Official Title*:* Effects of a Dairy Product Enriched With Lactoferrin on Iron Status of Women With Gestational Diabetes. A Pilot Randomized Controlled Double-blind Trial.

Document upload*:* Informed Consent Form

Document date: Version 1.0, January 16, 2023.

NCT number*:* Not available

INFORMED CONSENT FORM

Title of the research:
Effects of a Dairy Product Enriched With Lactoferrin on Iron Status of Women With Gestational Diabetes. A Pilot Randomized Controlled Double-blind Trial.
Version 1.0 dated January 16, 2023

Principal Investigator:
Prof. Simona Bo
Associate Professor, Department of Medical Sciences, University of Torino
Clinical Nutrition and Dietetics Unit.

Study Site:
AOU Città della Salute e della Scienza di Torino
Corso Bramante 88/90, 10126 Torino, Italy.

I, the undersigned _____

Born in _____, on _____, residing at _____

_____

Telephone number _____email _____

declare that:

- ✓ I have been diagnosed with Gestational Diabetes;
- ✓ I voluntarily agree to participate in the study entitled *"Pilot study to evaluate the effects of dairy products enriched with milk-derived bioactive compounds on the health status of women with gestational diabetes,"* the aim of which is to assess the impact on metabolic and intestinal parameters of a 125g protein yogurt enriched with lactoferrin (100mg/125g), administered twice daily for two months, versus a protein yogurt without lactoferrin;

- ✓ I have received thorough explanations from the researchers regarding the request for my participation, particularly about the study objectives and procedures;

- ✓ I have been fully informed by the researchers about the diagnostic methods involved, which include blood tests for metabolic and pro-inflammatory variables, administration of questionnaires, anthropometric measurements, and metataxonomic analysis of complex microbial ecosystems—specifically, analysis of the gut microbiota through stool samples;

- ✓ I have had sufficient time to read carefully, understand, and, if necessary, have explained to me the contents of the attached information sheet, which I have signed as acknowledgement and which confirms what was explained to me verbally, particularly that the study will be conducted in compliance with international ethical standards;

- ✓ I have had the opportunity to ask questions and have received satisfactory answers about all aspects of the study, especially regarding possible diagnostic and therapeutic alternatives and the consequences of not undergoing the proposed procedure;

- ✓ I have been informed of any reasonably foreseeable risks or discomforts;

- ✓ I consent / I do not consent to the responsible physician informing my family doctor;

- ✓ I consent to allow monitors, auditors, and national or foreign regulatory authorities direct access to my clinical documentation for monitoring and verification purposes;

- ✓ I am aware that my participation is voluntary and that refusal to participate will not affect my right to receive the most appropriate treatment;

- ✓ I understand that I may withdraw from the study at any time without any negative consequences on my medical care, and without having to provide a reason, unless withdrawal results from the onset of adverse or unexpected effects, in which case I agree to promptly inform the investigator about their nature and extent;

- ✓ I acknowledge that my medical records will remain strictly confidential and that all data will be used solely for the purposes indicated in the study, in compliance with the General Data Protection Regulation (GDPR, EU Reg. No. 2016/679), Legislative Decree No. 101/2018, and the Italian Data Protection Authority's Guidelines on personal data processing in clinical trials (Official Gazette No. 190 of 14/08/2008), as well as any other applicable authorizations;

- ✓ I will be informed of any new data that may influence the risks or benefits of participation, or of any protocol modifications that may affect them;

- ✓ I have been informed that there is an active regional insurance program covering the civil and professional liability of the institution and its employees and collaborators; that I have the right to access all documentation related to me, and that I may contact the Ethics Committee if I deem it appropriate;

- ✓ I acknowledge that I will retain a copy of this informed consent form and related documents; and that for any issues or further information, I may contact the Investigator:

Principal Investigator:
Prof. Simona Bo, Associate Professor
Department of Medical Sciences, University of Turin
Clinical Nutrition and Dietetics Unit
Tel: 011/6336491

Dr. Ilaria Goitre, Nutrition Biologist
PhD Student in Medical Pathophysiology, University of Turin
Tel: 3382381326

I AGREE

I FREELY, SPONTANEOUSLY, AND WITH FULL AWARENESS AGREE TO PARTICIPATE IN THE PROPOSED STUDY.

I also acknowledge that I may revoke this consent at any time before the start of the study.

Date _____Interview start time_____

Interview end time _____

Witnesses, if present (name, surname, signature): _____

Participant's signature: _____

Investigator's (physician's) signature: _____

or

DO NOT AGREE

I FREELY, SPONTANEOUSLY, AND WITH FULL AWARENESS DO NOT AGREE TO PARTICIPATE IN THE PROPOSED STUDY.

Date _____Interview start time_____

Interview end time _____

Witnesses, if present (name, surname, signature): _____

Participant's signature: _____

Investigator's (physician's) signature: _____

STATEMENT BY THE INVESTIGATOR

I, the undersigned… ..... ,
hereby confirm and attest, in agreement with the signature of the consenting person, that in my opinion, they have fully understood all the above information, point by point.

Date: ……………………

Place and time: ……………………………………………………..………

Signature: ………………………………………………………………