

EFBRI

**An Evolving Ethical Framework
Informing Breastfeeding
Research and Interventions**

**Part II: Public Health
Ethics Framework**

This framework is a compilation of ethical principles designed to guide breastfeeding interventions. It aims to assist policy-makers, practitioners, and all stakeholders in navigating the ethical issues presented by breastfeeding interventions.



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Preliminary Remarks

All public health interventions should pursue the purposes of producing benefits to individuals and communities, preventing harms at the individual and societal levels, respecting and promoting individuals' autonomy, and distributing health benefits fairly across social groups to promote health equity.

Breastfeeding is an embodied social practice that encompasses behaviors, values, beliefs, and social roles. It interacts with the implementation of policies, strategies, and actions aimed at protecting, promoting, and supporting breastfeeding. Achieving equity in breastfeeding requires political leadership to create an enabling environment that supports the availability of and access to quality breastfeeding support. Policymakers are called to adopt a holistic view of what is needed for breastfeeding and how to address the needs of diverse, vulnerable populations.

It is important to recognize that any public health intervention, including breastfeeding and lactation interventions, has the potential to expose vulnerabilities among pregnant women, infants, communities, and disadvantaged minority groups. Therefore, breastfeeding and lactation interventions should be conducted through a process of ethical reflection, accompanied by the establishment of appropriate protections, oversight procedures, and governance mechanisms.

The purpose of this framework is to provide ethical recommendations for breastfeeding and lactation interventions, aiming to improve breastfeeding practices and maternal and infant health. Furthermore, this framework intends to offer guidance in evaluating the ethical considerations that need to be taken into account when promoting breastfeeding or counselling pregnant women and mothers who intend to breastfeed or are currently breastfeeding.

Research is essential to generating a knowledge base and developing evidence-based breastfeeding and lactation interventions. Interventions can be accompanied by research, which can raise specific ethical challenges and entail the requirement of review by a research ethics review committee. Therefore, users of EFBRI Part II are strongly encouraged to also get acquainted with EFBRI Part I, in case they are planning interventions with (eventual) research components.

1. Vulnerability

Vulnerable individuals are those who may be at increased risk of harm or exploitation due to various intersectional factors such as gender, ethnicity, race, age, disability, socioeconomic status, health conditions, or any other situational contexts.

Individuals may be considered vulnerable if they are:

- Socially, economically, or politically disadvantaged and therefore susceptible to exploitation.
- Incapable of making voluntary informed decisions for themselves, including those whose autonomy is compromised temporarily or permanently.
- Able to give consent, but whose voluntariness or understanding is compromised due to situational conditions.
- Unduly influenced by the expectation of benefits or fear of negative consequences in case of refusal to participate.

The key principle when planning breastfeeding and lactation interventions for vulnerable persons is to make sure they are provided with conditions and support which respect their well-being and interests.

i. Principles to consider when engaging with vulnerable populations (e.g., pregnant women and infants):

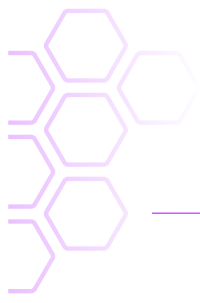
- a. Vulnerable populations have an equal right to be included in interventions to ensure that benefits reach them as well.

- b. If any vulnerable groups are solely recruited, the intervention should address the health needs of the group.
- c. Participants must be empowered to the maximum extent possible, enabling them to decide whether to give assent/ consent for participation.
- d. Special care must be taken to ensure participants' privacy and confidentiality to prevent vulnerability enhancement.
- e. When including vulnerable populations, additional protections must be in place to safeguard their dignity, rights, safety, and well-being.
- f. In low-resource contexts, interventions should proceed only when the balance of potential benefit and harm is certain, with collaboration with the community as an ethical prerequisite.

ii. Additional safeguards/ protection mechanisms:

When vulnerable individuals, such as pregnant women and infants, are part of the targeted groups, particular precautions should be taken to avoid harm and exploitation.

- a. Additional safety measures can include the consultation of ethics experts in the process of policy design or implementation.
- b. Decision-makers should carefully consider risk minimization strategies and additional safeguards that are suitable for the respective target group.
- c. Particular care must be taken to ensure that participation is voluntary, without coercion, force, duress, undue influence, threat, or false claims, and undue incentives.



- d. Vulnerable individuals may require information tailored to their specific needs about the evidence, benefits, risks, and alternatives.
- e. Efforts should be made to minimize stigma or discrimination, especially when participants are enrolled in different interventions.
- f. Support systems should be established to address associated medical and social problems reflecting on the social, cultural and political conditions.
- g. When possible, ancillary care, such as support services or counseling centers, should be provided.
- c. Proposed interventions should understand the compounding influences of diverse yet interrelated determinants, such as socioeconomic status, environmental conditions, age, gender, religion, sexual orientation, and participants' level of education.
- d. To achieve health equity, interventions should be sensitive to social and cultural contexts when promoting programs or schemes.
- e. The welfare of related community members who have not directly participated in the interventions should be duly taken into account.
- f. The interventions should duly take into account conflicting commitments and time constraints of vulnerable mothers and infants. For instance, healthcare professionals should provide time-sensitive follow-up or counseling services regarding breastfeeding for vulnerable pregnant women, whether during home visits or in-clinic appointments.

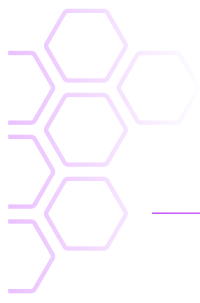
2. Sensitivity to Social and Cultural Context

Shared conventional beliefs, practices, and values can significantly impact health and well-being. Breastfeeding and lactation interventions should be carefully designed and implemented, taking into account the social and cultural contexts. Community representatives should be involved in this process to ensure researchers are able to adequately capture the community's social norms and values.

- a. Interventions should respect women's bodies, values, and preferences within their specific settings.
- b. The values and concerns of communities should be considered during the planning and implementation stages of interventions, as well as while using data from these interventions.

3. Responsibility and Accountability

As there are multiple breastfeeding and lactation interventions, it becomes necessary for stakeholders to thoroughly assess the evidence and effectiveness of interventions before local implementation. The process of selecting interventions should be transparent, and should include responsible representatives of the individuals and communities during the implementation stage.



i. Being fair, honest, and transparent:

- a. Ethical conduct of interventions requires engagement with all stakeholders, including participants, public health providers/professionals, sponsors, government agencies, ethics counselors, institutions, NGOs, researchers, and any other relevant group.
- b. The involved stakeholders must make every effort to establish sustainable systems to continue the best interventions.

ii. Distributive justice:

- a. Efforts must be made to ensure that individuals or communities invited for interventions are selected in a way that distributes the benefits and burdens of interventions equitably.
- b. Vulnerable individuals/groups should not be included in interventions solely for the benefit of others who are better-off than themselves.
- c. Interventions should not lead to or worsen existing social, racial, or ethnic inequalities.
- d. Where relevant, plans for direct or indirect benefit sharing in all types of interventions with participants should be included, especially if there is potential for commercialization or other conflict of interest.

iii. Benefits to the individual, community, or society:

The individual, social and scientific value of interventions should justify the risk, which

includes the probability of causing discomfort or harm in physical, psychological, social, economic, or legal aspects.

4. Informed Consent

The increasing prevalence of public health interventions raises the need to analyze the scope of governments' and institutions' power concerning individual choice. Moreover, target groups sometimes cannot avoid interventions, which implies that participants' informed consent pertains primarily to data collection rather than the administration of the intervention.

Public health officials, researchers, and all stakeholders involved in implementing interventions must develop culturally appropriate ways to communicate information. Ensuring individuals' privacy and confidentiality of information is essential unless there is an overriding moral concern (e.g., health or safety) justifying the release of such information and the release is permitted required by law during or after the interventions.

i. Individual-level consent:

- a. Consent to be involved in the intervention.
- b. Consent for the processing of routinely held data on individuals.
- c. Consent regarding the collection of supplementary data.

ii. Community-level consent:

- a. Interventions should encourage individuals and communities targeted to actively participate in decision-making, not merely as passive respondents.
- b. In certain settings, the community plays a significant role in acquiring consent and reaching out to individuals, making it necessary to engage with community members before implementing any interventions.
- c. Consent procedures must respect local cultural customs; however, community traditions do not substitute for individual consent.

5. Health Promotion and Communication

All public health interventions, including breastfeeding and lactation interventions, give rise to ethical issues as they shape individuals' views of the world and are often influenced or funded by prominent public or private organizations. Ethical evaluations of these interventions become necessary to address unintended effects, such as shame or guilt, stigmatisation, stereotyping, or labeling, which can impact the psychological well-being of individuals or groups.

Key ethical concerns in health promotion include issues related to infringing on people's privacy, interfering with their right to freedom of choice and autonomy in the pursuit of promoting individual or societal health.

- a. Breastfeeding and lactation interventions should be evidence-based, timely, accurate, respectful, credible, and consistent to fully empower decision-making, especially for vulnerable populations.
- b. All communication related to interventions and health promotion efforts should be empathetic, respectful, non-judgmental, non-paternalist and non-stigmatizing towards individuals or communities.
- c. When developing breastfeeding and lactation interventions, particularly communication materials in various formats (pamphlets, posters, audio, or videos), special consideration should be given to diverse cultural and societal values and beliefs to ensure sensitivity and avoid stigmatization in conveying messages.
- d. Communication strategies should not be deceptive or manipulative.
- e. All health promotion interventions should be communicated in simple language understandable by the general public, unless exclusively directed to a specific group presumed to possess higher knowledge on the topic.
- f. All health communication interventions should follow the principle of "do no harm," as they may directly or indirectly harm individuals or communities on physiological, psychological, social, or cultural levels. For instance, health promotion interventions might cause anxiety in some pregnant women or inadvertently stigmatize certain populations by using derogatory depictions of their body image, self-conception, or perspectives of motherhood.

6. Financial and Non-Financial Incentives

Individuals might be motivated to participate in public health interventions, such as implementation studies or breastfeeding counseling programs, based on prospective benefits, which may include financial payments, access to healthcare, education, infant-care resources, etc. Whilst compensation of the participants for their time and effort is in general ethically acceptable, ethical issues of exploitation, undue inducements, biases, and inequality must nevertheless be carefully considered.

i. Participants

- a. Care must be taken in disclosing information about the program to avoid unduly influencing or manipulating participants.
- b. Incentives should not be used as a way to induce behavioral change in ways which harm a mother's or a child's health or wellbeing (e.g., by encouraging breastfeeding despite known medical contraindications, e.g., drug or alcohol addiction).
- c. Acceptable forms of incentives for participants attending a breastfeeding training or implementation study include reimbursement of travel costs, loss of earnings, or other expenses incurred during participation. Compensation for damages resulting from the public health intervention is also considered acceptable and strongly suggested.

- d. When a specific intervention requires participants to have certain resources or devices, providing these resources to participants as incentives is considered appropriate. For example, for interventions using text messaging or phone consultations to provide education on correct feeding practices, providing participants with a mobile device for use would be acceptable.
- e. Healthcare professionals and policymakers should ensure that participants do not enroll in a program solely for its benefits without considering its risks and burdens. (See Section 7: Risk Minimization and Equitable Distribution of Benefits)

ii. Healthcare professionals, volunteers, and other stakeholders:

- a. Depending on the context, it can be ethically problematic for healthcare professionals to receive incentives for inducing behavioral changes. In this regard, interventions which can potentially harm a mother's or a child's health or wellbeing raise strong ethical concerns. Participants, especially new mothers, are more likely to adopt certain behaviors if encouraged to do so by their doctor or healthcare professional.
- b. Monetary and similar incentives should never interfere with healthcare professionals' professional judgment or ability to provide treatment, education, or awareness regarding infant health.

- c. Encouraging dialogue between sponsors, stakeholders, local researchers, and community leaders is essential for determining appropriate incentives for new mothers and their infants based on the value of the respective intervention. In most scenarios, the reimbursement of costs incurred is the most appropriate incentive.

7. Risk-Minimization and Equitable Distribution of Benefits and Risks

Most medical interventions, including diagnostic, therapeutic, and preventative interventions, entail risks and potential harms. Special care must be taken to determine whether the goals of the intervention outweigh the inherent risks and burdens to participants. Issues of risks and harms must be addressed and balanced against the expected potential benefits of participation.

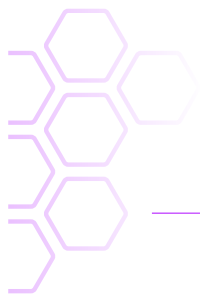
i. Evidence:

- a. Interventions that have been shown to be effective in specific populations must still undergo careful evaluation and assessment before being introduced in another population to ensure that risks and benefits are judged appropriately for the specific community.
- b. When assessing the risks and benefits of an intervention, special consideration must be given to the interests of the participants, and not only to the interests of science, industry, or society.

- c. If an intervention involves predictable and expected risks and hazards beyond minimal harms, provisions or measures must be in place to ensure protection of participants.
- d. An intervention that involves receiving professional medical care may only be justified by the potential benefits it may bring to participants. This should include an assessment of the benefits, risks, and discomforts of the intervention, along with a comparison of the advantages of the best current methods (if they exist).
- e. When there is evidence that a particular intervention has a better expected overall balance of benefits over risks, it would not be appropriate to assign participants to other interventions.
- f. When a benefit from the intervention serves as an inducement and is greater than the expected risk, participants may be more willing to expose themselves to risks or harms they would normally consider unacceptable. Issues with inducement are further discussed in Section 6: Financial and Non-Financial Incentives.

ii. Information and Communication:

- a. In the case of intervention studies, participants must be clearly informed about the relevant aspects of the study, including aims, procedures, possible risks and harms, and the potential benefits and discomforts. This forms the basis for obtaining informed consent, further discussed in Section 4: Informed Consent.



- b. When new interventions are introduced to a community, participants may not fully understand the possible risks involved. Collaborations with local researchers and representatives can help communicate these possible intervention risks in a comprehensible and appropriate manner for each participant.

iii. Data Collection:

Data collection in the context of breastfeeding and lactation interventions (e.g., for implementation purposes, quality control or public health research) should be guided by the following considerations:

- a. Collect the minimum information necessary to achieve the goals of the intervention. If there is insufficient evidence on an intervention, it can be advisable to offer it as part of a research study to build a body of evidence for future decisions.
- b. Provide counseling services for women, families, caregivers, or volunteers to ensure the intervention is properly understood and assessed for any negative impacts.
- c. Present interventions (e.g., on a website) in a manner that avoids discrimination or stigmatization of individuals or communities. Follow relevant legal norms regarding data protection and management.

iv. Welfare, Precaution, and Proportionality:

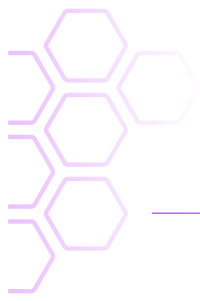
- a. Interventions should adhere to the foundations of public health, which are to promote health, prevent harm, and reduce health inequities. Therefore, the potential risks of an intervention should be weighed not only against the expected benefits but also against the harms of not providing any intervention.
- b. The intervention should be assessed to determine if it is the least intrusive way of effectively achieving the desired goal.
- c. While health education and awareness interventions may not be intrusive and are not thought to bring harms, unanticipated harms can still occur. Researchers should engage in constant monitoring of interventions to ensure participants continue to be positively impacted.
- d. Participants who suffer physical injury or harm as a direct result of an intervention must receive comprehensive medical care, and their rights to compensation should not be waived, even in cases of predictable risks.
- e. When certain interventions may offer potential benefits to a particular group but cause potential harms to another group, a proportionality assessment (which is an assessment of whether the expected benefits of the intervention are sufficient to support risks to the participants) can be helpful to determine justifiability.

8. Conflict of Interest

- a. While designing and implementing breast-feeding and lactation interventions, it becomes necessary to ensure effective procedures are deployed for the identification, disclosure, management, and promotion of the appropriate resolution of conflict-of-interest situations.
- b. Wherever there is close interaction between public-interest and business-interest actors, measures to address conflicts of interest should ensure the integrity of decision-making processes for both professionals in a position of trust and public institutions.
- c. Corporations and all other manufacturers and distributors of breastmilk substitutes and other foods that may displace breastfeeding (e.g., toddler formulas and foods) have an ethical responsibility to adhere to the World Health Assembly's International Code of Marketing of Breast milk Substitutes and subsequent resolutions, and physicians have the responsibility to avoid supporting companies that do not adhere to this Code.
- d. Procedures should be in place while implementing the interventions to ensure that the public has reason to trust public institutions and the actors' independence and integrity.
- e. Public officials, policymakers, or any stakeholders involved in interventions should not enter into contractual obligations that are contingent upon reaching particular conclusions from a proposed intervention.
- f. Researchers involved in intervention studies should disclose any potential material conflicts of interest to their study collaborators, sponsors, research participants, journal editors, and their employer.

9. Post-Intervention Support

- a. Public institutions, sponsors, researchers, and other stakeholders should strive to continue providing beneficial interventions that were part of the policy or research initiative even after the completion of the intervention until the local administrative and social support system is restored to provide regular services.
- b. The benefits accruing from interventions should be made accessible to individuals, communities, and populations whenever relevant. In some cases, the community may indirectly benefit more than the individual participants, such as through improving living conditions, establishing counseling centers, clinics, or schools, and providing education on breastfeeding and lactation, maternal health, and infant health.
- c. Efforts should be made to communicate the findings of the intervention to individuals and communities wherever relevant, using context sensitivity in messaging, and with the option of providing findings in local languages to ensure better understanding.



- d. The intervention team should make plans, wherever applicable, for post-intervention access and sharing of academic or intervention benefits with the communities.
- e. Public institutions, program planners, and researchers have a responsibility to the study participants, future patients, and the wider scientific and general community to publish the results of their intervention findings.
- f. Intervention findings with major importance for public health should be published in a form that gives due regard to cultural and other sensitivities while being aware of potential risks such as stigma, shame, or stereotyping to communities and groups.

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Competing interests

The authors declare that they have no competing interests.

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is provided in good faith. It is not a legal document and does not supersede any national or international legal regulations. The resulting framework, intended for researchers, reviewers and funders, is a synthesis of relevant Swiss and international norms and ethics principles related to breastfeeding and lactation research and interventions. It is a guide for globally accepted best practices and in accordance with Swiss and international research and public health ethics standards yet does not intend to replace any national norms, cultural values or country-specific review processes. The framework lays out rules and principles but does not claim to specify Good Clinical Practice or safety standards. The framework focuses on humans only but does not cover animal ethics or environmental ethics. The framework will be refined as necessary based on periodic reviews. Therefore, we cannot guarantee its status as definitive guide and do not assume any liability. Liability claims against the authors and/or the publisher regarding damages whether material or immaterial caused by the use or non-use of the provided framework are excluded as a matter of principle.

