



## SCNIR

Severe Chronic Neutropenia International Registry

European Office

SCNIR@mh-hannover.de

[www.severe-chronic-neutropenia.org](http://www.severe-chronic-neutropenia.org)

At the  
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### INFORMEND CONSENT

TO PARTICIPATE IN THE REGISTRY AND BIOBANK

**Name:** \_\_\_\_\_ **Date of Birth:** \_\_\_\_\_

I / We,

- was / were informed by the treating physician orally and in writing (information form) about the SCN international registry (SCNIR) and the biobank of the SCNIR. In particular I was / we were informed about the scope and benefits of the participation in the SCNIR, rights of participants and data protection.
- had enough time to consider our decision about participating in the SCNIR and the biobank.
- was / were informed that the participation in the SCNIR and the biobank is voluntary and that I / we can withdraw my / our consent at any time without giving any reasons, without any disadvantages for me / us.
- was / were informed that participation in the SCNIR is independent of the participation in the biobank

I / We,

agree to participate in the SCNIR and the biobank by signing in initials / date to each section:

#### **Participation in the registry and data protection**

Please tick "agree" if you authorize the data coordinating center of the SCNIR Europe at the Medical School Hannover to read medical records and results, to request and document clinical information from the treating physicians (release of confidentiality). The data is stored and evaluated in a protected database. No information that identifies you can be shared with anyone outside of SCNIR Europe. All information is encrypted (pseudonymised) before being entered into the SCNIR database. The data may be stored indefinitely and used for medical research projects. Upon revocation of participation, the collected data will be deleted.

The European Medicines Agency (EMA) requires pharmaceutical manufacturers to report on the drug safety of medicines used to treat neutropenia, such as *filgrastim*. For this purpose, anonymized pooled data are evaluated and forwarded as a report.

Agree  Not agree  Initials\_\_\_\_\_ Date\_\_\_\_\_

#### **Contact in case of loss of medical contact**

Please tick “agree” if you agree that we contact you in case that the inquiry of reports from your treating physician/your child’s treating physician after the registration should not be possible at any time, e.g. after a change of physician which was not communicated to the registry. In this case, we will contact you directly to inquire about your current physician or your current findings. Please indicate at this point a current email address for contact.

Agree  Not agree  Initials\_\_\_\_\_ Date\_\_\_\_\_

E-Mail-address:\_\_\_\_\_

**The following paragraph may not be applicable according to national data protection law. Please ask your treating physician.**

#### **Participation in the SCNIR biobank for scientific use**

Please tick "agree" if you consent to the collection, storage and use of your biomaterials and data as described in the information sheet. The biomaterial will be stored in the biobank of the SCNIR Europe in Tübingen, Germany. (This is not applicable for diagnostic workup of biomaterial sent to the SCNIR laboratory in Tübingen).

You also agree that the purposes of scientific and medical research for which your biomaterials and data are used will not be limited. You transfer the ownership of the biomaterials to the biobank of the European SCNIR in Medical University Hospital Tübingen. By participating in the registry and cell bank, you allow the pseudonymized linking of your clinical data / your child's data with research results. Biological materials and / or data may be used indefinitely for medical research projects. Scientific publications of research results will be published anonymously. You have been informed that you can revoke your consent to the biobank of the SCNIR at any time without giving any reason. With the revocation you can decide whether the remaining biomaterials and the collected data shall be destroyed, deleted or anonymized. Data from previous analyzes cannot be removed anymore. The data collected is subject to all legal data protection rules, as well as data protection in accordance with current EU guidelines as listed in the information sheet.

Agree  Not Agree  Initials\_\_\_\_\_ Date\_\_\_\_\_

#### **Renewed contact**

In individual cases it may be possible that a research result from the biobank's samples could be of considerable importance for your health / your child's health. Please tick below if you would like to receive feedback from this research or not.

#### **Contact**

Desired Not desired Initials\_\_\_\_\_ Date\_\_\_\_\_

**Signatures**

_____ Patient	_____ Date
_____ Minor Patient	_____ Date
_____ Parent / legal guardian	_____ Date
_____ Parent / legal guardian	_____ Date
_____ Physician	_____ Date

Please keep a copy of this document carefully for your records.