

PATIENT INCLUSION – FIRST STEPS

SOCS1 Registry - a level 3 ESID Registry project

All essential documents for download: <https://www.uniklinik-freiburg.de/cci/studien/socs1-registry.html>,
For username and password please contact: annette.uhlmann@uniklinik-freiburg.de

Inclusion criteria

1. male and female patients with SOCS1 heterozygous mutations, all ages
2. confirmation of functional relevance of the mutation (at least one of the following):
 - reduction or absence of protein expression
 - abrogation of SOCS1 protein function, e.g. STAT1-phosphorylation upon IFN- γ , proliferation of activated T cells upon IL-2, or demonstration of SOCS1 loss of function upon luciferase assay in transfected cells
3. patients (or their legal representatives) able to communicate with the investigator, to understand and comply with the requirements of the registry project and to provide (or having provided) informed consent

How to include a patient

1. Patient Consent: <http://esid.org/Working-Parties/Registry/Informed-patient-consent>
 - **Patients must sign the actual version of the ESID Registry patient consent** – if the patient has signed this Version previously, no new consent required
 - let the consent be dated and signed by patient and investigator
 - give a copy of the signed document to patient, keep original in the patient record
2. Patient registration fax
 - Complete fax, date and sign; send to Clinical Research Unit (CRU) CCI by **fax: +49 (0)761 270-74250 or by E-mail: annette.uhlmann@uniklinik-freiburg.de**
 - shortly after you will receive the confirmation form with
 - i. validation of patient eligibility
 - ii. the SOCS1 project-specific patient identification number. **Please use this number for marking each single page of SOCS1 paper CRF.**
3. Patient identification log

Note the SOCS1 patient ID number in the patient identification log (template for download available) together with the patient's ESID ID and the patient's name, so that you can identify the patient during the whole documentation period. Please keep the log at your centre at a safe place! **The SOCS1 patient ID number will be used in all future correspondence on this patient.**

How to document patient data

- download "**CRF retrospective documentation**" from <https://www.uniklinik-freiburg.de/cci/studien/socs1-registry.html> and print
- complete all data fields, date and sign on last page detailed guidance in "CRF instructions" on <https://www.uniklinik-freiburg.de/cci/studien/socs1-registry.html>
- send completed CRF to Clinical Research Unit CCI by **fax: +49 (0)761 270-74250 or by E-mail: annette.uhlmann@uniklinik-freiburg.de**
- keep original hard copy with your files

You need further support? Please contact us

For technical support:

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