ANNEXURES
ANNEXURE - I

RESEARCH CONSENT FORM

TITLE OF THE RESEARCH PROJECT : STUDIES ON PREVALENCE OF CARDIO METABOLIC RISK FACTORS AND ANAEMIA IN RELATION TO ANTIOXIDANT STATUS OF POSTMENOPAUSAL WOMEN FROM DIFFERENT ETHNIC COMMUNITIES.

NAME OF THE GUIDE : DR. MANJUNATHA R. AITHALA, M.D.
NAME OF THE CO-GUIDE : DR. SANKAR ROY, M.D.

01. PURPOSE OF RESEARCH :
   I have been informed that this study will evaluate the cardio metabolic risk factors present in women comprising of subjects from two different ethnic and non-ethnic communities of India and also evaluate the relationship among cardio metabolic risk profile of the subjects with their menopausal status, anaemia status and status of their antioxidant defence system. This will help to take measures to prevent future development of cardio metabolic disorders and also will be helpful to understand some of the causative factors behind development of such risk in subjects.

02. PROCEDURE :
   I understand that the procedure of the study will involve recording of various anthropometric parameters, blood pressure, complete lipid profile, fasting blood glucose level, complete haematological parameters and ECG at rest. The procedure will require withdrawal of 10 ml venous blood from me and other non-invasive investigations. I understand none of the procedures will interfere with any of my physiological parameters.

03. RISK AND DISCOMFORTS :
   I understand that the procedures involved in the study will not cause any discomfort to me and they do not involve any risk to my health.

04. BENEFITS :
   I understand that my participation in the study may not have a direct benefit to me, but this may be a potential beneficial effect in the field of cardio metabolic risk in women.

05. CONFIDENTIALITY :
   I understand that medical information produced by this study will become part of institutional record and will be subject to the confidentiality and privacy regulation of the said institute. Information of a sensitive personal nature will not be part of medical record, but will be stored in investigator's research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secured location.

   If data are used for publication in the medical literature and for teaching purpose, no names will be used, and other identities such as photographs and audio or video tapes will be used only with my special written permission. I understand that I may see the photographs and video tapes and hear audio tapes before giving the permission.

06. REQUEST FOR MORE INFORMATION :
   I understand that I may ask more questions about the study at any time. Concerned researcher is available to answer my question or concerns. I understand that I
shall be informed of any significant new findings discovered during the course of this study which might influence my continued participation.

07. REFUSAL OR WITHDRAWAL OF PARTICIPATION:
I understand that my participation is voluntary and I may refuse to participate or may withdraw my consent and discontinue participation in the study at any time without prejudice to my present or future care at this hospital.
I also understand that researcher may terminate my participation in this study at anytime after she has explained the reason for doing so and has helped to arrange for my continued care by my own physician.

08. INJURY STATEMENT:
I understand that in the unlikely event of injury to me resulting directly from my participation in this study, if such injury were reported promptly, then medical treatment will be available to me, but no further compensation would be provided.
I understand that by my agreement to participate in this study I am not waiving any of my legal rights.

I have explained to ……………………………………………………………………. the purpose of the research, the procedures required, and the possible risk and benefits to the best of my ability.
Signature of the Research Scholar Date
I confirm that ……………………………………………………………………. has explained to me the purpose of the research, the study procedure that I will undergo, possible risks and discomforts as well as benefits that I may experience. Alternatives to my participation in the study have also been discussed. I have read and understood this consent form. Therefore, I agree to give my consent to participate as a subject in this research project.
Signature of the participant Date
Signature of Witness Date

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ANNEXURE - II
PROFORMA FOR RECORDING GENERAL AND SOCIODEMOGRAPHIC INFORMATION

SUBJECT IDENTIFICATION NUMBER :
NAME :
FATHER'S/ HUSBAND’S NAME :
COMPLETE RESIDENTIAL ADDRESS :
AREA OF RESIDENCE ( URBAN/ RURAL) :
DATE OF BIRTH/ AGE :
RELIGION/CASTE :
ETHNICITY ( SPECIFY) :
OCCUPATION ( SPECIFY) :
LEVEL OF EDUCATION ( Unknown/ 8th Standard/ 12th Standard/ Above) :
MONTHLY FAMILY INCOME ( Rs. <10,000/, Rs. <20,000/, Rs. <30,000/, Rs. >30,000) :
PHYSICAL ACTIVITY ( Sedentary / Mild/ Moderate/ Heavy ) :
DIET ( Veg/ Non-veg) :
HABITS ( Alcohol/ Smoking/ Any other) :
MARITAL STATUS ( Married/ Unmarried/ Widow/ Single ) :
NUMBER OF CHILDREN :
HISTORY OF PREGNANCY ( Miscarriage/ Normal/ Cesarean) :
HISTORY OF CONTRACEPTIVE USE :
HISTORY OF PAST ILLNESS :
HISTORY OF ANY ENDOCRINE DISORDER :
ANY SIGNIFICANT CHRONIC ILLNESS ( DIABETES/ HYPERTENSION/ DYSLIPIDEMIA/ ANY SURGERY) :
HISTORY OF PRESENT DRUG USE:
MENSTRUAL STATUS / DATE OF LAST PERIOD :

ANNEXURE - III

PROFORMA FOR RECORDING OBSERVATIONS :

SUBJECT IDENTIFICATION NUMBER :

ANTHROPOMETRIC PARAMETERS :
01. Height (cm) :
02. Weight (kg) :
03. Waist circumference ( cm) :
04. Hip circumference (cm) :
05. Thigh circumference (cm) :
06. BMI (kg/m$^2$):
07. WHR ( Waist-Hip Ratio) :
08. WHtR (Waist-Height Ratio) :
09. WTR( Waist- Thigh Ratio) :
10 HTR ( Height-Thigh Ratio ) :

HAEMATOLOGICAL PARAMETERS :
01. Total RBC count (millions/mm$^3$)
02. Total WBC count (thousands/mm$^3$)
03. Platelet count (lakhs/mm$^3$)
04. Neutrophil (%)
05. Eosinophil (%)
06. Basophil (%)
07. Lymphocytes (%)
08. Monocytes (%)
09. Haemoglobin content (gm%)

**PHYSIOLOGICAL PARAMETERS:**
01. Heart Rate (beats/min):
02. Blood Pressure (mmHg):

**BIOCHEMICAL PARAMETERS:**
01. Fasting Blood Sugar (mg/dl):
02. Triglyceride (mg/dl):
03. Total cholesterol (mg/dl):
04. HDL-C (mg/dl):
05. LDL-C (mg/dl):
06. VLDL-C (mg/dl):
07. HDL-C/TC ratio:
08. TG/HDL-C ratio:
09. HDL-C/LDL-C ratio:
10. HDL-C/ VLDL-C ratio:

**ANTIOXIDANTS:**
01. Plasma Malondialdehyde (MDA):
02. Erythrocyte Catalase (CAT):
03. Erythrocyte Superoxide dismutase (SOD):
04. Erythrocyte Glutathione peroxidase (GPx):
06. Blood Glutathione (GSH):
07. Plasma Vitamin C (VIT-C):
08. Serum Vitamin E (VIT-E):