

MOMI Biobank Boilerplate Text 11.25.2022

The Magee Obstetric Maternal & Infant (MOMI) Clinical Database is an electronic database comprised of all deliveries at the UPMC Magee-Womens Hospital. At present, MOMI contains over 300 variables for over 200,000 deliveries from January 1, 1995 to the present. It is populated in real time and includes data from medical records coding, admitting services, outpatient encounters, ultrasound, and other ancillary systems for all mother-infant pairs delivered at Magee. The export interface allows rapid updates of all MOMI data contained in the hospital's central data repository. Data administrators review, clean, code, and store these data. MOMI staff members perform validation studies to assess the accuracy and completeness of the data.

The **Steve N. Caritis MOMI Biobank Research Study (PI: Dr. Jeyabalan; STUDY19100240**) is approved to collect and store obstetric biological samples from the 1st, 2nd, and 3rd trimesters and from labor and delivery from consented participants. Specimens include: maternal blood, fetal blood, urine, placenta, umbilical vein and artery samples, amnion, chorion, decidua, myometrium, amniotic fluid, and adipose tissue. A unique, web-based inventory system, maintained by UPMC and called the Biospecimen Inventory and Operational System (BIOS), is used to organize the biological sample inventory and accurately links to annotated clinical data from the MOMI Clinical Database.

Facilities

Laboratory:

Magee-Womens Research Institute (MWRI): MWRI is a seven-story, 125,000 sq ft modern laboratory facility, which is home to basic and translational research, core space and conference rooms, and clinical research facilities. The facility includes research laboratories with adjacent offices for faculty, common research facilities, and cores. The proximity of the research building to the hospital is a strength for investigators as they seek to bring advancements in health care from the bench to the bedside. The MWRI will house the infrastructure needed for storing the biological samples as part of the biobank.

Clinical:

Magee Womens Hospital (MWH): MWH, with nearly 11,000 deliveries per year is one of the leading academic hospitals in the country that is totally dedicated to women's health. Outpatient enrollment for clinical trials takes place in MWH clinics and offices, the Ultrasound unit, and the offices of the Maternal-Fetal Medicine and Family Planning. In-patient recruitment occurs in the labor suite (with over 30 deliveries a day), the obstetrical triage area (with over 60 visits daily) and the antepartum wards (where daily census averages 30 pregnant women with medical or obstetrical complications). There is a dedicated biological fluid collection team in place 24 hours daily (weekdays) for collection of placentas, myometrial specimens, maternal and umbilical cord blood.

Magee Womens Hospital Clinical Research and Translational Center (MWCTRC): Clinical Research and Translational Center (CTRC): An important clinical research resource is Magee-Womens Hospital's Clinical and Translational Research Center (MWCTRC), which is funded by the University of Pittsburgh Clinical and Translational Science Award. This center supported an average of



5,693 outpatient visits annually, representing the clinical activities of 100 separate research protocols funded by the NIH or private foundations. The unit is centrally located within the hospital and is designed for patient convenience to provide a dedicated research space to investigators from the University of Pittsburgh and MWRI faculty. The main physical unit consists of exam rooms, consultation rooms, a four-bay infusion area for extended outpatient visits, and a laboratory for processing and storage of samples. The ambulatory CTRC is an ancillary site that is located within the outpatient clinic and includes two examination rooms, phlebotomy area, three consult rooms, a reception area, and work-stations for study personnel. There are experienced nurses and laboratory technicians to assist investigators with their study needs.

Magee-Womens Hospital Obstetric Specimen Procurement Unit (MWH OSPU): The OSPU is a well-established unit at MWH designed for procurement of specimens (e.g., placenta/placental biopsies, umbilical cord segments, cord blood, maternal blood and urine, subcutaneous fat) from pregnant women during the antepartum and peri-partum periods. This unit was established in 2003 and is located within the labor and delivery suite of Magee-Womens Hospital. Staffing includes onsite technicians 24 hours during weekdays and additional limited weekend coverage. Activities of the unit are supervised by a medical director and research nurse coordinator with extensive labor and delivery experience. Centrifuges, freezers (-80°C and -20°C) as well as refrigerators are located onsite for immediate processing and storage of specimens. The unit is funded by investigators' grants and by contributions from MWH and Magee-Womens Research Institute and Foundation.

Computer:

MWRI and MWH each has its own IT support team, including an IT director and two well-trained professionals. All network lines and MWRI servers are connected to UPMC servers, with direct access to all University of Pittsburgh computer services. Computers for the biobank include Microsoft Office software in addition to broadband internet access. The biobank will use the UPMC Biospecimen Inventory and Operations System (BIOS), to centralize and streamline specimen cataloging and archiving. BIOS is already used by other studies at the university including the Health Science Tissue Bank. Security is maintained on the server and workstations though the latest security patches and service packs, and each workstation is protected by a firewall.



MOMI at UPMC Hamot

MWRI research operations in Erie is located within the Magee-Womens, UPMC Hamot hospital, northwestern Pennsylvania's regional referral center for women's and pediatric specialty and subspecialty services.

Clinical:

Magee-Womens, UPMC Hamot obstetrical and gynecologic services support approximately 2,500 births and 1600 gynecologic procedures per year (2019). There is a 24-bed level three neonatal intensive care unit. The 10-room labor suite and five operating rooms are staffed with 24/7 anesthesia coverage. The operating room is fully equipped with advanced laparoscopic and robotic equipment.

Clinical services are rendered by 30 Board certified OB Gyn specialists from the University of Pittsburgh Physicians group (at the hospital-based clinic and two community offices) and a large private practice group. Subspecialty services are offered in Gynecologic Oncology, Female Pelvic Medicine and Reconstructive Surgery (Urogynecology), Maternal Fetal Medicine and Reproductive Endocrinology.

Full time research coordinator staff provide screening, enrollment and follow-up for clinical trials in the ambulatory and in-patient settings.

CTRC:

Magee-Womens UPMC Hamot Clinical and Translational Research Center (MWHamot CTRC) is situated on the 1st floor of Magee-Womens, UPMC Hamot immediately adjacent to outpatient OBGYN and Pediatric clinical offices as well as the Obstetrical Triage unit and the ObGyn Ultrasound suite. The proximity between the CTRC and sites of clinical care facilitates recruitment, retention, and follow-up of subjects in clinical studies. The CTRC contains two multipurpose interview/telemedicine/consult spaces, a reception area, and workstations for study personnel. Exam rooms, phlebotomy, and laboratory processing of biospecimens is conducted in the adjacent clinic offices. The CTRC is supported in part through grants from the Hamot Health Foundation, MWRI Foundation, and the Erie Community Foundation.

Laboratory:

Magee-Womens Hamot Obstetric Specimen Procurement Unit (MWHamot OSPU) is located on the 3rd floor of Magee-Womens UPMC Hamot, within the labor and delivery unit and in immediate proximity to the operating rooms. The 134 square foot biosafety level 2 (BSL2) laboratory is staffed on weekdays and early evenings by technicians experienced in procurement and processing of placentas, myometrium, maternal and umbilical cord blood and other tissues. Available equipment includes: centrifuges, refrigerator, -80 freezers, barcode scanner and label maker, liquid nitrogen dewar and scale. Activities of the unit are supervised by the medical director.