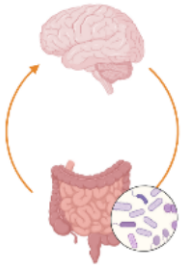
Hôpital Erasme – Hôpital Universitaire de Bruxelles (HUB)
Department of Infant, Child, Adolescent and Young Adult Psychiatry
Clinic for Neurodevelopmental and Learning Disorders



ADHD and the gut-brain axis: exploring the link between gut microbiota, cognition and symptoms

Information sheet and informed assent form for children (6–12 years)

Version for children without ADHD (control group)

English version – translated from the French original

Review date: 11 April 2025

Principal Investigator	Prof. Dr Isabelle Massat – Child Psychiatrist, Senior Research Associate (FRS-FNRS); Director of the Clinic for Neurodevelopmental and Learning Disorders, HUB
Investigators	Barbara Luyens – Neuropsychologist, PhD candidate Dr François Felgueroso-Bueno – General practitioner, PhD candidate Prof. Dr Véronique Delvenne – Head of the Department of Infant, Child, Adolescent and Young Adult Psychiatry, HUB
Sponsor	Hôpital Erasme – Hôpital Universitaire de Bruxelles (HUB)
Ethics Committee approval	CCB B4062025000026 – Ethics Committee, Hôpital Erasme, Brussels



1. Information about the study "ADHD and the gut-brain axis: exploring the link between gut microbiota, cognition and symptoms"

The research team of Prof. Dr Isabelle Massat, Director of the Clinic for Neurodevelopmental and Learning Disorders at the Hôpital Universitaire de Bruxelles (HUB), within the Department of Infant, Child, Adolescent and Young Adult Psychiatry, would like to better understand how what happens in our tummy, such as the microbiota (the "gut flora"), is linked to the way we think, concentrate and feel.

To do this, she is going to compare children who have ADHD (Attention Deficit Hyperactivity Disorder) with other children like you, who do not have ADHD.



- **Why is your help important for this study?** Even if you do not have ADHD, your participation is very valuable. It will allow the researchers to better understand the differences and similarities between all children. Thanks to you, we will be able to make progress in research on the brain and the gut. **<u>It is very important for research.</u>**
- To understand all of this, to help us, and to move science forward, **here is what we will ask you to do:**



  - To better understand what is going on in your tummy, we need to collect stool samples (poo). So you will just have to do a poo, one single time, in a small pot when you are quietly at home.



  - If you take part in this study, you will also be seen by doctors and experts who will ask you questions and have you play games to see how you feel, how you think and how you concentrate.

We hope that all of this will help us better understand how **the gut and the brain** are connected and communicate, and how what we eat can help us feel better.



2. If you take part in this study, here is what you need to know:

- It is a **serious study** that has been approved by people who make sure that everything is done fairly and safely at the Hôpital Universitaire de Bruxelles (HUB).
- **You are free to decide whether or not you want to take part.** If you change your mind later, that is absolutely fine, and it will have no consequences on our relationship. It will not cause any problem with your parents.
- The information you give us will remain **confidential**, which means that nobody will know that you took part.
- You will receive a document with **the results of the study** at the end, or we will explain them to you and answer all your questions.

3. Now, here is how the study will go:







- ✓ You will be seen only once by doctors and experts at the Erasme Medical Center.
- ✓ You will need to give a poo sample on the day of the visit or in the days that follow. You can do it at home; it will be put in a small pot and handed to the doctors.
- ✓ They will keep these samples in a very cold freezer and send them to a specialised laboratory to be analysed.
- ✓ All information about you will remain secret.
- ✓ Your parents will be asked to fill in questionnaires.

It is important to know that everything that happens in this study is **safe and complies with medical rules.**

If you want to take part, we ask you to cooperate well, to tell us everything you feel and not to hide any information about your health.

➔ **Before giving your agreement, do you have any questions?**

4. Informed assent of the child:

It's your turn to answer:

Questions	**YES**	**NO**
Do you know why you are doing this activity?		
Has an adult explained to you what you are going to do?		
Have you asked questions, and were they answered properly?		
Do you know that you can say “I want to stop” whenever you want?		
Do you know that all the information about you will remain secret?		
Do you agree that we use your answers?		
Do you know that your doctor might be contacted if needed?		
Do you know that the information we collect will only be used for this study?		
Do you have a copy of this paper to remember it, and do you know that you can talk about it with an adult whenever you want?		

✍ Your first name, last name and signature: _____

Date: ____ / ____ / _____

Doctor's signature _____