

RULES FOR THE INFANT NUTRITION SCIENCE COALITION

These Rules (these “Rules”) govern the organization and operation of the Infant Nutrition Science Coalition (the “Coalition”) described herein. These Rules apply to the International Life Sciences Institute (“ILSI”), which convenes the Coalition, the Oregon State University, and the legal entities that have agreed to them in a written document transmitted to ILSI’s Executive Director. These Rules are also binding for those individuals who choose to participate in the activities of the Coalition.

1.0 Background.

Human milk is the gold standard for infant nutrition. However, there are families in which the choice to breast feed is not possible because of medical or other structural barriers, and in those cases infant formula is the best alternative. There are compositional gaps between human milk and infant formula, and these can translate into physiological differences between human milk fed and infant formula fed infants. Despite being the subject of extensive research, some fundamental questions remain regarding the functionalities of individual constituents of human milk. Answering these questions has the potential to improve the understanding of this complex biofluid, and ultimately update the composition of infant formula for the benefit to infant health and development.

2.0 Purpose of the Coalition.

The Coalition is a forum for scientists from consumer health groups, academia, industry, nonprofit organizations, and government (collectively, the “Members”) to review existing data, establish where science has been settled and where questions remain, and define research needs to:

1. Further define and compare the composition of human milk and infant formula, including the definition of appropriate methods for collection and analysis
2. Increase understanding of the physiological effects of the components of human milk and infant formula and determine adequate non-human translational models
3. Develop comprehensive markers of normal infant development, past current anthropomorphic measurements (length, weight, head circumference) used to define healthy growth

3.0 Initial Activities of the Coalition.

At the time these Rules are established, the Members anticipate that the Coalition will carry out four tasks (collectively the “Initial Project”), comprising: 1) development of a perspectives paper; 2) convening of a workshop; 3) publication of proceedings of the workshop; and, 4) facilitating discussion on other pre-workshop activities such as establishing informal discussions at key scientific meetings. From time to time, the Members may, but are not required to, agree to fund and pursue activities in addition to the initial four tasks. However, unless and until a Member has executed a separate agreement to fund a specific activity, the Member will not be obligated to fund that activity.



4.0 Role of ILSI.

ILSI will serve as a coordinator of Coalition activities and may, from time to time, contract with other parties for the provision of services for the support of the Coalition. ILSI's particular responsibilities in relation to specific tasks or activities may be set forth in greater detail in appendices to these Rules.

5.0 Funding of the Coalition Activities.

Funding for Coalition activities will be provided by Members who are legal entities, and who have signed agreements with ILSI promising to pay funds to ILSI and agreeing to these Rules. Except as otherwise provided in these Rules, payments of funds to ILSI by Coalition Members are non-refundable.

Funding Structure for Initial Project

- 3-tiered funding structure with two thresholds (pre-revenue and \$100 million revenue) to maximize inclusion of a diversity of industry funders.
- Ratio of funding for the three tiers is **3:1:0.5**.

3-Tier Model

- | | Funding Amount (\$USD) |
|--|------------------------|
|--|------------------------|

Total Initial Project Cost Estimate \$200,000

No Initial Project activities will commence unless and until ILSI has collected at least \$100,000 USD (representing 50% of the Initial Project budget) from legal entities that have agreed in writing to be bound by these Rules. Within three business days after ILSI confirms the fulfillment of this condition, ILSI will notify the Members by email that the Coalition has entered into effect (the "Effective Date"), and Initial Project activities may commence.

After the Effective Date, these Rules and the Coalition shall remain in effect until such time that the Coalition is concluded, or a new or modified set of Rules is adopted by the Coalition Steering Committee.

6.0 Governance of the Coalition.

Strategic direction of the Coalition will be set by a Coalition Steering Committee composed of representatives from industry, academia and government. The Coalition Steering Committee will choose a chairperson or two co-chairpersons and will meet monthly to oversee progress, ensure alignment, and provide strategic directions on the four key tasks.



7.0 Coalition Communications.

All statements on behalf of the Coalition must be made through ILSI. Members shall not make any public statements on behalf of the Coalition without the written consent of ILSI. Coalition Members and staff shall avoid making public statements that are inconsistent with Coalition policies, such as statements that amount to lobbying, advocacy of policy positions, or endorsement of commercial interests.

8.0 Intellectual Property.

It is not anticipated that the Coalition will develop any patentable inventions in the course of its activities. If any intellectual property (including but not limited to works of authorship that are susceptible of copyright protection) is developed as a result of the work done through the Coalition, the ownership of such intellectual property shall, subject to the provisions of these Rules regarding publication, be determined by applicable law.

Except as expressly provided for in these Rules, no party grants to any other party any rights to use its trade names, trademarks, service marks, logos, or designations (each a “Mark” and collectively the “Marks”)

9.0 Confidentiality.

Generally, Members of the Coalition will not share confidential information with ILSI or with other Members in the course of Coalition activities. If a Member desires to share any confidential information in the context of Coalition activities, the Member must contact ILSI prior to disclosing any such confidential information and make the appropriate, written arrangements to protect the confidentiality of such information. Except as explicitly provided to the contrary in a written nondisclosure agreement that is co-signed by ILSI and one or more Coalition Members, all information shared in the context of the Coalition shall be deemed to be non-confidential and non-proprietary.

10.0 Ethical Principles.

The Coalition is committed to advancing public health by supporting the scientific study of human milk and infant formula and its role in infant and maternal health. We believe that achieving this goal requires open, active, and ethical collaborations among scientists with diverse technical and professional expertise. Our collaborators share a commitment to conducting research for public benefit, with mutual respect for human dignity, ethical scientific practices, and the highest standards of research integrity.

We recognize that the Coalition’s scientific credibility and impact depend on the high ethical standards our members and staff uphold. As such, Coalition Members commit themselves to respect the following values in the conduct of Coalition activities:

Collaboration

The Coalition fosters respectful and inclusive interactions that acknowledge diverse perspectives, methodologies, and interpretations in the study of human milk and infant formula. We enhance our ability to conduct meaningful and rigorous scientific research through interdisciplinary collaboration.

Respect

The Coalition is dedicated to maintaining a safe and collegial environment, ensuring that all activities take place in a climate of understanding and mutual respect for the dignity, autonomy, and rights of participants, researchers, and the broader scientific community.

Transparency

Access to reliable scientific information is essential for advancing knowledge and informing public health decisions. The Coalition is committed to generating robust, openly accessible information while upholding privacy protections for Coalition participants.

Independence

All Coalition Members must act in alignment with the Coalition's mission to advance the science of human milk, infant formula, and maternal-infant health. The Coalition does not promote specific commercial interests, advocate for policy or legislative changes, or endorse individual products.

Integrity

Coalition programs and activities will adhere to the highest ethical conduct and scientific rigor standards. Members will comply with all relevant laws, regulations, and ethical guidelines for research involving human subjects. We are committed to transparency in disclosing potential conflicts of interest and ensuring that our work serves the public good.

11.0 Antitrust.

The Coalition recognizes that its Members may be competitors. As such, the Coalition's commitment includes compliance with applicable antitrust and competition laws designed to protect a free competitive economy. Therefore, all Coalition Members and participants are obligated to assist in this commitment by assuring that their conduct, actions, and activities are in accordance with applicable antitrust and competition laws economy in the countries and states where Coalition activities are carried out. Coalition Members and participants are reminded not to communicate or exchange with each other any commercially sensitive information, such as information relating to prices, marketing and advertising strategy, costs and revenues, or trading terms and conditions, including purchasing strategy, terms of supply, trade programs, and distribution strategy. Coalition Members should contact appropriate ILSI personnel and consult with their corporate legal counsel if any proposed Coalition activity in which they may be involved raises antitrust or competition law concerns.



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12.0 Miscellaneous.

Liability.

Each Coalition Member participates in the Coalition at its own risk. To the fullest extent permitted by law, shall not be liable to any Coalition Member for damage, loss, or claims arising from acts or omissions by ILSI in its performance under these Rules, unless such damage, loss, or claim arises solely from ILSI's own gross negligence or intentional misconduct. To the fullest extent permitted by law, if a Coalition Member, its employees, agents, or representatives are held liable to a third party for any acts or omissions under this Agreement, the sole remedy to which the Coalition Member shall be entitled against ILSI, or its employees, agents, representatives, students, or trustees, is a refund of that Coalition Member's financial contribution to ILSI.

Disclaimer of Warranties.

NEITHER ILSI NOR ANY COALITION MEMBER MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, ANY INFORMATION OR DATA, WHETHER TANGIBLE OR INTANGIBLE, MADE OR DEVELOPED UNDER OR OUTSIDE THE SCOPE OF THESE RULES. ILSI, BROAD INSTITUTE, AND ALL COALITION MEMBERS HEREBY EXPRESSLY DISCLAIM ANY WARRANTIES, REPRESENTATIONS, OR GUARANTEES, EXPRESS OR IMPLIED, WITH RESPECT TO ANY INFORMATION OR DATA ARISING AS A RESULT OF COALITION ACTIVITIES OR THAT USE OF ANY KIND INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF OWNERSHIP, MERCHANTABILITY, ADEQUACY, SUITABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, USE, OR RESULT. WITHOUT LIMITATION OF THE FOREGOING GENERALITY, NOTHING CONTAINED HEREIN OR IN ANY DISCLOSURE OF ANY INFORMATION OR DATA SHALL BE CONSTRUED AS EXTENDING ANY REPRESENTATION OR WARRANTY OF ANY INFORMATION OR DATA WILL BE FREE FROM INFRINGEMENT OF PATENTS OR OTHER PROPRIETARY RIGHTS OF THIRD PARTIES.

Legal Compliance.

Each party bound by these Rules agrees that in the course of Coalition activities, the party will comply with all applicable laws, rules, and regulations. In particular, but without limitation, parties whose work on Coalition activities is required to be reviewed and approved by an Internal Review Board ("IRB") or an Institutional Animal Care and Use Committee ("IACUC") shall comply with those requirements when they are applicable.

Governing Law.

These Rules shall be governed by and construed in accordance with the internal laws of the District of Columbia, without reference to its conflict of laws principles.