## **Data Privacy Framework Policy**

#### **POLICY PURPOSE AND SCOPE**

Theradex Systems, Inc. (and its subsidiaries and affiliates, collectively referred to as "Theradex," Company," "we" or "our") has been providing full oncology clinical trial services in the US, UK and Europe for over three decades. Theradex US operations are based in Princeton, New Jersey and EU operations are based outside London in the United Kingdom.

Theradex Oncology respects the relationships we have with our customers and respects the privacy of all individuals whose Covered Information (see Definitions) may be processed by Theradex Oncology in the performance of our services and our business operations.

Theradex Oncology complies with the EU-U.S. Data Privacy Framework (EU-U.S. DPF), the UK Extension to the EU-U.S. DPF, and the Swiss-U.S. Data Privacy Framework (Swiss-U.S. DPF) as set forth by the U.S. Department of Commerce. Theradex Oncology has certified to the U.S. Department of Commerce that it adheres to the EU-U.S. Data Privacy Framework Principles (EU-U.S. DPF Principles) with regard to the processing of personal data received from the European Union in reliance on the EU-U.S. DPF and from the United Kingdom (and Gibraltar) in reliance on the UK Extension to the EU-U.S. DPF. Theradex Oncology has certified to the U.S. Department of Commerce that it adheres to the Swiss-U.S. Data Privacy Framework Principles (Swiss-U.S. DPF Principles) with regard to the processing of personal data received from Switzerland in reliance on the Swiss-U.S. DPF. If there is any conflict between the terms in this privacy policy and the EU-U.S. DPF Principles and/or the Swiss-U.S. DPF Principles, the Principles shall govern. To learn more about the Data Privacy Framework (DPF) program, and to view our certification, please visit https://www.dataprivacyframework.gov/.

In relation to data transfers, where applicable, Theradex Oncology may also rely on alternative transfer safeguards, including data transfer/processing agreements and EU approved Standard Contractual Clauses. For more information, please refer to the EU/UK privacy notice linked below.

Theradex Oncology has established an ongoing privacy program to ensure adherence to global relevant privacy laws and regulations.

See more at: http://www.TheradexOncology.com/privacy

### **APPLICABLE TO**

This Policy applies to all Covered Information of Individuals, either in electronic or paper format, received by Theradex in the U.S. from the EEA, including Human Resources Covered Information

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and/or Personal Information, consumers, healthcare professionals patients, medical research subjects, clinical investigators, customers, suppliers, vendors, business partners and investors

With regard of the processing of EU/UK personal data or personal data coming from adequacy countries, in case of discrepancy between the Data Privacy Framework and the Global Data Protection & Privacy (DP&P) Policy (Policy 00-002), the DP&P policy shall prevail.

### **Limitations on Scope:**

Adherence to the DPF Principles may be limited:

- (i) to the extent required or allowed by applicable law, rule or regulation;
- (ii) to the extent necessary to respond to lawful requests by public authorities, including to meet national security, law enforcement, legal or governmental requirements; and/or
- (iii) to protect the health or safety of an Individual.

Also, this Policy may not apply or may be limited when Covered Information is collected or processed by the following:

Theradex Oncology, under an agreement that contains the requisite Model Contract Clauses approved by the European Commission with respect to the Covered Information; and Theradex Oncology, when necessary for the performance of a contract (e.g., an employment contract) between an Individual and Theradex Oncology.

#### **POLICY STATEMENT**

### For purposes of this Policy, the following definitions shall apply:

**Agent**" means any third party that uses Covered Information provided to it by Theradex Oncology to perform tasks on behalf of and/or under the instructions of Theradex Oncology or to which Theradex Oncology discloses Covered Information for use on its behalf.

**"European Economic Area"** (EEA) means for the purposes of this Policy all countries within the European Union (EU).

"Human Resource (HR) Covered Information" means any information, in the worker context, that (1) is transferred from the EEA to the U.S.; and (2) identifies or can be used to identify an individual. This information may be about EEA Personnel or applicants and may include information such as name, contact information, individual identification numbers, titles, dates, languages, family information, work status, user access activity data, internet/email/network activity data, facility security records, device/location identifiers, training records, business transactions, compensation, performance ratings, or eligibility for participation in Theradex Oncology's benefits programs.

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"Individual" means any natural person located in the EEA & UK whose Covered Information is shared with Theradex Oncology in the United States.

"**Personal Information**" means any information or set of information about an identified or identifiable individual, other than in the human resources context that is:

- 1) is transferred from the EEA & UK to the U.S.; and
- 2) identifies or can be used to identify an individual.

### "Covered Information includes but is not limited to:

- a) first name or initial and last name;
- b) home or other physical address;
- c) telephone number;
- d) email address or online identifier associated with the individual;
- e) Social Security number or other similar identifier;
- f) employment, financial or health information; or
- g) any other information relating to an individual that is combined with any of the above.

The term "Covered Information" does not include anonymized information or information that is reported in the aggregate (provided that such aggregated information is not identifiable to a natural person). This includes personal data coming from both EEA & UK.

"**Personnel**" includes, but is not limited to, any employee (permanent or temporary), director, officer, contractor, worker, temporary worker, job applicant, and retiree of Theradex and any and all of their respective dependents.

"**DPF Principles**" collectively means the seven (7) privacy principles, as well as the supplemental privacy principles and the associated guidance details of which can be found at <a href="https://www.dataprivacyframework.gov/">https://www.dataprivacyframework.gov/</a>.

"Sensitive Personal Information" means Personal Information that reveals race, ethnic origin, political opinion, religious or philosophical beliefs, trade union membership, genetic data, biometric data where processed to uniquely identify a person, any information that concerns medical or health conditions or sex life, or information relating to the commission of a criminal offense.

### **Notice**

Where Theradex Oncology collects Covered Information directly from Individuals, it will provide clear and conspicuous notice of the purposes for which it collects and uses Covered Information about the Individuals, the types of third parties to which Theradex Oncology discloses that information, and the choices and means, if any, Theradex offers Individuals for limiting the use and disclosure of Covered Information about them. This explanation will be provided as soon as practicable and, in any event, before Theradex Oncology discloses the Covered Information or uses such information for a purpose materially different than that for which it was originally collected or processed. Where

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Theradex Oncology receives Personal Information from its subsidiaries, affiliates or other entities, including when acting as a CRO processing Personal Information under the direction of a customer, it will use such information in accordance with the notices provided by such entities and the contractual obligation agreed upon with such third party.

## Types of Covered Information collected, Purposes of Collection and Uses of Covered Information:

**Research Data.** Theradex Oncology collects and processes Personal Information relating to: study participants (pseudonymized/de-identified), clinical research investigators and their staff as well as medical and healthcare professionals. Theradex Oncology collects Personal Information such as contact information, qualifications, debarment status and account information to facilitate the proper conduct of research studies and to carry out other study related services. Information collected may be transferred to the sponsor of a study, business partners, Theradex Oncology affiliates and third-party service providers performing study-related duties and may furthermore be transferred to regulatory authorities;

**Customer, Vendors and Consultant Data.** Theradex Oncology maintains contact information, account numbers and information relating to billing, together with other information which may be necessary for the daily operation of Theradex Oncology's services including conducting customer, product and service surveys, direct marketing of products and services, handling customer complaints and questions and making required legal disclosures;

**Human Resources Covered Information.** Theradex Oncology maintains resumes, contract information, residential address, date of birth, gender, government identification number, account information, qualifications and training records, debarment status, performance reviews, which is processed to support its human resources functions and activities, e.g., administration of employee benefits, compensation, management of employee performance, business planning, disciplinary procedures including the investigation and reporting of complaints and for compliance with legal obligations, policies and procedures;

**Covered Information** Theradex Oncology may also use the Covered Information collected above to comply with our legal and regulatory obligations, policies and procedures, and for internal administrative purposes in accordance to applicable law;

**Personal Information** collected may be disclosed to the sponsor of a study, business partners, Theradex affiliates and third-party service providers performing study-related duties and may furthermore be disclosed to regulatory authorities.

#### Choice

When applicable, Theradex Oncology will offer Individuals the opportunity to opt-out prior to disclosure of Covered Information is (a) to be disclosed to a third party, or (b) to be used for a

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purpose materially different from the purpose for which it was originally collected or subsequently authorized by the Individual.

Theradex Oncology will not process Sensitive Personal Information about Individuals for purposes other than those for which the information was originally obtained or subsequently authorized by the Individual unless the Individual explicitly consents to the processing ("opt-in"), or as required or permitted, or where not prohibited by law or regulation.

In some cases, even if an Individual opts-out of disclosures of their Covered Information, Theradex Oncology may still disclose such Covered Information:

- (i) if required to do so by law;
- (ii) if disclosure is required to be made in response to lawful requests by public authorities, including to meet national security or law enforcement requirements; or
- (iii) if we believe disclosure is necessary or appropriate to prevent physical harm to an individual or financial loss or in connection with an investigation of suspected or actual illegal activity.

Where there is a legitimate interest, Theradex Oncology also may transfer Covered Information when a material event concerning its business operation(s), assets or shares, such as purchase, merger, joint venture or acquisition, is proposed or occurs.

## **Accountability for Onward Transfer**

Transfers to third parties are covered by the provisions in this Policy regarding notice and choice.

Theradex Oncology may also share an Individual's Covered Information with Agents who assist Theradex Oncology in connection with providing services that these individuals or entities perform for, or with, Theradex Oncology. Theradex Oncology may, for example, provide an Individual's Covered Information to Agents for hosting our databases, for data processing services, or to send to that Individual the information that they requested.

Theradex may transfer Covered Information for specified, limited purposes, to an Agent and will endeavor to obtain written agreement with such Agent providing for at least the same level of privacy protection as is required by the DPF Principles (or any other applicable law) and this Policy and will notify Theradex if it makes a determination it can no longer meet this contractual obligation.

Where Theradex Oncology knows that any third party to whom it has provided Covered Information is using or disclosing Covered Information in a manner contrary to this Policy, Theradex Oncology will take reasonable steps to prevent or stop the use or disclosure.

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Unless Theradex proves that it is not responsible for any event giving rise to the damage, it shall remain liable under the Principles if a third party processes the Covered Information received in a manner which is inconsistent with the Principles.

### Security

Theradex Oncology will employ reasonable and appropriate technical, administrative and physical safeguards designed to protect Covered Information in its possession from loss, misuse and unauthorized access, disclosure, alteration and destruction, taking into due account the risks involved in the processing and the nature of the Covered Information Theradex Oncology is processing.

#### **Data Integrity and Purpose Limitation**

Theradex Oncology endeavors to take reasonable steps to use Covered Information only in ways that are compatible with and relevant to the purposes for which it was collected and for which notice was provided or for which consent was given or subsequently authorized by the Individual. Theradex will take reasonable steps designed to ensure that only Covered Information that is relevant to itsintended use, accurate, complete, current, and otherwise reliable in relation to the purposes for which the information was obtained is used by Theradex Oncology for as long as Theradex Oncology retains possession of such information. Theradex Oncology Personnel have a responsibility to assist Theradex Oncology in maintaining accurate, complete and current Covered Information. When acting as a CRO, Theradex Oncology endeavors only to process Personal Information that is relevant to the services it provides, and only for purposes compatible with those for which the Personal Information was collected; wherever possible, such Personal Information is de-identified.

#### **Access**

Theradex Oncology will, on request, provide an Individual with confirmation regarding whether Theradex Oncology is processing Covered Information about them. In addition, upon request of an Individual, Theradex Oncology will take reasonable steps to correct, amend, or delete their Covered Information that is found to be inaccurate, incomplete or processed in a manner non-compliant with this Policy or the DPF Principles, except where the burden or expense of providing access would be disproportionate to the risks to that Individual's privacy, where the rights of persons other than the Individual would be violated or where doing so is otherwise consistent with DPF Principles. Where Theradex Oncology processes Personal Information as a CRO under the direction of its customers, Theradex Oncology works with such customers so that the customers can provide a way for Individuals to correct or update their Personal Information.

## **Recourse, Enforcement and Liability**

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Theradex Oncology encourages Individuals covered by this Policy to raise questions about the processing Covered Information about them by contacting Theradex Oncology through the contact information provided below. Any Personnel that Theradex Oncology determines is in violation of this Policy will be subject to disciplinary action up to and including termination of employment, where applicable.

In compliance with the EU-U.S. DPF, the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF, Theradex commits to resolve DPF Principles-related complaints about our collection and use of your personal information. EU, UK and Swiss individuals with inquiries or complaints regarding our handling of personal data received in reliance on the EU-U.S. DPF, the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF should first contact Theradex at: <a href="mailto:DPO@theradex.com">DPO@theradex.com</a>.

In compliance with the EU-U.S. DPF, the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF, Theradex Oncology commits to cooperate and comply respectively with the advice of the panel established by the EU data protection authorities (DPAs), the UK Information Commissioner's Office (ICO) and the Swiss Federal Data Protection and Information Commissioner (FDPIC) with regard to unresolved complaints concerning our handling of personal data received in reliance on the EU-U.S. DPF, the UK Extension to the EU-U.S. DPF and the Swiss-U.S. DPF.

In compliance with the EU-U.S. DPF, and the UK Extension to the EU-U.S. DPF, Theradex commits to cooperate and comply respectively with the advice of the panel established by the EU data protection authorities (DPAs) and the UK Information Commissioner's Office (ICO) with regard to unresolved complaints concerning our handling of human resources data received in reliance on the EU-U.S. DPF and the UK Extension to the EU-U.S. DPF in the context of the employment relationship.

The Federal Trade Commission has jurisdiction over Theradex Oncology's compliance with the EU-U.S. Data Privacy Framework (EU-U.S. DPF), the UK Extension to the EU-U.S. DPF, and the Swiss-U.S. Data Privacy Framework (Swiss-U.S. DPF).

For complaints from Theradex Oncology personnel that Theradex cannot resolve, individuals may have a right to invoke binding arbitration under Annex I of the DPF. More information regarding this can be found at <a href="https://www.dataprivacyframework.gov/s/article/ANNEX-I-introduction-dpf?tabset-35584=2">https://www.dataprivacyframework.gov/s/article/ANNEX-I-introduction-dpf?tabset-35584=2</a>.

#### **Contact Information:**

Questions, comments, concerns or complaints regarding this Policy or Theradex Oncology's processing of Covered Information should be submitted to Theradex Oncology by clicking here, or send inquiries to: <a href="mailto:DPO@Theradex.co.uk">DPO@Theradex.co.uk</a>.

#### Changes to the DPF Policy

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## **Data Privacy Framework Policy**

This Policy may be revised and amended from time to time to ensure that an appropriate level of protection for Covered Information is maintained. All amendments will be posted on this website. Theradex Oncology will provide appropriate notice of any such amendment.

### **LINKED DOCUMENTS**

• Policy 00-002: Data Protection and Privacy Policy

## **REFERENCES**

- The U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA"")
- Privacy and Security Rules, 45 C.F.R. Parts 160-164
- EU and UK General Data Protection Regulation (GDPR)

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