

The Development of a Research Human Milk Bank

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Abstract

Although there are well-established clinical human milk banks in the United States, there are no milk banks specifically intended to foster research on human milk. The authors' goal was to establish a milk bank with a core data set to support exploratory and hypothesis-driven studies on human milk. Donations to the Cincinnati Children's Research Human Milk Bank are accepted within the context of ongoing, hypothesis-driven research or on an ad hoc basis. Donors must give informed consent, and scientists wishing to use the samples must have Institutional review board approval for their use. Development of more research human milk banks can potentially provide resources for multidisciplinary collaboration and advance the study of human milk and lactation. *J Hum Lact.* 21(1):59-66.

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For many years, there have been donor human milk banks in the United States and elsewhere for the purpose of feeding human milk to infants. The first descriptions about how to build and operate a "Mother's Milk Bureau" were published in the early 20th century.¹⁻⁴ Since then, donor milk banks have evolved to meet the changing needs of mothers and children. Currently, all North American donor milk banks operate under the guidelines of the Human Milk Banking Association of

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Table 1. Design Elements for a Research Human Milk Bank

<i>Necessary Element</i>	<i>Procedures of Cincinnati Children's Research Human Milk Bank</i>
Institutional review board (IRB)-approved recruitment methods IRB-approved consent process	Ad hoc donors and participants in hypothesis-driven studies Written consent to use sample and data for future research and permission to recontact
Standardized milk collection	Morning collection, entire contents of 1 breast, electric breast pump, at predefined stage(s) of lactation
Core data set and data management system	Standardized data collection on mothers: health and perinatal history, prepartum and postpartum body mass index, environmental chemical exposure history, dietary history Standardized data collection on infants: gestational age at birth, birth growth parameters, congenital and medical conditions
Sample storage procedures	Aliquoting to 2-mL vials to minimize freeze-thaw effects; storage in cryogenic freezer using bar-code labels
Scientific protocol development and approval	Each new scientific use requires protocol development, reviewed for scientific merit by director and committee of research human milk bank and approval by IRB

North America (HMBANA), which has instituted standards for collecting, screening, processing, and distributing donated human milk to meet the specific medical needs of individuals for whom it is prescribed.⁵ Milk banks primarily serve the needs of sick preterm infants but also are used for pediatric conditions such as failure to thrive, severe allergies, metabolic disorders, immunodeficiencies, renal failure, and various congenital conditions.⁶⁻¹⁰ In recent years, donor human milk banks have demonstrated remarkable growth,¹¹ as clinicians have come to value the importance of banked human milk not only as a nutritional option but also as a potentially life-saving therapy. While donor milk banks have increasingly contributed to scientific research on human milk,¹²⁻²¹ these banks are designed for clinical use and do not fully meet requirements that are distinct to research (Table 1). Laboratory scientists have historically established their own research milk banks through informal donations of milk from lactating women or "leftover" milk that was not fed to infants in the hospital setting, but like clinical banks, they have typically lacked standardized collection of milk and information or written, informed consent from the mother to use her milk for research purposes. Cohort studies have been conducted with standardized data and milk collection, but the samples are designated for specific purposes and may not be available as a core resource for other research purposes.²²⁻²⁵

The following serves as an overview of the development of the Cincinnati Children's Research Human Milk Bank (RHMB). We wanted to establish a human milk bank that would be in full compliance with

research regulatory requirements and provide an ongoing resource for interdisciplinary research on human milk. While other facilities may have requirements specific to their home institution, many of the aspects of developing a research bank, including the approach to collecting samples, start-up costs, regulatory hurdles, data collection strategies, personnel training, and the like, may be similar to those that we have encountered. Our experience may assist researchers in other institutions who may be thinking about starting a similar repository.

Establishing an RHMB

In 2002, we initiated development of the Cincinnati Children's RHMB. Consistent with the goals of the Human Milk Research Program and the Translational Research Initiative at Cincinnati Children's Hospital Medical Center, the mission of our research milk bank is to further the scientific understanding of human milk and lactation by facilitating a productive partnership between clinical and basic scientists. Our goals are to further knowledge of bioactive factors in human milk, involve scientists and trainees from many disciplines, test novel hypotheses, and advance the translation of research on human milk to clinical applications. To stimulate interdisciplinary research with basic scientists, we identified the need for banked samples associated with a core data set that provides useful clinical characterization of the mothers. After consultation with the institutional review board (IRB), potential collaborators, and investigators who had established other

Table 2. Participation in the Research Human Milk Bank (as of November 15, 2004)

<i>Study Description</i>	<i>No. of Participants</i>	<i>No. Consented to Have Milk and Data Set Information Stored Within the Research Human Milk Bank</i>	<i>No. Consented to Be Recontacted</i>
Ad hoc collection	35	35	35
Cincinnati Breastfeeding Cohort	29	29	29
Study of Breastfeeding and Allergy	42	41	40

forms of research banks, we submitted protocols and developed appropriate written consent processes for the research bank, which were approved by Cincinnati Children's IRB. The overall requirements of the RHMB are summarized in Table 1.

IRB Approval and the Informed Consent Process

Collection and testing of human milk for research purposes requires approval by federally mandated IRBs and, typically, signed consent by the donor mother. The federal regulations governing IRBs and human research obligates investigators to submit a protocol, account for subject consent procedures, and restrict use of the research data and samples to the study's original purpose, as stated in the approved protocol and subject consent form. Should novel hypotheses arise that are not covered by the originally approved protocol and mother's consent, use of her data and stored milk samples for new purposes must be again reviewed and approved by the sponsoring IRB, and if donor consent for use of her data and samples for these novel purposes is lacking, such IRB approval is not guaranteed. Thus, in the current regulatory era, having stored milk samples from donors is not equivalent to having a research bank in which samples can be freely used for future hypothesis testing.

We developed 2 different models of inclusion of mothers' milk in our research bank, each of which has its own IRB-approved protocol and consent process. The first model involves a general collection approach, taking the milk of any mother willing to donate to the bank. The second model involves inclusion of milk samples from lactating mothers enrolled in ongoing, hypothesis-driven studies, with the approval and written consent of study participants. These samples are collected in a standardized way, as is the core data set. We discuss both models below, with emphasis on model 2, which provides standardized milk and data collection.

Model 1: Ad hoc Collection of Human Milk

To establish the bank, we developed an IRB-approved protocol for the collection of donor milk from mothers of infants in Cincinnati Children's neonatal intensive care unit who had milk not needed by their own infants, women in the community, and employees who were breastfeeding. This was a rather straightforward process since we requested very little information about women donating these samples, other than the gestational age of the infant at birth, the postpartum day of milk expression, and whether the milk was fresh or frozen at time of donation. Donors sign a basic consent form, providing permission to have their milk used for research purposes that are not known at the time of collection. In cases in which milk is left after an infant either has been discharged or has died, current protocol is for one of the neonatal intensive care unit staff to call the mothers to obtain phone consent for the use of these samples.

This IRB approval allows us to advertise for donors through flyers, word of mouth, and other local media. News coverage early in the development of the RHMB attracted donations from women in the community who brought us samples. From this ad hoc collection approach, we rapidly acquired large quantities of milk but could not establish standardized milk collection. The value of this approach has been to supply scientists with samples appropriate for refining assays, defining methodology, and exploratory research such as initial detection of factors not previously known to be in human milk and preliminary estimation of the concentration of specific bioactive factors in human milk. Because of a surplus of such ad hoc donations, we are not advertising at present and are taking only a limited volume of milk (approximately 60 mL) from mothers who contact us and express interest in donating to the bank. Mothers who contact us because they have a large volume of stored milk at home and wish to donate it are provided with HMBANA's list of donor milk banks and are encouraged to call the banks directly. To date, we

have had 35 mothers contact us to donate milk to the RHMB (Table 2).

Model 2: Standardized Collection of Human Milk From Donors Enrolled in Hypothesis-Driven Studies

At present, this is the primary mechanism by which contributions are made to the bank. We have 2 active protocols for hypothesis-driven studies that contribute to this bank and 1 more protocol in development. The 2 active protocols are (1) characterization of human milk oligosaccharides over the course of lactation in mothers of term infants and (2) comparison of human milk cytokines and infant peripheral cytokines in breastfeeding mothers with and without a history of allergic asthma. Active protocol 1 has enrolled 29 mothers to date and involves milk collection weekly in the first month and monthly thereafter. Active protocol 2 has enrolled 42 lactating mothers to date and involves collection of a single milk sample at 4 weeks postpartum (Table 2). The protocol in development is a cross-sectional characterization of the maternal milk of premature infants in neonatal intensive care. We worked with our IRB to discern the best way for mothers to not only consent to the originally intended study but also provide consent to have their milk and data stored and potentially used as part of the RHMB. We also wanted to ensure that we had permission to contact mothers again in case more information was required than was originally collected. Nearly every mother who has been a participant in one of our human milk studies has also been willing to donate her extra milk to the bank. Figure 1 provides an excerpt of the consent form that allows human milk samples and subject data to be processed and stored within the RHMB. For this method, that is, collecting samples in conjunction with specific studies, maternal consent is part of the originally intended study, and the mother is further asked for consent to have samples placed in the milk bank.

Mothers who donate to the RHMB frequently tell us the pleasure they feel in being able to contribute to scientific pursuits regarding human milk and breastfeeding. All mothers who donate to the bank must be at least 18 years of age, have no postpartum medical complications, and have sufficient milk supply so that taking 1 milk sample from the mother would not compromise the infant's health. Infants must not have medical complications that preclude breastfeeding. For our ad hoc donations, we do not offer any payment. For the clini-

cally characterized sample collection model, mothers are compensated via the originally intended study, not by the RHMB per se.

Standardized Milk Collection

To ensure uniformity of sample and data collection within our bank, we developed standardized collection procedures. We visit the mother between 10 AM and noon, and collect the entire contents of 1 breast by using an electric breast pump.

At the time of the mother's first milk collection, one of our trained research nurses meets with the mother, usually at the mother's home, to review with her the consent process and collection protocol. Mothers are asked not to feed their infant on the anticipated side of collection for at least 2 hours. Following procedures designed to minimize both bacterial and environmental contamination, the mother is asked to begin by cleansing her nipple in a circular fashion with a sterile, chemical-free wipe. The research nurse hands the mother the pre-assembled pump kit with the tubing attached. The mother then places the pump kit over her nipple. The electric pump is turned on at a minimal setting and advanced according to the mother's comfort. The pump is left on for approximately 15 minutes or until there is no more milk left to be expressed. At the conclusion of the pumping, the research nurse carefully places the lids on the bottles in which the milk was collected and places the collection bottles in a cooler containing a refrigerator pack. For some studies, particularly in which enzymatic activity of the milk can potentially affect analysis, the research nurse adds certain reagents to an aliquot of the milk sample at the mother's home. The research nurse completes an information sheet that records the circumstances in which the sample was collected including time of day, the last time the infant fed, the use of the left or right breast, the amount of milk collected, the storage vesicle, and any reagents added to a sample of milk.

The samples are brought as soon after collection as possible to the RHMB on the campus of Cincinnati Children's for processing. Once delivered to the laboratory, fresh milk is placed in a refrigerator. The milk bank coordinator then transfers the information about the sample into the database, aliquots the milk, and, if requested, distributes aliquots that day to the proper laboratories awaiting the specimens and freezes the remaining volume at -70°C . Laboratory protocols for

Table 3. Basic Supplies to Start a Research Human Milk Bank

Lab-grade refrigerator for short-term storage
–70°C freezer for long-term storage
Transfer pipettes
Freezer racks
Cryogenic tubes (we store all samples in 2- or 4-mL tubes)
Storage boxes for cryogenic tubes
Bar-coding software
Computer in which to maintain database (we use a laptop)
Cryogenic labels
Cryogenic indelible markers
Printer that accommodates cryogenic labels and is compatible with bar-coding system
Aliquoting materials including transfer pipettes
Duplicating costs, mainly for consent forms
Office supplies to maintain all paperwork in secured location
If donors are collecting milk samples at home, the RHMB must supply the following:
Electric breast pump (we had 2 donated from Medela, Inc)
Breast pump kits
Breast shields
Storage and transport receptacles for breast milk
Sealed plastic bags for transport of receptacles containing milk samples
Travel vehicle for picking up samples

most of our ongoing investigations require only a small volume of milk (less than 1 mL) compared to the amount mothers typically provide from a single collection (60 to 120 mL). To minimize the number of freeze-thaw occasions, all samples are stored in 2- or 4-mL vials in preparation for future distribution.

Core Dataset

In our hypothesis-driven studies, we have included a core set of questions regarding demographic characteristics, a brief medical history of the mother and her infant, perinatal history (including length of pregnancy), medication use, environmental exposures to chemical contaminants, and any difficulties with lactation at the time of collection. Maternal age, height, and weight are also recorded. These core items provide a standardized data set across different hypothesis-driven studies.

Study Personnel and Equipment

The personnel currently involved in the RHMB include a full-time nurse coordinator and, on a part-time basis, faculty, a laboratory technician to assist with sample management, and data management staff (R.A.) to provide database design and a system of information management. The coordinator of the milk bank is a nurse lactation consultant (B.S.D.) who has substantial working knowledge of laboratory protocol and proce-

dures. She is adept in sample management, using the computerized tracking system, managing the refrigerators and freezers, ordering appropriate supplies, and other tasks. She has a functional relationship with representatives from all of the collaborating laboratories and keeps track of the requests, collection procedures, milk volumes, and processing required for each collaborating laboratory. The coordinator also understands and ensures that the clinical research regulatory requirements of the RHMB are met, including maintaining active IRB approval status. The RHMB is overseen by faculty with distinct roles. The scientific director (A.L.M.) oversees the design of the bank, develops and reviews research protocols and procedures, and facilitates the exchange of scientific ideas among groups. The medical director (S.R.G.) addresses clinical lactation questions that can arise from donors, maintains contact with breastfeeding groups and lactation consultants, and is involved in the recruitment of donors.

In 2002, we spent approximately US \$20,000 in start-up equipment costs. While costs may vary depending on timing, location, manufacturers, and added features, we list the basic equipment required to initiate the bank in Table 3.

Database Setup

Although there are many options for software and database development, the characteristics of the data-

Witnessing and Signatures

I have read the information given above. The investigator and/or her designee have personally discussed with me the study [specific study to which the mother is consenting] and have answered my questions. I am aware that, like in any research, the investigators cannot always predict what may happen or may possibly go wrong. I have been given enough time to consider if I (or my child and I) should participate in this study. I hereby consent to take part in this study as a research study subject.

Participant signature: _____ Date: _____

There may be times when I provide more milk than is actually required for the study titled [specific study to which the mother is consenting]. I have been informed about the opportunity to have my extra milk stored within Cincinnati Children's Research Human Milk Bank for use in other studies related to the biologic factors in human milk. I am aware that I will not know for which studies my milk may be used nor the results of any of these studies. If I do have extra milk, I consent to the following:

Yes	No	
☐	☐	My extra milk may be saved indefinitely and used for future studies on human milk.
☐	☐	The information that I provide for this study may be used for future studies on human milk.
☐	☐	I give permission to be contacted by the personnel of the Research Human Milk Bank if more information is needed for future studies that include my breast milk.

Participant signature: _____ Date: _____

Figure 1. Research human milk bank consent form (excerpt).

tracking system that we use has several distinct, necessary features. Our database was created in Microsoft Access and consists of relational tables linked by a key subject identification number. When a subject consents to be a part of the RHMB, her demographic information is entered into the database. At that time, a unique donor identification number is automatically generated for the subject and is used to link to additional information about the subject and samples. The demographic sections also allow for tracking multiple informed consents, whether a subject is part of ongoing research projects, and whether the subject agrees to be contacted in the future. It also tracks whether a subject withdraws consent at any time. Once a subject is entered into the database and a unique identification number has been created, each donated sample is logged into the database. Donor identification number, aliquot identification number, date of sample collection, date of milk expression, method of milk expression, stage of lactation, volume of sample, and location of sample is then entered into a sample-type specific table. The bar-code system records when samples are removed from the bank, but information about each sample always remains in the database.

Funding/Ongoing Sustainability

The initial start-up costs for our bank totaled approximately US \$20,000 in equipment, not including personnel costs covered by other grant funding. Our initial start-up funding was from several sources. We used funds from a private donor to purchase our refrigerator and freezer. Medela, Inc supplied the RHMB with 2 breast pumps. The scientific director and nurse coordinator's salary is supported in part by funding from the National Institutes of Health (NICHD HD 13021). The majority of the start-up and second-year renewal costs were supported by a grant awarded from Cincinnati Children's Research Foundation Translational Research Initiative. Operational costs for the RHMB are currently rolled into other awarded and pending grants.

Scientific Application of the RHMB

In addition to providing ideal infant nutrition, human milk contains multiple bioactive agents, including anti-infective factors, anti-inflammatory factors, immunomodulatory factors, hormones, and multifunctional agents that affect the health and development of the

breastfed infant. Research on human milk provides the opportunity to understand the mechanisms by which the breastfeeding mother protects her infant. Such research has the potential to contribute important new insights regarding the uniqueness and efficacy of human milk and the role of breastfeeding in infant development while also identifying novel mechanisms for disease prevention and treatment.

Although in its early stages of development, the research bank has begun to stimulate and support novel research with clinical and laboratory-based scientists in immunobiology, infectious disease, endocrinology, and environmental health. In immunobiology and infectious disease, the bank is supporting research on the longitudinal pattern of expression in human milk of protective immune factors, including oligosaccharides, cytokines, and β -defensins; anti-inflammatory factors/antioxidants; and the diversity of strains of cytomegalovirus (CMV) recovered from human milk and the effects of freezing on CMV.²⁶ In endocrinology, we have assayed samples from the bank and are the first to report the presence in human milk of adiponectin. Adiponectin is a major adipokine that may have an important role in early metabolic regulation.²⁷ We have a collaboration with the Cincinnati Children's Environmental Health Center and with the Centers for Disease Control and Prevention, and we plan to use milk samples in the bank to examine the expression of major environmental contaminants in the milk of Cincinnati women.

For every newly proposed use of samples and data from the RHMB, a brief addendum protocol is submitted to the IRB. We collaborate with laboratory-based investigators in this process to clearly specify the scientific aims and hypotheses of the proposed study, the number of subjects and samples required, and the justification for the research.

Conclusions

The RHMB at Cincinnati Children's is less than 2 years old but has begun to help realize our goal of stimulating interdisciplinary research on bioactive factors in human milk. The establishment of the Cincinnati Children's RHMB has created collaborative opportunities among investigators and increased the potential to attract research funding to advance understanding of human milk constituents in relation to infant health outcomes. We are currently in the second year of operation and are working with a variety of laboratories. This

year, we are expanding the milk bank to include the milk and data of mothers of preterm infants in the neonatal intensive care unit. We aim to continue development of the RHMB to further the understanding of the biologic properties of human milk by facilitating interdisciplinary partnership between clinical and bench researchers. Development of RHMBs does not provide support for all research questions that investigators can and should ask. But this development provides a potentially useful resource to stimulate and support initial collaborations and help to advance the study of human milk and lactation.

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