

New England Research Institutes, Inc. - EU Privacy Policy

Last revised and effective as of: September 20, 2018

Browsing our website at <https://www.neriscience.com/> and any subdomains (the "Website") does not require you to register for an account or actively provide any personal information to us, but as indicated below, we and third parties may use cookies and action tags to passively collect information from visitors to our Website. **For further information on cookies, action tags, and log files, please see our Website Privacy Policy.**

New England Research Institutes, Inc. is a full-service contract research organisation (CRO) that provides clinical trial, epidemiology, public health and disparities, and bio-behavioural research services to pharmaceutical, biotechnology, medical device, and federal sponsors. In connection with these services, we conduct clinical trials, registries, focus groups, and observational studies (each, a "Study"; collectively, "Studies"). This EU Privacy Policy describes how we, New England Research Institutes, Inc. ("NERI", "we", "us", or "our"), handle personal information (as defined below) that we collect on our Website and through other online and offline channels in connection with your interaction with our CRO business, including without limitation our Studies (collectively, the "Business"). NERI also has a [Website Privacy Policy](#) that applies only to information collected through the Website with respect to NERI's operations in the United States.

As used in this EU Privacy Policy, the terms "using" and "processing" information include but are not limited to using cookies on a computer, subjecting the information to statistical or other analysis and using or handling information in any way, including, but not limited to collecting, storing, evaluating, modifying, deleting, using, combining, disclosing, and transferring information within our organisation or among our affiliates within the United States or internationally.

As described in further detail below, NERI complies with the EU-U.S. Privacy Shield Framework and the Swiss-U.S. Privacy Shield Framework as set forth by the U.S. Department of Commerce regarding the collection, use, and retention of personal information transferred from the European Economic Area (the "EEA") and Switzerland, respectively, to the United States ("transfer data"). As used in this EU Privacy Policy, "personal information" means any information relating to an identified or identifiable natural person in the EEA and/or Switzerland; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

With respect to such transfer data, NERI has certified to the Department of Commerce that it adheres to the Privacy Shield Principles. If there is any conflict between the terms in this EU Privacy Policy and the Privacy Shield Principles, the Privacy Shield Principles shall prevail. To learn more about the Privacy Shield Frameworks, and to view our listing on the Privacy Shield List, please visit <https://www.privacyshield.gov/>.

Types of Personal Information Collected

As described above, personal information is information relating to an identified or identifiable natural person transferred to the United States from the EEA or Switzerland. While the types of personal information collected vary, the following types of information generally are collected from the following categories of individuals:

Study Participants – The information collected from individuals participating in our Studies (“Participants”) is collected with written consent of the Participant and redacted at the respective Study site. The types of personal information generally collected from individuals participating in our Studies, which may be key-coded or de-identified prior to transfer, include respective Study data, demographic information (such as year of birth, gender, race, ethnicity, country of birth); vital signs; health history information, including medical and surgical history and other information from Participants’ medical records; dates of service related to health care; information regarding medications, lifestyle, sexual history, habits, and health conditions; biopsy reports; results of tests, treatments, and procedures (such as transplants, blood tests, MRIs, and X-rays); medicines and the effects of medicines on Participants’ physical, mental, and social health and side effects. Prospective data related to a Study is also collected, including any adverse events and outcomes from the protocol.

Study Site Staff, Vendors, and Contractors – The types of personal information collected from Study site staff, vendors, and contractors generally include name, e-mail address, telephone number, business or home address, curriculum vitae, biographical sketches, medical licence information, and financial disclosure information.

Website Visitors – The types of personal information collected from visitors to our Website may generally include name, email address, physical address, questions and comments, IP addresses, browser types, unique device identifiers, device types, what type of Internet browsing device you are using, requested URL, information such as how you arrived at our Website (including referring URL), network name, the country, state, and city where your server is located, browser language, the pages you view, the date and time of your visit, domain names, and other statistical data involving use of the Website. Some of the personal information collected from website visitors is collected passively using cookies, action tags, and log files. For further information on such use of cookies, action tags, and log files, please see our [Website Privacy Policy](#).

General Inquirers and Representatives of Our Business Partners and Clients – The types of personal information collected from individuals inquiring about our Business, including our Studies, and from individuals who represent our business partners and clients, including Study sponsors, generally include name and contact information and queries.

Our Lawful Bases for Processing Personal Information

We will only use your personal information to the extent that the law allows us to do so. Under the General Data Protection Regulation (EU) 2016/679 (the “GDPR”) we are required to state our legal bases (our justifications) for processing your personal information. We will generally rely on the following legal bases:

- where you have given us your consent; or
- where it is necessary to perform a contract we have entered into or are about to enter into with you.

Purposes for Which Personal Information is Collected and Used

Purposes of Information Collected From Study Participants – Personal information generally is collected from the Participant and used for the purposes of: contacting the Participant; conducting Studies; conducting our Business, including providing services to our clients, including Study sponsors; regulatory documentation and submissions to relevant agencies, ethics committees and competent authorities; responding to audit and inspection requests by relevant agencies, ethics committees, and competent authorities; data analytics; presenting and sharing the results and data from Studies; and searching public records in connection with mortality data. In addition to the above, personal information may be used in the future for new scientific, medical, and pharmaceutical research activities, including activities that are unanticipated. These activities may include, but are not limited to, periodic follow-up or related studies.

Purposes of Information Collected From Study Site Staff, Vendors, and Contractors - Personal information generally is collected from Study site staff, vendors, and contractors and used for the purposes of contacting such individuals; conducting Studies; conducting our Business including providing services to our clients, including Study sponsors; ensuring appropriate qualifications and training; administering the receipt of services from such individuals; regulatory documentation and submissions to relevant agencies, ethics committees, and competent authorities; responding to audit and inspection requests by relevant agencies, ethics committees, and competent authorities; data analytics; presenting and sharing the results and data from Studies; and searching public records in connection with mortality data. In addition to the above, personal information may be used in the future for new scientific, medical, and pharmaceutical research activities, including activities that are unanticipated. These activities may include, but are not limited to, periodic follow-up and related studies.

Purposes of Information Collected Through Website - In general, the personal information collected through our Website is used to process your transactions, to conduct and improve our Business, to help us understand who uses the Website, to improve the Website, for internal

operations and overall systems administration, and, if you request information or request that we contact you, to respond to your requests. We may also use the information gathered through the Website (including personal information) for statistical purposes, to perform statistical analysis of user behaviour, and to evaluate and improve the Website and our Business. Some of this information may be linked to personal information and personally identifiable information for internal purposes. If you opt in, we will use your personal information to send you NERI marketing materials.

Purposes of Information Collected From General Inquirers and Representatives of Our Business Partners and Clients – Personal information generally is collected from inquirers and representatives of our business partners and clients, including Study sponsors, in order to respond to the relevant inquiry, to conduct and improve our Business (including conducting Studies), to carry out our relationships with our business partners and clients, including Study sponsors, and for internal operations.

Types of Third Parties To Which Personal Information Is Disclosed

In connection with the purposes described above, personal information may be shared with the following types of third parties:

Third Parties Generally

With respect to our Website, your non-personally identifiable information may be provided to third parties, including where such information is combined with similar information of other users of the Website. In addition to the above, when individuals use our Website, third parties (including without limitation third-party analytics and other service providers) may directly collect information about our Website visitors, including about our visitors' online activities over time and across different websites. The third parties to which information may be provided, or who may directly collect information, may include analytics and other service providers, vendors and website tracking services, affiliates, actual or potential commercial partners, clients (including Study sponsors), licensees, researchers, and other similar parties.

Please note in particular that the Website uses Google Analytics, including its data reporting features and the DoubleClick cookie to view Demographics & Interest Reporting. Information collected by Google Analytics includes but is not limited to web metrics. For information on how Google Analytics collects and processes data, please see the site "How Google uses data when you use our partners' sites or apps", currently located at www.google.com/policies/privacy/partners/. For information on opting out of Google Analytics, we encourage you to visit Google's website, including its list of currently available opt-out options presently located at <https://tools.google.com/dlpage/gaoptout>. For information on opting out of the DoubleClick cookie specifically, see the DoubleClick opt-out page at <https://adssettings.google.com/anonymous?sig=ACi0TCgPDS213eyFljx4kCZox8YH0ejRjY0OWL>

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tout](https://www.fda.gov/oc/privacy-policy)

Laws and Legal Rights

Your personal information may be disclosed upon a good faith belief that disclosure is required in order to comply with an applicable statute, regulation, rule or law, a subpoena, a search warrant, a court or regulatory order, lawful requests by public authorities, including to meet national security or law enforcement requirements, or other valid legal process. Personal information may be disclosed in special circumstances upon a reasonable belief that disclosing this information is necessary to identify, contact, or bring legal action against someone, to detect fraud, or to protect our rights or property or the safety and/or security of our Website, our Business or the general public.

Agencies, Regulatory Bodies, and Other Third Parties in Connection with Studies

Your personal information may be disclosed to relevant agencies, regulatory bodies, Study sponsors, data and safety monitoring boards, clinical event/endpoint committees and all other regulatory authority and site institutional review boards and ethics committees. With respect to our Studies, your information (including personal information) may be disclosed to a variety of third parties, including third parties that purchase a Study database and third parties with which we have contracted to provide access to our databases, including research Study databases. Other types of third parties to which your information (including personal information) may be provided include our clients (including Study sponsors), vendors, affiliates, actual or potential commercial partners, licensees, researchers, and other similar parties. The results of our Studies also may be presented at meetings or in publications, but your identity will not be disclosed in those presentations or publications.

Study Physicians and Staff

Personal information may be disclosed to the physicians and other staff associated with our Studies.

Outside Contractors

We may employ independent contractors, vendors, and suppliers (collectively, "Outside Contractors") to provide specific services and products related to the Website and/or our Business, including hosting, maintenance, auditing, monitoring, and other services. In the course of providing products or services to us, these Outside Contractors may have access to your personal information. We use reasonable efforts to ascertain that these Outside Contractors are capable of protecting the privacy of your personal information.

Sale of Business or Bankruptcy

Your personal information may be transferred to a third party in connection with a sale, merger or other transfer of all or substantially all of the assets of NERI or any of its Corporate Affiliates (as defined below), or any portion of NERI or any of its Corporate Affiliates, or in the event that we discontinue our business, or in the event that we file a petition or have filed against us a petition in bankruptcy, reorganisation or similar proceeding, provided that the third party agrees to adhere to the terms of this EU Privacy Policy.

Affiliates

Your information (including personal information) may be disclosed to our Corporate Affiliates. For purposes of this EU Privacy Policy, "Corporate Affiliate" means any person or entity which directly or indirectly controls, is controlled by or is under common control with NERI, whether by ownership or otherwise; and "control" means possessing, directly or indirectly, the power to direct or cause the direction of the management, policies or operations of an entity, whether through ownership of fifty percent (50%) or more of the voting securities, by contract or otherwise. Any information identifying you that is provided to our Corporate Affiliates will be treated by those Corporate Affiliates in accordance with the terms of this EU Privacy Policy.

Choice

If you no longer wish to have your personal information disclosed to third parties, you may choose to "opt out" by notifying us. To do so, send an email to privacy@neriscience.com. Please be aware that your personal information may have been previously disclosed to third parties.

NERI will provide you with notice before using your personal information for a purpose other than that for which it was originally collected or subsequently authorised by you, and you may choose to "opt out" of such use by following the directions provided in the notice. However, even after any "opt-out", your personal information may be used and disclosed to a third party upon a good faith belief that such disclosure is required in order to comply with an applicable statute, regulation, rule or law, a subpoena, a search warrant, a court or regulatory order, lawful requests by public authorities, including to meet national security or law enforcement requirements, or other valid legal process. Without limitation of any other provision contained in this EU Privacy Policy, following your "opt-out", your information that already has been gathered may continue to be used and to be disclosed to third parties, provided that such information will be anonymised in order to ensure that you cannot be identified anymore.

Sensitive Information

If information is collected from you revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the

purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation, administrative or criminal proceedings or sanctions (which are treated outside pending proceedings), or information with respect to personal sexuality ("Sensitive Information"), such Sensitive Information will not be (a) disclosed to a third party or (b) used for a purpose other than those for which it was originally collected or subsequently authorised by you without obtaining your affirmative "opt-in" (unless (i) we have another justification for processing your Sensitive Information, as set out in Article 9(1) of the GDPR for 'special categories of personal data' or (ii) there is a good faith belief that such disclosure or use is required in order to comply with an applicable statute, regulation, rule or law, a subpoena, a search warrant, a court or regulatory order, lawful requests by public authorities, including to meet national security or law enforcement requirements, or other valid legal process). In addition, NERI will treat as sensitive any personal information received from a third party where the third party identifies and treats it as sensitive.

Transfers Outside of the EEA and Switzerland

Before we disclose any of your personal information to a third party outside of the EEA or Switzerland we will ensure that we either obtain your consent to transfer the personal information or that the transfer is made subject to appropriate safeguards (as referred to in Article 46 of the GDPR), such as adhering to the EU-U.S. and Swiss-U.S. Privacy Shield Frameworks (as the case may be). NERI's accountability for personal information that it receives under the Privacy Shield Framework and transfers to a third party is outlined in the Privacy Shield Principles. In particular, NERI remains liable under the Privacy Shield Principles if third-party agents that it retains to process personal information on NERI's behalf process such personal information in a manner inconsistent with the Privacy Shield Principles, unless NERI can prove that it is not responsible for the event giving rise to the damage.

Data Integrity and Purpose Limitation

Except as may be authorised by you, we use your personal information in a way that is compatible with and relevant for the purpose for which it was collected. To the extent necessary for these purposes, we take reasonable steps to ensure that personal information is accurate, complete, current, and reliable for its intended use.

Your Rights

You have the right to access your personal information held by us and you may correct, amend, or delete such personal information, to the extent that it is inaccurate or has been processed in violation of the Privacy Shield Principles, except where the burden or expense of providing access would be disproportionate to the risks to your privacy in the case in question or where the rights of persons other than the individual would be violated or as otherwise described in the Privacy Shield Principles. If you wish to access your personal information, please contact us in either of the ways described below (under the section titled **Recourse, Enforcement, and Liability**).

Under certain circumstances you also have the right to access a copy of your information (generally free of charge), request that your personal information is erased, object to the processing of your personal information, to have the processing of your personal information restricted or to request that a copy of your personal information (if you provided the personal information to us and it is processed electronically) transferred to another organisation in an electronic form. For further details of your rights in respect of your personal information, please contact us in either of the ways described below (under the section titled **Recourse, Enforcement, and Liability**).

Without limitation of any other provision contained in this EU Privacy Policy, access to personal information associated with Studies may be limited if necessary to maintain the integrity of the research effort.

Retention of Personal Information

We will only retain your personal information for as long as necessary within the current regulatory requirements as applied through the NERI standard operating procedures (SOP) to fulfil the purposes for which we collected that personal information. To determine the appropriate retention period for personal information, we consider the amount, nature, and sensitivity of the personal information, the potential risk of harm from unauthorised use or disclosure of that personal information, the purposes for which we process your personal information and whether we can achieve those purposes through other means, and the applicable legal requirements.

Recourse, Enforcement, and Liability

You have the right to complain to your relevant data protection authority at any time, however, before you make a complaint to an authority, we would appreciate the opportunity to deal with your complaint ourselves.

NERI uses the self-assessment method to verify the attestations and assertions made in this EU Privacy Policy and to ensure that its privacy practices have been implemented as presented in this EU Privacy Policy. Any questions, complaints, or concerns regarding this EU Privacy Policy should be directed to NERI at the e-mail or postal/courier address referenced in the section below titled **“Who Do I Contact If I Have Any Privacy Questions?”**. NERI will investigate and attempt to resolve any disputes/complaints, including correcting any personal information, using personal information consistent with the Privacy Shield Principles, reversing or correcting the effects of noncompliance, and assuring that future processing of personal information will be in conformity with this Policy, including the Privacy Shield Principles.

For any complaints that cannot be resolved by NERI directly, NERI commits to cooperate with the panel established by the EU Data Protection Authorities (DPAs) and the Swiss Federal Data Protection and Information Commissioner (Commissioner), as applicable, to investigate unresolved disputes/complaints and comply with the advice given by the panel and/or the Commissioner. With respect to the Privacy Shield Principles, the panel established by the DPAs and/or the Commissioner, as applicable, is the independent

dispute resolution body designed to address complaints and provide appropriate recourse to you free of charge.

As further described in the Privacy Shield Principles, a binding arbitration option will be made available to you in order to address residual complaints that have not been resolved by other means. See Section C of Annex I to the Privacy Shield Principles at <https://www.privacyshield.gov/article?id=C-Pre-Arbitration-Requirements> and <http://trade.gov/td/services/odsi/swiss-us-privacyshield-framework.pdf>. The Federal Trade Commission has jurisdiction over NERI's compliance with the Privacy Shield Frameworks and the Privacy Shield Principles.

Adherence by NERI to the Privacy Shield Principles and the above-set forth provisions may be limited (a) to the extent necessary to meet national security, public interest or law enforcement requirements; (b) by statute, government regulation, or case law that creates conflicting obligations or explicit authorisations; or (c) if the effect of the EU or Member State law is to allow exceptions or derogations, provided that such exceptions or derogations are applied in comparable contexts.

WHO DO I CONTACT IF I HAVE ANY PRIVACY QUESTIONS?

If you have any questions or comments about this EU Privacy Policy or feel that we are not abiding by the terms of this EU Privacy Policy, please contact us in either of the following ways:

By email: jroberts@neriscience.com

By postal mail or courier:

New England Research Institutes, Inc.
Attn: Jeffrey Roberts, Regulatory Compliance Director
480 Pleasant Street, A100
Watertown, MA 02472
U.S.A.