

## Theradex Privacy Shield Policy



Theradex, 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 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 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 in the performance of our services and our business operations. To demonstrate our commitment to the protection of Covered Information, including Covered Information transferred out of the European Economic Area (“EEA”) to the United States for the performance of our services and business operations, we adhere to the Privacy Shield Principles and publically certify that we comply with the EU-U.S. Privacy Shield Framework (“Privacy Shield”), as set forth by the U.S. Department of Commerce and the Federal Trade Commission (“FTC”). The FTC has jurisdiction over Theradex’s compliance with the EU-US Privacy Shield Framework. Further details of the Privacy Shield and the Privacy Shield Principles can be found on the website at <https://www.privacyshield.gov>. We also use model contractual clauses and other mechanisms approved by the European Union, respectively, for transfers of Covered Information from the EEA.

Information regarding Theradex’s Privacy Shield certification is available at <https://www.privacyshield.gov/list>.

To monitor implementation of the Company's global policies for the protection of Covered Information, Theradex has instituted the role of Global Chief Privacy Officer, currently filled by the Director of Quality Assurance, who shall serve as the point of contact for questions regarding this Privacy Shield Policy. This individual has the responsibility to receive, investigate, track and guide resolution of any incidents / complaints that Theradex may receive or identify regarding data privacy and confidentiality. Further, Theradex has established an ongoing privacy awareness training program which is required globally for all Theradex personnel.

- See more at: <http://www.TheradexOncology.com/privacy>

### **THERADEX PRIVACY SHIELD POLICY (THE “POLICY”):**

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

### **LIMITATIONS ON SCOPE:**

Adherence to the Privacy Shield 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

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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, under an agreement that contains the requisite Model Contract Clauses approved by the European Commission with respect to the Covered Information; and  
  
Theradex, when necessary for the performance of a contract (e.g., an employment contract) between an Individual and Theradex
- **DEFINITIONS:** For purposes of this Policy, the following definitions shall apply:
  - “**Agent**” means any third party that uses Covered Information provided to it by Theradex to perform tasks on behalf of and/or under the instructions of Theradex or to which Theradex discloses Covered Information for use on its behalf.
  - “**Covered Information**” HR Covered Information (as defined below) and Personal Information (as defined below).
  - “**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’s benefits programs.
  - “**Individual**” means any natural person located in the EEA whose Covered Information is shared with Theradex 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 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).
  - “**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.
  - “**Privacy Shield 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 <https://www.privacyshield.gov>.

- “**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 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 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 discloses the Covered Information or uses such information for a purpose materially different than that for which it was originally collected or processed. Where Theradex 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 choices made by the Individuals to whom such Personal Information relates. Theradex staff will have documented training on the Theradex Privacy policy to ensure compliance with the policy.

Much of the data collected by Theradex is Key-Coded Data which is not subject to the Privacy Shield Principles.

Annex II of the EU-U.S. Privacy Shield Framework Principles Issued by the US Department of Congress describes Key-Coded data as follows:

Invariably, research data are uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects. Pharmaceutical companies sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he or she can identify the research subject under special circumstances (e.g., if follow-up medical attention is required). A transfer from the EU to the United States of data coded in this way would not constitute a transfer of personal data that would be subject to the Privacy Shield Principles.

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

- **Research Data.** Theradex collects and processes Personal Information relating to: study participants, clinical research investigators and their staff as well as medical and healthcare professionals. Theradex 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 affiliates and third-party service

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providers performing study-related duties and may furthermore be transferred to regulatory authorities;

- **Customer, Vendors and Consultant Data.** Theradex maintains contact information, account numbers and information relating to billing, together with other information which may be necessary for the daily operation of Theradex'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 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;
- **Prospective Data.** Prospective study participants, prospective investigators and users of Theradex applications and websites who ask questions regarding Theradex's services may be asked to provide Personal Information in order to provide the requested information, products or services. Personal Information provided may be used for the processing of requested transactions, improving the quality of our services, sending communications about our products and services, enabling our business partners and service providers to perform certain activities on our behalf and complying with our legal obligations, policies and procedures.

Covered Information Theradex may also use the Covered Information collected above to comply with our legal and regulatory obligations, policies and procedures, and for internal administrative purposes.

### CHOICE

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

Theradex 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 may still disclose such Covered Information: (i) if required to do so by law, (ii) if disclosure is required to be made to law enforcement authorities, 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. Theradex 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 may also share an Individual's Covered Information with Agents who assist Theradex in connection with providing services that these individuals or entities perform for, or with, Theradex. Theradex 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 he or she 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 Privacy Shield Principles and this Policy and will notify Theradex if it makes a determination it can no longer meet this contractual obligation.

Where Theradex 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 will take reasonable steps to prevent or stop the use or disclosure. With respect to such onward transfers to Agents, and to the extent Theradex is responsible for the event, Theradex shall remain liable should its Agents process Covered Information in a manner inconsistent with the Privacy Shield Principles and this Policy.

## **SECURITY**

Theradex 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 is processing.

## **DATA INTEGRITY AND PURPOSE LIMITATION**

Theradex 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 its intended use, accurate, complete, current, and otherwise reliable in relation to the purposes for which the information was obtained is used by Theradex for as long as Theradex retains possession of such information. Theradex' Personnel have a responsibility to assist Theradex in maintaining accurate, complete and current Covered Information. When acting as a CRO, Theradex 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 will, on request, provide an Individual with confirmation regarding whether Theradex is processing Covered Information about them. In addition, upon request of an Individual, Theradex 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

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the Privacy Shield 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 Privacy Shield Principles. Where Theradex processes Personal Information as a CRO under the direction of its customers, Theradex 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**

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

Any questions or concerns regarding the use or disclosure of Covered Information should also be directed to Theradex's Global Chief Privacy Officer through the contact information given below. Theradex will investigate and attempt to resolve complaints and disputes regarding use and disclosure of Covered Information in accordance with the principles contained in this Policy.

In addition, Theradex has agreed to cooperate with the American Arbitration Association ("AAA") and with the EU's local data protection authorities with respect to unresolved complaints. For more information and to submit a complaint to AAA, visit <http://info.adr.org/safeharbor>. Theradex will investigate and attempt to resolve complaints from Theradex Personnel in accordance with the Privacy Shield Principles. For complaints from Theradex Personnel that Theradex cannot resolve, Theradex participates in the dispute resolution procedures of the EU data protection authorities' panel and agrees to cooperate with the local EEA data protection authorities. Theradex Oncology will cooperate with the EU data protection authorities (DPA) and comply with any advice given by such authorities with regard to human resources data transferred from the EU in the context of the employment relationship. Such independent dispute resolution mechanisms are available to Individuals free of charge. If any request remains unresolved, Individuals may have a right to invoke binding arbitration under Privacy Shield.

**CONTACT INFORMATION:** Questions, comments, concerns or complaints regarding this Policy or Theradex' processing of Covered Information should be submitted to Theradex by clicking here, or send inquiries to: [PrivacyDesk@TheradexOncology.com](mailto:PrivacyDesk@TheradexOncology.com)

**CHANGES TO THE PRIVACY SHIELD 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 will provide appropriate notice of any such amendment.

PRIVACY POLICY - EFFECTIVE DATE: 07-15-2017