

**Ximedica, LLC**  
**European Union Privacy Shield Policy &**  
**US-Swiss Safe Harbor Policy**

This EU-U.S. Privacy Shield Policy (the "**Policy**") sets forth the privacy principles that Ximedica ("the Company") follows with respect to transfers of personal information belonging to Participants enrolled in regulated research studies and to its Customers, whether in electronic, paper or verbal format, between countries in the European Union ("EU") or Switzerland and the United States ("U.S.").

To learn more about the Privacy Shield program and to view Ximedica's certification, please visit <https://www.privacyshield.gov/list>.

**PRIVACY SHIELD:** The United States Department of Commerce and the European Commission have agreed on a set of data protection principles (the "**Privacy Shield Principles**") to enable U.S. companies to satisfy the EU law requirement that personal information transferred from the EU to the United States be adequately protected.

Consistent with our commitment to protect personal privacy, Ximedica complies with the EU Privacy Shield Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information from European Union member countries. Ximedica has certified that it adheres to the Privacy Shield Privacy Principles of notice, choice, accountability for onward transfer, security, data integrity and purpose limitation, access, and recourse, enforcement and liability. Ximedica adheres to the Privacy Shield Principles as stated in this Policy.

If there is any conflict between the policies and the Privacy Shield Privacy Principles, the Privacy Shield Principles shall govern. To learn more about the Privacy Shield program, and to view our certification page, please visit <https://www.privacyshield.gov>. The Federal Trade Commission (FTC) has jurisdiction with enforcement authority over Ximedica's compliance with the Privacy Shield.

The Company complies with the US-Swiss Safe Harbor Framework as set forth by the US Department of Commerce regarding the collection, use, and retention of personal information from Switzerland. The Company has certified that it adheres to the Safe Harbor Privacy Principles of notice, choice, onward transfer, security, data integrity, access, and enforcement. If there is any conflict between the policies in this privacy policy and the Safe Harbor Privacy Principles, the Safe Harbor Privacy Principles shall govern.

If there is any conflict between the policies in this privacy policy and the Safe Harbor program, the Safe Harbor principles shall govern. To learn more about the Safe Harbor program, and to view our certification page, please visit <http://www.export.gov/safeharbor>. The Federal Trade Commission (FTC) has jurisdiction with enforcement authority over Ximedica's compliance with the Safe Harbor.

**DEFINITIONS:** The following definitions shall apply throughout this Policy:

**"Agent"** means any third party (e.g., business partners, vendors) that processes Personal Information under the instructions of, and solely for, Ximedica or to which Ximedica discloses Personal Information to use or perform tasks on Ximedica's behalf.

**"Customer"** means a hospital, clinic, medical device or pharmaceutical company that provides treatment using devices created and tested by Ximedica on behalf of Customer. Customers are the data controllers and Ximedica is the data processor.

**"Participant"** means an individual in one of the EU member countries enrolled in a regulated research study sponsored by Ximedica, or one of its affiliated companies, or a Customer.

**"Personal Information"** means any information or set of information that identifies or could be used by or on behalf of Ximedita to identify a **Participant** (e.g., name, address, place of birth, date of birth, gender, weight, height). Personal information **does not** include information that is encoded, anonymized and/or aggregated and is not subject to re-identification, or publicly available information that has not been combined with non-public personal information.

**"Sensitive Personal Information"** means Personal Information that receives heightened protection under various laws of jurisdiction in which Ximedita operations are located, including but not limited to: race, ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, or that concerns health or sexual orientation.

**"Ximedita"** means Ximedita, LLC its successors, subsidiaries, divisions and groups in the United States.

**PRIVACY PRINCIPLES:** The privacy principles in this Policy are based on the following Privacy Shield Principles.

1. **NOTICE:** When Ximedita collects Personal Information directly from Participants, it will inform them about the purposes for which it collects, processes and uses their Personal Information, the types of non-agent third parties to which Ximedita discloses that information, and the choices and means, if any, that Ximedita offers individuals for limiting the use and disclosure of their Personal Information.

Notice will be provided in clear and conspicuous language at the time of collection, or as soon as practicable thereafter, and in any event before Ximedita uses the information for a purpose other than that for which it was originally collected. Personal Information about Participants may be used in a manner consistent with the general research purpose for which the data were originally collected; this includes use in future medical and pharmaceutical research activities that are unanticipated at the time of original collection.

If Ximedita receives Personal Information from its subsidiaries, affiliates or other entities in the EU or Switzerland, it will use such information in accordance with the notices such entities provided and the choices made by the individuals to whom such Personal Information relates.

Where Ximedita acts as a data processor on behalf of a Customer, it will provide information to the Customer, who is the data controller, about how Ximedita processes Personal Information, and the Customer will be responsible for informing its Participants about the collection, processing and use and will obtain consent from Participants and, where necessary, from their staff as part of the enrollment process; the Personal Information of Participants may be used in a manner consistent with the consents obtained or information provided by the Customer at the time of enrollment.

2. **CHOICE:** When Ximedita collects Personal Information directly from Participants, it will offer the Participant the opportunity to opt-out (which may include not participating in the study) whether their Personal Information is: (a) to be disclosed to a non-agent third party, or (b) to be used for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual.

For Sensitive Personal Information, Ximedita will give Participants the opportunity to affirmatively and explicitly opt-in and consent and to the disclosure of the information to a non-agent third party or the use of the Personal Information for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual. Ximedita will provide Participants with reasonable methods to exercise their choices.

Where Ximedita receives Personal Information as a data processor for the Customer, Ximedita will work with the Customer to provide reasonable mechanisms for Participants to exercise their choices and process the data as directed by the Customer.

For Sensitive Personal Information, Ximedita will give Participants the opportunity to affirmatively and explicitly opt-in and consent to the disclosure of the information to a non-agent third-party or the use of the Personal Information for a purpose other than the purpose for which it was originally collected or subsequently authorized by the Participant. Where Ximedita is the data processor for the Customer, Ximedita will process the data as directed by the Customer.

3. **DATA INTEGRITY AND PURPOSE LIMITATION:** Ximedita will use Personal Information only in ways that are compatible with the purposes for which it was collected or subsequently authorized by the Participant. Where Ximedita is a data processor of Participant or Customer data for the Customer, Ximedita will process that data consistent with the direction of the Customer. Ximedita will take reasonable steps to ensure that Personal Information is relevant to its intended use, accurate, complete, and current.
4. **ACCOUNTIBILITY FOR ONWARD TRANSFER:** When transferring Personal Information, it collects to its Customers, Agents (e.g. business partners or vendors) or other third-party controllers (i.e., entities that will control how personal data is processed) for general research purposes related to medical and pharmaceutical research activities, Ximedita will comply with the Notice and Choice Principles as described above. Consistent with Privacy Shield timing requirements for onward transfer compliance, Ximedita will obtain assurances from its agents and third party business partners that such data may only be processed for limited and specific purposes consistent with the consent provided by the individual and that the recipient will safeguard Personal Information consistently with this Policy. Examples of appropriate assurances that may be provided by agents and third party business partners include but are not limited to: a contract obligating the third party to provide at least the same level of protection as is required by the relevant Privacy Shield Principles. If Ximedita has knowledge that an agent or third party business partner is using or disclosing Personal Information in a manner contrary to this Policy, Ximedita will take reasonable steps to prevent or stop the use or disclosure. Ximedita may be liable in cases of third party onward transfer of data of EU individuals pursuant to the EU-US Privacy Shield.
5. **ACCESS AND CORRECTION:** Ximedita recognizes the individual's right to access their personal data. Upon request, Ximedita will grant Participants reasonable access to Personal Information that it holds about them. In addition, Ximedita will take reasonable steps to permit individuals to correct, amend, or delete information that is demonstrated to be inaccurate or incomplete. Where Ximedita is a data processor for the Customer, Ximedita will act at the direction of the Customer.
6. **SECURITY:** Ximedita will take reasonable precautions to protect Personal Information in its possession from loss, misuse and unauthorized access, disclosure, alteration and destruction.
7. **RECOURSE, ENFORCEMENT AND LIABILITY:** Ximedita will use a self-assessment verification approach and will conduct compliance audits of its relevant privacy practices to verify adherence to this Policy. Relevant Ximedita employees will receive Privacy Shield training annually. Self-assessment efforts are enforceable under Article 5 of the Federal Trade Commission. The FTC can enforce self-regulatory efforts made by Ximedita. Any employee that Ximedita determines is in violation of this Policy will be subject to disciplinary action up to and including termination of employment.

Any questions or concerns regarding the use or disclosure of Personal Information should be directed to the Ximedita Privacy Officer at the address given below. Ximedita will investigate and attempt to resolve complaints and disputes regarding use and disclosure of Personal Information in accordance with the principles contained in this Policy.

8. **PUBLIC RECORD AND PUBLICLY AVAILABLE INFORMATION:** In accordance with Privacy Shield, in cases where Ximedita discloses public records or publicly available information from the EU without combining that information with non-public information, our general policies on Notice, Choice, and Accountability for Onward Transfer may not apply.

9. **EU-US PRIVACY SHIELD:**

Ximedica complies with the EU-US Privacy Shield Framework as set forth by the US Department of Commerce regarding the collection, use, and retention of personal information from the European Union member countries. Ximedica has certified that it adheres to the Privacy Shield Principles of notice, choice, accountability for onward transfer, security, data integrity and purpose limitation, access, and recourse, enforcement and liability. If there is any conflict between the policies in this privacy policy and the Privacy Shield Principles, the Privacy Shield Principles shall govern. To learn more about the Privacy Shield program, and to view our certification page, please visit <https://www.privacyshield.gov/>.

In compliance with the EU-US Privacy Shield Principles, Ximedica commits to resolve complaints about your privacy and our collection or use of your personal information. EU individuals with inquiries or complaints regarding this privacy policy should first contact Ximedica at:

Ximedica, LLC  
55 Dupont Drive  
Providence, RI 02907  
Attn: Privacy Officer  
Email: [privacyofficer@ximedica.com](mailto:privacyofficer@ximedica.com)

Ximedica has further committed to refer unresolved privacy complaints under the EU-US Privacy Shield Principles to BBB EU Privacy Shield, a non-profit alternative dispute resolution provider located in the United States and operated by the Council of Better Business Bureaus. If you do not receive timely acknowledgment of your complaint, or if your complaint is not satisfactorily addressed, please visit [www.bbb.org/EU-privacy-shield/for-eu-consumers/](http://www.bbb.org/EU-privacy-shield/for-eu-consumers/) for more information and to file a complaint.

Please note that if your complaint is not resolved through these channels, under limited circumstances, a binding arbitration option may be available before the Privacy Shield Panel.

10. **US-SWISS SAFE HARBOR:** Ximedica complies with the US-Swiss Safe Harbor Framework as set forth by the US Department of Commerce regarding the collection, use, and retention of personal information from Switzerland. Ximedica has certified that it adheres to the Safe Harbor Privacy Principles of notice, choice, onward transfer, security, data integrity, access, and enforcement. If there is any conflict between the policies in this privacy policy and the Safe Harbor Privacy Principles, the Safe Harbor Privacy Principles shall govern. To learn more about the US-Swiss Safe Harbor and to view our certification page, please visit <http://www.export.gov/safeharbor/swiss>

In compliance with the US-Swiss Safe Harbor Principles, Ximedica commits to resolve complaints about your privacy and our collection or use of your personal information. Swiss citizens with inquiries or complaints regarding this privacy policy should first contact Ximedica at:

Ximedica, LLC  
55 Dupont Drive  
Providence, RI 02907  
Attn: Privacy Officer  
Email: [privacyofficer@ximedica.com](mailto:privacyofficer@ximedica.com)

Ximedica has further committed to refer unresolved privacy complaints under the US-Swiss Safe Harbor to an independent dispute resolution mechanism operated by the Council of Better Business Bureaus. If you do not receive timely acknowledgment of your complaint, or if your complaint is not satisfactorily addressed, please visit [www.bbb.org/us/safe-harbor-complaints](http://www.bbb.org/us/safe-harbor-complaints) for more information and to file a complaint.

11. **LIMITATION ON SCOPE OF PRINCIPLES:** Ximedica may be required to disclose an individual's personal information in response to a lawful request by public authorities, including to meet national security or law enforcement requirements.
12. **CHANGES TO THIS POLICY:** This Policy may be amended from time to time, at Ximedica's sole discretion, consistent with the requirements of the Privacy Shield Principles. The revisions will take effect on the date of publication of the amended policy, as stated.
13. **CONTACT INFORMATION:** Questions or comments regarding this Policy should be submitted to the Ximedica Privacy Officer by mail or e-mail as follows:

Ximedica, LLC  
55 Dupont Drive  
Providence, RI 02907  
Attn: Privacy Officer  
Email: [privacyofficer@ximedica.com](mailto:privacyofficer@ximedica.com)

**EFFECTIVE DATE: December 22, 2016**