PARTICIPANT INFORMATION SHEET

Study Title: Comprehensive Type 1 Diabetes Autoantibody Screening in Children: A Proactive Approach to Early Detection and Intervention.
Abbreviated title: T1D WATCH STUDY
Protocol Code: T1D WATCH STUDY (2025)
Promoter: Germans Trias i Pujol Research Institute (IGTP), Badalona, Barcelona, Spain.
Principal Investigator: Bibiana Quirant Sánchez / Concepción Violán Fors
Centre: Germans Trias i Pujol University Hospital / Primary and Community Care Management Barcelonès Nord i Maresme

- **Invitation**

We invite you to authorize your child or child under your guardianship to participate in a research project called the T1D WATCH STUDY. In this study, we are evaluating, by means of a capillary sample extraction, the prevalence of type I diabetes in children aged 2 to 10 years by studying autoantibodies.

Before you decide if you want to participate, it's important for you to understand why this study is being conducted. Please take the time to read this fact sheet and discuss it with your friends, family, or doctor. Also, do not hesitate to ask if something is not clear to you or if you want more information.

Both parents can give consent. If the consent is signed by only one of them, he or she must confirm that the other parent does not object to the participation of his or her child or ward in the study or that he or she is the sole legal guardian.

- **What is the objective of the study?**

The T1D WATCH study aims to detect type 1 diabetes early in children between 2 and 10 years of age in the Barcelonés Nord area. This disease causes the body to stop producing insulin because the immune system attacks the cells in the pancreas responsible for making it. This forces people to rely on insulin for a lifetime.

In recent years, it has been observed that there are more children with signs that could lead to the development of type 1 diabetes. If the disease can be detected before the first symptoms appear, interventions can be made to help delay it and avoid serious complications, such as diabetic ketoacidosis, which can be very dangerous.

Other countries have already conducted similar studies and have found that early detection significantly improves the health and well-being of children with diabetes. Therefore, in this study, a blood test will be performed to look for antibodies that indicate the risk of type 1 diabetes. If the result is positive, some genetic and immunological factors of the children will be studied in more depth.

In addition, we want to know how early detection affects the metabolic health of children, as well as how they and their families experience it on an emotional level. The project will also assess whether this screening is easy to perform, whether the population is willing to participate, and whether it is an economically viable option compared to the traditional way of diagnosing the disease.

The results could be very important for children's health: detecting diabetes early would allow for earlier action, better information and support for families, and the avoidance of many complications. It could also contribute to the development of new treatments that protect insulin-producing cells.

Finally, this study will help to know how many children are at risk of type 1 diabetes in Spain and could be used to implement early detection programs throughout the country. Given that the Spanish health system covers the entire population and has a good primary care network, it would be possible to apply this type of screening to reduce the problems associated with type 1 diabetes.

- **Why have I been invited to participate?**

Your child or ward has been invited to participate in this study because it is a population-based study in which participants are randomly selected from the general population. They are invited to participate randomly, not because they have any risk factors for developing type I diabetes.

- **Do I have to participate in this study?**

No. Your child or ward's participation in this study is completely voluntary. If they choose to participate, they are free to withdraw their participation at any time without the need to justify the decision. Your decision to withdraw or not participate will not affect the regular health care you receive.

The samples and data obtained during the participation will be stored and analyzed, unless they request their destruction. However, it will not be possible to return the samples to them or delete the data already processed at the time of their removal.

- **What will happen if I participate in the study?**

If they decide to authorize their child or ward to participate, they will be asked to sign an informed consent form, which will explain in detail what the study consists of and what it means to participate in it. During the first visit, a nurse will review a questionnaire about your child's health and habits, and a small blood draw will be done to check for antibodies related to type 1 diabetes. This visit will last approximately 30 minutes and will take place at the usual health center.

If the results are normal, participation will end, although in some cases an interview may be proposed to find out their opinion on the study. If the results indicate risk, further testing will be done and, if necessary, you will be referred to the hospital to confirm the diagnosis and begin appropriate follow-up.

They may also be invited to participate in discussion groups, interviews or questionnaires to assess how they have experienced and how the program can be improved.

Participation is very important to help improve the health and quality of life of the children in our community. If you have any questions or want more information, do not hesitate to contact your health center.

- **What are the possible drawbacks of participating in the study?**

Drawing blood may cause discomfort or the appearance of a small bruise at the puncture site. All possible measures will be taken to minimize this effect.

- **What are the possible benefits of participating in the study?**

After testing your child or ward, they will be informed of the specific situation. If the presence of type I diabetes is detected, they may benefit from early diagnosis and the possibility of starting appropriate treatment earlier. This treatment will follow the recommendations of the internationally accepted Clinical Practice Guidelines and will be the same as the treatment they would receive outside the study. In addition, the information obtained could help us improve the early detection of type I diabetes in children.

- **Expenses and compensation**

There will be no cost to participate in the study. They will also not receive financial compensation for participating.

- **What happens if a problem arises?**

If you have any questions or problems related to the study, you can contact the researchers and managers who will do their best to answer your questions. You will find the contact details on this document.

- **Will my participation be kept confidential?**

Yes. All information collected will be treated with strict confidentiality. Once obtained, it will be transferred to a database where an encrypted identification code will be created without registering information that allows its identity to be recognized.

The Institut Català de la Salut (ICS), the IDIAPJGol and the IGTP will be responsible for the processing of the data. The database will be stored on an ICS server located in the North Metropolitan Research Support Unit (USR Metro-Nord), which complies with security standards. Access will be restricted by password.

The data will only be stored on ICS servers with secure access via VPN and verified credentials. The information that leaves the center will not contain names or addresses.

Participants may exercise their rights over their data in accordance with the GDPR and Organic Law 3/2018 on Data Protection.

- What **will happen to my samples?**

The blood samples will be analysed at the Germans Trias i Pujol Hospital. Any identifying information will be removed. Samples will be coded and used for this study only. Upon completion, they will be stored in a private collection (T1D Watch ref C.0008760, ISCIII) and will only be used for related studies.

- **What will happen to the results?**

The results will be presented at conferences and published in scientific journals. A report will be sent to the Ethics Committee without identification of participants.

- **Who reviewed the study?**

This study has been reviewed and approved by the Ethics Committee of the HGTiP and the IDIAP Jordi Gol and complies with the Declaration of Helsinki.

- **What happens if I decide not to be part of the study?**

They may be withdrawn at any time, but the information collected up to that point may be used.

CONTACT DETAILS IN CASE YOU NEED MORE INFORMATION
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Thank you so much for reading this fact sheet.