



INFORMED CONSENT FOR BABYNEXT NEONATAL DNA SCREENING

(Minors and person with legal guardians)

Mandatory compilation and subscription of consent by both parents

The undersigned _____
Date of birth _____ Place of birth _____
Resident in: _____ Address _____
Documento di Identità: _____ Nr. _____
TAX Code: _____
Telephone: _____ e-mail: _____

AND

The undersigned _____
Date of birth _____ Place of birth _____
Resident in: _____ Address _____
Documento di Identità: _____ Nr. _____
TAX Code: _____
Telephone: _____ e-mail: _____

Parent/s or Guardian/s of: _____

Date of birth: _____ Place of birth: _____

I/WE DECLARE:

- of having received, during the meeting with Doctor _____ on the date _____, detailed information about the genetic analysis I am about to perform, of having understood and considered all the aspects of the exam and of having understood the benefit and the purpose of the genetic test and its possible limits. I had the chance to ask all the questions I considered worthwhile and I received answers I consider complete. In particular:
 - It has been explained to me the test purpose;
 - It has been explained to me the test limits;
 - I have discussed the possible risks, benefits and limits connected to the test;
 - I have understood that the result of the genetic test may have medical and psychological consequences for my family and I;
 - I have understood the meaning of possible test results (even unexpected);
 - I've been informed about the people who will have access to the biological sample;
 - I've been informed about the people who will have access to the test result;
 - I have been informed about how to digitally store data in accordance with the law in the country;
 - I have been informed about how the sample taken for scientific research purposes is to be stored;
 - To have the possibility to revoke the consent at any time, by signing the relevant revocation act.

Therefore,



I/WE AUTHORIZE:

to the collection of biological material from the minor, or from the protected person:

☐ salivary DNA ☐ Other _____

the execution of/and/the following analysis: ☐ **BABYNEXT CARING FOR LIFE** ☐ **BABYNEXT CARING FOR LIFE PLUS**
(Babynext + Lactose Intolerance + Celiac Disease)

☐ **BABYNEXT FIRST** ☐ **BABYNEXT FIRST PLUS**
(Babynext + Lactose Intolerance + Celiac Disease)

INDICATION TO THE ANALYSIS (if present):

FURTHERMORE, I/WE DECLARE:

<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	To be informed at any time about the results of the genetic analysis carried out, following a written request stating that the data resulting from the analysis need to be reopened and that a licensed physician may proceed to re-evaluate the data of which I am the sole owner;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	to share the results with Dr. _____;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	to know any unexpected information or any incidental communication, if this knowledge represented a concrete benefit in terms of therapy and/or prevention;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	to know whether the child may be a healthy carrier of a genetic alteration of predisposition to adult-onset disease, if this knowledge would represent a concrete benefit in terms of treatment and/or prevention;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	that biological material can be used in the future, in compliance with the current legislation on the protection of personal data, for further investigations for diagnostic purposes for the examined pathology at the centre that performs the analysis;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	that the biological material may be used in the future, in compliance with current data protection regulations, for further investigations for diagnostic purposes at other centers, including those outside the European Union;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	to request the biological sample to perform further analysis on the sample at any time;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	to be informed about the results of further investigations carried out for diagnostic purposes;

<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	to be informed of the results of the analyses, including unexpected news that may have a benefit in terms of treatment, prevention, or awareness of reproductive choices;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	that the anonymized biological material and related reports may be used, in compliance with current data protection regulations, for research purposes and/or studies aimed at the protection of the community in the medical, biomedical and epidemiological fields and for information on laboratory performance;
<input type="checkbox"/> I agree	<input type="checkbox"/> I DO NOT agree	<p>that the result of the test will be stored through computer systems for digital preservation in accordance with the provisions of the new technical rules issued by the Agency for Digital Italy (AgID).</p> <p>agree that Eurofins Genoma Group will store the data resulting from the test performed within a recognized and validated database within the national territory.</p> <p>agree that the data resulting from the genetic analysis performed will be kept for 20 years, and may be requested to be reviewed at any time.</p> <p>authorize Eurofins Genoma Group to be custodian of the data resulting from the analysis in compliance with the current regulations on Privacy, data breach and retention, and law.</p>

Ownership of the data as a right in rem to enjoyment will remain throughout the retention period of the authorized parties, such as parents or guardians of the minor, and of the minor himself or herself upon reaching the age of 18.

Consent to the processing of personal data according to the Regulation (EU) 2016/679.

For the purposes of what was said and agreed upon above, I declare that Eurofins Genoma Group S.r.l. has informed me that the processing of personal data provided by me will be carried out in accordance with the law and respecting the rights and the consequent obligations, i.e.: **1) OWNER OF THE PROCESSING:** The Owner of the processing is the company Eurofins Genoma Group s.r.l. - Via di Castel Giubileo 11 - 00138 Roma; **2) PURPOSE OF THE PROCESSING:** a) Implement the contractually agreed operations; b) Perform at any institution, public or private, the obligations connected with or instrumental to the contract, including those of a fiscal and tax nature; c) For management purposes, and / or for research or statistical purposes. **3) PLACE OF THE PROCESSING:** The place of the processing are the Eurofins Genoma Group S.r.l. operational headquarters in Rome at Via Castel Giubileo no. 11, and in Milan c/o Affori Centre at Via Enrico Cialdini 16; **4) LEGAL BASIS OF THE PROCESSING OF THE DATA:** The legal basis of the processing is in the contract and in the cases established by art. 6 § 1. Lett. c) of the Regulation (EU) 2016/679 and by the national law; **5) SOURCE OF THE PERSONAL DATA:** The source is the interested party, i.e. the doctor; **6) PERSONAL DATA PROCESSING AND CONSERVATION:** The processing will be performed, for the purposes expressed above, in written form and/or on paper, magnetic, electronic or telematic form, using automated instruments with the purpose of memorising, manage and transmit the same data and in any case always suitable to guarantee the confidentiality and security of the same. The data will be processed for the duration of the contractual relationships established and also subsequently for the fulfilment of all legal obligations; **7) CATEGORIES OF PERSONAL DATA PROCESSED:** Eurofins Genoma Group S.r.l. processes the following data: identification and contact data of the concerned person; particular categories of personal

data, such as: genetic data, biometric data, data about health and all data provided for the performing of the analysis established with this request; **8) CATEGORIES OF THE DATA RECIPIENTS:** the data may be communicated to external parties with whom Eurofins Genoma Group s.r.l. maintains relationships necessary for the performance of its activities (banks, insurance companies, consultants, carriers, etc.) and, again for the purposes stated above, to the following categories of persons in charge and / or responsible: a) Sales office agents; Corresponding T.S.A. agents (Technical scientific assistance); **9) TRANSFER OF THE DATA ABROAD:** Data are not transmitted abroad. In any case, the data transmitted will be exclusively those strictly necessary for carrying out the procedure. In any case, the recipients of the data will in any case be bound to respect confidentiality and regulations of the Regulation (EU) 2016/679; **10) RIGHTS OF THE INTERESTED PARTY:** The interested party has the right to have his / her data processed in a lawful, correct and transparent manner. Furthermore, he/she has the right, whenever possible, to be informed at any time on how personal data are used; to request the access (Article 15); the correction (article 16) or the cancellation (article 17) of the personal data held. He can also request the limitation of the processing that concerns him/her (Article 18), in addition to the right to data portability (Article 20); to revoke the consent given at any time (Article 7) without prejudice to the lawfulness of the treatment based on the consent given prior to the revocation; to oppose at any time for reasons connected with his/her particular situation to the processing of personal data concerning him / her (article 21); if the interested party considers that the treatment concerning him / her is in violation of the legislation in force on this matter, he/she has the right to lodge a complaint (Article 77) with a supervisory authority, particularly in the Member State in which he/she normally resides, works or the place where the alleged violation has occurred. For Italy, this authority is the Guarantor for the Protection of Personal Data <http://www.garanteprivacy.it/>. The interest party may obtain further information on his / her rights, including the circumstances in which they apply, by contacting the supervisory authority of the Member State in which he / she normally resides. All the after mentioned rights may be exercised at any time by writing to the data controller about the references indicated above.

THEREFORE, I/WE AUTHORISE

The processing of my personal data according to articles 7 and 9, paragraph 2, letter "a") of the Regulation (EU) 2016/679. Data will not be spread or given to third parties.

Date ____/____/____

Parent/s or Legal Guardian/s signatures: _____

Name of the Specialist:

Date and Signature:

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FILL IN THIS FORM ONLY IN CASE OF REVOCATION OF CONSENT

REVOCATION OF CONSENT

I the undersigned taken note that according to article 17 of the Regulation (EU) 2016/679 I have the right to the deletion of personal and specific data I have communicated and for which I have given my consent for the processing, and that this deletion has to happen without unjustified delay in case: a) personal data are not necessary in relation to the purposes for which were collected or otherwise processed; b) does not subsist other legal basis for the processing; c) I oppose to the processing according to the article 21, paragraph 1 of the above mentioned Regulation and does not subsist no right reason prevalent to proceed to the processing, or I oppose to the processing of data according to art. 21 par.2 of the same Regulation (processing of data for direct marketing purposes); d) personal data are illicitly processed; e) personal data have to be deleted to fulfil a legal obligation established by the right of the Union or by the State member to which is subjected the owner of the processing.

NOW, THEREFORE

I/We the undersigned _____ on the date _____

I/We declare to **REVOKE** the consent previously given and to be aware about possible consequences deriving from my revoke.

Parent/s or Legal Guardian/s signatures: _____
