



## Splenectomy Registry

## PATIENT INFORMATION FORM

**Intercontinental Cooperative ITP Study Group (ICIS)**  
**[www.itpbasel.ch](http://www.itpbasel.ch)**

### Information for Patients/Parents

Dear Patient  
Dear Parent

You are being asked to participate in a scientific study, because splenectomy is planned in relation to Idiopathic Thrombocytopenic Purpura (ITP).

The surgical removal of the spleen, also called splenectomy, is an approved method of therapy for chronic ITP. Splenectomy can be performed as a laparotomy (open splenectomy) or as a laparoscopy (surgical method using two to three little abdominal cuts for suctioning out the spleen). Nonetheless, there are still some unanswered questions which are addressed in this ongoing study, the Splenectomy Registry.

The Registry will serve the purpose of collecting as much information of ITP patients worldwide as possible, to find answers to the following:

- How can the success rate of splenectomy be favorably influenced?
- Which patients groups will respond well to splenectomy?
- Which is the best possible management before and during splenectomy?
- Individual planning of surgical method of splenectomy

### General Information

If you decide to participate in this registry information such as gender, age, blood count and management of your ITP will be collected in a database over 10 to 15 years. The treating physician will forward this information to the study administration at registration of a patient, within 3 months when splenectomy was performed and further yearly. Additional physical examinations or administrative procedures are not necessary.

### How will the registry results be used?

The results of this registry will be communicated at conferences and published periodically in scientific journals, so that physicians treating ITP patients are informed.

### Confidentiality

Personal information such as your name and address will not be entered to the database, i.e. your information will be anonymized as a number. The database is safeguarded. Your name will not be mentioned in publications related to this registry.

**Your participation is voluntary**

Participation in the Splenectomy Registry is voluntary. If you would like to participate, your signature is mandatory (see consent form).

If you choose not to participate, you may do so without giving reasons. Your medical care will not be influenced in any way by your decision.

**Questions?**

In case you have any questions please contact your treating physician.

Institution *to be completed with local information*

Name

Tel



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**Location:** *to be completed with local information*

**Sponsor:** *to be completed with local information*

**Researching Physician:** *to be completed with local information*

**Patient:**

**Last and first name:**

.....

**Patient's parents or legal guardian**

**(If patient is a minor and incapable of making a decision or suffers from a disability rendering him or her unable to make a decision);**

**First and last name:**

.....

**Please read this document carefully.**

**Please ask if you do not understand something or need additional information.**

- The undersigned physician has informed us both in writing and verbally of the registry's objectives and schedule.
- We have read and understood the patient information dated October 2010 (rev. 22.11.10) regarding the abovementioned registry. Our questions regarding participation in this registry have been answered satisfactorily. We have received a copy of the patient information. We will also retain a copy of the signed consent form.
- We had sufficient time to reach our decision.
- We have been informed of our right to privacy protection. We consent to the recording and archiving of data collected within the Splenectomy Registry. We agree to the anonymous (unique patient number) transmission of these data to Splenectomy Database. All persons with authorized access to this information are bound to observe strict confidentiality. The patient's name will never be publicized.
- We agree to allow test center specialists and authorities of the ethics commission access to original data in the patient history for testing and control purposes under strict adherence to doctor/patient confidentiality.
- We are fully aware that participation in the registry is voluntary. We may withdraw our consent at any time without explanation. This will not negatively influence further treatment and care.

Place, date	Patient's signature
Place, date	Mother's signature
Place, date	Father's signature
Place, date	Researching physician's signature