

# Privacy notice for clinical trial site personnel

This privacy notice is addressed to:

- Clinical investigators (principal investigator, sub-investigator or co-investigator);
- Other Site staff such as nurses, pharmacists or technicians, whose Personal Data may be processed in the course of the clinical trial sponsored by Novartis.

You are receiving this Privacy Notice because Novartis Healthcare A/S and affiliates (“Novartis”) will process information about you, which constitutes “Personal Data.”

This privacy notice is provided to you to ensure transparency in relation to collection, use and disclosure of your Personal Data by Novartis for purposes related to the conduct of clinical trials sponsored by Novartis (“Novartis Clinical Trials”) which are being carried at your Clinical Trial Site (the “Site”). For the purposes described in this Privacy Notice, Novartis is responsible for the processing of your Personal Data acting as a “Controller”.

## Collection of Personal Data

For the purposes described in this Privacy Notice, we may collect the following information about you including:

- name, identification number, address and other contact details,
- financial information (e.g. bank account number, financial interests in any of the Novartis group companies),
- qualifications, publications and information contained in the CV you provide to us where necessary,
- previous experience in clinical trials within or outside of Novartis and type of the GCP training received,
- technical data related to your use of Novartis IT systems.

## Purposes and legal basis for processing your Personal Data

### Processing purpose

1. to conduct Novartis Clinical Trials in accordance with good clinical practice and applicable laws;
2. to support applications for and to comply with the conditions of any marketing approval granted in respect of any medication studied under a Novartis Clinical Trial (“**Study Medication**”)
3. to support applications to vary the terms of any marketing approval granted in respect of a Study Medication;
4. to carry out research related to the development of pharmaceutical

### Legal basis

Novartis’ legitimate interest to conduct clinical trials to test potential treatments as well as compliance with legal and regulatory obligations;

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Novartis’ legitimate interest to conduct clinical trials to test

- products, diagnostics or medical aids and improve clinical trial practice; potential treatments;
5. to comply with the US Financial Disclosure regulation, which is intended to ensure that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to the Federal Drug Administration of the U.S.A. ("FDA") are identified and disclosed to the FDA<sup>1</sup>; Legitimate interest and compliance with legal and regulatory obligations;
6. to ensure traceability and follow-up of drug safety notification. compliance with legal and regulatory obligations.

If applicable to Novartis Clinical Trial, your Personal Data (name and contact information) may be incorporated in subject recruitment advertisements (print media or on Internet). Any such advertisement would be approved by the Ethical Committee before it is made public.

## Sharing of Personal Data

In the course of our activities and for the purposes listed in this Privacy Notice, your Personal Data can be accessed by, or transferred to the following categories of recipients, on a need to know basis to achieve such purposes:

- the sponsor of the Clinical Trial,
- our personnel (including personnel, departments or other companies of the Novartis group),
- our independent agents or brokers (if any),
- our suppliers and services providers that provide services and products to us,
- our partners in the context of consortia or industry initiatives,
- our IT systems providers, cloud service providers, database providers and consultants,
- our business partners who offer products or services jointly with us or with our subsidiaries or affiliates,
- any third party to whom we assign or novate any of our rights or obligations ,our advisors and external lawyers in the context of the sale or transfer of any part of our business or its assets,
- national and/or international regulatory bodies or Ethics Committees.

The above third parties are obliged to protect the confidentiality and security of your Personal Data, in compliance with applicable laws.

If we transfer your Personal Data to other jurisdictions, we will make sure to protect your Personal Data by (i) applying the level of protection required under the local data protection/privacy laws applicable in the country of destination, (ii) acting in accordance with our policies and standards and, (iii) for entities located in the European Economic Area (i.e. the EU Member States plus Iceland, Liechtenstein and Norway, the "EEA"), unless otherwise specified, by transferring your Personal Data on the basis of standard contractual clauses approved by the European Commission. You may request additional information in relation to international transfers of Personal Data and obtain a copy of the adequate safeguard put in place by exercising your rights as described below.

For intra-group transfers of Personal Data, the Novartis group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of Personal Data outside the EEA and Switzerland. Read more about the Novartis Binding Corporate Rules at [novartis.com/privacy-policy](https://novartis.com/privacy-policy)

## Duration of storage

We will keep your Personal Data as long as needed for legal and regulatory requirements. Please note that we

are required to retain Clinical Trial Documentation for a minimum of 25 years.

## What are your rights and how can you exercise them?

Under conditions provided by the law, you have a right to request a copy of the personal information we hold about you. You may also object to its use or ask for it to be updated, restricted, deleted, or transferred to another organisation. If you wish to contact us regarding our use of your Personal Data or you wish to exercise your data privacy rights, you may send an email to [dataprivacy.nordics@novartis.com](mailto:dataprivacy.nordics@novartis.com).

If you are not satisfied with how we process your Personal Data, please address your request to our Data Protection Officer at [global.privacy\\_office@novartis.com](mailto:global.privacy_office@novartis.com), who will investigate your concern. In any case, you also have the right to file a complaint with a responsible supervisory authority, in addition to your rights above.

Contact information for Nordic supervisory authorities:

Denmark: [www.datatilsynet.dk](http://www.datatilsynet.dk)

Finland: <https://tietosuoja.fi/etusivu>

Iceland: <https://www.personuvernd.is/>

Norway: [www.datatilsynet.no](http://www.datatilsynet.no)

Sweden: <https://www.imy.se/>

**<sup>1</sup>Clinical investigators:** principal investigator, sub-investigator or co-investigator who are directly involved in the treatment or evaluation of research subjects in NOVARTIS Clinical Trials affected by this law, must disclose information to Novartis regarding their financial interests in companies belonging to the Novartis group as well as those of their spouse and each dependent child.

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**Source URL:** <https://www.novartis.com/dk-da/privacy-notice-clinical-trial-site-personnel>

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