Statement of Work
Fenton Breast Scan

I. Background

The Clinical Research Branch (CRB) conducts or oversees clinical research studies within the Division of Intramural Research (DIR), National Institute of Environmental Health Sciences (NIEHS). This study will measure various endpoints from participants in the NIEHS CRB "First Period" Study. The participants in the First Period Study will be adolescent girls that live in the areas surrounding Research Triangle Park and may or may not have per- and polyfluoroalkyl substances (PFAS) in their drinking water. Irregular cycling is a reported health effect associated with PFAS exposure in the U.S. and other countries and may be related to many later life diseases (including polycystic ovarian syndrome and breast cancer). The participants in this cohort have provided blood samples in which PFAS levels will be determined. Mammary gland development during puberty is modified by PFAS exposures in mice, but pubertal endpoints in girls exposed to PFAS have been rarely studied. After performing an online search in the local area, it was determined Department had everything need to provide the us with the data we need for this project. The objectives of this study is to use UNC School of Medicine Radiology Department and in particular Dr. Cherie Kuzmiak to interpret the Imaging. In addition UNC will collect breast scans from adolescent participants of the First Period Study, and to compare breast development, PFAS measurements, and other data collected at the NIEHS CRB.

II. Technical Requirements

Independently and not as an agent of the Government, the Contractor shall furnish all the qualified personnel, equipment, and facilities not otherwise provided by the Government. Study participants requiring breast scans will be furnished by the government.

To successfully perform the work needed, UNC must provide the following:

1. A Biomedical Research Imaging Center and an Radiology Clinical Research Service Center in which all study related procedures are conducted in adherence with ICH Good Clinical Practices and Federal Regulations.
2. Since the adolescent participants are within the Research Triangle Park (RTP) area, the contractor should be within a 40 minute radius of the RTP area. The contractor shall inform the study participants of the process that will be performed, and retain identity of all study images and evaluations of breast morphology after collection.
3. Pregnancy test kits for 25 participants. These kits must be able to provide results within 30 minutes so as not to delay performing the MRI scans.

4. Equipment needed to conduct the work: a high contrast MRI breast imager with dedicated breast coils to image the breast morphology, specifically recording dense and non-dense areas, measure fat and total adipose content, and epithelial outgrowth. UNC Radiology should have the ability to image 25 adolescent participants, w/o contrast. Breast MRIs with "T1 weighted" to sequences with and without fat saturation are required to provide strong tissue contrast between adipose and fibroglandular breast tissue with high spatial resolution.
5. Radiologist Dr. Cherie Kuzmiak will be able to read and interpret MRIs, have PET imaging expertise, quantitate three-dimensional (3D) MRI-based assessment of total breast volume, total fibroglandular tissues, identify fatty vs stromal tissue, and determine breast density using digital breast tomosynthesis, automated whole breast ultrasound, or dedicated 3D-breast computer tomography in adolescent girls.
6. A UNC research coordinator that will be responsible for patient oversight and management. Ensure images are processed, identified according to study participant IDs provided and transmitted to NIEHS CRB. The contractor shall be able to transmit the images and evaluations to the NIEHS.
7. The ability to repeat analysis twice in 1 year, approximately 6 months apart.

III. Deliverables

The contractor shall provide the following deliverables:

1. A schedule of work to be performed and a time line for said work.
2. Secure (ensuring confidentiality of participants) backup of all MRI and pregnancy test result. All raw data and interpreted results, radiologist notes, and other stored information shall be submitted in the form of spreadsheet and/or PDF as applicable.
3. The names of each participate to the Contracting Officer Representative. Identification of the participants is needed to compare with other clinical data obtained at the NIEHS CRU.
4. The radiologist shall help in interpretation of results and is expected to be a co-author on resulting manuscripts.

IV. Period of Performance

1. The Period of Performance is 07/26/2021 to 07/25/2022