

Establishing a Nonprofit Human Milk Bank and Becoming a HMBANA Member

Opening a milk bank requires a team steeped in food manufacturing and food safety processes and legislation. If you are passionate about donor milk and want to bring milk banking to your community, HMBANA encourages you to reach out to your nearest HMBANA member milk bank before considering your next steps. You may elect to partner with your nearest milk bank to serve as an outreach center, distribution center, collection center, or in some other way before investing the considerable time and resources required to develop an independent, nonprofit human milk bank.

With that in mind, here is some basic information about what it takes to develop a new human milk bank, as well as the role HMBANA plays in that process. HMBANA is a membership organization that accredits milk banks. As such, HMBANA does not assist in milk bank development. Rather, HMBANA provides accreditation to interested parties when they have applied to HMBANA for accreditation, have been accepted under the relevant criteria, and have paid the accreditation fee. Accreditation includes HMBANA membership.

Guidance on the Development of a New Milk Bank

This document is intended to provide some guidance in the developing, pre-accreditation process for a community undertaking the creation of a donor human milk bank. It is not inclusive of all of the knowledge and technical experience needed to successfully found a milk bank.

It is incumbent upon the group developing the milk bank to establish the necessary nonprofit operations, as well as follow the required laboratory, technical, regulatory, and HMBANA guidelines prior to applying for an audit for accreditation.

What is a Nonprofit Milk Bank?

Nonprofit milk banks are food manufacturing facilities that operate under federal and local food codes, as well as the Human Milk Banking Association of America (HMBANA) guidelines.

Significant infrastructure, resources, and staff are required to meet these guidelines. In addition, milk banks are integral members of the communities in which they operate. As such, HMBANA members are expected to support and promote breastfeeding, integrating that mission on the principle that, when available, mother's own milk is the superior nutrition for babies.

Steps Involved in Creating a Nonprofit Milk Bank

If, once you understand the implications of the above constraints and demands, you still want to develop a nonprofit milk bank, there are several steps involved. Here is a short list of some of



the key processes related to developing a food manufacturing facility that pasteurizes donor human milk (otherwise known as a milk bank). It is important to research these things before seeking to engage HMBANA member banks or other technical consultants.

- Research, research, research. Learn everything you can about milk banking, breastfeeding, preterm infant nutrition, and donor milk feeding. There are hundreds of quality peer reviewed articles available, including [HMBANA publications](#).
- Study [PATH's human milk banking resource kit](#). This kit provides an understanding of global milk banking and tools for developing an integrated milk bank model that focuses on communal breastfeeding promotion.
- Conduct a needs assessment for your local community. Is there already a milk bank in your region? Are local hospitals being adequately served with their donor milk needs? PATH provides a great resource for [conducting a needs assessment](#).
- Developing a milk bank requires significant knowledge and understanding of regulatory requirements. Many food manufacturing consulting firms offer certification courses and learning opportunities for individuals or groups wanting to start a food manufacturing plant. These courses are highly recommended. Regulatory knowledge to attain includes:
 - Federal and local (state/province, county, city) food code regulations and licensing requirements for establishing a food manufacturing facility.
 - The Food Safety Modernization Act (FSMA).
 - FDA Title 21 CFR 110.
- Register your nonprofit organization with the IRS or CRA and your state/province. The US 501c3 is required. Acquiring that determination from the IRS in the US is a long process that often requires significant funds.
- Review HMBANA's publication: "[Guidelines for the Establishment and Operation of a Donor Human Milk Bank.](#)"
- Create a business plan.
 - Startup funding of at least \$150,000 suggested.
 - Establish a board of directors.
 - Establish a medical advisory board.
 - Acquire staff members.
 - At least one staff member must receive Preventive Controls Qualified Individual (PCQI) training and certification.
 - Pasteurization staff must meet required trainings and certifications (Current Good Manufacturing Practices - cGMP - or equivalent).
- Design a food-manufacturing facility.
 - Must meet federal, state/province, and local food code guidelines.
 - Engage architect and construction professional and must meet local building codes.
 - Must meet state/province licensing requirements.
 - Must meet specifications outlined in HMBANA guidelines.
- Create a food safety plan.
 - Assemble food safety team (must include PCQI).
 - Conduct hazard analysis.
 - Create food safety plan.
- Create standard operating procedures (SOPs).

- SOPs and sanitation SOPs (SSOPs) must reflect current good manufacturing practices (cGMPs), a food safety plan, federal and state food code, and HMBANA guidelines.

A Word About Consultants

An individual or group seeking to establish a new milk bank will likely need assistance from multiple consultants in the concept, planning, construction, and development phases before opening. These may include, but are not limited to, consultants in food manufacturing, nonprofit operations, lab construction, architecture and building regulations, FDA requirements, and current HMBANA milk banking guidelines.

HMBANA does not suggest or endorse consultants. Leadership of current milk banks may be available for mentoring and guidance; however, they may decline such opportunities as well. Visits and tours of existing milk banks may be available, but this must be negotiated directly with current operating milk banks. HMBANA plays no brokering role, nor does it maintain a list of members available for such services.

HMBANA Accreditation Process

[Upon expression of interest](#), HMBANA will share additional details in addition to this document, such as next steps in relation to where a founding milk bank group is, assuming that they have demonstrated a viable effort.

To be considered in the pipeline for an accreditation audit, a group must have done the following: received its 501c3, received a PCQI, hired a medical director, enlisted local healthcare provider champions, established a timeline and funding plan, and provided HMBANA with a 50% deposit (\$2500) of the initial accreditation fee.

After completing the above steps and any other steps identified, as well as being authorized by your state/province authorities to operate as a food manufacturer, please contact HMBANA with the evidence of your completed steps.

At that point you will be asked to provide the balance of your \$5000 accreditation audit fee and an audit can be scheduled. After your facility is accredited, future accreditation will be included in HMBANA's annual membership dues as a membership benefit.