

HP-HISTOLOGY

Study of the histological characteristics of the stomach of children
according to the new Sydney classification

Data Controller	Groupeement des Hôpitaux de l'Institut Catholique de Lille (GHICL) Rue du Grand But – BP 249 – 59462 LILLE Cedex FRANCE
Chief Data Processing Officer	Professor Nicolas Kalach University Professor & Hospital Doctor Head – Department of Paediatrics, Hôpital Saint Vincent de Paul Boulevard de Belfort – BP 387, 59020 LILLE Cedex – FRANCE ✉ kalach.nicolas@ghicl.net ☎ +33 (0)3 20 87 76 17
Clinical Research and Innovation Division	✉ drci@ghicl.net ☎ +33 (0)3 20 22 57 37
Protocol number	RNIPH-2023-18

Information sheet

Dear Parent/Guardian,

Your doctor has suggested that your child take part in a medical study that does not involve any additional consultations or examinations. This study is called HP-HISTOLOGY: a study of the histological characteristics of the stomach of children according to the new Sydney classification.

This research is led by Professor Nicolas Kalach, head of the paediatric department at Saint Vincent de Paul hospital in Lille, France.

The purpose of this information sheet is to explain the study process. You will then have time to think about the information you have read before making your decision. You can contact your doctor at any time if you have any further questions.

HOW THE STUDY WORKS?

Your child is going to have a gastrointestinal endoscopy. As your doctor has explained, when your child has this test, they will also have a health assessment, including a clinical examination, to get their medical history and find out about their symptoms and medications taken. Several pieces of tissue will be taken from their stomach (called biopsy samples). These samples will be sent to your hospital's laboratory for histological, biochemical and bacterial analyses.

Histological analysis involves using a microscope to look for changes in the tissue. The sample taken is first prepared then fixed and placed in glass slides (histology slides) to be observed under a microscope. These histology slides can be stored for several years.

For this study, the researchers want to review the histological analyses of gastric biopsy samples taken from children treated in around twenty hospitals in Europe. They will then describe the histological characteristics of these samples in a standardized form.

HOW WILL YOU PARTICIPATE?

Your participation consists of **giving your consent** for us to **use the following the data** collected from your child during their care and from their medical record **for research purposes**:

COMPLIANCE

This study complies with current regulations and its legal basis is the fulfilment of public service duties.

DECISION TO PARTICIPATE IN THE RESEARCH

You are free to decide whether or not your child will participate: you can refuse or, if you decide that your child will take part, you can change your mind without having to give a reason. Either way, your decision will not affect your relationship with the medical team or the care that your child receives. Whatever you decide, simply let your doctor know as soon as possible.

CONFIDENTIALITY AND PATIENT PROTECTION

➤ Collection and use of data

During your child's care, a lot of information is collected and recorded in their medical record, and tissue samples are taken.

If you agree to your child taking part in this study, your doctor, or a qualified person acting on your doctor's behalf, will collect only the information in your child's medical record that is needed for the study: sociodemographic data (gender & age) and health data (clinical data, medical history, treatment data and test results).

This information will be entered into a specific secure database called HP-HISTOLOGY. The information will be coded, in other words identified by a number and initials (rather than the surname and first name). Only your child's doctor will be able to link the coded data to your child and their medical record. Their name and any other information identifying them will be kept in your hospital's paediatric department and will remain confidential.

Once all the necessary information has been gathered, statistical analyses will be carried out on the HP-HISTOLOGY database information in order to reach overall conclusions.

Throughout this process, the data controller, Saint Vincent de Paul hospital in Lille (France), will have access to the coded data. This data may be shared with people acting on its behalf, or with its research partners. Authorised health authorities may also consult the data to ensure that the study is conducted properly, as well as any other person required to do so by law.

The data collected will be used for this study and may also be used in papers published about the study. The data will remain coded at all times and your child's identity will never be revealed in a study report or publication.

➤ Data retention period

The coded data will be kept for up to two years after the research results are last published and will then be archived for a maximum of 15 years after the end of the research, in accordance with regulations. After this period, the data will be irreversibly anonymized or destroyed.

➤ Access to your child's medical record

By agreeing to take part in the study, you allow the data controller, qualified persons acting on its behalf, its research partners or collaborators, French health authority representatives, or any other person required by law, to consult your child's medical record, kept at the hospital, to ensure that the study is conducted properly. Patient confidentiality will always be upheld.

➤ Your rights concerning your data

In accordance with General Data Protection Regulation 2016/679 of 27 April 2016 and the French Data Protection Act as amended by Act 2018-493 of 20 June 2018 and implementing decree 2018-687 of 1 August 2018, you have:

- the right to access your personal data;
- the right to rectify your personal data (you can ask for your data to be rectified, updated or supplemented);
- the right to object at any time to the processing of this data;
- the right to limit its processing (in certain cases);
- the right to delete your data.

The right to object means that you can withdraw the consent you originally gave for your data to be collected and processed and that you can object to data already collected from being used.

You also have a right to the portability of your data (meaning that you can ask to recover your data so that it can be given to another data controller). However, you may not be able to exercise some of these rights until the end of the study.

You can access any of your child's study data, either directly or through a doctor of your choice, in accordance with provisions L.1111-7 of the French Public Health Code. However, some of this information may not be available until the end of the study.

To exercise your rights concerning your child's data, ask to discuss this with the doctor monitoring your child in this study. Otherwise, you can contact the Data Protection Officer (DPO) at Saint Vincent de Paul Hospital (GHICL) at the address below.

If you believe that the use of your personal data is in violation of applicable data protection regulations, you may file a complaint with the French Data Protection Authority (CNIL).

RESULTS OF THE STUDY

Once the research data has been collected, it will be processed and analysed by qualified personnel.



The data will remain confidential at all times.

At the end of the study, if you wish, you can contact the doctor in charge of the research to be notified of the overall study results once they are available.

CONTACT DETAILS FOR FURTHER INFORMATION

If you have any questions about this research, please feel free to ask your medical team. You can also contact:

- the research team: +33 (0)3 20 22 57 37
- Professor Kalach, who is the doctor in charge of the study: +33 (0)3 20 87 76 17
- the Data Protection Officer (DPO):
 Sandrine Rémy
 Rue du Grand But - BP 249
 59462 LILLE Cedex, France

 + 33 (0)3 20 27 57 00
 contact.dpo@ghicl.net

OBJECTION FORM TO KEEP

I, the undersigned, (surname used) (first name),

acting as the ☐ guardian ☐ legal representative of:

(surname used) (first name), born on,



☐ object to him/her taking part in HP-HISTOLOGY.

☐ consent to him/her taking part in HP-HISTOLOGY.

Date: _____

Signature: _____

"The personal data collected on this form is needed to allow GHICL to process your objection request. It will be kept for the appropriate retention period. In accordance with the applicable regulations, you have the right to access, rectify and delete this data and to limit (in certain cases) the processing of this data, as well as the right to file a complaint with the French Data Protection Authority (CNIL)."

HP-HISTOLOGY – RNIPH-2023-18
 Professor Kalach – Department of Paediatrics
 Hôpital Saint Vincent de Paul
 Boulevard de Belfort – BP 387, 59020 LILLE – FRANCE
 kalach.nicolas@ghicl.net  + 33 (0)3 20 87 76 17

HP-HISTOLOGY

Study of the histological characteristics of the stomach of children
according to the new Sydney classification

Data Controller	Groupeement des Hôpitaux de l'Institut Catholique de Lille (GHICL) Rue du Grand But – BP 249 – 59462 LILLE Cedex FRANCE
Chief Data Processing Officer	Professor Nicolas Kalach University Professor & Hospital Doctor Head – Department of Paediatrics, Hôpital Saint Vincent de Paul Boulevard de Belfort – BP 387, 59020 LILLE Cedex – FRANCE ✉ kalach.nicolas@ghicl.net ☎ +33 (0)3 20 87 76 17
Clinical Research and Innovation Division	✉ drci@ghicl.net ☎ +33 (0)3 20 22 57 37
Protocol number	RNIPH-2023-18

Objection form to be given to the doctor

I, the undersigned, (surname used) (first name),

acting as the ☐ guardian ☐ legal representative of:

(surname used) (first name), born on,

☐ object to him/her taking part in HP-HISTOLOGY.

☐ consent to him/her taking part in HP-HISTOLOGY.

Date: _____

Signature: _____

"The personal data collected on this form is needed to allow GHICL to process your objection request. It will be kept for the appropriate retention period. In accordance with the applicable regulations, you have the right to access, rectify and delete this data and to limit (in certain cases) the processing of this data, as well as the right to file a complaint with the French Data Protection Authority (CNIL)."

HP-HISTOLOGY – RNIPH-2023-18
Professor Kalach – Department of Paediatrics
Hôpital Saint Vincent de Paul
Boulevard de Belfort – BP 387, 59020 LILLE – FRANCE
✉ kalach.nicolas@ghicl.net ☎ +33 (0)3 20 87 76 17