

CONSENT TO CONTRIBUTE TO THE
**CELL BANK OF THE
SEVERE CHRONIC NEUTROPENIA
INTERNATIONAL REGISTRY (SCNIR)**

- ADULT PATIENT OR PARENT, FOR MINOR PATIENT -

ADDRESS:

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Patient Identification: _____

INTRODUCTION

On a separate form you gave your consent for you/your child to participate in the Severe Chronic Neutropenia International Registry (SCNIR).

In addition to the neutropenia database of the SCNIR in which the clinical information of neutropenia patients is collected and documented, the registry maintains a cell bank for the long-term storage of biological material derived from neutropenia patients. The material may be used for the following purposes:

1. To re-evaluate and confirm the diagnosis by reviewing the patient's blood and bone marrow smears that are requested together with the clinical information provided by the registration form since an accurate diagnosis is essential for the correct classification into the different subtypes of neutropenia.
2. To provide biological material to research laboratories that are specialized in investigations concerning the underlying causes and potential future consequences of the different subtypes of neutropenia, e.g. the increased leukemia risk of patients with congenital neutropenia.

Please note the following information concerning a contribution to the cell bank:

1. Your/Your child's contribution is absolutely voluntarily and independent of your participation in the SCN International Registry.
2. You/Your child may decide not to have any biological material provided to the cell bank or may withdraw your consent to contribute to the cell bank at any time. You will not experience any disadvantages in either case.
3. Your/Your child's contribution to the cell bank of the SCN International Registry does not necessarily result in immediate personal benefits. However, the research to which you contribute will give us knowledge that may help you/your child and other patients in the future.

CURRENT RESEARCH INFORMATION

In the recent past, genetic markers were identified for subgroups of neutropenia patients that may either be involved in the inheritance of the disease (genetic markers that exist from birth) or, in the case of genetic alterations that are acquired during lifetime, which may indicate an increased leukemia risk.

However, the actually underlying causes of the different subtypes of neutropenia are still not fully understood. Further research is required to investigate both, the common grounds and the differences between the various forms of neutropenia in order to understand their individual late effects and recognize their symptoms as early as possible.

For these reasons, the SCNIR would appreciate it if all registered patients, who provide clinical data, have also a small bone marrow or blood sample (approx. 5 ml heparinized bone marrow aspirate and/or 5-10 ml heparinized blood) sent to the registry by their treating physician when undergoing routine control examinations. This material will be stored in liquid nitrogen and may be provided for important research projects on SCN by the SCNIR.

In general, additional blood draws or bone marrow puncture are not required. Samples for the cell bank of the SCNIR may be taken during routine examinations. Since research results are not necessarily unambiguous, it may become necessary to repeat certain investigations in distinct cases to clearly understand the meaning of the result in context with the disease. However, for these investigations an individual consent by the patient/the patient's parent(s) will be requested.

RISKS AND POTENTIAL CONSEQUENCES

Research results may lead to the disclosure of potential risks and late effects, e.g. the increased leukemia risk in congenital neutropenia. The knowledge of an increased leukemia risk may cause emotional stress for the patient and her/his family and may also lead to fear of the future in individual cases. However, the patient/patient's parent(s) may order in writing that research results are withheld from her/him/them.

DATA ANALYSIS AND STORAGE OF RESEARCH RESULTS

All research data are stored under an identification number that may be decoded exclusively in the data collection center where also the clinical data are stored. However, the research data will not become part of the general database of the SCNIR but will be stored in a separate "research database". This database will simultaneously be used to keep track of all collected biological material that is stored in liquid nitrogen at the Medical School Hannover until usage. The close cooperation with all scientific laboratories where the patient's cells are analyzed, guarantees that the SCNIR is promptly informed of all relevant research results. Thus, important results may rapidly be forwarded to treating physicians and patients and this knowledge may directly be used to improve the diagnosis and treatment of neutropenia.

