



DOCUMENT OF CONSENT OF THE PARENTS OR LEGAL REPRESENTATIVE FOR PARTICIPATION IN A RESEARCH PROJECT

Official title: Description of the impact of the Sentido's® Model on the adaptive behaviors of children between 3 and 7 years of age, on the autism spectrum and other associated neurodevelopmental challenges.

Clinical Trials Registry: NCT06477666

Document date: October 30, 2023



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STUDY TITLE: Description of the impact of the Sentido's® model on the adaptive behaviors of children between 3 and 7 years of age, on the autism spectrum and other associated neurodevelopmental challenges.

PRINCIPAL INVESTIGATOR: BÁRBARA MURIEL TOMÁS

Mr./Mrs. _____
(ID) _____ as the father/mother of the child

_____ (ID) _____ I authorize my child to participate in this study freely and voluntarily.

I HEREBY DECLARE:

1. I have read and understood the information sheet regarding this study.
2. I have had the opportunity to ask questions.
3. My questions have been satisfactorily answered.
4. I have received sufficient information about the study and the procedures to be performed.
5. I understand that participation is voluntary and I can withdraw from the study at any time without having to provide explanations and without this affecting my child's therapeutic interventions.



6. In accordance with the provisions of Argentine Law 25,326 on Personal Data Protection (General Provisions), enacted by the Senate and Chamber of Deputies of the Argentine Nation assembled in Congress on October 4, 2000, which establishes general principles relating to data protection, rights of data subjects, responsibilities of users and those responsible for archives, registers and databases, control mechanisms, sanctions, and actions for the protection of personal data, I have been informed that my child's personal data, obtained through completing this form, as well as data resulting from his/her participation in the project will be processed under the responsibility of THERAPEUTIC ORGANIZATION SENTIDO'S CAIP & CICI (PEDIATRIC COMPREHENSIVE CARE CENTER AND INTENSIVE BEHAVIORAL INTERVENTION CENTER), for the purpose of managing my child's participation in this research project. Additionally, I have been informed of the following aspects:
- a. That data profiling will be conducted to analyze or predict health-related aspects concerning my child.
 - b. That the indicated treatments are legitimized by the consent granted by me.
 - c. That the personal data obtained by completing this form, as well as those resulting from my child's participation in the project, will be retained for the duration necessary to complete this research study, estimated at 24 months, and will subsequently be destroyed, without being able to be retained unless previously anonymized. In any case, they may not be transferred without my express consent, which I do not grant herein.
 - d. That I can contact the Data Protection Officer of THERAPEUTIC ORGANIZATION SENTIDO'S CAIP & CICI by directing my request in writing to the address Francisco Bher 840, CP 9000, Comodoro Rivadavia, Chubut, Argentina.



e. That in accordance with the rights conferred upon me by current data protection regulations, I may contact the competent Supervisory Authority to file any complaint I deem appropriate, and I may also exercise the rights of access, rectification, limitation of processing, deletion, portability and opposition to the processing of my personal data and withdraw the consent given for their processing, by directing my request to the responsible researcher at the contact address provided in this document.

7. I agree that my written consent and other data will be available to the clinical research project in which my child is participating, and to the researcher responsible for it, Bárbara Muriel Tomás, always respecting confidentiality and guaranteeing that the child's data will not be publicly available in such a way that he/she can be identified.
8. The data collected for this study will be included, together with those of other people participating in this study, in a personal database of the Sentido's CAIP & CICI Therapeutic Organization, to which only the researchers approved for this project will have access, all of them being subject to the confidentiality inherent to their profession or derived from a confidentiality agreement.
9. I sign this information and consent document voluntarily to express my desire for my child to participate in this research study on "Description of the Impact of the Sentido's® Model on the Adaptive Behaviors of Children Between 3 and 7 Years Old, on the Autism Spectrum and Other Associated Neurodevelopmental Challenges" until I decide otherwise. By signing this consent I do not waive any of my rights or those of the child. I will receive a copy of this document to keep for future reference.

Therefore, I agree and consent to the detailed study being carried out with the assistance of the necessary personnel with appropriate qualifications and specialization.



Researcher

Mother/Father/Guardian

I declare that I have provided the study participant and/or authorized person with all the information necessary to perform the intervention explained in this document and I declare that I have confirmed, immediately before the application of the technique, that the participant does not present any of the contraindication cases listed above, and that I have taken all the necessary precautions for the correct intervention.

Comodoro Rivadavia, _____ day of _____ of 2023/2024

For any query and/or complaint regarding non-compliance with the Principles of Ethics in Scientific Research, please contact:

Bioethics Committee in Science and Technology

University Institute of Health Sciences - H.A. Barceló Foundation (CBCyT)

Address: French 2464 CABA

Telephone: 011-4800-0200, option French Headquarters

Email: cbcyt@barcelo.edu.ar