1. PURPOSE

1.1. Within the framework of Privacy Shield Principals and in accordance with the principles inherent in Good Clinical Practices (GCP) of the International Conference on Harmonization (ICH), this procedure outlines the Clinilabs' privacy policy.

1.2. This procedure establishes minimum standards within Clinilabs regarding privacy and confidential information.

1.3. Certain information may be subject to more stringent privacy safeguards as a result of the requirements of GCP, ICH, or other national and international requirements.

2. SCOPE

2.1. This procedure applies to all personal information received by Clinilabs in any format including electronic, paper, or verbal and must be followed by all Clinilabs' employees, including consultants, contractors, and temporary personnel.

2.2. The Privacy Shield Principles apply to the data once data have been transferred to the United States.

3. REFERENCES

3.1. Privacy Shield of Department of Commerce - https://www.commerce.gov/privacyshield

3.2. EU-US Privacy Shield Principles – 15 U.S.C. 1512 – Effective Feb 2016 https://www.commerce.gov/sites/commerce.gov/files/media/files/2016/eu_us_privacy_shield_full_text.pdf.pdf

3.3. U.S. Federal Trade Commission - https://www.ftc.gov/

4. RESPONSIBILITIES

4.1. Legal Counsel / Paralegal or Designee (President) is responsible for investigation of all reported breaches or potential breaches of this procedure along with Quality and Regulatory Compliance manager.

4.2. All Clinilabs' personnel must adhere to the requirements of this procedure.

5. GENERAL REQUIREMENTS

5.1. Background

5.1.1. The EU-U.S. Privacy Shield Framework is designed by the U.S. Department of Commerce and European Commission to provide companies on both sides of the Atlantic with a mechanism to comply with EU data protection requirements when transferring personal data from the European Union to the United States in support of transatlantic commerce.

5.1.2. The Privacy Shield Framework provides a set of robust and enforceable protections for the personal data of EU individuals and also makes it easier for them to understand and exercise their rights.

5.1.3. The U.S. Federal Trade Commission (FTC) provides enforcement assistance to EU Data Protection Authority (DPA) regarding compliance with the Privacy Shield Framework. The Department of Commerce refers search for and address false claims of participation to the FTC.

5.1.4. Clinilabs respects individual privacy and values the confidence of its customers, employees, clinical trial participants, healthcare professionals, consumers, business partners, investors, and others. Not only does Clinilabs strive to collect, use, and disclose personal information in a manner consistent with the laws of the countries in which it does business. The Clinilabs corporate privacy program is designed to respect and protect the data privacy rights of every person with whom we transact business.

5.1.5. The EU-US Privacy Shield Principles sets forth the privacy principles that Clinilabs follows with respect to transfers of personal information from the member states of the European Union (EU) to the United States (US), as well as within the United States.

5.2. Privacy Principles

5.2.1. The privacy principles in this procedure are based on the EU-US Privacy Shield Principles.

5.2.2. Clinilabs is voluntarily joining the Privacy Shield Framework, self-certifying with the Department of Commerce and will publicly commit to comply with the Framework's requirement.

5.2.3. Clinilabs may voluntarily withdraw from Privacy Shield Framework. After withdrawal from Privacy Shield Framework, Clinilabs will continue to apply the principles to the personal information received while participating in the Privacy Shield Framework. Clinilabs will also **annually certify** its commitment to apply principles to the Department of Commerce.

5.2.4. EU individuals are able to pursue legal action through private causes of action in the U.S. state courts, including private causes of action for misrepresentation and similar types of claims.

5.3. Notice

5.3.1. Where Clinilabs directly collects Personal Information directly from individuals, it will inform them about:

5.3.1.1. The purposes for which it collects and uses the information,

5.3.1.2. The types of third parties to which Clinilabs discloses that information,

5.3.1.3. Privacy Shield link for EU subjects,

5.3.1.4. Clinilabs contact information for complaints or inquires,

5.3.1.5. Individuals rights to access their personal data,

5.3.1.6. The choices and means, if any, Clinilabs offers individuals for limiting the use and disclosure of their Personal Information,

5.3.1.7. Clinilabs' commitment to subject to the Principles all personal data received from the EU in reliance on the Privacy Shield,

5.3.1.8. Independent dispute resolution body designated to address complaints and provide appropriate resolution free of charge to the individual and whether it is:

5.3.1.8.1. The panel established by DPAs
5.3.1.8.2. An alternative dispute resolution provider based in the EU
5.3.1.8.3. An alternative dispute resolution provided based in the United States,

5.3.1.9. Clinilabs being subject to investigatory and enforcement powers of the FTC, the Department of Transportation or any other US authorized statutory body,

5.3.1.10. The possibility of individuals to invoke binding arbitration under certain conditions,

5.3.1.11. The requirements to disclose personal information in response to lawful requests by public authorities, including to meet national security or law enforcement requirements, and

5.3.1.12. Clinilabs liability in cases of onward transfers to third parties.

5.3.2. Notice will be provided in clear and conspicuous language when individuals are first asked to provide personal information to Clinilabs.

5.3.3. Where Clinilabs receives Personal Information from third parties, affiliates or other entities, 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.

5.4. Choice

5.4.1. Clinilabs will offer individuals the opportunity to choose whether their Personal Information is:

5.4.1.1. To be disclosed to a third party, or

5.4.1.2. To be used for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual.

Individuals may decline (opt-out) permission for such disclosure or use of Personal Information.

5.4.2. For sensitive personal information, Clinilabs will give individuals the opportunity to affirmatively and explicitly (opt-in) consent to the disclosure of the information to a third party or to the use of the information for a purpose other than the

purpose for which it was originally collected or subsequently authorized by the individual.

5.4.2.1. In addition, Clinilabs will treat as sensitive any personal information received from a third party where the third party identifies and treats it as sensitive.

5.4.3. Clinilabs will always have contracts/agreements with all third parties or agents.

5.4.4. Clinilabs will provide individuals with reasonable mechanisms to exercise their choices.

5.4.5. When an individual decides or be asked to withdraw from a clinical trial, any personal data collected previous to withdrawal may be processed along with other data collected as part of the clinical trial as long as this was made clear to the participant in the notice at the time he/she agreed to participate.

5.5. Accountability for Onward Transfer

5.5.1. Clinilabs will transfer personal information to a third party / agent with an agreement/contract specifies purposes consistent with the consent provided by the individuals.

5.5.2. Where personal data collected for one research study are transferred to Clinilabs, these data may be used for another research activity when notice and choice have been provided in the first instance. Such notice will provide information about any future specific uses, unanticipated research activities or the data, such as periodic follow-up, related studies, or marketing.

5.5.3. During the conduct of blinded studies, participants cannot be given access to information about which treatment each participant may be receiving. This restriction will be explained during informed consent process. However, upon request, participants may receive treatment information upon conclusion of the trial and analysis of the results.

5.5.4. Clinilabs may share an individual's Personal Information with regulators, agents, contractors or partners of Clinilabs in connection with services that these individuals or entities perform for, or with, Clinilabs. Clinilabs may, for example, provide an individual's Personal Information to contractors or business partners for hosting our databases, for data processing services, or to send to that individual the information that he or she requested.

5.5.5. Clinilabs will obtain assurances from its agents and contractors that they will safeguard personal information received from us in a manner consistent with this procedure. Appropriate assurance of compliance may be given in a number of ways, which may include one or more of the following:

5.5.5.1. A contract between Clinilabs and the third party which includes provisions obligating the third party to provide at least the same level of protection as is required by the relevant Privacy Shield Framework principles.

5.5.5.2. The third party is subject to the EU Data Protection Directive itself.

5.5.5.3. The third party has filed its own Privacy Shield certification.

5.5.5.4. The third party has Binding Corporate Rules approved by the European Commission or is subject to another European Commission adequacy finding (e.g. Argentina, Canada, Guernsey, Hungary, Isle of Mann, Switzerland).

5.5.6. Only limited and specified personal data are transferred to the third party acting as an agent.

5.5.7. Where Clinilabs has knowledge that an agent, contractor or partner is using or disclosing Personal Information in a manner contrary to this Policy, Clinilabs will take reasonable steps to prevent or stop the use or disclosure.

5.5.8. Provide a summary or a representative copy of the relevant privacy provision of its contract with that third party/ agent to the Department of Commence upon request.

5.6. Security

5.6.1. Clinilabs will employ reasonable safeguards to protect Personal Information in its possession from loss, misuse and unauthorized access, disclosure, alteration and destruction.

5.6.2. For Personal Information subject to electronic storage or transmission, Clinilabs maintains an internal private, secure global network that is protected from computer virus infection and monitored for unauthorized access.

5.6.3. Both electronic and paper based records holding Personal Information are maintained in access controlled facilities for which business continuity plans are required.

5.7. Data Integrity and Proposed Limitation

5.7.1. Clinilabs will use Personal Information only in ways that are compatible with the purposes for which it was collected or subsequently authorized by the individual. Clinilabs will take reasonable steps to ensure that Personal Information is relevant to its intended use, accurate, complete, and current.

5.7.2. Clinilabs will adhere to the Principles for as long as personal information retained.

5.8. Access

5.8.1. Upon request, individuals will be granted reasonable access to Personal Information that Clinilabs holds about them.

5.8.2. In addition, upon request, Clinilabs will take reasonable steps to permit individuals to correct, amend, or delete information that is found to be inaccurate or incomplete.

5.8.3. The individuals request for access of personal information may not be granted if the burden or expense of providing access would be disproportionate to the risks to the individual's privacy in the case in question, or where the rights of persons other than the individual would be violated.

5.9. Recourse, Enforcement and Liability

5.9.1. All reported breaches or potential breaches of this procedure will be investigated by the Legal Counsel / Paralegal and the investigative agents the Officer assigns, who will take such actions as they deem appropriate in the investigation and if necessary, remediation of the situation.

5.9.2. Any employee/contractor or third party that Clinilabs determines is in violation of this Policy will be subject to disciplinary action up to and including termination of employment or contract termination, in addition to any remedy to which Clinilabs may be entitled at law or in equity, for such violation.

5.9.3. In the event of criminal or other serious violations of the law, these actions could also be subject to notification of the appropriate legal body.

5.9.4. If the Clinilabs becomes subject to an FTC or court order based on non-compliance, Clinilabs will make public any compliance or assessment report submitted to the FTC.

5.10. Dispute Resolution

5.10.1. Any questions or concerns regarding the use or disclosure of Personal Information should be directed to the Legal Counsel / Paralegal. Clinilabs will investigate and attempt to resolve complaints and disputes regarding use and disclosure of Personal Information in accordance with the principles contained in this procedure.

5.10.2. Individual may bring a complaint directly to Clinilabs. Clinilabs will investigate, expeditiously resolve the disputes and send respond to the individual within **45 days.**

5.10.3. In compliance with the Privacy Shield Principles, Clinilabs commits to resolve complaints about our collection or use of your personal information. EU individuals with inquiries or complaints regarding our Privacy Shield policy should first contact Clinilabs Drug Development Corporation at:

Berrin Önbas-Uzun, Vice President of Quality and Regulatory Compliance
Clinilabs Drug Development Corporation
4 Industrial Way West, 2nd Floor, Eatontown, NJ 07746, USA
E Mail: bonbas@clinilabs.com
Phone: +1 212-994-4575

5.10.3.1. She will forward the received information to the responsible bodies internally for investigation.

5.10.4. Clinilabs has further committed to refer unresolved Privacy Shield complaints to American Arbitration Association (AAA), an alternative dispute resolution provider located in the [United States]. 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 or visit http://go.adr.org/privacyshield.html for more information or to file a complaint. The services of American Arbitration Association (AAA), are provided at no cost to you.

5.10.5. The filing party may also file a case by mail or email, please complete the appropriate Privacy Shield Program Notice of Arbitration Form and forward to the International Centre for Dispute Resolution (ICDR).

International Centre for Dispute Resolution Case Filing Services
1101 Laurel Oak Road, Suite 100, Voorhees, NJ 08043, United States
Phone: +1.212.484.4181
Email box: casefiling@adr.org

5.10.6. Upon receipt of the Demand for Arbitration, the ICDR will make an initial Determination, subject to the appointed arbitrator(s) final determination, regarding the eligibility of the complaint pursuant to the EU-U.S. or Swiss-U.S. Privacy Shield programs and if deemed eligible the ICDR/AAA shall prepare a dated letter of initiation that will be communicated to the parties with respect to the arbitration and shall acknowledge the commencement of the arbitration.

6. ABBREVIATIONS AND DEFINITIONS

6.1. Abbreviations

6.1.1. **AAA** American Arbitration Association

6.1.2. **ICDR** International Center for Dispute Resolution

6.1.3. **ICH** International Conference on Harmonization

6.1.4. **EU** European Union

6.1.5. **DPA** Data Protection Authorities

6.1.6. **FTC** U.S. Federal Trade Commission

6.1.7. **GCP** Good Clinical Practices

6.2. Definitions

6.2.1. **Agent:** Any third party that uses personal information provided by Clinilabs to perform tasks on behalf of and under the instructions of Clinilabs.

6.2.2. **Personal Data and Personal Information:** Any information or set of information that identifies or could be used by or on behalf of Clinilabs to identify an individual. Personal Information does not include information that is encoded or stripped of all personal identifiable information, or which is publicly available.

6.2.3. **Sensitive Personal Information:** Personal information that reveals race, ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, or that concerns the health or sex life of an individual. In addition, Clinilabs will treat as Sensitive Personal Information any information received from a third party where that third party treats and identifies the information as sensitive.

6.2.4. **"Processing"** of personal data means any operation or set of operations which is performed upon personal data, whether or not by automated means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure or dissemination, and erasure or destruction.

6.2.5. **"Controller"** means a person or organization which, alone or jointly with others, determines the purposes and means of the processing of personal data.

7. FORMS AND TEMPLATES

7.1. None

8. REVISION HISTORY

VERSION NUMBER	CHANGES
001	Original document as CL-SOP-QA-7009
002	CL-SOP-QA- 7009-001 converted into a Policy.
003	Format corrected, section 5.9 updated and in section 5.10, Legal Counsel replaced with Legal Counsel.
004	CLINiLABS replaced with Clinilabs in the footer. Abbreviations are added.

VERSION NUMBER	AUTHOR	APPROVERS	CHANGES
005	Sylvia Pisconti	Berrin Önbas-Uzun Gary Zammit	First electronic approval, The Safe Harbor Privacy Principles – replaced with EU-US Privacy Shield Principles throughout the policy.
006	Aysenur Sayakci	Berrin Önbas-Uzun Gary Zammit	Sections 4.1, 5.10.3 to 5.10.6 are added. Company logo is updated.

Signatures

Aysenur Sayakci

Document ID: CL-POL-GA-1001
Revision: 006
Electronically signed by Aysenur Sayakci
Title: Senior Associate, Quality and Regulatory Compliance
Date: 4/3/2018 2:58:01 PM
Reason: Approval of Document

Berrin Onbas-Uzun

Document ID: CL-POL-GA-1001
Revision: 006
Electronically signed by Berrin Onbas-Uzun
Title: VP, Quality & Regulatory Compliance
Date: 4/3/2018 3:04:10 PM
Reason: Approval of Document

Gary Zammit

Document ID: CL-POL-GA-1001
Revision: 006
Electronically signed by Gary Zammit
Title: President & CEO and Principal Investigator
Date: 4/5/2018 11:27:14 AM
Reason: Approval of Document