Information Notice and Expression of Consent for the Processing of Personal Data (1)

(Pursuant to the guidelines for the processing of personal data in clinical trials of medicinal products – adopted by the Italian Data Protection Authority with Resolution No. 52 of July 24, 2008, Official Gazette No. 190 of August 14, 2008, in accordance with Legislative Decree No. 196 of June 30, 2003 "Personal Data Protection Code", and in compliance with the General Data Protection Regulation, EU 2016/679)

Study Title: Efficacy of Bifidobacterium bifidum on symptoms of infant colic and atopic dermatitis: a randomized, placebo-controlled trial

Data Controllers and Respective Purposes
The Investigational Site and the Sponsor (UOC Pediatrics, AOU Sant'Andrea, Rome), which commissioned the study described to you, for their respective areas of competence and in accordance with the responsibilities set out under Good Clinical Practice regulations (Legislative Decree 211/2003), will process your child's personal data (hereinafter "Data") solely to the extent and in the manner necessary to achieve the objective of the study.

To this end, the indicated Data will be collected by the Investigational Site and transmitted to the Sponsor, who may pseudonymize them (a technique that modifies and masks a natural person's personal and sensitive data so that they cannot be directly or easily attributed to them) to prevent identification. These data will subsequently be redirected to external parties acting on their behalf, including the Microbiology–Organoid Lab of the Department of Public Health and Infectious Diseases at Sapienza University of Rome.

The processing of your child's personal data is indispensable for conducting the study; refusal to provide them will prevent participation in the trial.

Nature of the Data

The physician following your child in the study will collect your child's Data, such as: their name, initials, gender, age, date of birth, as well as information concerning their health and biological samples. The Study physician will replace your child's name and other general personal identification details—excluding age/date of birth and gender—with a code that will identify him/her (hereinafter "Pseudonymized Data"). Pseudonymized Data will be recorded, processed, and stored alongside this code. Only the physician and authorized personnel will be able to link this code to your child's identity.

Processing Methods
The Data, processed using both electronic and manual tools, will be disclosed only in a strictly pseudonymized and aggregated form, for example through scientific publications, statistics, and scientific conferences. Your child's participation in the study implies that, in accordance with clinical trial regulations for medicinal products and the General Data Protection Regulation, personnel from the Sponsor or external companies acting on behalf of the Sponsor, the Ethics Committee, and Italian and foreign health authorities may have access to data concerning your child—including

those contained in the original medical records—under conditions that guarantee confidentiality of identity.

Exercise of Rights

You may exercise your rights pursuant to Art. 7 of the Privacy Code, as repealed and replaced by Art. 15 et seq. of EU Regulation 2016/679 (e.g., accessing personal data, integrating, updating, rectifying them, objecting to their processing for legitimate reasons, etc.) by contacting the investigational site and Sponsor UOC Pediatrics AOU Sant'Andrea in Rome directly, through Dr. Maurizio Mennini.

You may withdraw your child from the study at any time, without providing any justification: in this case, all associated biological samples will be destroyed.

As with health data, pseudonymized biological samples will also be used exclusively for trial purposes.

Once the study has ended, the samples will be destroyed. They will not be destroyed only if: a) it is no longer possible to link them to your child's identity because they were pseudonymized during the trial itself, or b) in the presence of your specific informed consent and agreement with the biobank for sample storage.

The destruction of biological samples will not automatically result in the deletion of clinical data and analytical results already obtained within the scope of the study. Such data will be stored in a pseudonymized form for the period stipulated by applicable law, exclusively for scientific, statistical, regulatory, and audit purposes related to the clinical trial.

Furthermore, no additional data concerning your child will be collected, without prejudice to the use of data already collected to evaluate the study results without altering them.

Consent

By signing this form, I consent to the processing of my child's personal data for research purposes within the limits and according to the conditions set forth in the information notice provided in this document.

I therefore give my informed consent to the processing of my child's personal data and declare that I am aware that the Clinical Site and the Sponsor (identified below), each within their respective areas of competence, undertake to store said data using the archiving measures provided for by Regulation (EU) 2016/679 (hereinafter "GDPR").

For the Sponsor and Clinical Investigational Site: UOC Pediatrics, AOU Sant'Andrea, Rome

Data Controller: Prof. Pasquale Parisi

Data Processor for the study: Designated pursuant to Art. 37 et seq. of the Regulation, Dr. Maurizio Mennini (contact e-mail: dott.mauriziomennini@gmail.com), who in turn may authorize personnel involved in patient data management through a specific authorization act.

Data Protection Officer (DPO) for the Sponsor: Isabella Lucati (contact e-mail: dpo@ospedalesantandrea.it)

Name and Surname of the Subject/Parent/Legal Guardian: _____

(in block letters)

Signature: _____

Date: _____

(1) To be submitted to data subjects together with the informed consent form describing the scientific features of the study, or integrated into it;

(2) When the full list of third parties to whom data will be transmitted (including non-EU countries) cannot be known at the time of drafting the information notice, it must be specified how and when the complete list will be made available.