Integrity Policy for Clinical Studies
Sponsored by Isofol Medical AB (publ)

Introduction

Your privacy is important to us, and so is being transparent about how we collect, process and transfer personal data about you.

You are involved in clinical studies sponsored by us, either as a participant (subject/patient) or by collaborating professionally with us. This policy is intended to help you understand:

- What personal data we collect about you,
- Why we collect personal data about you,
- How we store, secure and transfer the personal data,
- How to access and control your personal data,
- How to contact us for questions regarding personal data protection.

What Personal Data We Collect about You

- *If you agree to participate as a subject/patient in a clinical study sponsored by us:*

  We collect personal data, including special categories of data such as health data about your physical or mental health or condition, and other personal data such as partial date of birth and gender. More detailed information about which data we collect about you in the study you agree to participate in will always be included in the written patient information you receive. The personal data we collect does not include any contact or identifying information from you as a subject/patient. Instead, all data will be identified by a unique study identification number only and we are not able to link the unique number to any specific person (this link is only possible to make for the clinic where you participate as a subject/patient). The legal bases for our processing of your personal data are the agreement that you enter with us as you enter the study and the legal requirements placed upon us by regulatory authorities for the conduct of clinical studies in the public interest. You may also provide your consent for your personal data to be used in additional research activities from time to time that may not be required by regulatory authorities. Such consent will be explicitly requested as part of your enrolment in our trial activities.

- *If you collaborate professionally with us in the clinical studies sponsored by us:*

  We may collect information about your qualifications, experience and expertise, your financial interest in Isofol Medical AB, personal data and contact information such as name, date of birth, personal identification number, e-mail address and phone number, invoice and delivery address, as relevant. The legal basis for our processing of your personal data is to perform our contractual obligations as specified in the written agreement between you (or your employer) and us and to comply with legal requirements. For example, the Clinical Trial Agreement, if you are an investigator or study nurse involved in our clinical studies, or other agreement, if you are a service provider. In many cases, there will be additional agreements in place between us, detailing the processing of personal data even further.

Why We Collect Personal Data about You

It is necessary to collect data from study participants to be able to answer the scientific questions in the clinical studies sponsored by us. Your Personal Data is necessary to ensure the integrity of our studies and adequate scientific rigor to enable us to prove the effects of our treatments.

Integrity Policy for Clinical Studies
Sponsored by Isofol Medical AB (publ)

The data collected from professional collaborators is needed to ensure that the clinical studies are conducted properly and according to legal requirements. We collect personal CVs to document that our collaborators have the required expertise and experience to perform the services in question.

How We Store, Secure and Transfer the Personal Data

The data collected from study participants and professional collaborators is stored in electronic databases, printed paper archives and IT cloud solutions.

The personal data collected will be archived for as long as dictated by any applicable legislation for clinical research or our contractual obligations. When the data is no longer needed for these purposes, it will be securely deleted.

If we entrust the personal data to any third-party provider, we ensure all reasonable legal, technical and organisational precautions are taken, to secure the personal data according to applicable data protection legislation. We enter specific data protection agreements with relevant providers to specify acceptable processing of the personal data entrusted to providers.

We may share personal data from study participants and professional collaborators with Health Authorities, Ethic Committees, other participating clinics (patient safety reporting data) and clinical research organisations that are essential to the performance of clinical trials, research and regulatory activities. We may also share coded study participant data and professional collaborator personal data with business partners during due diligence activities aimed at furthering the development of our product pipeline. We only share personal data on a need to know basis and under contractual restrictions.

Our general policy is to store and process personal data only within the EU/EES. However, occasionally personal data will be transferred to countries outside EU/ESS for processing by our clinical research partners. This is primarily done to analyse and assess the benefits and risks of our products, or for documenting any adverse reactions. If we transfer personal data outside of EU/ESS, we ensure that the service provider applies similar protection of the personal data as is applicable in EU/ESS by e.g. contractual mechanisms relying on the standard contractual clauses offered by the European Commission, along with any additional measures necessary to ensure their appropriate implementation. Should there be a European Commission adequacy decision for the country in question, we base our data transfer on that adequacy decision.

How to Access and Control Your Personal Data

You have the right to access the personal data collected about you.

You have the right to have the personal data we have collected about you corrected, in case of errors or missing information.

To the extent our processing of your personal data is based on consent, you have the right to withdraw such consent. You also have the right to request your personal data to be erased. We will carry out the erasure of your personal data after such request in a timely manner, should there be no legal or contractual obligations preventing us from doing so. However, to preserve the integrity of the research being conducted in the clinical studies to abide by current international legislation, it may not always be possible to delete personal data already collected about you.

Integrity Policy for Clinical Studies
Sponsored by Isofol Medical AB (publ)

Contact Information for Questions Regarding Personal Data Protection

Isofol Medical AB (publ), organization number 556759-8064, Arvid Wallgrens Backe 20, SE-413 46 Gothenburg, Sweden, is the controller of the personal data collected from clinical studies sponsored by us and we ensure that all collection, storage, processing, and transfer follow applicable personal data protection regulations.

If you have any questions related to personal data protection, or if you want to exercise your rights, you can reach us at info@isofolmedical.com and we will reply as soon as possible.

We have appointed a Data Protection Officer, NDA Regulatory Service AB, who can provide more details about how we ensure that we comply with relevant personal data protection regulations. Please contact our DPO at isofol-dpo@ndareg.com.

Changes to the Integrity Policy for Clinical Studies Sponsored by Us

We may need to update this integrity policy for clinical studies sponsored by us from time to time, to ensure that changes in our organization or in legal requirements are reflected. The most recent and current version is available on our website: www.isofolmedical.com