

Human Milk Biorepository

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Disclosures

- Receive research grant funding for the study of medications and vaccines in pregnancy from
 - Amgen
 - AbbVie
 - UCB
 - Seqirus
 - Pfizer
 - Celgene
 - Bristol Myers Squibb
 - GSK
 - Janssen
 - Roche Genentech
 - Sanofi/Genzyme
 - Teva
 - Sandoz
 - Novartis

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Mother's Milk and Infant Health



CTRI and Rady Children's Establish Research-only Breast Milk Biorepository

July 28, 2014 – UC San Diego Clinical and Translational Research Institute (CTRI) and [Rady Children's Hospital-San](#)

Objectives

- To establish a national research resource to:
 - Measure levels of medications, recreational drugs, environmental exposures in breast milk
 - Evaluate differences in composition/content of milk samples based on maternal characteristics
 - e.g., oligosaccharide profiles in breast milk samples from diabetic, obese mothers vs. not
 - Examine microbiome; perform untargeted metabolomic analysis
 - Link to infant/child health outcomes

Recruitment

- Women enrolled at any time during breastfeeding
- Recruited from:
 - Newborn nurseries and NICU at UCSD/Rady Children's Hospital
 - General Pediatrics
 - Direct to consumer through social media
 - WIC
 - Blood Bank clients
 - U.S. and Canada through MotherToBaby cohort studies

Informed consent

- Breastfeeding women ages 18 and older who speak English or Spanish are eligible for participation
- Women must have sufficient breast milk supply to donate (in excess of what is required to feed their infant)
 - Minimum quantity excepted is 1mL but request is for 50mL or more
 - No requirement with respect to the age of the offspring or the duration or frequency of breastfeeding to be eligible
- Eligible women who agree to participate provide written informed consent

Informed consent: optional components

- Release of pediatric and maternal medical records at enrollment and on an annual basis thereafter
- Developmental questionnaires completed by the mother for their child up to 3 times, depending on the child's age
- Re-contact up to two times per year with information about additional approved research projects they may wish to learn more about
- Consent to use samples for genetic analyses

Data collection: maternal interviews at sample collection

- Demographics
- Pregnancy and family health history
- Mother's sleep and exercise habits
- Medications including dose and timing, substances, illnesses while breastfeeding
- Birth size, Apgar scores, infant sex, multiple birth, mode of delivery, gestational age at delivery, health problems
- Offspring adverse reactions to breastfeeding exposures

Data collection: maternal interviews at sample collection (2)

- Breastfeeding History (# of children previously breastfed and duration)
- Current breastfeeding behaviors (exclusive vs. supplemented, quantity and duration of feeding)
- Circumstances of breast milk collection

Data collection: questionnaires

Mother at time of sample collection/on-line

- NutritionQuest food frequency questionnaire
- Edinburgh Postpartum Depression Scale
- Perceived Stress Scale
- State-Trait Anxiety Inventory

Mother for child at ages 3-5m, 12-16m, 24-28m, 30-36m

- MacArthur Bates Communicative Development Inventories
- Ages and Stages Questionnaire
- Infant-Toddler Social and Emotional Assessment
- Modified Checklist for Autism in Toddlers

Milk collection methods

LOCAL

- In office visits
- Women are instructed to alcohol swab breast and areola and then pump 50mLs of breast milk with a closed system hospital grade *Medela Symphony* or *Hygeia Enjoye* breast pump and a sterile collection kit
- Women give a full expression of milk; fore-milk, hind-milk, or a combination thereof
- Samples may be stored on ice for a maximum of 3 hours prior to aliquot

Milk collection methods

NATIONAL

- Women are instructed to pump 50mL into the sterile milk collection bag provided by the repository using their own hand or electric breast pump
- Expressed breast milk must be refrigerated until pick-up from a scheduled courier and pick up must be within 24-hours of collection
- Breast milk cannot have been frozen
- Shipments made overnight to repository

Sample storage

- Once received, each sample is aliquoted into:
 - 10 1mL cryovials
 - 5 5mL centrifuge tubes
 - 1 15mL centrifuge tube
- Samples are stored long term in -80°C freezers at UCSD with sample tracking software to monitor inventory

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Asthma

Asthma-related Fact Sheets

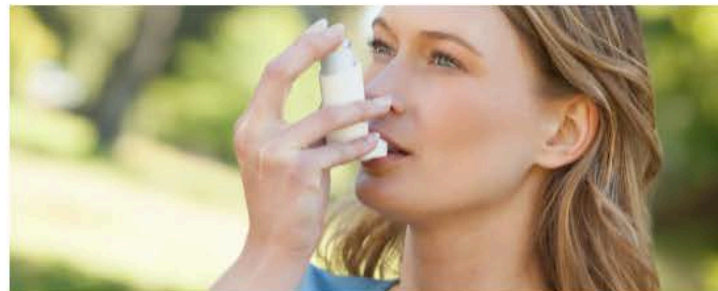
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Link to MotherToBaby Pregnancy Studies

- MotherToBaby study participants represent several thousand pregnant women throughout U.S. and Canada enrolled for exposure to a wide variety of medications and vaccines, as well as unexposed comparison women who are followed to a minimum of one year post partum

Link to MotherToBaby Pregnancy Studies

- Participants who choose to breastfeed are asked to complete a standard breastfeeding questionnaire at 2 and 6 months post partum
- Women are additionally consented to participate in the Human Milk Biorepository

Steering Committee provides oversight

- Phil Anderson, PharmD – pharmacy
- Brookie Best, PharmD - pharmacy
- Jason Sauberan, PharmD – neonatal pharmacy
- Edmund Caparelli, PharmD – clinical pediatric pharmacology
- Jae Kim, MD and Lance Prince, MD - neonatology
- Lars Bode, PhD – pediatric gastroenterology/neonatology
- Gretchen Bandoli, PhD – postdoctoral fellow

Human milk biorepository infrastructure

- Goal is to make this a resource for researchers
- Initial funding obtained to
 - Support the biorepository space, storage and sample tracking software – CTSA award
 - Develop the Velos interview database – CTSA award
 - Provide research assistance, purchase of supplies, breast pumps, shipping costs – Rady Children’s Hospital
 - Perform untargeted metabolomic analysis and microbiome analysis for first 1,000 samples – UCSD Microbiome and Microbial Science Initiative – Rob Knight Lab UCSD
 - Develop assays for target exposures – UCSD Skaggs School of Pharmacy and Pharmaceutical Sciences

Website: www.mommymilkresearch.org



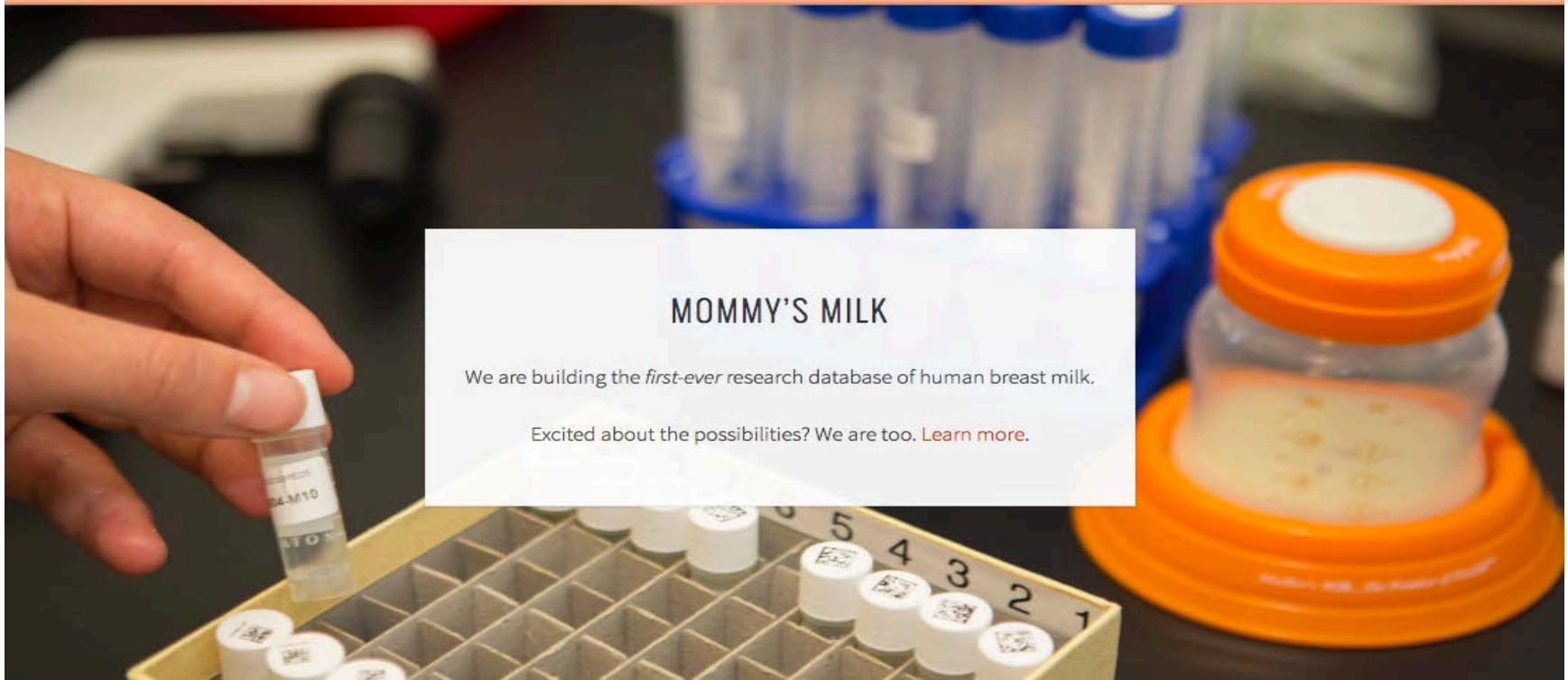
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HUMAN MILK RESEARCH BIOREPOSITORY

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We are building the *first-ever* research database of human breast milk.

Excited about the possibilities? We are too. [Learn more.](#)



Long term goals

- Maintain a constant, rotating inventory of well-characterized general samples and
- Additional inventory incorporated for purposeful studies as these are designed and received ethics approval
- To modify sample collection protocols to meet evolving guidance for lactation studies
- To contribute to knowledge regarding drug safety in lactation