



The Arab Republic of Egypt  
Ministry of Higher Education  
Health Research Ethics Committee  
Assiut University  
Faculty of Medicine

## **NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH**

The application technical and ethical guidelines format are to be read before completing this form to ensure that the questions are answered appropriately.

You may find it helpful to read both national technical and ethical guidelines and then fill the format. You can add extra pages.

Before requesting an individual's consent to participate in research, the investigator must read chapter three in the Guidelines for Ethical Conduct of Research Involving Human Subjects.

The Arabic version of the informed consent is the form to be used to take the consent from the Egyptian research participants, so you should fill it in details and in a language or another form of communication that the individual can understand the research subject.

Ministry of Higher Education  
2007

**Do not include this page with your application form**



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<b>NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROPOSAL</b>
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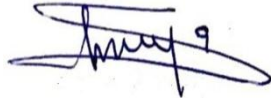
Please read the technical and ethical guidelines thoroughly before filling the form

**Technical proposal form**

**Applicant**

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□ Signature



### **Title of the study**

**Peripartum depression and its predictors: A longitudinal observational hospital-based study**

### **Introduction/methodology/data collection/data analysis**

Depression is a common public health problem. It is an important cause of morbidity for mothers in their peripartum period with an estimated prevalence of 7-58% or even higher in some countries. A common prevalence of antepartum depression reported in different studies is ~13%. The suggested mechanisms of peripartum depression include complex interplay between biological factors (fluctuation in reproductive and hypothalamic pituitary adrenal axis hormones), immune system activity, genetics and psychosocial stressors. Therefore, WHO and U.S. Preventive Services Task Force recommend screening women for presence of manifestations of depression in their peripartum period and determine their risks for preventive and treatment implications.

Studies which estimated the prevalence of antepartum depression are few compared to those which addressed similar topic in postpartum period. Here, we aimed to estimate the prevalence and the severities of depression symptoms and major depressive disorder in women in the antepartum and postpartum period and their demographic, social, obstetric, psychological and hormonal predictors.

This is a longitudinal observation study completed over a period of three years (2017-2020). The initial sample size composed of 1100 women who were consequently recruited from the antenatal outpatient clinic of the department of Obstetrics and Gynecology, Mansoura University, Mansoura, Egypt. The following were the methods used for women's assessment: Edinburgh postpartum depression scale (EPDS) screening questionnaire, designed unstructured clinical questionnaire to gather information about the women's reactions to recent life circumstances, events and stress related to her pregnancy, BDI-II and STAI-AD for categorization of the severity of manifestations of depression or anxiety, parenting stress index - short form (PSI-SF), psychiatric interviewing to confirm the diagnosis of major depressive disorder according to DSM-5, and measurement of T3, T4 and TSH levels in the

antepartum and postpartum periods.

Data were processed using SPSS for windows, version 20.0 (SPSS Inc., Chicago, IL, USA). Comparative statistics were carried out with t- and Chi. Square tests or ANOVA if variables are more than two. Correlation analyses between antepartum score of BDI-II and the results of demographic, socio-economic and psychometric testing's scores were carried out with Spearman's rho correlation coefficient. Multiple logistic regression models was carried out to check for demographic, clinical and psychosocial factors which independently predict or associate with antepartum and postpartum severe depression symptoms. Significance was considered with probability value less than 0.05.

### **Budget**

Personal

### **Confidentiality**

As a corresponding author, I declare that written informed consent was obtained from the patients for publication of their clinical, laboratory and socioeconomic and psychometric data.

### **For office use only**

Proposal No.: AUFM\_NP/OG\_422/2016

Date Received: 15<sup>th</sup> December 2016

### **Approved**



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