Integrity Policy for Clinical Studies

1. Introduction

This Integrity Policy (the "**Policy**") describes how Isofol Medical AB (publ), reg. no 556759-8064, ("**Isofol**", "**we**", "**us**" and "**our**"), process your personal data when you participate in a clinical study (the "**Study**"). It also explains the rights you have in relation to your personal data.

If you have any questions regarding how Isofol processes your personal data, please contact us using the contact information at the end of this Policy.

We may need to make updates or changes to this Policy. You can find the latest version of this Privacy Notice on our website www.isofolmedical.com.

2. What personal data do we process?

We cannot administer your participation in the Study without your personal data. That said, where we do not need your personal data, we will make this clear to the clinic (the "**Clinic**") where you participate as a subject/patient. When we process special categories of your personal data, we must ensure we have an additional lawful basis to use these types of personal data.

2.1 Definitions of personal data

Definitions	Personal data categories
Identity and Contact Details	• Name • Address • Telephone number • Email
Study Participation Data	• Gender • Genetic data • Relevant medical history (including disease, stage of disease, height, weight, age, country of residence, ethnicity, prior medical treatments and procedures and pre-existing medical conditions/comorbidities) • Information about your physical and/or mental health which is collected as part of the physical examination and treatment. This includes your general health during the Study, data gathered as part of our monitoring of your disease during the Study, treatments, your compliance with treatment, the pain you are experiencing and your response to treatment under the Study, any side-effects experienced by you and questionnaires completed by you about your overall quality of life • Your Clinic appointments, homecare visits, number of visit and dates of visits

Collaborator Qualification Data	• Qualifications • CV • Work experience and expertise • Financial interest in Isofol
Collaborator Contact Details	• Name • Billing address • E-mail address • Telephone number
Invoice	• Invoice details

3. Pseudonymisation of your personal data

The Clinic will only transfer pseudonymised study participation data ("**Study Participation Data**") to Isofol. The Study Participation Data collected during the Study will be stored by Isofol in pseudonymised form. This means that a unique study identification number will be used to identify your Study Participation Data. Isofol will never have direct access to your name or other personal data which could identify you. Only the clinical test site, including your doctor and nurse(s), will know that the Study Participation Data is linked to you. No publication related to the Study will refer to you by name or other personal data.

We will take specific steps and measures (as required by applicable data protection laws) to protect your personal data from unlawful or unauthorized processing and accidental loss, destruction or damage. Only Clinic personnel involved within the Study will have access to your Study Participation Data in a non-pseudonymised format, on a need-to-know basis.

In addition to pseudonymisation (replacing your name with a unique study identification number), we may also convert some of your personal data into statistical or aggregated form to better protect your privacy and prevent possible identification. Anonymised data cannot be linked back to you.

4. How we process your personal data as a data subject/patient

In this section we describe the processing of personal data related to subjects/patients participating in the Study.

4.1 Performing the Study (primary purposes including reliability and safety purposes)

What we do and why:	The personal data that we process:
We process your personal data to be able to conduct the scientific and medical research, as well as management, administration, and coordination of the Study.	• Study Participation Data

We collect and analyse your Study Participation Data to ensure the safety and reliability of the Study as well as to ensure compliance with our policies governing our research procedures. We collect and analyse your Study Participation Data to create the clinical trial master file. We also process your personal data to handle complaints, including investigating issues, considering appropriate resolution and mitigating actions and reviewing outcomes.	

Our legal basis for processing personal data and special categories of personal data:

We process your Study Participation Data for the purpose of performing the Study in compliance with the rules regulating the conduct of clinical investigations Regulation (EU) No 536/2014 and the competent authority decision granted to us in accordance with the Swedish Act on Ethical Review (*Sw. Lag (2018:1091) med kompletterande bestämmelser om etisk granskning till EU:s förordning om kliniska prövningar av humanläkemedel*). This includes that we will collect your informed consent to participate in the Study.

The processing is also necessary for reasons of public interest to conduct clinical studies relating to health and we have a legal obligation to process your personal data to ensure the safety and reliability of the Study in compliance with the rules regulating the conduct of clinical investigations.

How long we keep your personal data:

We will keep the Identity and Contact Details and the Study Participation Data included in the clinical trial master file for a maximum of 25 years after the end of the Study, or for the time necessary in order to comply with applicable laws.

How we share and transfer your data:

We will share your personal data with the following recipients:

- Authorized supervisory authorities
- Vendors for safety handling, central imaging, IMP handling, statistics, data management, pharmacokinetic testing and pharmacogenetic testing

Local CROs in EU, North America, Japan and Australia

Isofol will transfer your personal data to countries outside the EU/EEA within the scope of the Study. We will transfer the personal data to the following recipients; • Research institutes and authorized authorities involved in the Study located in United States of America, United Kingdom, Japan, Australia, India. You will find more information regarding how we transfer personal data to countries outside the EU/EEA below under section 10. You are also welcomed to contact us by using the contact information at the end of this Policy.

4.2 Clinical investigation (secondary research purposes)

What we do and why:	**The personal data that we process:**
We collect and analyse your Study Participation Data to create medical reports regarding the use and benefits of our products and to perform research to develop, improve or assess our products.	• Study Participation Data
Our legal basis	
We have a legitimate interest in processing your Study Participation Data for the purpose of performing the Study, which include being able to conduct our scientific and medical research.	
Our legal basis for processing special categories of personal data:	
We process your Study Participation Data for the purpose of public interest, for which we perform scientific research to further develop, assess and improve our products in compliance with the competent authority decision granted to us in accordance with the Swedish Act on Ethical Review (*Sw. Lag (2018:1091) med kompletterande bestämmelser om etisk granskning till EU:s förordning om kliniska prövningar av humanläkemedel*).	
How long we keep your personal data:	
We will process and store your personal data until the Study is over, and for a maximum of twenty-five (25) years thereafter, or for the time necessary in order to comply with applicable laws.	
How we share and transfer your personal data:	
We will share your personal data with the following recipients: • Vendors for safety handling, central imaging, IMP handling, statistics, data management, pharmacokinetic testing and pharmacogenetic testing	

Isofol will transfer your personal data to countries outside the EU/EEA within the scope of the Study. We will transfer the personal data to the following recipients;

- Research institutes and authorized authorities involved in the Study located in United States of America, United Kingdom, India.

You will find more information regarding how we transfer personal data to countries outside the EU/EEA below under section 10. You are also welcomed to contact us by using the contact information at the end of this Policy.

5. How we process your personal data as a Collaborator

In this section we describe the processing of personal data related to professional collaborators ("**Collaborator**") to the Study.

5.1 Qualifications of Collaborators

What we do and why:	**The personal data that we process:**
In order to evaluate Collaborator candidates in the Study and ensure that they have the right experience and expertise, we will process data relating to qualifications, experience and expertise, as well as financial interest in Isofol.	• Collaborator Qualification Data • Financial interest in Isofol
Our legal basis for processing:	
The legal basis is legitimate interest, where it is our legitimate interest to evaluate Collaborator candidates. We have a legal obligation to obtain information about your financial interests in Isofol according to market abuse regulation (EU) 596/2014.	
How we share and transfer your personal data:	
We will share your personal data with the following recipients: • Companies within our group • Qualification and audit vendors Isofol will transfer your personal data to countries outside the EU/EEA. We will transfer the personal data to the following recipients; • Microsoft Azure • Microsoft 365	
For how long we will store your personal data:	
Retention period: We will store your personal data until the collaboration has ended, and for one (1) year thereafter. The information about your financial interests in Isofol will be stored until the Study is over, and for ten (10) years thereafter.	

5.2 Administration of relationship

What we do and why:	The personal data that we process:
In order to administer and maintain our relationship with you as a Collaborator or contact person of a Collaborator, we will contact and communicate with you.	• Collaborator Contact Details
Our legal basis for processing:	
The legal basis is legitimate interest, where it is our legitimate interest to be able to communicate with you and administer our relation within the frame of our collaboration.	
How we share and transfer your personal data:	
We will share your personal data with the following recipients: • Companies within our group • Vendors for safety handling, central imaging, IMP handling, statistics, data management, pharmacokinetic testing and pharmacogenetic testing • Local CROs in EU, North America, Japan and Australia Isofol will transfer your personal data to countries outside the EU/EEA. We will transfer the personal data to the following recipients; • Microsoft Azure • Microsoft 365	
For how long we will store your personal data:	
Retention period: We will store your personal data until the collaboration has ended, and for ten (10) year thereafter.	

5.3 Contractual obligations

What we do and why:	The personal data that we process:
In order to ensure that we fulfil the contractual obligations in relation to the collaboration we will process data relating to contact information and billing information of our Collaborators.	• Collaborator Contact Details • Invoice
Our legal basis for processing:	
The legal basis is contractual obligations, where we need to process the information in order to fulfil our contractual obligations towards our Collaborators.	

How we share and transfer your personal data:
We will share your personal data with the following recipients: • Companies within our group • Vendors for safety handling, central imaging, IMP handling, statistics, data management, pharmacokinetic testing and pharmacogenetic testing • Local CROs in EU, North America, Japan and Australia Isofol will transfer your personal data to countries outside the EU/EEA. We will transfer the personal data to the following recipients; • Microsoft Azure • Microsoft 365
For how long we will store your personal data:
Retention period: We will store your personal data until the collaboration has ended, and for one (1) year thereafter. Invoicing details will be stored seven (7) years.

6. Legal claims

In addition to the processing purposes listed above, we may be required to process personal data in the unlikely event of legal claims, if it is necessary for the establishment, exercise or defence of those legal claims. This processing of your personal data is based on our legitimate interest of establishing and/or defending legal claims. We will process such personal data for ten (10) years from creation or for the time necessary to fulfil the purpose in the relevant case.

7. Object to processing

When we base our processing of your personal data on legitimate interests, you have the right to object to the processing. You may make such a request by contacting us by using the contact details at the end of this Policy.

8. Safeguards

Whilst there is a theoretical possibility for us to link the study identification number associated with your Study Participation Data back to you if we would gain access to the relevant information (e.g., your name or other personal details) held by the Clinic, we have put technical and organisational measures in place to ensure that this additional information is held separately and not provided to us, as a sponsor of the Study. This includes pseudonymisation of the information and giving clear instructions to the Clinic not to share this information with us and to only provide the Study Participation Data with your assigned study identification number.

We will also apply appropriate security to protect your personal data and our staff are required to keep personal data confidential. We will securely delete your personal information as set out in this Policy.

9. How long do we keep your personal data?

Unless where you have given your specific consent for processing of your personal data or if specified in a specific section above, your personal data will be retained as long as necessary to fulfil the purposes for which the personal data is being processed and/or as long as we are obligated by law which shall be at least 10 years after the clinical investigation has ended or, in the event that the product is subsequently placed on the market, at least 10 years after the last product has been placed on the market. All retention of personal data will be in accordance with good clinical practice.

10. Where we process your personal data

Where necessary for the purposes listed above, we will transfer your personal data to countries outside of the EU/EEA. Whenever we transfer your personal data to a such a country (a "**Third Country**"), we ensure that appropriate safeguards are provided for. Such appropriate safeguards may include Isofol signing a contract with the recipient of the personal data incorporating the EU Commission's standard contractual clauses for the transfer of personal data to a country outside the EU/EEA. Transfers of personal data to Third Countries can also be based on a valid adequacy decision by the EU Commission. We always require that our IT service providers ensure that any transfers of personal data to countries outside the EU/EEA are performed in accordance with all applicable legal requirements including, where required, entering into an agreement with their suppliers based on the EU Commission's standard contractual clauses.

Through this link, you can find the standard contract clauses applicable to transfers of personal data to a recipient outside of the EU/EEA. If you have any questions relating to transfer of personal data, please contact us using the contact information at the end of this Policy.

The countries outside the EU/EEA to which our suppliers currently transfer personal data are: United States of America, United Kingdom, Japan, Australia and India.

11. From where will Isofol obtain your personal data?

Your personal data will be obtained from you directly during the Study or from your pseudonymised health records provided by the Clinic for the purpose of this Study. All personal data will be provided to Isofol in pseudonymised form.

12. Your rights

In this section we describe your rights as a data subject. You can exercise them by contacting us using the contact information at the end of this Policy. Please note that not all rights listed below are absolute and there are exemptions which can be valid. We may not be able to fulfil your data subject rights due to the fact that Isofol only access pseudonymised personal data and is not able to identify data subjects. We may also not be able to fulfil your data subject rights in order to preserve the integrity of the research conducted in the Study, e.g., your right to erasure.

Your rights are the following:

12.1 Right of access.

You have the right upon request to get a copy of your personal data which we process and to get complementary information regarding our processing of your personal data.

12.2 Right of rectification.

You have the right to have your personal data rectified and/or complemented if they are wrong and/or incomplete.

12.3 Right to erasure.

You have the right to request that we erase your personal data without undue delay in the following circumstances: (i) the personal data is no longer necessary in relation to the purposes for which they were collected or otherwise processed; (ii) you withdraw your consent on which the processing is based (if applicable) and there is no other legal ground for the processing; (iii) you object to our processing of personal data, and we do not have any overriding legitimate grounds for the processing; (iv) the processed personal data is unlawfully processed; or (v) the processed personal data has to be erased for compliance with legal obligations.

12.4 Right to restriction.

You have the right to restrict the processing of your personal data in the following circumstances: (i) you contest the accuracy of the personal data during a period enabling us to verify the accuracy of such data; (ii) the processing is unlawful, and you oppose erasure of the personal data and request restriction instead; (iii) the personal data is no longer needed for the purposes of the processing, but are necessary for you for the establishment, exercise or defence of legal claims; or (iv) you have objected to the processing of the personal data, pending the verification whether our legitimate grounds for our processing override your interests, rights and freedoms.

12.5 Right to data portability.

If your personal data has been provided by you and our processing of your personal data is based on your consent or on the performance of a contract with you, you have the right to receive the personal data concerning you in a structured, commonly used and machine-readable format in order to transmit these to another service provider where it would be technically feasible and can be carried out by automated means.

12.6 Right to object.

You have the general right to object to our processing of your personal data when it is based on our legitimate interest. If you object and we believe that we may still process your personal data, we must demonstrate compelling legitimate grounds for the processing which override your interests, rights and freedoms, or for the establishment, exercise or defence of legal claims.

12.7 Right to withdraw consent.

When our processing of your personal data is based on your consent, you have the right to withdraw your consent at any time. Please note that the lawfulness of any processing based on your consent before its withdrawal is not affected by the withdrawal.

13. Complaints to the supervisory authority

The data protection authority in Sweden is '**Integritetsskyddsmyndigheten**'. If you believe that our processing is performed in breach of applicable data protection legislation, we encourage you in first-hand to contact us in order for us to oversee your complaints. You may at any time also file a complaint with the supervisory authority.

14. Contact details

If you have any questions about the processing of your personal data or want to exercise any of your rights, please contact us at:

Email: info@isofolmedical.com

Email DPO: Isofol.dpo@ndareg.com

Post: Isofol Medical AB (publ)