Exposure of Reproductive Aged Pregnant and Non-Pregnant Women to Common Environmental Pollutants and Endocrine Disrupting Chemicals: Implications to their Reproductive Health, Pregnancy and Fetal Outcomes

SCIENTIFIC TITLE

Exposure of Reproductive Aged Pregnant and Non-Pregnant Women to Common Environmental Pollutants and Endocrine Disrupting Chemicals: Implications to their Reproductive Health, Pregnancy and Fetal Outcomes

PROJECT DESCRIPTION

The general objective of this study is to determine the exposure to common environmental pollutants and endocrine disrupting chemicals (EDCs) of reproductive aged nonpregnant and pregnant women in the Philippines.

PROJECT DURATION

<table>
<thead>
<tr>
<th>Start Date</th>
<th>Duration in Months</th>
<th>Target Completion Date</th>
<th>Actual Completion Date</th>
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<tbody>
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<td>2021-03-01</td>
<td>24</td>
<td>2023-03-01</td>
<td>2023-03-01</td>
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</tbody>
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PROJECT STATUS

Ongoing

REASON FOR PROJECT PENDING/SUSPENSION/TERMINATION

Unspecified

IMPLEMENTING AGENCY (PRIMARY SPONSOR)

<table>
<thead>
<tr>
<th>Institution</th>
<th>Classification</th>
<th>Region</th>
<th>LTO #</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of the Philippines</td>
<td>Public Higher Education Institution - State Universities and Colleges</td>
<td>Philippines</td>
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COOPERATING AGENCY (SECONDARY SPONSOR)

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<thead>
<tr>
<th>Institution</th>
<th>Classification</th>
<th>Region</th>
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<tbody>
<tr>
<td>Philippine General Hospital</td>
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FUNDING AGENCY (SOURCES OF MONETARY OR MATERIAL SUPPORT)

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<td>Philippine Council for Health Research and Development, Department of Science and Technology</td>
<td>P 7,459,127.44</td>
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CONTACT FOR PUBLIC QUERIES

<table>
<thead>
<tr>
<th>Name</th>
<th>E-Mail</th>
<th>Phone Number</th>
<th>Institution and Institution Address</th>
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</thead>
<tbody>
<tr>
<td>Rodmie Oliver E. Pumaras</td>
<td><a href="mailto:repumaras@up.edu.ph">repumaras@up.edu.ph</a></td>
<td>09758588385</td>
<td>College of Medicine, University of the Philippines Manila</td>
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</table>

CONTACT FOR SCIENTIFIC QUERIES
IMPLEMENTING AGENCY (PRIMARY SPONSOR)

<table>
<thead>
<tr>
<th>Name</th>
<th>Expertise</th>
<th>Affiliation</th>
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</thead>
<tbody>
<tr>
<td>Erlidia F. Llamas-Clark, MD, MPH, PhD</td>
<td>Gynecology, Sonology, Population Health and Epidemiology</td>
<td>University of the Philippines - Manila, College of Medicine</td>
</tr>
</tbody>
</table>

RESEARCH CLASSIFICATION

Clinical Trial

HEALTH CONDITION(S) OR PROBLEM(S) STUDIED

The primary purpose of this study is to be able determine the magnitude of exposure and associated reproductive health-related conditions and diseases of Filipino women that may be associated with exposure to harmful environmental pollutants. Understanding the association of this harmful human exposures will be helpful in making people aware and assisting in decreasing exposure to these EPs and EDCs may affect future reproductive health outcomes. In addition, this study would add to the database of knowledge on EDCs in the Philippines, contribute to the currently limited pool of research regarding the seemingly minute daily exposures that can have potential harmful effects for policies and other related research to be guided accordingly.

PRIMARY OUTCOMES

The general objective of this study is to determine the exposure to common environmental pollutants and endocrine disrupting chemicals (EDCs) of reproductive aged nonpregnant and pregnant women in the Philippines.

KEY SECONDARY OUTCOMES

Specific Objectives: The study aims the following: 1. Component Study 1. To determine the magnitude (prevalence) of exposure among nonpregnant and pregnant women aged 18–49 years to common EPs/EDCs such as Bisphenol A, pesticides, phthalates, and perfluorinated compounds among others; 2. Component Study 2. To determine the risk factors associated with the most common EPs/EDCs such as Bisphenol A, pesticides, phthalates, and perfluorinated compounds among 18–49-year-old non-pregnant women with those diagnosed with polycystic ovarian syndrome (PCOS). 3. Component Study 3. To identify the associated pregnancy, maternal and fetal effects: such as a) 100 and b) among 18–49-year-old-pregnant women who were exposed to the common environmental/EDC exposures Bisphenol A, pesticides, phthalates, and perfluorinated compounds A) Maternal complications: 1. Metabolic-endocrine disorders: a. Gestational diabetes mellitus b. Hypertension in pregnancy c. Thyroid dysfunction B) Fetal/child complications 1. Congenital anomalies – at 22-24 weeks 2. Intrauterine growth restriction - from 24-28 weeks 3. Electrolyte imbalances – Hypocalcemia, hypomagnesemia, hypoglycemia 4. Hypothyroidism – cretinism 5. Low birth weight 6. Prematurity

RECRUITMENT STATUS

Recruiting

COUNTRIES OF RECRUITMENT

Philippines

FDA DOCUMENT TRACKING NUMBER

Unspecified

FDA APPROVAL DATE

0000-00-00

ERC APPROVAL DATE

0000-00-00
FIRST ENROLMENT DATE
0000-00-00

TARGET SAMPLE SIZE (PHILIPPINES)
1200

ACTUAL SAMPLE SIZE (PHILIPPINES)
1156

REASON FOR THE DIFFERENCE BETWEEN TARGET & ACTUAL SAMPLE SIZES
Assumption of margin of error

DATE OF FIRST ENROLMENT
0000-00-00

KEY INCLUSION AND EXCLUSION CRITERIA (CT)

INCLUSION CRITERIA
• All 18-49 y/o women
• No other known illness
• Not taking any prolonged use of hormonal medications (e.g. contraceptive pills)

EXCLUSION CRITERIA
• Women 49 y/o
• Menopausal women
• Any Chronic illness/ Comorbidity/Pre-existing disease such as hypertension, endocrine disorder, with seizure on medications or any disease diagnosed during the study
• Women ≥45 years old,
• Menopause (≥ 12 months without menstruation)

STUDY TYPE
Observational

INTERVENTION NAME
Unspecified

INTERVENTION DESCRIPTION
Unspecified

AMENDMENT APPROVAL DATE/REASONS
<table>
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<tr>
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<th>Reason</th>
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<td>Amendments related to the protocol</td>
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<td>Informed consent</td>
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METHOD OF ALLOCATION

Randomized

MASKING / BLINDING

Double Blind

MASKING DETAILS

The medical technologist examining does not know the patient's details and likewise patients does not know details of the examiner.

ASSIGNMENT

Single

PURPOSE

This is to promote privacy of the patients and safety of their information as prescribed by the Data Privacy Act of 2012.

PHASE

Phase I/II

RESEARCH UTILIZATION

<table>
<thead>
<tr>
<th>Utilization</th>
<th>Utilization Info</th>
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<tbody>
<tr>
<td>Publication</td>
<td>Expected Output We will aim to have the following output: 1. Results/findings of environment exposure to fetal-maternal health and associations 2. Reports/publications/presentations will be done for information dissemination 3. Medical students or postgraduate students interested in research may join the team in various capacities 4. Free use and later donation of the research ultrasound machine in exchange for free utilities and no payment of pelvic ultrasound of 1,200 women during the duration of the study. 5. Patient Information that will be collected may be incorporated in a patent/biobank registry system developed in PGH if any additional future information is needed. I will use and abide by the approved 714 UP PGH Biobank Standard Operating Procedure for collecting patient information and biospecimens in the 2 component studies and in relation to the Project 2.</td>
</tr>
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<td>Oral Presentation</td>
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<td>Drug Literature</td>
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