

Hospital Donor Milk Implementation Toolkit

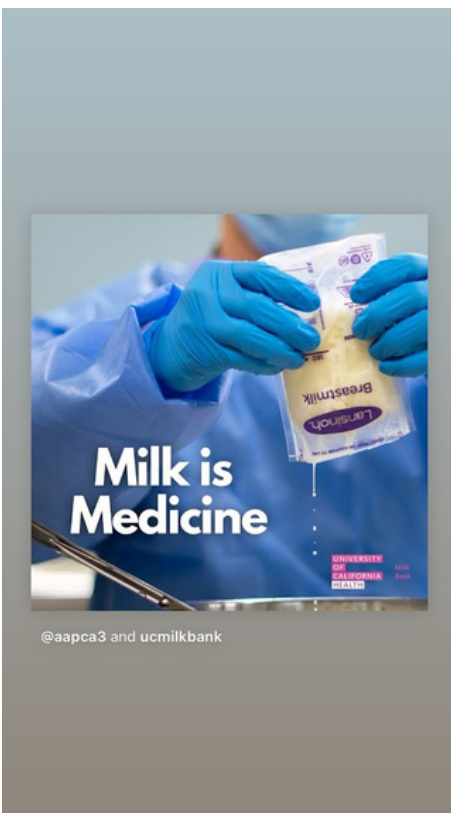


The American Academy of Pediatrics states that human milk is the optimal nutrition for very low birthweight (VLBW) infants and decreases the risk of significant complications of prematurity, most notably Necrotizing Enterocolitis (NEC). Donor milk feeding is recommended when birth parent's own milk is not available, is insufficient, or is contraindicated. The goal is an all-human milk diet (exclusive of fortifier) for VLBW infants until about 34-36 week corrected gestational age.

The aim of this document is to provide healthcare staff with tools they can use to implement a donor milk program in their hospital. The provision of pasteurized donor human milk (PDHM) in the NICU is a cost-effective strategy to improve VLBW outcomes, reduce inequities in human milk feeding, increase birth parents' own milk provision, and reduce liability to the hospital.

The authors of this toolkit ardently believe that all families and infants deserve quality, equitable, compassionate medical care. This toolkit was created to be implemented in California but is applicable to all states. Please utilize this toolkit to develop materials that appropriate for your institution.

Included in the Toolkit



1. First Steps to a Hospital Donor Milk Program
2. The Business Case for Donor Milk
3. HMBANA Resources
4. Sample Donor Milk Policy
5. Sample Donor Milk Consent
6. Additional Considerations
7. Sample Donor Breastmilk Handout
8. Sample Small Baby Feeding Plan
9. Staff Education
10. HMBANA Donate Milk Flyer

First Steps to a Hospital Donor Milk Program

First steps in constructing a donor milk program

1. Determine where to purchase donor milk; [find your local milk bank](#).
2. Develop criteria for donor milk provision at your institution.
3. Review and modify your infant feeding and milk handling/preparation guidelines to include donor milk.
4. Create a process to receive, log, and track delivered frozen donor milk, including documentation of temperature and condition on arrival.
5. Develop a patient consent process: documented verbal consent after education vs. written consent form that can double as patient education.
6. Consider how the new workflows can be integrated with your current EMR.
7. Provide staff education and consistent messaging to families to improve adoption of the new practice.
8. Refer to human milk handling best practices to construct your policies:
 - [AAP Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant](#)
 - [Best Practice for Expressing, Storing, and Handling Human Milk in Hospitals, Homes, and Childcare Settings](#)
 - [Guidelines for Preparation of Human Milk and Formula in Health Care Facilities](#)

About HMBANA

The Human Milk Bank Association of North America (HMBANA) is a nonprofit organization of 30+ nonprofit milk banks with an impeccable safety record. All HMBANA milk banks adhere to strict standards set by FDA and HMBANA and are accredited yearly. Donors give milk without compensation and are carefully screened (like blood donation). All milk is pasteurized and provided, at cost, to hospitals to feed infants when mothers' own milk is not available or sufficient. HMBANA milk banks provided 10 million ounces of high quality, safe donor milk to hospitals and families in 2023 and have a robust supply to meet the needs of NICUs.

Find a milk bank near you at hmbana.org to order donor milk and learn more.



100% NICU 100% CALIFORNIA

EQUITABLE DONOR MILK ACCESS

Background

- Necrotizing Enterocolitis (NEC) occurs in **7%** of VLBW infants
- NEC may lead to compromised or dead bowel, sepsis, major surgery, short gut syndrome, death, and neurodevelopmental impacts in survivors
- For VLBW infants, mothers' own milk and donor milk provide the most protection against NEC, while formula does not provide any protection and can increase the risk of NEC
- Most mothers express milk for their infant but 80% will need some extra milk during their long hospital stay
- The cost of donor milk is less than \$5 per ounce
- Surgical NEC adds 50 days to baby's NICU stay and adds 36 days on the ventilator
- The economic burden of NEC amounts to 20% of the total cost of the initial care of all newborns in the US and represents approximately \$5 billion spent annually on NEC.

CHALLENGE

Although the American Academy of Pediatrics states that human milk is the optimal nutrition for Very Low Birth Weight (VLBW) infants and decreases the risk of significant complications of prematurity, most notably NEC, the NICU does not have donor milk available for these vulnerable infants.

SOLUTION

The creation of a donor milk program at the hospital in conjunction with lactation support, will increase mothers' own milk supply and allow for pasteurized donor milk use when mother's own milk is not available, is insufficient, or is contraindicated.

BENEFITS

1

Protection from NEC

Mothers' own milk and donor milk provide the best protection for VLBW infants against necrotizing enterocolitis

2

Cost Effective

Strategy to provide optimal nutrition and decrease morbidities and potential life long complications from NEC can save money and lives.

3

Equitable Access

Availability of donor milk in the NICU reduces inequities in human milk feeding and increases mothers' own milk provision

4

Decreased Liability

A donor milk program aligns practice with recommendations and protects the hospital from liability

Jump Start the Implementation of Pasteurized Donor Human Milk in your Hospital

Resource Links

[Academy of Breastfeeding Medicine](#)
[American Academy of Pediatrics](#)
[American Nutrition and Dietetics](#)
[American Essential Hospitals - Use of Donor Human Milk](#)
[Baby Friendly NICU Toolkit](#)
[Center for Disease Control](#)
[HMBANA Equitable Access to Donor Milk Blueprint](#)
[Neonatal Quality Improvement Collaborative of Massachusetts - neoQIC](#)
[NEC Society](#)
[PATH](#)
[The Joint Commission](#)
[UCSD SPIN Program](#)
[UCSF NICU Toolkits](#)
[United States Breastfeeding Committee](#)
[WHO - World Health Organization](#)

Current Recommendations for PDHM Use

[Surgeon General Call to Action \(2011\)](#)

[AAP Donor Milk Policy \(2017\)](#)

[AAP Breastfeeding and the Use of Human Milk \(2022\)](#)

[AAP Human Milk and VLBW \(2021\)](#)

[AAP/ACOG Guidelines for Perinatal Care \(2017\)](#)

[AAP Pediatric Nutrition \(2020\)](#)

[HHS Dietary Guidelines \(2025\)](#)

[AAP Red Book \(2021\)](#)



Find your nearest **HMBANA** milk bank
Adapted from [UC Health Milk Bank](#)

SAMPLE HOSPITAL POLICY: PASTEURIZED DONOR HUMAN MILK

(Information that is italicized may differ hospital to hospital)

Policy Statement

Infants receive improved nutrition and immunologic protection from breastmilk. For the very low birth weight infant (VLBW), human milk provides the most protection against Necrotizing Enterocolitis (NEC). Not all mothers are able to provide breastmilk for their infant due to physiologic instability, maternal medications, inadequate production to meet infant need, or surrogacy. Pasteurized Donor Human Milk (PDHM) may be used as an alternative in certain circumstances when mother's breastmilk is not available or insufficient.

The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of PDHM.

Related Policies

List related policies here

Definitions

DTR: Dietetic Technician, Registered

EMR: Electronic Medical Record

HMBANA: Human Milk Banking Association of North America

NICU: Neonatal Intensive Care Unit

PDHM: pasteurized donor human milk (from a licensed milk bank)

Policy

1. The *NICU nurse manager* or designee is responsible for overseeing the acquisition, receipt, storage, and issuance of PDHM in the hospital.
2. Informed consent/assent is required from the parent/guardian for the infant to receive PDHM. *Consent/assent can be written or verbal.* This can be done prenatally or after delivery.
3. PDHM will be obtained from a milk bank that is accredited or licensed, and is registered with the US Food and Drug Administration (FDA) as a food facility.
4. An active feeding order is needed prior to feeding PDHM.

5. PDHM should be received and tracked by a milk management/administration system or other paper tracking system.

Criteria for Pasteurized Donor Human Milk Use

1. Infants are eligible for PDHM if they meet certain criteria. For some infants PDHM is more critical based on their medical condition. Priority will be given to infants with medical indications.
2. The following conditions are medical indications for initiation and continuation of PDHM if maternal breastmilk is not available at any time during hospital stay:
 - a. Gestational age at birth \leq 34 weeks
 - b. Birth weight \leq 1500 grams
 - c. Infants with history of bowel injury or compromise such as gastroschisis, necrotizing enterocolitis (NEC), atresia or short bowel syndrome
 - d. Duct dependent critical congenital heart disease
 - e. Other medical conditions at the discretion of the Attending Physician
3. At 34 weeks, if maternal milk is not available, the medical staff will gradually transition the infant to the appropriate infant formula. However, the provider, in collaboration with the interdisciplinary team and patient's family, may extend the use of PDHM if warranted.
4. *Infants > 32weeks may receive PDHM with the plan to transition to maternal milk within 5 days from initiation of usage.*

PDHM Storage and Handling

1. PDHM will be received from the milk bank in a frozen state with documented cold chain verification. On arrival, PDHM will be inspected and the following documented:
 - a. Date/time of delivery
 - b. Quantity of bottles received
 - c. Lot number(s) received in shipment
 - d. Expiration date
 - e. WarmMark verification (cold chain verification)
 - f. Product is inspected and documented (yes/no):
 - i. Bottle intact in satisfactory condition
 - ii. PDHM in a frozen state
2. Store and handle PDHM per policy *Breastmilk Collection, Storage, and Preparation* policy except where differences are noted in this policy.

- a. The hospital continuously monitors the temperature of refrigerators, freezers, and other storage equipment.
 - b. Daily records are maintained of controlled environment temperatures.
3. PDHM can be thawed and stored in refrigerator for 48 hours. PDHM that is fortified expires after 24 hours.
 4. PDHM that has been offered for a feed but not completely consumed can be refrigerated and offered for the next feeding. Discard if not consumed within 6 hours.

PDHM Administration

1. Obtain consent/assent for PDHM use from the parent and provide the opportunity to ask questions and/or refuse the use of donor milk. Document consent/assent in infant's EMR.
2. Provider to place PDHM order. RN to verify PDHM order.
3. Trace and document PDHM use: receipt, storage, preparation, administration and disposal. This includes the dates, times, and staff involved when PDHM is accepted, prepared, and administered. When PDHM is fed to an infant, the unique bottle number will be recorded in their electronic medical record.
 - a. The hospital retains PDHM records for minimum of 10 years beyond the date of disposition or expiration (whichever is latest).

Misadministration/Adverse Events

1. In the case of an adverse reaction or misadministration of PDHM, the reaction will be reported promptly through the *adverse event reporting system* as well as to the source facility.
 - a. All associated batch(es) of PDHM with compromised integrity or suspected cause of adverse reaction will be sequestered.
2. In the case of misadministration (PDHM given without consent), the *charge nurse* should ensure that they themselves or the nurse involved with the error contacts:
 - a. The provider (NNP, Fellow or Pediatric Hospitalist) and the Attending Physician responsible for the care of the recipient infant.
 - b. The administrative nurse on duty or on call if after hours or weekend
 - c. Ensure an *adverse event report* is filed and Risk Management notification is marked in the report.
3. The Attending physician of the recipient infant will inform the recipient parent/guardian about the PDHM misadministration and discuss the extremely low risk of

infection/transmission due to pasteurization. If requested by parents, the provider will contact the milk bank where the PDHM was obtained for records of testing of the PDHM.

4. In the case of an adverse event to the PDHM, this will be promptly reported through the *adverse event reporting system*.
 - a. The Attending provider will then notify the infants' parents/guardians of the event and provide a basic explanation of the need for testing and order testing/labs as appropriate.
 - a. The Attending physician of the recipient infant will follow up on all testing and communicate the results to the parents/guardians as well as the directors of *Lifesharing* and Risk Management.
 - b. Documentation of the adverse event, the final reports and all documentation about the notification process must be made part of the infants' health record.

Recall

1. In the event of a recall, all PDHM bottles from the recalled batch will be sequestered and an *adverse event reporting system* will be generated. The director of *Lifesharing* and Risk Management will be notified.
2. A feeding history report will be generated to determine if any infants received PDHM from the recalled batch.
3. The medical team will be notified of the infants affected by the recall. The Attending provider will then notify the infants' guardians of the recall and provide a basic explanation of the need for testing and order testing as appropriate.
 - a. The Attending physician of the recipient infant will follow up on all testing and communicate the results to the guardians and health system leadership

References

AAP COMMITTEE ON NUTRITION, AAP SECTION ON BREASTFEEDING, AAP COMMITTEE ON FETUS AND NEWBORN. Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States. *Pediatrics*. 2017; 139(1): e20163440.

Parker MG, Stellwagen LM, Noble L, et al; AAP Section on Breastfeeding, Committee on Nutrition, Committee on Fetus and Newborn. Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant. *Pediatrics*. 2021;148(5):e2021054272

Mills KI, Kim JH et al. Nutritional Considerations for the Neonate With Congenital Heart Disease. *Pediatrics* (2022) 150 (Supplement 2): e2022056415G.

Human Milk Banking Association of North America (2019) Best Practices for Expressing, Storing and Handling of Human Milk in Hospitals, Homes and Childcare Settings. 4th edition. Raleigh, NC HMBANA.

“Infant Feedings: Guideline for Preparation of Human Milk & Formula in Health Care Facilities,” (2019) Pediatric Nutrition Practice Group of the American Dietetic Association. 3rd edition.

Steele C (2018) Best Practices for Handling and Administration of Expressed Human Milk and Donor Human Milk for Hospitalized Preterm Infants. *Front. Nutr.* 5:76.

Additional Considerations to Developing a Hospital Donor Milk Program

Human Milk Handling Best Practices

- Best Practice for Expressing, Storing, and Handling Human Milk in Hospitals, Homes, and Childcare Settings
- Guidelines for Preparation of Human Milk and Formula in Health Care Facilities

Donor Milk Management

Ordering Process

- Who will place the donor milk order?
- Will it go through hospital procurement?
- Frequency of orders? Once a week? Once a month?

Inventory Management (allow time for ordering processing, and shipping)

- How much freezer space is there for donor milk?
- Who will track inventory?
- Who will receive the milk shipment and place in inventory?

Temperature verification

- Who does the daily temperature checks on freezers?
- Electronic vs manual monitoring?
- How will it be logged daily?
- Who responds if a freezer is out of range?

Milk tracking in the hospital

- Do you have an electronic milk tracking system?
- Does your EMR allow milk tracking?
- Does your milk bank use labels your system can read?
- Labels should include product, expiration date, and nutritional content
- Ideally, label should be scannable to track milk to baby

Additional Considerations to Developing a Hospital Donor Milk Program

Milk misadministration

- Create a donor milk misadministration policy
- What happens if donor milk is given to infant whose family did not consent?

Recall

- Create a donor milk recall policy
- Be able to trace milk given to infant, back to batch, back to milk bank and donors
- Yearly mock recall

Retention or records

- Donor milk records should be retained for 10 years

Donor Milk Preparation

Milk lab logistics

- Who will prepare the milk? Milk tech, nursing, lactation?
- Where will milk be prepared?
- What additional information does the staff need to prepare donor milk?

Milk Handling

- Thawing protocols
- Feeding preparation
- Split bottle between multiple infants vs. one bottle assigned to an individual baby

Documentation

- Integrate donor milk into breastmilk documentation workflows
- Consider electronic milk management system

Donor Breastmilk

Breastmilk is the best food for babies. When mother's own milk is not available, pasteurized donor human milk from a donor milk bank is often the next best choice.

Breastmilk:

- Provides the best nutrition for your baby
- Helps with growth and development
- Helps protect your baby from getting sick
- Is easier to digest than formula

UC San Diego Health provides donor milk from the UC Health Milk Bank, a Human Milk Banking Association of North America (HMBANA) donor milk bank.

At the UC Health Milk Bank:

- We follow strict guidelines to make sure the milk is as safe as possible.
- We screen everyone who donates milk. We also test their blood much like when someone donates blood.
- Milk is heat treated (pasteurized) to kill any germs that could cause disease.
- The milk is tested before and after heating to check for germs. There is a very small chance that your baby could get sick from germs in the milk.

Your baby's care team **recommends donor milk** if your milk supply is not meeting your baby's needs. If you have more questions, **please ask your baby's health care team.**

Receiving donor milk depends on the supply available for use. Premature and sick babies will receive donor milk before healthy babies.

If you want to continue to use donor milk at home, please ask your baby's health care team about how it may be ordered.

For more information on Donor Milk and Breastfeeding check out:

- UC Health Milk Bank website: ucmilkbank.ucsd.edu
- HMBANA website: hmbana.org

Leche materna de donante

La leche materna es el mejor alimento para los bebés. Cuando no se dispone de leche materna, la mejor opción suele ser la leche humana pasteurizada de donante procedente de un banco de leche de donantes.

Leche materna:

- Proporciona la mejor nutrición para su bebé
- Ayuda al crecimiento y al desarrollo
- Ayuda a proteger al bebé de las enfermedades
- Es más fácil de digerir que la leche de fórmula

UC San Diego Health proporciona leche de donante del UC Health Milk Bank (Banco de leche de UC Health), un banco de leche de donantes de la Human Milk Banking Association of North America (HMBANA, Asociación de Bancos de Leche Humana de América del Norte).

En el UC Health Milk Bank:

- Seguimos directrices estrictas para garantizar que la leche sea lo más segura posible.
- Examinamos a todas las personas que donan leche. También analizamos su sangre, al igual que cuando alguien dona sangre.
- La leche se somete a un tratamiento térmico (pasteurización) para eliminar los gérmenes que puedan causar enfermedades.
- La leche se analiza antes y después de calentarla para comprobar la presencia de gérmenes. Hay muy pocas probabilidades de que su bebé enferme por los gérmenes de la leche.

El equipo que atiende a su bebé **recomienda leche de donante** si su producción de leche no cubre las necesidades de su bebé. Si tiene más preguntas, **consulte al equipo de atención médica de su bebé.**

Recibir leche de donante depende del suministro disponible para su uso. Los bebés prematuros y enfermos reciben leche de donante primero que los sanos.

Si desea seguir utilizando leche de donante en casa, por favor pregúntele al equipo de atención médica de su bebé cómo puede solicitarla.

Para más información sobre la leche de donante y la lactancia materna, consulte:

- Sitio web del UC Health Milk Bank: ucmilkbank.ucsd.edu
- Sitio web de la HMBANA: hmbana.org

Small Baby Feeding Plan

Small babies get many benefits from their parent's milk, including better health, growth, and development. Human milk reduces the risk of necrotizing enterocolitis (NEC), a devastating intestinal disease of premature infants.

SMALL BABIES NEED SPECIAL NUTRITION

- Your baby may need intravenous (IV) nutrition after birth until they are able to digest milk in their tummy
- Tiny amounts of milk are given by a feeding tube and increased little by little each day
- When a baby is born early, they miss the extra nutrients provided by the placenta so milk is fortified with a nutritional supplement to boost the calories and minerals to help baby grow



YOUR MILK IS MEDICINE

Pumping and giving your baby your milk is one thing that you can do to make a big difference; your *milk is specially created for your baby*

- To establish a good milk supply, pump your milk within 6 hours of delivery; the sooner the better. Pump at least 6-8 times a day – it is best not to go more than 4 hours in between pumping, and be sure to pump at least once at night (between 12 and 5 am)
- Be sure you go home from the hospital with a double electric pump and a pumping plan; meet with your lactation consultant in the hospital before you go home
- The goal is to pump at least 600-800 mLs (20-27 ounces) a day within 2 weeks of your baby's birth

DONOR MILK IS A BRIDGE

Your baby needs to eat soon after birth. You can help shorten the time baby needs IV nutrition with bringing in your own milk. Even so, the amount we are feeding your baby is usually more than what you can produce in the first few days of life. Most tiny babies need pasteurized donor human milk until parent's own milk is enough to meet baby's needs. Fortified donor milk is also a complete nutrition for families who are not able to provide their own milk.

DONOR MILK IS SAFE

Donor milk is donated by healthy individuals. This is very similar to blood donation. They are screened and the milk is heat treated (pasteurized) and tested for safety. Milk banks process donated milk to meet criteria set by the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, and the Human Milk Banking Association of North America.

PROTECT YOUR MILK SUPPLY

Your milk is full of nutrients and other things to help your baby thrive, even after baby is home

- Keep pumping regularly to keep your milk supply up
- If you start a new medication or treatment; label your milk and notify your healthcare team
- If you are advised to stop pumping or discard your milk; please check with us first! "Pump and Store until you know more!"

WE ARE HERE TO HELP

Ask your nurse, lactation consultant, or healthcare team if you have any questions. We are here to help. We want your baby to feed, grow well, and go home as soon as they are ready!

DONOR MILK – STAFF EDUCATION



Human milk is the optimal nutrition for all infants, and donor milk is recommended when parents' own milk is insufficient or unavailable.

Information about donor milk

- Donors voluntarily provide their extra milk and do not receive any compensation for their donation.
- Donors receive instructions on health and lifestyle considerations, pumping techniques, cleaning of equipment, and storage.
- UC Health Milk Bank pools milk from multiple donors in each batch to ensure that adequate calories, protein, and protective human oligosaccharides are present in every bottle. Each batch is then analyzed to ensure nutritional targets in each bottle to facilitate adequate growth of fragile infants.
- Donor milk is pasteurized (heat-treated) to eliminate bacteria or viruses. Our milk is also tested after pasteurization. Although some bio-nutrients are lost in pasteurization, most of the important factors remain intact.

Accreditation and regulation

- UC Health Milk Bank is accredited by the Human Milk Banking Association of North America (HMBANA). HMBANA regulates nonprofit milk banks in the US and Canada and sets international standards.
- We follow all FDA and CDPH standards. These standards are similar to requirements for blood and tissue donation.
- UC Health Milk Bank is overseen by a medical advisory board composed of the leading experts in human milk and neonatal nutrition. They help us ensure best practices for a safe, quality product.

The Standard in Newborn Nutrition.

These rigorous, overlapping, screening and safety steps ensure that donor milk from a HMBANA accredited milk bank is safe for the most vulnerable infants. Donor milk from an accredited HMBANA milk bank has an impeccable 40-year safety record.

Safety of donor milk

- Donors must meet health standards and adhere to HMBANA's strict criteria. Potential donors are screened for social/health risk factors and medication use. Approval from donor's healthcare provider is also required.
- Screening is a continuous process. Donors are asked questions regarding their health and lifestyle prior to their approval and at the time of each milk drop off. We build relationships with our donors to ensure all milk received is safe for fragile infants.
- Donors are required to have a blood test to screen for communicable diseases, including Hepatitis B and C, HIV, syphilis, and HTLV.
- We have detailed Food Safety procedures and specially trained staff that ensure our milk is properly processed and tested before approval. Milk bank leadership* includes medical staff who are experts in the field of donor milk banking.
- Post-pasteurization cultures are conducted to test for bacteria.
- Each bottle is labeled with an expiration date 1 year after the earliest date of expression in the batch.
- Milk is shipped overnight on dry ice to ensure it remains and arrives frozen. Each insulated box is sent with a WarmMark temperature tracker.

Alison Wolf, CPNP, IBCLC: Executive Director of the UC Health Milk Bank*
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Donor Milk Saves Lives

HMBANA Nonprofit Milk Banks

The Human Milk Banking Association of North America (HMBANA) sets safety standards for nonprofit human milk banks in the US and Canada. HMBANA milk banks collect milk from healthy donors before it is processed and tested for safety. Milk banks distribute this life-saving resource to premature and fragile infants in hospitals and at home.

Milk Bank Safety

Milk donors are screened and blood tested. When their milk arrives at the milk bank, it is gently heated to kill bacteria and viruses. Donor milk is tested for bacteria before it is distributed to hospitals and babies at home. HMBANA milk banks follow strict safety guidelines from the Food and Drug Administration (FDA) to keep donor milk safe.



Donor Milk is Life-Saving!

Preterm infants have fragile digestive systems. For these babies, human milk reduces the risk of life-threatening conditions. HMBANA milk banks provide donor milk for babies in the neonatal intensive care unit (NICU) when a parent's own milk is not available.

Donate Your Extra Breast Milk



Find a Milk Bank



Screening



Interview



Blood Draw



Drop Off

hmbana.org