

Policy

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POL-001	Privacy and Personal Data		
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Authorization

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Document History

Date	Author	Version	Description of Change(s)
14-Dec-2016	Rona Osmani	5.0	Updated sections below per Privacy Shield Certification requirements. <ul style="list-style-type: none">- Section 4.1 subject to enforcement powers of FTC- Section 4.6 meet national security or law enforcement requirement- Section 4.7 WCC works with limited data set and recourse taken in event confidential subject data is received
10- Nov - 2016	Rona Osmani	4.0	Section 4.7 updated with additional required details for Privacy Shield Certification. Reference to QAhelp@wcclinical.com added.
30- Sep - 2016	Rona Osmani	3.0	Replaced Safe Harbor compliance section (5) with Privacy Shield compliance. Document published via quick approval by head of quality (R.Osmani).
18-Aug-2016	Rona Osmani	2.0	Biennial review performed. Section 5 added on sponsor confidentiality.
06-AUG-2014	Rehta Mehta	1.0	Change the Author to R. Mehta. Removed approver K. O'Brien (left company) and added R. Mehta. Minor edits and updated to latest template.

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Valid Day of Print

1 PURPOSE

The purpose of this Policy is to state the expectations of WorldCare Clinical, LLC (WCC) for complying with applicable data privacy law and protecting the privacy of personal data which is received, collected, maintained and utilized in connection with WCC execution of daily business activities.

2 SCOPE

This policy is applicable to all WCC employees within the WCC organization.

3 HOW TO USE THIS DOCUMENT

Employees using this Policy shall execute the steps defined in the Procedure section below. Additional information includes references to supporting documentation and regulations, clarifying information, and further directions for navigating decision steps in the Procedure details.

4 CONFORMANCE WITH PRIVACY SHIELD PRINCIPLES

WCC complies with the EU-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 Union to the United States. WCC 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 policy and the Privacy Shield Principles, the Privacy Shield Principles shall govern.

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

4.1 Notice

When WCC obtains personally identifiable data through its subsidiaries, affiliates or other entities in the EU member countries and Switzerland, notice will be provided in clear and concise language of the purpose of providing the data. WCC will provide information regarding its participation in the Privacy Shield. This notice will be given when the data is requested or as soon as practicable thereafter. WCC is subject to the investigatory and enforcement powers of the Federal Trade Commission (FTC.)

4.2 Choice

WCC will offer individuals the opportunity to choose (opt out) whether their personally identifiable data is to be (a) disclosed to a non-agent third party or (b) used for a purpose that is materially different from the purpose(s) for which it was originally collected or subsequently authorized by the individual. WCC will provide

clear, conspicuous, and readily available mechanisms for individuals to exercise their choices.

4.3 Accountability for Onward Transfer

Before WCC transfers information to a third party that is acting as an agent it will: transfer data only for limited and specified purposes; ascertain that the third party is obligated to provide at least the same level of privacy protection as is required by the Principles; take reasonable and appropriate steps to ensure that the agent effectively processes the personal information transferred in a manner consistent with the organization's obligations under the Principles; require the agent to notify the organization if it makes a determination that it can no longer meet its obligation to provide the same level of protection as is required by the Principles; upon notice take reasonable and appropriate steps to stop and remediate unauthorized processing; and provide a summary or a representative copy of the relevant privacy provisions of its contract with that agent to the US Department of Commerce, upon request.

WCC is not required to provide notice or choice when disclosure is made to a third party that is acting as an agent to perform task(s) on behalf of and under the instructions of WCC. WCC will not share the personal information it receives with any third parties.

4.4 Security

WCC will employ reasonable precautions to protect an individual's personally identifiable data in its possession from disclosure, loss, alteration, destruction, misuse, and unauthorized access.

In order to store or transmit electronic personally identifiable data, WCC maintains an internal private, secure global network that is protected from computer virus infection and monitored for unauthorized access. Both electronic and paper based records holding personally identifiable data are maintained in access controlled facilities for which business continuity plans are required.

4.5 Data Integrity and Purpose Limitation

WCC will use personally identifiable data only in ways that are compatible with the purpose for which the information was obtained or subsequently authorized by the individual. WCC will take reasonable steps to ensure that the personally identifiable data it collects is up to date, accurate, complete and relevant only to its intended use. If WCC learns that an agent, contractor or partner is using or disclosing personally identifiable data in a manner contrary to this Policy, WCC will promptly take reasonable steps to prevent or stop the use or disclosure.

4.6 Access

Upon request individuals will be provided with personally identifiable data that WCC holds about them. WCC also will take the reasonable steps to provide individuals with the means to correct, amend, or delete information that is found to be inaccurate or incomplete. Due to regulatory, statistical, and contractual requirements, we are not able to grant direct access to research data to research participants or clinical investigators.

WCC is required to disclose personal information in response to lawful requests by public authorities, including to meet national security or law enforcement requirements.

4.7 Recourse Enforcement and Liability

WCC is not considered a Covered Entity or Business Associate as defined in HIPAA (Health Insurance Portability Accountability Act of 1996). WCC is a Cooperative Group and as part of the day to day operations, WCC utilizes limited data sets when exchanging data to other organizations. The use of limited data sets, for the purpose of clinical research, exempts WCC from data use agreements.

In instances where WCC receives confidential subject data from sponsor or an investigator site which can directly identify a subject, the following actions will occur:

1. Informing the respective site and/or sponsor that data was received with confidential subject information and request site to refrain from sending this data again.
2. Obscuring the subject identifier by best means available (identifiers on paper and film source data are obscured by markers whereas electronic source data masking is system dependent)

It is the responsibility of the sponsor to follow-up with WCC regarding the collection, selection and management of subject/identifier/data used in clinical trials to ensure that the subject confidentiality is in accordance with applicable regulations.

WCC has provided its employees with appropriate training to ensure that all individuals who process personally identifiable data are fully aware of their responsibilities with respect to data protection. Any employee that WCC determines is in violation of this Privacy Shield Principles will be subject to disciplinary action up to and including termination of employment.

In compliance with the Privacy Shield Principles, WCC commits to resolve complaints about our collection or use of your personal information. EU individuals

with inquiries or complaints regarding our Private Shield policy should first contact WCC at: QAHelp@wcclinical.com

WCC has further committed to cooperate with EU data protection authorities (DPAs) with regard to unresolved Privacy Shield complaints concerning human resources data transferred from the EU in the context of the employment relationship. If you do not receive timely acknowledgment of your complaint from us, or if we have not addressed your complaint to your satisfaction, please contact the EU DPAs for more information or to file a complaint. The services of EU DPAs are provided at no cost to you.

5 SPONSOR CONFIDENTIALITY

Reasonable efforts shall be made by WCC employees to maintain sponsor confidentiality. In order to protect sponsor confidentiality, WCC employees will adhere to the following best practices:

- Client names must not be referenced in external out of office notifications. Instead the WCC study code or other method will be used.
- Documents containing sponsor name or identifiable study information should be kept out of WCC public spaces.
- Conversations in WCC public spaces regarding specific sponsors should be kept to a minimum when visitors are present on WCC premises.
- Documents containing Sponsor name or identifying information that is to be disposed should be shredded.
- Documents in the file storage room should not be visibly labeled with sponsor name. Instead the WCC code should be used to visibly identify the files.
- Sponsor names should not be disclosed to third party contractors unless a Confidentiality Agreement or Non-disclosure Agreement is in place.

6 INDIVIDUALS RESPONSIBLE FOR ENSURING COMPLIANCE AND POL VALIDATION

The Department Manager or designee is responsible for assuring training and compliance with this POL and monitoring its ongoing validity. Each employee is responsible for following the procedure and reporting any inability to do so to their respective manager.

7 DEVIATIONS

Any circumstances indicating that this POL cannot be followed must be reported to the Department Manager or designee. Inability to conform to this POL must result in either a deviation request or prompt revision of the POL.

8 ASSOCIATED POLICIES, SOPs and WORK INSTRUCTIONS

Document Number	Title
POL-000	Quality Policy Manual
POL-003	Records Management
SOP-0007	Privacy and Confidentiality
SOP-0013	Security
SOP-0022	CAPA
EU Directive 95/46/EC	European Commission's Directive on Data Protection
https://www.privacyshield.gov/EU-US-Framework	EU-U.S. Privacy Shield Framework Principles Issued by the U.S. Department of Commerce
Canada, 01 April 2011	<i>The Personal Information Protection and Electronic Documents Act</i>
Japan, 01 April 2005	Law on Protection of Personal Information