EFBRI

An Evolving Ethical Framework Informing Breastfeeding Research and Interventions

University of Zurich[UZH]

Version 1.1

LactaHub

Institute of Biomedical Ethics and History of Medicine
Winterthurerstrasse 30
8006 Zurich
Switzerland

Mirriam Tyebally Fang
Nikola Biller-Andorno

EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions

Version 1.1, August 2022
Published exclusively on LactaHub – A Resource for Evidence-Based Breastfeeding Intelligence
www.LactaEthics.org
ethics@lactahub.org

LactaHub is a partnership project of
The Global Health Network (University of Oxford)
and the Family Larsson-Rosenquist Foundation

Illustrations by Nadja Stadelmann
Layout by FRANCHI design.identity

Index

Preliminary Remarks 4

Principles 7

Concluding Remarks 15

Further Information 16

Preliminary Remarks

What is EFBRI?

EFBRI is an evolving ethics framework that aims to delineate ethical rules and principles guiding biomedical research involving human beings within the scope of breastfeeding and lactation in accordance with established international research ethics standards.

What need does EFBRI seek to address?

EFBRI seeks to address the need for a globally applicable and acceptable ethics framework that both encompasses and consolidates international rules, standards and guidelines for biomedical research involving human beings, within the scope of breastfeeding and lactation.

As an evolving framework, EFBRI is intended to develop and expand to reflect the dynamic nature of biomedical research and general ethical evolution, as well as accommodate the diverse needs of the professionals utilising it. For instance, based on these needs, a second module focused on breastfeeding interventions is currently being developed. The creators encourage user feedback and suggestions on the EFBRI with the aim of building a comprehensive and practical resource.

Why is such an ethics framework needed?

Biomedical research must be conducted in an ethical manner to protect the dignity, identity and integrity of all human beings while also aiming to advance the health and well-being of individuals and their families as per the 1997 Oviedo Convention. This is challenging as national and international ethics rules, standards, guidelines and cultural values vary.

As stated by the Council for International Organisations of Medical Sciences (2002): 'The challenge to international research ethics is to apply universal ethical principles to biomedical research in a multicultural world with a multiplicity of health-care systems and considerable variation in standards of health care.'

Whilst researchers must abide by their country's ethical standards, rules and values, a solely national approach may present problems in international, collaborative situations if one country's framework does not satisfy the ethical requirements of another country. The same could be true for reviewers or funders that operate internationally in the absence of a uniform, global standard employing global best practices. Hence, a comprehensive yet consolidated ethics framework would be instrumental in facilitating international research and collaboration, review and funding activities.

In response to the above, the University of Zurich, under the leadership of Prof. Dr. med. Dr. phil. Nikola Biller-Andorno, has compiled an ethics framework for researchers, reviewers and funding entities involved in biomedical studies with women and children within the context of breastfeeding and lactation.

Who is EFBRI for (target audiences)?

EFBRI is aimed at scientific professionals involved in medical research studies or activities focused on breastfeeding and lactation. It can also be used to assess published research findings to determine whether they align with appropriate ethical requirements before being implemented as policy or translated into community practice.

EFBRI can be used by a range of stakeholders and decision-makers from researchers, policymakers and planning and implementation specialists, to educators and healthcare professionals working directly with mothers and children. The EFBRI can also be used by funding bodies to guide international funding activities.

EFBRI offers guidance for researchers, reviewers and funders with the aim of ensuring studies are designed and conducted in accordance with both Swiss and international research ethics standards. Although it does not claim to replace national norms, cultural values or country-specific review processes, it hopes to contribute to the creation of globally accepted best practices in breastfeeding and lactation-related research.

How was EFBRI developed?

The principles elaborated here are based on the following key documents:

A. Federal Act of 30 September 2011 on Research Involving Human Beings (Human Research Act, HRA), Confederation of Switzerland
B. Federal Act of 19 December 2003 on Research Involving Embryonic Stem Cells (Stem Cell Research Act, StRA), Confederation of Switzerland
C. The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No 164), 1997, Oviedo (Spain), ratified by Switzerland in 2008
D. World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (1964/2013)
E. International Ethical Guidelines for Health-related Research Involving Humans, Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) (2016)
F. Universal Declaration of Human Rights (1948)

The fundamental principles elaborated in these documents were compared and consolidated where they overlapped. Principles specific to Switzerland were further evaluated for global relevance. There were no explicit conflicts between documents.

These principles were then examined with a view to their applicability against relevant research protocols and against a review of the breadth of human-milk-related research already published in peer-reviewed literature, including the physiology of breastfeeding; infant nutrition, including the biochemistry of breastmilk and its alternatives; gene-nutrient interactions; the effects of hormones; models of metabolic functions; outcomes of changes in diet; infant and/or maternal health issues; impediments to breastfeeding; and the social and economic implications of breastfeeding. This was done to ensure that the scope and content of

the framework would be relevant to research broadly focused on breastfeeding and lactation.

The document was reviewed and revised together with an advisory board with legal and medical expertise (in both neonatal care and gynecology) and a research background. The resulting framework is not a legal text but a synthesis of relevant Swiss and international norms relevant to the scope of breastfeeding and lactation research. It lays out rules and principles but does not specify Good Clinical Practice or safety standards. The framework focuses on human participants only and does not cover animal ethics or environmental ethics.

A consolidated checklist of the general components required to outline adherence to these principles is provided in a separate document.

Definitions

In deference to Swiss law, the definitions provided below are in accordance with the relevant Swiss Federal Acts (Human Research Act, Stem Cell Research Act).

A. Research means method-driven search for generalisable knowledge.
B. Research concerning diseases means research on the causes, prevention, diagnosis, treatment and epidemiology of impairments of physical and mental health in human beings.
C. Research concerning the structure and function of the human body means basic research, in particular on human anatomy, physiology and genetics, and non-disease-related research concerning interventions and impacts on the human body.
D. Research project with an expected direct benefit means a research project whose results can be expected to improve the health of the participants.
E. Biological material means bodily substances derived from living persons.
F. Embryo means the offspring, from the fusion of the cell nuclei (karyogamy) to the completion of organ development.
G. Surplus embryo means an embryo produced in the course of an in vitro fertilisation (IVF) procedure that cannot be used to establish a pregnancy and therefore has no prospect of survival.
H. Embryonic stem cell means a cell from an IVF embryo with the ability to differentiate into the various cell types, but not to develop into a human being, and the cell line derived therefrom.
I. Parthenote means an organism derived from an unfertilised oocyte.
J. Health-related personal data means information concerning the health or disease of a specific or identifiable person, including genetic data.
K. Genetic data means information on a person's genes, obtained by genetic testing.
L. Child means a legal minor under 14 years of age.
M. Adolescent means a legal minor aged 14 years, up till the age of 19[1].
N. Clinical trial means a research project in which persons are prospectively assigned to a health-related intervention in order to investigate its effects on health or on the structure and function of the human body.

[1] The upper limit of adolescence was taken based on the World Health Organization report, Health for the World's Adolescents (2014) available at https://apps.who.int/adolescent/second-decade/ [accessed 14th October 2021]. Correspondingly, the period of adolescence is included in the age-based definition of 'child' according to the Convention on the Rights of the Child (UN Commission on Human Rights, Convention on the Rights of the Child., 7 March 1990, E/CN.4/RES/1990/74)

Principles

Classifying breastmilk

There is no global consensus on how breastmilk (human milk) should be classified. There are different legal frameworks governing human milk globally. The four most common classifications are as:

1. Food
2. Medical product of human origin
3. Nutritional therapy
4. Undefined (This usually means to indicate that human milk is in a class of its own and does not fall into previously defined categories. The regulations applied to it may then be a hybrid based on several suitable categories.)[2]

Research protocols should assume the classification of human milk as a biological material of human origin[3]. The handling of human milk and its derivatives and considerations around consent to participate in a research study should be in line with that of other human tissues.

Where different, research protocols should also be in line with the country-specific regulatory framework governing human milk.

1. Purpose of Research and Scientific Relevance

a. Research should fill a gap in the existing scientific knowledge with respect to breastfeeding and lactation.
b. The scope of such research includes but is not limited to: an understanding of the structure and function of the human body and its derivatives, an understanding of human disease affecting mothers and infants, efforts to improve preventive, diagnostic and therapeutic interventions and efforts to contribute to best practices in mother and infant care.
c. Research may involve humans only if it addresses a topic of scientific relevance.

2. Human Research

a. Research on a person may only be undertaken if:
   i. the necessary consent has been given expressly, specifically and is documented;
   ii. there is no alternative of comparable effectiveness to research on humans;
   iii. the risks incurred by that person in participating are not disproportionate to the potential benefits of the research;
   iv. regulations concerning scientific integrity are complied with, especially with regards to handling conflicts of interest; and
   v. scientific quality requirements are met.
b. In selecting participants, no group of persons shall be disproportionately included in or excluded from research without good reason. Nobody should be subjected to discrimination in connection with research.

[2] Strengthening human milk banking: a resource toolkit for establishing and integrating human milk bank programs: a global implementation framework. Seattle: PATH; 2019. Available from: https://www.path.org/programs/maternal-newborn-child-health-and-nutrition/strengthening-human-milk-banking-resource-toolkit-0/ [cited 2021 Feb 1]

[3] Principles on the donation and management of blood, blood components and other medical products of human origin: report by the Secretariat. Geneva, World Health Organization; 2017. Available from: https://apps.who.int/iris/handle/10665/274793 [cited 2021 Feb 1]

c. Careful assessment of the predictable risks and burdens in relation to the foreseeable benefits to individuals and groups involved in the research should be documented.
d. Measures to minimise risks must be clearly stated. These measures should be implemented before the commencement of the research.
e. No person may receive payment or any other pecuniary benefit for participation in a research project with an expected direct benefit. Participation in a research project with no expected direct benefit may be appropriately remunerated.

3. Research Infrastructure

a. The research team should be appropriately qualified with regards to its ethics and scientific background.
b. Medical-related research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or healthcare professional.

4. Research Protocol

a. The design and performance of each research study involving human subjects must be clearly described and justified.
b. The research must be based on thorough knowledge of the scientific literature and other relevant sources of information and adequate laboratory and (as appropriate) animal experimentation.
c. Clinical trials involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.
d. Ethical considerations and how they have been addressed should be clearly stated.
e. Any intervention in the health field, including research, must be carried out in accordance with relevant professional standards and obligations.
f. Information should be included regarding: funding, sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.
g. The research protocol should:
    i. state clearly provisions for the regular monitoring, documentation and assessment of risks/harms and outcomes at appropriate intervals;
    ii. state clearly provisions for physicians and/or researchers to assess whether to continue, modify or immediately stop the study without delay when risks are found to outweigh potential benefits or when there is conclusive proof of definitive outcomes; and
    iii. describe appropriate arrangements for post-trial provisions where necessary.
h. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be provided for. Liability towards participants must be appropriately covered through insurance or in another suitable manner.
i. In advance of a clinical trial, provisions should be made for post-trial access for all participants who still need an intervention identified as beneficial during the trial.

j. Appropriate technical and organisational measures must be taken to prevent the unauthorised use of biological material(s) or health-related personal data collected and/or stored for research purposes.
k. The research protocol must be submitted for consideration, comment, guidance and approval to the concerned national research ethics committees before the study begins.
l. Upon approval, no further amendment to the protocol may be made without repeat consideration and approval by the ethics committee in authority.

5. Review by Research Ethics Committees

a. The responsible research ethics committee is that of the country and state in whose territory the research is conducted.
b. If a research project is carried out according to a standard protocol but in different geographical locations (multi-center research projects), authorisation is required from the ethics committee which is responsible at the site of activity of the project coordinator (the lead committee).
c. The lead committee requests input from research ethics committees responsible for the other research sites.
d. Funders can establish additional review systems to ensure the proposals they decide to support meet international research ethics standards (cf. WMA, CIOMS and WHO, documents listed on p.5).

6. Consent for Participation in Research

a. The necessary consent must be specific, expressly given and documented. It should be made clear that consent may be freely withdrawn at any time, without having to state any reason.
b. Consent must be given in writing. In the event of an exemption in accordance with national laws, the non-written consent must be formally documented and witnessed.
c. Participation must be voluntary. No individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.
d. In no case must the permission of another person replace the requirement of individual informed consent by the pregnant or breastfeeding woman.
e. The persons concerned must receive comprehensible oral and written information on:
    i. the nature, purpose and duration of and procedure for the research project;
    ii. the foreseeable risks and burdens;
    iii. the expected benefits of the research project, in particular for themselves or for other people;
    iv. the measures taken to protect the personal data collected;
    v. their rights and the safeguards prescribed by law for their protection.
f. In exceptional cases, the persons concerned may be given incomplete information regarding individual aspects of a research project before it begins insofar as this is essential for methodological reasons and if the research project entails no more than minimal risks and burdens. Participants must subsequently be duly informed as soon as possible and may choose to give or withdraw consent for the use of their data or biological material.

g. Participants must be allowed an appropriate period for reflection prior to consent.
h. In the event consent is required by participants in a therapeutic relationship with the research team:
   i. the responsibility for the protection of research subjects rests with the physician, healthcare professionals and/or researchers and never with the research subjects, even though they have given consent;
   ii. patients should be involved in research by their physicians only to the extent that this is justified by its potential preventative, diagnostic or therapeutic value, and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects;
   iii. informed consent must be sought by an appropriately qualified individual completely independent of the therapeutic relationship if the participant is in a dependent relationship with the physician or there is good reason to believe the participant may consent under duress.
i. If incapable of giving informed consent, the physician must seek informed consent from the legally authorised representative and the caveats pertaining to a vulnerable research participant must be met.
j. Where the participant is a minor, the opinion of the participant shall be taken into consideration as far as possible in the consent procedure. Increasing weight must be accorded to the views of children and adolescents lacking capacity, the older and more mature they are.
k. If the intention to make further use of biological material sampled or health-related personal data collected exists for research purposes, the consent of the persons concerned must be obtained at the time of such sampling or collection, or they must be informed of their right to dissent.
l. If the requirements for informed consent for further use of biological material sampled or health-related personal data collected are not met, further use may be made for research purposes in exceptional cases if:
   i. it is impossible or disproportionately difficult to obtain consent or to provide information on the right to dissent, or this would impose an undue burden on the person concerned;
   ii. no documented refusal is available; and
   iii. the interests of research outweigh the interests of the person concerned in deciding on the further use of his or her biological material and data.
m. In the event post-hoc or proxy consent is necessary (e.g. in emergency situations), the person concerned must be duly informed about the research project as soon as this becomes possible:
   i. the participant may subsequently give or withhold consent;
   ii. the biological material and data may not be used for the research project if the person concerned refuses to give post-hoc consent.

7. Additional Requirements for Research Involving Vulnerable Groups

a. Research with a vulnerable group is only justified if:
   i. the research is responsive to the health needs or priorities of this group;

ii. The group benefits from the knowledge, practices and interventions that result from the research;
iii. Equivalent findings cannot be obtained by other means;
iv. The risks are minimised and outweighed by the prospect of potential individual benefit;
v. Special protections are taken allowing no more than minimal risks for procedures that offer no expected direct benefit.

b. Additionally, when this vulnerable population includes:
   i. women of child-bearing potential, they must:
      1. be informed in advance of the possibility of risks to the foetus;
      2. have guaranteed access to pregnancy tests;
      3. have access to effective contraceptive methods before and during the research; and
      4. have access to safe, legal abortion;
   ii. pregnant and breastfeeding women, they must:
      1. be informed in advance of the possibility of risks to the foetus;
      2. (depending on the study intervention) provide short- and/or long-term follow-up of the foetus and the child; and
      3. consent independently (Refer to Section 6(d));
   iii. A research project may only be carried out in adolescents who are capable of judgement if:
      1. the adolescent has given informed consent in writing; and
      2. the legal representative has given informed consent in writing if the research project entails more than minimal risks and burdens.

c. A research project may only be carried out in individuals who lack capacity if:
   i. this is permitted by the consent of the person concerned;
   ii. informed consent has been given in writing by the legal representative if no duly documented consent granted while in a state of capacity is available; and
   iii. the person concerned does not visibly express opposition to the research intervention either verbally or by his or her behaviour.

8. Use of Biological Material and Genetic Data

a. The human body or parts thereof may not be disposed of or acquired as such for research purposes in return for payment or other non-cash advantages.
b. Parts of the human body removed in the course of an intervention may be stored and used for a purpose other than that for which it was removed if this is done in conformity with appropriate information and consent procedures.
c. Biological material or health-related personal data which has been sampled or collected or of which further use has been made for research purposes may only be passed on for purposes other than research if:
   i. legal basis exists for such a transfer; or
   ii. informed consent to the transfer has been given by the person concerned.
d. Biological material or genetic data may be exported for research purposes if informed consent has been given by the person concerned.

e. Non-genetic health-related personal data may be disclosed abroad for research purposes if the requirements specified in Section 12(d) of this document.
f. With regards to the use of genetic material for research:
   i. tests predictive of genetic diseases or which serve to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes and subject to appropriate genetic counselling; and
   ii. an intervention seeking to modify the human genome may only be undertaken for preventative diagnostic or therapeutic purposes, and only if its aim is not to introduce any modification in the genome of any descendants.

9. Use of Embryos for Research

a. Research projects designed to modify properties of an embryo or foetus in-vivo for non-disease-related reasons are prohibited.
b. A pregnant woman may only be asked whether she wishes to make her embryo or foetus available for research purposes after she has decided to undergo an abortion.
c. The time and method of induced abortion must be chosen without regard to the research project.
d. The person who carries out such a research project must not be involved in the abortion or be authorised to issue instructions to the persons involved in this procedure.
e. Embryos and foetuses from spontaneous abortions including stillbirths may only be used for research purposes with the consent of the couple concerned.
f. Embryos and foetuses from spontaneous abortions may be used for a research project when death has been determined.
g. The following is prohibited:
   i. creating an embryo for research purposes, to derive stem cells from such an embryo, or to use such cells;
   ii. modifying the genetic material in a germ cell, to derive embryonic stem cells from an embryo that has undergone germ line modification, or to use such cells;
   iii. creating a clone, chimera or hybrid, to derive embryonic stem cells from an embryo that has undergone germ line modification, or to use such cells;
   iv. developing a parthenote, to derive embryonic stem cells therefrom, or to use such cells;
   v. importing or exporting an embryo, a clone, chimera, hybrid or parthenote.
   vi. using surplus embryos for any purpose other than the derivation of embryonic stem cells; and
   vii. deriving stem cells from a surplus embryo after the seventh day of its development.

10. Use of Placebo

a. The benefits, risks, burden and effectiveness of a new intervention must be tested against the best proven interventions except when:
   i. no proven intervention exists; and
   ii. no standard treatment is available.

b. If, for compelling and scientifically sound methodological reasons, the use of any intervention less effective than the best proven one, the use of placebo or no intervention is necessary to determine the efficacy or safety of an intervention:
   i. patients who receive any intervention less effective than the best proven one, placebo or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.

11. Research in Emergency Situations

a. A research project with an expected direct benefit may be carried out in emergency situations if:
   i. the necessary measures have been taken so that the wishes of the person concerned can be determined as soon as possible;
   ii. the person concerned does not visibly express opposition to the research intervention through either verbally or by his or her behaviour; and
   iii. a physician who is not participating in the research project is called in to safeguard the interests of the person concerned before he or she is involved in the project; in exceptional cases, where there are good reasons for doing so, the physician may be called in at a later stage.
b. A research project with no expected direct benefit may be carried out in emergency situations if, in addition to the requirements specified above:
   i. it entails no more than minimal risks and burdens; and
   ii. it can be expected to yield substantial findings which could, in the long term, be beneficial for persons with the same disease or disorder or in the same situation.

12. Data Protection

a. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.
b. In discharging their duties, ethics committees and other enforcement bodies are entitled to process personal data. Sensitive personal data may be processed insofar as this is necessary.
c. Confidential data may only be transmitted to foreign authorities and institutions or to international organisations if:
   i. this is required by agreements under international law or resolutions passed by international organisations;
   ii. this is necessary to avert an imminent danger to life or health; or
   iii. this would enable serious offences under the Human Research Act to be exposed.
d. With regards to responsibilities and procedures for exchanging data with foreign authorities and institutions and with international organisations:
   i. Personal data may not be disclosed abroad if this seriously endangers the privacy of the data subjects, in particular, due to the absence of legislation that guarantees adequate protection.

ii. In the absence of legislation that guarantees adequate protection, personal data may be disclosed abroad only if:
    1. sufficient safeguards, in particular contractual clauses, ensure an adequate level of protection abroad;
    2. the data subject has consented in the specific case;
    3. the processing is directly connected with the conclusion or the performance of a contract, and the personal data is that of a contractual party;
    4. disclosure is essential in the specific case in order either to safeguard an overriding public interest or for the establishment, exercise or enforcement of legal claims before the courts;
    5. disclosure is required in the specific case in order to protect the life or the physical integrity of the data subject;
    6. the data subject has made the data generally accessible and has not expressly prohibited its processing; and
    7. disclosure is made within the same legal person or company or between legal persons or companies that are under the same management, provided those involved are subject to data protection rules that ensure an adequate level of protection.

e. The appropriate data protection and information authority in the host country should be informed of the safeguards under Section 12(d)(ii)(1) and the data protection rules under Section 12(d)(ii)(7).
f. Biological material and genetic data may be anonymised for research purposes if the person concerned or the legal representative have been informed in advance and have not dissented to anonymisation.

13. Right of Participants to Their Own Data

a. Participants are entitled to know any information collected about his or her health and all personal data held in relation to them. The wishes of individuals not to be so informed should be observed.
b. The persons concerned are entitled to be informed of results relating to their health. The information is to be communicated in an appropriate manner.
c. Restrictions may be placed by law on the exercise of these rights.

Concluding Remarks

As elaborated in the Oviedo Convention, the application of biology and medicine should protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms. Research questions and standards should be reflective of this.

They should further aim to advance the goal of achieving adequate health and well-being of the individual and their family and recognise the special care and assistance entitled to motherhood and childhood (art. 25, UDHR) of which various aspects of infant nutrition are an inextricable part of. While research aims to generate new knowledge in the interest of society, this goal must never take precedence over the rights and interests of individual research subjects.

The principles above are applicable primarily to medical research involving human subjects, including research on identifiable human material and data. The main human research participants are likely to involve two vulnerable populations – women, particularly pregnant and post-partum mothers and children, particularly infants.

The International Ethical Guidelines for Health-related Research Involving Humans make it clear that it is important to consider specific characteristics of subpopulations involved or affected by the proposed research activities without classifying entire classes of individuals as vulnerable. Classifying entire classes of individuals as vulnerable would limit the valuable and necessary benefits of their participation and representation in research. The characteristics to consider are those that increase the likelihood of them being wronged or of incurring additional harm. For example, pregnant women in themselves must not be considered vulnerable simply because they are pregnant, but because specific circumstances, such as a risk to the foetus, may require special protections. In the case of infants and children, this vulnerability pertains primarily to their distinctive physiologies and health needs and the increased risk of being harmed in the research conducted as well as the inability to protect their own interests. It is important to identify the different characteristics pertaining to vulnerability that could co-exist and also realise that these factors can be context-dependent. In the evaluation of benefits and harms, it is also important to consider the co-dependence of the mother-child unit and the impact of one entity on the other.

This framework will be refined as necessary based on periodic reviews to ensure it remains in accordance with Swiss and international ethics rules, standards and guidelines and applicable to prospective developments in research.

Further Information

Acknowledgments

The authors would like to thank the Technical Advisory Board. The support of the Family Larsson-Rosenquist Foundation is gratefully acknowledged.

Funding

The development of EFBRI was funded by the Family Larsson-Rosenquist Foundation through a grant to University of Zurich, Institute of Biomedical Ethics and History of Medicine.

Author information

Affiliations
University of Zurich
Institute of Biomedical Ethics and History of Medicine
Winterthurerstrasse 30
8006 Zurich
Switzerland
Mirriam Tyebally Fang, M.B.B.S (NUS), M.R.C.S (Edin.); Nikola Biller-Andorno, MD, PhD, MHBA

Contributions
Mirriam Tyebally Fang drafted the document, Nikola Biller-Andorno provided feedback and approved the final version of the draft.

Corresponding author
Correspondence to Nikola Biller-Andorno: biller-andorno@ibme.uzh.ch

Competing interests
The authors declare that they have no competing interests.

DISCLAIMER. EFBRI – An Evolving Ethical Framework Informing Breastfeeding Research and Interventions 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 related to breastfeeding and lactation research. It is a guide for globally accepted best practices and in accordance with Swiss and international research 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 human participants 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.

University of Zurich[UZH]

LactaHub

Checklist

Checklist of general components required to outline adherence to the principles of ethical research standards in Switzerland that have global relevance.

This checklist relates to research concerning human diseases and concerning the structure and function of the human body that involves persons, deceased persons, embryos and foetuses, non-anonymised biological material and health-related personal data.

- ⎔ Clear scientific question
- ⎔ Relevant purpose
- ⎔ Appropriate methodology, including:
  - ⎔ Clear study protocol
  - ⎔ An outline of relevant ethical issues with strategies to minimise them
- ⎔ Supporting preliminary work
- ⎔ Qualified research staff
- ⎔ Appropriate laboratory/research infrastructure
- ⎔ Ethical clearance obtained at all study participation sites
  - ⎔ Research ethics committee approval should be made available
- ⎔ Relevant and justified reason for geographical location of study, especially if not country where lead research team is based
- ⎔ (where applicable) Contribution to capacity building if study is based in a low- or middle-income country
- ⎔ Considers sociocultural and socio-economic factors, especially in multi-ethnic or multi-location studies

- ⎔ Justified sampling strategy
  - ⎔ If human participation,
    - ○ Non-discriminatory inclusion/exclusion criteria
    - ○ Benefit to population sampled
    - ○ Identification of vulnerable participant population, including reasons for their inclusion, identification of risks, and mitigation of these risks
  - ⎔ If biological material, include
    - ○ how are tissues sampled
    - ○ number of samples required
    - ○ whether these are in addition to routine diagnostic or therapeutic procedures

- ⎔ Informed consent, including
  - ⎔ Content
  - ⎔ Procedure
  - ⎔ Justifications for proxy or post hoc consent where necessary
  - ⎔ Details on compensation: Participants should be remunerated within acceptable limits (must not constitute undue inducement)
  - ⎔ Actual consent material should be attached

- ⎔ Direct risks/benefits to participants from research outlined
  - ⎔ Identify therapeutic benefit
  - ⎔ Risk/burdens of participation minimised
  - ⎔ Risk/burden should not be disproportionate to benefits received

- ⎔ Respect for data protection, including data handling, and storage

- ⎔ Clinical trials should be registered in a public registry

- ⎔ Strategy regarding informing study participants about results where relevant

- ⎔ (where applicable) Strategy regarding handling incidental findings/ findings of uncertain significance

- ⎔ If study affects healthcare received
  - ⎔ Justify whether results should be disclosed to healthcare provider and how it affects healthcare received
  - ⎔ Provide access to appropriate interventions where necessary

- ⎔ Funding needs detailed and justified for costs requested