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
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 Diego announce the establishment of a research-only breast milk biorepository. This initiative aims to support a wide range of research projects focused on understanding the role of breast milk in infant health and development.
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
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.
• 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.mommysmilkresearch.org

MOMMY’S MILK

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