

# The Steve N. Caritis Magee Obstetric Maternal & Infant (MOMI) Database and Biobank

The Steve N. Caritis Magee Obstetric Maternal & Infant (MOMI) Database and Biobank is a resource for the study of normal and abnormal pregnancy. Together the MOMI Database and Biobank collect and distribute obstetric biological samples and provide linked, annotated clinical information. MOMI is a core resource of the Magee-Womens Research Institute, is affiliated with the University of Pittsburgh Medical Center, and is supported by the University of Pittsburgh Clinical and Translational Science Institute and the RK Mellon Foundation.

The MOMI 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 MOMI Database has been cited in over 40 publications.

The MOMI Biobank is approved to collect and store retrospective and prospective obstetric biological samples from the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> trimesters and from labor and delivery, including: 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 Database.

The MOMI Database and Biobank is under the direction of Dr. Janet Catov, Associate Professor of OB/GYN. It is maintained by a dedicated data administrator responsible for designing, coding, testing and supporting all MOMI updates and research requests. The Medical Director and chair of the Ethics Committee of the MOMI Biobank is Dr. Arun Jeyabalan, Associate Professor of OB/GYN, Division Chief, Maternal Fetal Medicine.

Appropriate IRB approval is required for all data and/or specimen requests, except for summary aggregate data. The full IRB protocol and IRB approval letter must be provided to the MOMI staff before request fulfillment. MOMI staff can assist with IRB submission requirements. In addition to IRB approval, MWRI conducts an internal review and approval process in collaboration with the University of Pittsburgh before request fulfillment.

If you receive MOMI data and/or specimens for a grant application or for use in a manuscript, we request the following acknowledgement: "Data and/or materials were obtained from the Steve N. Caritis MWRI Magee Obstetrical Maternal Infant (MOMI) Database and Biobank supported by the RK Mellon Foundation and the University of Pittsburgh Clinical and Translational Science Institute (5UL1 TR001857-02)."



# MOMI Database & Biobank Request Form Requestor Information

Contact information:
contact information.
Name: Click or tap here to enter text. Email: Click or tap here to enter text. Phone: Click or tap here to enter text. Address: Click or tap here to enter text.
Affiliation information (complete one):
☐ University of Pittsburgh or Magee-Womens Research Institute
Department: Click or tap here to enter text.
Requestor's status: $\square$ Faculty $\square$ Staff $\square$ Student $\square$ Other: Click or tap here to enter text.
☐ Academic Institution (not University of Pittsburgh)  Institution name: Click or tap here to enter text.
Department: Click or tap here to enter text.
Requestor's status: ☐ Faculty ☐ Staff ☐ Student ☐ Other: Click or tap here to enter text.
Collaborator at University of Pittsburgh? ☐ Yes ☐ No  If yes, name of collaborator: Click or tap here to enter text.
Collaborator's department: Click or tap here to enter text.
Collaborator's department. Chek or tap here to enter text.
☐ Company (for-profit), Non-profit, or Other Entity
Company name: Click or tap here to enter text.
Requestor's status: ☐ Researcher ☐ Staff ☐ Other: Click or tap here to enter text.
Collaborator at MWRI or University of Pittsburgh? ☐ Yes ☐ No
If yes, name of collaborator: Click or tap here to enter text.
Collaborator's department: Click or tap here to enter text.
Description of company, non-profit, or other entity and type of work. Please be specific:
Click or tap here to enter text.



# MOMI Database & Biobank Request Form Project Information

Appropriate IRB approval is required for all data and/or specimen requests except for summary aggregate data. The full IRB protocol and IRB approval letter must be provided to the MOMI staff before request fulfillment.
Purpose of sample request: ☐ Research ☐ Education ☐ Other
Project status (check all that apply): ☐ Pre-Award ☐ Awarded/Funded ☐ Active Funding agency: Click or tap here to enter text.  Award type: Click or tap here to enter text.
Project is IRB-approved: ☐ Yes ☐ No  If yes, date of IRB approval: Click or tap to enter a date.  IRB protocol number: Click or tap here to enter text.  *Include IRB approval letter and full protocol with submission of this MOMI Request Form.
Protocol title: Click or tap here to enter text.
Project short title: Click or tap here to enter text.
Project period: Start date: Click or tap to enter a date. End date: Click or tap to enter a date.



## MOMI Database & Biobank Request Form Project Information

Please provide a brief description of the aims justifying this request:

Click or tap here to enter text.

Please provide a brief description of testing that will be performed on samples:

Click or tap here to enter text.

Please provide a description of where samples will be analyzed and your plans for residuals:

Click or tap here to enter text.

### Additional information:

Click or tap here to enter text.



# MOMI Database & Biobank Request Form Request Information

Request Type:
☐ MOMI Database data only
☐ MOMI Biobank specimens only
☐ MOMI Biobank specimens with associated MOMI Database data
☐ MOMI Database data with indication of existing Biobank specimens
☐ Study recruitment services
MOMI Data:
Note that MOMI data are available 6 weeks post-delivery.
De-identified data: ☐ Yes ☐ No
Please specify study inclusion and exclusion criteria
(Ex. All singleton liveborn deliveries 2015-2018; deliveries for mothers with gestational diabetes; mothers who participate in the MOMI Biobank with preeclampsia):
Click or tap here to enter text.
Please list MOMI Database variables needed
(For the complete list of MOMI Database variables and their descriptions, please visit <a href="http://momi-data-dictionary.com">http://momi-data-dictionary.com</a> ;
reach out to the contact listed below for more information about data sources, coding, and attributions):
Click or tap here to enter text.



# MOMI Database & Biobank Request Form Request Information

Banked Specimens
The following specimens are currently banked in the MOMI Biobank. Please indicate request.
☐ Maternal Urine (indicate one or more stages at which samples were collected): ☐ 1 <sup>st</sup> Trimester ☐ 2 <sup>nd</sup> Trimester ☐ 3 <sup>rd</sup> Trimester ☐ Labor & Delivery Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.
☐ Maternal Blood (indicate one or more stages at which samples were collected): ☐ 1st Trimester ☐ 2nd Trimester ☐ 3rd Trimester ☐ Labor & Delivery ☐ Serum ☐ Plasma ☐ Buffy Coat ☐ Double Spun Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.
□ Cord Blood: □ Serum □ Plasma □ Buffy Coat □ Double Spun Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.
□ Placenta: □ RNAlater □ Snap Frozen □ Paraffin Embedded □ OCT Embedded Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.
□ Umbilical Cord: □ RNAlater □ Snap Frozen □ Paraffin Embedded Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.
☐ Amnion & Chorion: ☐ RNAlater ☐ Snap Frozen ☐ Paraffin Embedded (Membrane Roll) Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.



# MOMI Database & Biobank Request Form Request Information

<u>Prospective Specimens</u> The MOMI Biobank is approved for the collection of additional maternal and infant specimens and may consider prospective collection. Please indicate requested specimens not on previous page.
□ Requested Prospective Specimen: Click or tap here to enter text. □ 1st Trimester □ 2nd Trimester □ 3rd Trimester □ Labor & Delivery
Number of samples: Click or tap here to enter text.  Frequency and time period if requesting more than one distribution: Click or tap here to enter text.
□ Requested Prospective Specimen: Click or tap here to enter text. □ 1 <sup>st</sup> Trimester □ 2 <sup>nd</sup> Trimester □ 1 <sup>nd</sup> Trimester □ Labor & Delivery Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.
□ Requested Prospective Specimen: Click or tap here to enter text. □ 1st Trimester □ 2nd Trimester □ 3rd Trimester □ Labor & Delivery Number of samples: Click or tap here to enter text. Frequency and time period if requesting more than one distribution: Click or tap here to enter text.



THE STEVE N. CARITIS
MAGEE OBSTETRIC MATERNAL & INFANT (MOMI)
DATABASE & BIOBANK

# MOMI Database & Biobank Request Form Request Information

Please list any additional request information:

Click or tap here to enter text.



### MOMI Database & Biobank Request Form Submission Information

Along with this completed MOMI Request Form, please attach the following documents and any additional documents that are related to your MOMI Database and Biobank Request:

• Signed MOMI User Agreement

If project is IRB-approved, please include:

- IRB approval letter
- Full IRB protocol

If project is not yet IRB-approved, please include:

• Project proposal and/or project abstract

Following submission of this MOMI Request Form, MOMI staff will follow-up to address feasibility of request, assist with IRB submission requirements, and/or provide fee information.

Please submit this completed form, MOMI User Agreement, and associated documents to the contact below:

Jeannette Wellman MOMI Data Manager Phone: 412-848-7505

Email: wellmanjl2@upmc.edu

Address: Magee-Womens Research Institute

204 Craft Ave. Pittsburgh, PA 15213



# Steve N. Caritis MOMI Database and Biobank (MOMI)

### **Data and Biospecimen User Agreement**

Subject to availability, and to approval of the MWRI MOMI Bio/Data Bank Research Review Committee, the MWRI MOMI Bio/Data Bank will provide data and/or specimens to qualified investigator(s) for use in research as detailed in the research plan submitted by the investigator. The following information outlines the **responsibilities of the investigator(s) in receiving data and/or specimens**. Please review the following and return a signed copy with your application.

By submitting this application, the Principal Investigator (PI), agrees to the conditions stated below:

#### Institutional Review Board:

The recipient investigator agrees to comply with all federal and local laws, regulations and guidelines applicable to investigator use of specimens/data. A copy of approval by a qualified Institutional Review Board or qualified ethics committee, if applicable, will be required by the MWRI MOMI Bio/Data Bank before data or specimens are provided.

#### Use of Materials:

The recipient investigator agrees that all data/specimens received from the MWRI MOMI Bio/Data Bank will only be used for the designated study and by the designated individuals listed on this application. The recipient investigator will not use the specimens/data for any other purpose, without the prior written consent of the MWRI MOMI Bio/Data Bank. If a secondary use is desired, the recipient investigator will submit a new request for review and approval.

The recipient investigator will not provide the specimens/data to any third party.

After completion of your project we require that unused samples be destroyed following appropriate methods for biohazard waste disposal. Alternatively, please contact us for further instruction if you wish to return residual specimens.

#### **Handling of Specimens:**

The recipient investigator agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of specimens. The recipient investigator further agrees to indemnify and hold harmless MWRI for costs, damages or expenses resulting from the use of the specimens provided by the MOMI Bio/Data Bank.

Biological specimens are provided without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. Recipient agrees to assume full responsibility for training and informing all personnel in the dangers, including biological and microbial exposures, and procedures for safe handling of human tissue.



#### **Participant Information:**

Clinical data and specimens have been de-identified as part of their normal processing in the MWRI MOMI Bio/Data Bank. The investigator will have no access to direct identifiers associated with MWRI MOMI Bio/Data Bank participants. A unique MWRI MOMI Bio/Data Bank number will be provided to the investigator for tracking individual specimens and data. The investigator agrees to make no attempt to try to identify individual MWRI MOMI Bio/Data Bank participants.

The recipient investigator further agrees to maintain the confidentiality of the data and not share any data or biospecimens with persons not included within the applicant group noted on the application. The investigator assumes responsibility for ensuring that all research group members listed on the application are aware of confidentiality requirements and will adhere to all IRB requirements on data and biospecimen privacy and security.

### Acknowledgement:

The recipient investigator agrees to acknowledge/cite the use of Steve N. Caritis MWRI Magee Obstetric Maternal and Infant (MOMI) Database and Biobank research materials in all oral and written presentations, disclosures, or publications resulting from any use or analyses conducted using samples or data. Please use the language as specified below:

"Data and/or materials were obtained from the Steve N. Caritis MWRI Magee Obstetrical Maternal Infant (MOMI) Database and Biobank supported by the RK Mellon Foundation and the University of Pittsburgh Clinical and Translational Science Institute (5UL1 TR001857-02)."

### Payment:

The recipient investigator agrees to be responsible for all charges for the procurement, processing and distribution of the data, samples, or services requested.



MWRI MOMI Bio/Data Bank Research Review Committee Chair
neview bate. Check of tap to effect a date.
Review Date: Click or tap to enter a date.
BIOS log date: Click or tap to enter a date.
Form Received Date: Click or tap to enter a date.
For Internal Use Only:
****************
Signature Date: Click or tap to enter a date.
Signature.
Signature:
Investigator Name and Title (print): Click or tap here to enter text.
Institution or Entity Name: Click or tap here to enter text.
I, the recipient investigator, have read and agree to the terms and conditions listed above.

Signature and Date