

## **New England Research Institutes, Inc. as a wholly owned subsidiary of Carelon Research EU-U.S. and Swiss-U.S. Privacy Shield Privacy Policy**

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Browsing our website at <https://www.carelonresearch.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 the use of cookies, action tags, and log files, please see our Website Privacy Policy.

New England Research Institutes, Inc., doing business as Carelon Research is a full-service contract research organization (CRO) that provides clinical trial, epidemiology, public health and disparities, and bio-behavioral 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-U.S. and Swiss U.S. Privacy Shield Privacy Policy (the "Privacy Shield Privacy Policy") describes how we, New England Research Institutes, Inc. dba Carelon Research ("NERI", "Carelon Research", "we", "us", or "our") handle information relating to an identified or identifiable natural person transferred to the United States from the European Union (including Switzerland) or the European Economic Area that NERI dba Carelon Research collects on our Website and through other online and offline channels in connection with your interaction with our CRO business, including without limitation Studies (collectively, the "Business"). NERI dba Carelon Research also has a Website Privacy Policy that applies only to information collected through the Website with respect to NERI dba Carelon Research's U.S. operations.

As used in this Privacy Shield Privacy Policy, the terms "using" and "processing" information include 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 organization or among our affiliates within the United States or internationally.

As described in further detail below, NERI dba Carelon Research 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 (as defined below) transferred from the European Union and Switzerland, respectively, to the United States. As used herein, "personal information" means information relating to an identified or identifiable natural person transferred to the United States from the European Union (including Switzerland) or the European Economic Area. With respect to such personal information, NERI dba Carelon Research 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 Privacy Shield 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, 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 European Union or European Economic Area. 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, redacted at the respective Study site, and typically transferred as a data set in key-coded form as described in Privacy Shield Supplemental Principle 14 Pharmaceutical and Medical Products, subsection (g) “Key-coded Data”, and therefore does not constitute a transfer that would be subject to the Privacy Shield Principles. To the extent that such information is not key-coded, the types of personal information generally collected from individuals participating in our Studies 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, phone number, business or home address, curriculum vitae, biographical sketches, medical license 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 site (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.

### **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 behavior, 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 dba Carelon Research 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.

Providing personal information through this website or Application is optional. Personally identifiable information will not be collected from you without your knowledge and approval.

If you do not wish to have your activity on our website or Application tracked, [you can opt-out at any time here](#) to discontinue first party cookie tracking of your web activity.

You also have the choice to opt-out of third-party cookies, web beacons or similar technologies, if you do not want third-party service providers to collect your anonymous information for marketing purposes, [visit the Network Advertising Initiative \(NAI\) website to perform the opt-out](#).

Additionally, you can direct your Internet browser to notify you and seek approval whenever a cookie is being sent to your hard drive. You may also delete a cookie manually from your computer, tablet or smartphone through your Internet browser settings or other programs. You can also set your browser to refuse all cookies. Please note that some parts of this website or Application may not function properly or be available to you, if you refuse to accept a cookie or choose to disable the acceptance of cookies.

### **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 dba Carelon Research or any of its Corporate Affiliates (as defined below), or any portion of NERI dba Carelon Research 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, reorganization or similar proceeding, provided that the third party agrees to adhere to the terms of this Privacy Shield Privacy Policy.

### **Affiliates**

Your information (including personal information) may be disclosed to our Corporate Affiliates. For purposes of this Privacy Shield Privacy Policy, "Corporate Affiliate" means any person or entity which directly or indirectly controls, is controlled by or is under common control with Carelon Research, 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 Privacy Shield 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.office@carelon.com](mailto:privacy.office@carelon.com). Please be aware that your personal information may have been previously disclosed to third parties. Also, NERI dba Carelon Research will provide you with notice before using your personal information for a purpose other than that for which it was originally collected or subsequently authorized 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 herein, 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 anonymized in order to ensure that you cannot be identified anymore.

## **Sensitive Information**

If information is collected from you specifying medical or health conditions, racial or ethnic origin, political opinions, religious, ideological, or philosophical beliefs, trade union membership, information on social security measures or 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 authorized by you without obtaining your affirmative “opt-in” (unless 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 dba Carelon Research will treat as sensitive any personal information received from a third party where the third party identifies and treats it as sensitive.

## **Onward Transfer**

Before we disclose any of your personal information to a third party we will require that such third party provide the same level of privacy protection as is required by the Privacy Shield Principles. NERI dba Carelon Research’s accountability for personal information that it receives under the Privacy Shield and transfers to a third party is outlined in the Privacy Shield Principles. In particular, NERI dba Carelon Research remains liable under the Privacy Shield Principles if third-party agents that it retains to process personal information on NERI dba Carelon Research’s behalf process such personal information in a manner inconsistent with the Privacy Shield Principles, unless NERI dba Carelon Research can prove that it is not responsible for the event giving rise to the damage.

## **Data Integrity and Purpose Limitation**

Except as may be authorized 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.

## **Access**

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**).

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

### **Recourse, Enforcement, and Liability**

NERI dba Carelon Research uses the self-assessment method to verify the attestations and assertions made herein and to ensure that its privacy practices have been implemented as presented herein. Any questions, complaints, or concerns regarding this Privacy Shield Privacy Policy should be directed to NERI dba Carelon Research 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 dba Carelon Research 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 dba Carelon Research directly, NERI dba Carelon Research 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 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. NERI dba Carelon Research commits to cooperate with EU data protection authorities (DPA) and the Swiss Federal Data Protection and Information Commissioner (FDPIC) and comply with the advice given by such authorities.

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 dba Carelon Research’s compliance with the Privacy Shield.

Adherence by NERI dba Carelon Research 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 authorizations; 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 Privacy Shield Privacy Policy or feel that we are not abiding by the terms of this Privacy Shield Privacy Policy, please contact us in either of the following ways:

By email: [privacy.office@carelon.com](mailto:privacy.office@carelon.com)

By postal mail or courier:

Carelon Research  
Attention: Regulatory Compliance Manager  
123 Justison Street  
Suite 200  
Wilmington, DE 19801