF ANTENATAL DEPRESSION TO IMPROVE MATERNAL HEATH, PAKISTAN**
Investigator:	Miss. Quratulain (Student Ph.D Public Health)
Department:	Institute of Social & Cultural Studies, University of the Punjab, Lahore
Supervisor:	Dr. Javaria Saleem
Director Institute:	Prof. Dr. Rubeena Zakar
Data Approval:	13.03.2020

Your request for collection of data from the outdoor pregnant women visited to Gynecology & Obstetric Department of Shaikh Zayed Hospital, Lahore is discussed and reviewed by the member of sub-committee, Institutional Review Board (IRB). You are allowed to collect data for your research.

You are directed to follow the rules and regulations as mentioned in your undertaking form.

PROF. DR. MUHAMMAD SUHAIL
Chairman IRB,
Institutional Review Board
Shaikh Zayed Medical Complex, Lahore

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This IRB approval is issued subject to the following conditions:-

1. A signed personal declaration of responsibility.
2. If the research protocol approved by the IRB changes significantly which alters the nature of the study, a new application for IRB clearance must be submitted.
3. It is the principal investigator's responsibility to retain all the necessary forms and informed consent for future reference.

C.C

1. The Deputy Dean, SZPGMI, Lahore

Thinking Healthy Program

Asalam-u-Alaikum,

Introduction:

Sheikh Zyed Hospital's Obstetrics and Gynaecology department welcomes you in Program, which aims to support the mental and physical health of pregnant mothers and their baby. We invite you to take part in this program but before participating, it is important for you to know the purpose of this program.

The purpose of the Program:

In Pakistan, pregnant women frequently face different problems such as stress, anxiety and restlessness. During pregnancy, the presence of stress and anxiety can adversely affect the health of both mother and baby. A special psychosocial based training will be delivered under the supervision of specialists at Sheikh Zyed Hospital's gynaecology department.

Why have I been chosen?

This program is for all mothers. You are selected for this program because you will become a mother soon and in our assessment phase we have seen signs of pregnancy related anxiety in you. Therefore, we will ask you some questions regarding your health and your child's health

Do I have to take part in this study?

It is entirely your decision whether you want to take part in the study or not. If you decide to take part, but later change your mind you are free to withdraw at any time. Your decision not to take part in the study or withdrawal at any stage will not affect the care you receive now or in the future.

How often will I be interviewed?

In addition to the questions about feelings and emotions as well as your family life, you will be interviewed three times by our research team during the duration of the study. This will happen at your first trimester, 3rd trimester and 6 weeks after the birth of your baby. The research team can conduct the interview in hospital. The research team consists of female researchers who will ask questions about your emotions, well-being and difficulties you are experiencing concerning your health.

What are the possible benefits of taking part?

Purpose of this program is to betterment of mother and child health. By participating in this study, you

will have the opportunity to share your relevant experiences, which may feel beneficial to you and beneficial for other mothers.

What are the possible disadvantages and risks of taking part?

This study does not involve any physical risks or harm. However sometimes, talking about your experiences and feelings may be difficult and can cause you to be upset. If you feel distressed you will be offered to speak to a counselor. Furthermore, you have the right to refuse to answer a question if you don't feel comfortable answering and can stop the interview at any time if you feel stressed, or simply do not wish to continue.

Will my information be kept confidential?

All the information I will collect from you will be strictly confidential. Information will be stored, in a locked cabinet, in our main office, with access available to only research team members. The information will be stored for five years, following the end of the program in 2022, before being destroyed. We might use the information for writing papers or doing presentations at conferences. However, all information will be made anonymous and your identity will not be revealed to anyone at any stage.

Confidentiality will only be breached if there is serious risk of harm to you or to others. Under these conditions we will inform the appropriate health professional so that urgent help can be provided to you.

Consent (baseline)

Please initial all boxes

1.	I confirm that I have read and understood the information the attached document for the study described above. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	Yes	No
2.	My participation is voluntary and I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	Yes	No
3.	Information will be kept confidential and I give permission to specialist of this program to have access to my medical records in case of any need.	Yes	No
4.	I agree to take part in the program.	Yes	No

Name of participant Date Signature

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☐ Ask the participant to mark a "left thumb impression" in this box if the participant (or participant's parent) is unable to provide a signature above.

Name of person taking consent Date Signature

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