

Consent Form

The Cerebral Palsy Register of Norway (CPRN) The Cerebral Palsy Follow-up Program (CPOP)

Background

Cerebral Palsy (CP) is the most common lifelong motor disorder among children. Symptoms and severity can vary. There is a need to gain increased knowledge about CP in general, and how to improve diagnosing, treatment and follow-up. Medical quality registers can contribute to the identification of causes, prevalence and the need for health care and assistance through the collection of information from those who participate in the register. This can contribute to the prioritization of health care services.

All children who are diagnosed with CP in Norway are asked to participate in **The Cerebral Palsy Register of Norway (CPRN)** and in **The Cerebral Palsy Follow-up Program (CPOP)**.

CPRN was approved as a national medical quality register in 2006 by the Norwegian Directorate of Health. **CPOP** is a systematic motor function follow-up program based on the CPUP follow-up program in Sweden. Collectively CPRN and CPOP constitute the register network for CP in Norway. CPRN and CPOP have a common reference group and by-laws. The CPRN database is located at the Vestfold Hospital Trust and the CPOP database is located at the Oslo University Hospital. They have their own respective license from The Data Inspectorate.

The main aims of CPRN

Generate increased knowledge of the causes and treatment of children/youths with CP through surveillance and systematic analyses, including to:

- Describe the prevalence of CP in Norway, including subtypes, severity and other associated impairments
- Improve the quality of pregnancy care and newborn medicine
- Ensure equal treatment and follow-up of children/youths with CP in Norway
- Increase knowledge of CP

The main aims of CPOP

Generate increased knowledge on the development of motor function in children/youths with CP through surveillance and systematic analysis, including to:

- Follow up and contribute to the prevention of hip dislocation, contractures and deformities
- Follow up the treatment of motor function and improve the quality of treatment according to international guidelines
- Increase knowledge of CP, specifically the various motor interventions, such as physical and occupational therapy, spasticity reducing treatments, orthopaedic surgery and orthotics
- Manage networks for physical and occupational therapists in habilitation services for children/youths with CP to ensure equal treatment nationwide

What does it mean to participate in CPRN and CPOP?

CPRN and CPOP record the name, person number, CP diagnosis and motor function of the child/youth. The information is collected by health professionals at the habilitation centers. The hospital that is responsible for giving the diagnosis will also be registered. Information from the medical journal may also be collected in order to clarify the details on the diagnosis and treatment that is given. Furthermore, the register may also obtain relevant information related to the CP diagnosis from other public registers, including: The National Population Register, The Medical Birth Registry of Norway, The Norwegian Newborn Quality Register and the Norwegian Mother and Child Cohort Study. Information can be combined with The Norwegian Patient Register in order to calculate the completeness of the register.

CPRN records information at the point of diagnosis, at 5 years of age and at approximately 15 years of age. Other information that is registered includes: cognition, nutrition, language and communication abilities, other medical diagnoses, treatment and MRI results.

CPOP records information from examinations performed once/twice a year or every second year depending on age and functional level by health professionals at the habilitation centers, in cooperation with primary health services. Depending on age and functional level the hips and back are routinely followed-up with x-ray controls. The following information is registered: gross motor function, hand function, joint mobility, spasticity and interventions, such as physical and occupational therapy, spasticity reducing treatments, orthopedic surgery and orthotics.

Possible advantages/disadvantages

The child/youth does not have direct advantages of being registered. However, the information will contribute to improving the diagnostic process and the treatment. Registration also helps to follow the development of the individual child/youth and their need for habilitation interventions, which in turn will improve the prioritization of health services. There are no disadvantages in participating.

What happens with the information?

The recorded information will only be used as described in this information sheet, and will not be directly identifiable to the child/youth in analyses of the data. A code will be used to connect the child/youth to a confidential name list. Only authorized personnel who work directly on the register will have access to the confidential data. It will not be possible to identify the child/youth in the results that are made public.

Information will be stored for a minimum of 20 years (2030). At that time the data will either be deleted, or an application will be submitted to The Data Inspectorate for an extension of data storage. In the case of an extension, the child/youth/parent will be able to reserve him/her self against further data storage.

Distribution of information

In the case of a request to link the coded data with other registers or other research entities, or if we would like to collect additional information, this must be approved by the Regional Committee for Medical and Health Research Ethics (REC) and consented by you. In addition, the respective health trusts and the leaders of CPRN and CPOP must also approve the distribution of information.

CPRN and CPOP will compare the mutually recorded information on those who have consented to both registers, to ensure the quality of the data on a yearly basis. Anonymous data will be sent yearly from CPOP to CPUP in Sweden, and from CPRN to a European database at the Surveillance of Cerebral Palsy in Europe (SCPE).

Voluntary participation

Registration in CPRN and CPOP is voluntary. If consent is given to be included in the register(s), you have the right to access the information that is registered on your child/youth. You also have the right to correct any mistakes in the information that is registered. If you change your mind in the future about participating in the register(s), you can withdraw consent and your information will be removed from the register(s). If you do not wish to consent, it will not have any consequences in regards to the treatment of your child/youth. If you are consenting on behalf of your child/youth, the consent must be renewed when the child reaches 16 years of age.

Leader of CPRN is:

Guro L. Andersen

MD PhD pediatrician tel.: 33308200 / 33308259

Leader of CPOP is:

Reidun Jahnsen

PhD physical therapist tel.: 02770 / 95738379

Consent declaration

I am willing to participate in/I am willing that my child participates in:

- CPRN *(box must be checked)*
 CPOP *(box must be checked)*

(name in capital letters)

(signature of participant over 12 years of age, date)

(signature of parent(s)/ guardian, date)

- *At least one parent/guardian must sign for children under 12 years of age*
- *Children between 12 and 16 years of age can sign together with at least one parent/guardian*
- *Youths 16 years of age and older can sign for themselves*

Participant

Name

Norwegian person number
(11 digits)

Address

Hospital/ Habilitation Center

Health personell

I confirm that I have given information about CPRN og CPOP:

(signature of health professional, date and name in capital letters)

6.2.2013

Send Consent Form to:
Vestfold Hospital Trust
The Cerebral Palsy Register of Norway
PB 2168
3103 Tønsberg