Information and assent form for participants aged

12-17 years

**Title of the study: Enter the simple title of the study here**

Hello,

At the department XXX, where you are currently staying, we want to perform a study in patients who receive intravenous nutrition (meaning through a tube directly in the bloodstream).

For this study we want to collect information like your age, weight, some general information about your illness and information about the prescribed intravenous diet. We can easily find this data in your patient file.

We would like to ask for your cooperation to participate in this study, whereby we ask you to allow us to collect and review the above data in your patient file. The study will be conducted by XXX.

Participation in this study is entirely voluntary. This also means that you can withdraw from the study at any time without this decision having consequences for yourself, your treatment or your parents/guardians.

Participation in this study will not bring any benefit to you and no extra effort is expected of you outside of normal care procedures.

All data will be treated confidentially and processed coded. This means that nobody outside the study team will know your name, in accordance with the law on privacy. This coded data can then be shared with other researchers for future studies in the context of the same or similar disease or treatment. These studies may take place in Belgium or abroad. Such new studies must always first be approved by the ethics committee. If you do not want your data to be used for future research, you can let your parents or the researchers know.

By signing the form below you agree to participate in this study. If you want to know more about the study or have any questions during the study, you can always contact your treating doctor or the investigator XXX.

# ASSENT FORM

|  |  |
| --- | --- |
| I, | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (name of the participant in capital letters) declare |

* that I have read and understood this form.
* that I have been able to ask all my questions and am satisfied with the answer.
* that I understand that my data will be viewed by the people who have the right to do so.
* that I am aware that information about my disease will be collected and coded and that my coded data will be used for current scientific research. My privacy will be respected at all times.
* that I am aware that my coded data may be used for future studies in the context of the same or similar disease or treatment, both in Belgium and abroad. Such new studies must always be approved by the ethics committee. If I do not want my data to be used for future studies, I will let my parents or the researchers know.
* that I understand that participation is completely voluntary.
* that I have had sufficient time to think about my participation.

 **I agree to participate in this study.**

|  |  |  |
| --- | --- | --- |
| Name and first name of the participant | Signature | Date |
| Name and first name of the doctor-investigator\* | Signature | Date |

2 copies must be completed. The original is kept by the investigator in the hospital for a period of at least 10 years, the copy is given to the participant.

\*Tick by the investigator if agreed

|  |  |
| --- | --- |
| I declare that I have provided the necessary information regarding this study (the nature, the purpose, and the foreseeable effects) orally and a copy of the information document to the participant. |  |
| I confirm that no pressure has been exerted on the participant to allow him/her to participate in the study and I am prepared to answer any additional questions. |  |