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1 Purpose

This policy sets forth confidentiality, security and privacy requirements with respect to Personal Data/Personal Information and Protected Health Information processed by MolecularMD to ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) and the Privacy Shield Frameworks.

Molecular MD 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 Union and Switzerland to the United States.

MolecularMD has certified to the Department of Commerce that it adheres to the Privacy Shield Principles of notice, choice, onward transfer, security, data integrity, access, and enforcement, along with the supplemental 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 MolecularMD's certification, please visit <https://www.privacyshield.gov>.

2 Scope

This privacy policy applies to all Personal Data/Personal Information (PI), Sensitive Information and Protected Health Information (PHI) as defined below that is received by MolecularMD from any source, including the European Economic Area (which includes the member states of the European Union (EU) plus Iceland, Liechtenstein, Norway and Switzerland) in any format, including but not limited to, electronic, paper or verbal.

The privacy policy applies to the follow MolecularMD covered entities:


1341 SW Custer Drive	840 Memorial Drive, First Floor
Portland, OR 97219 USA	Cambridge, MA 02139 USA

3 Related Documents

3.1	EU General Data Protection Regulation (GDPR)	R(EU) 2016/679
3.2	Health Insurance Portability and Accountability Act of 1996 (HIPAA)	PL 104-191
3.3	Business Continuity Plan	SOP-0078
3.4	Complaint Management	SOP-0115
3.5	Computer and Network Access Set-Up	FRM-0456
3.6	Employee Confidentiality Information Agreement	FRM-0010
3.7	Facility Access and Security	POL-0003
3.8	HIPAA Confidentiality Agreement	FRM-0363
3.9	MolecularMD Business Continuity Planning	POL-0013
3.10	Organizational Chart	AI-0005
3.11	Periodic Review	SOP-0002
3.12	Quality Assurance Auditing	SOP-0009

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3.13 Software, System, & Network Access Security


SOP-0133

4 Definitions, Acronyms, Abbreviations

- 4.1 Agreement:** The entire contract between the client and MolecularMD under which MolecularMD performs services for the client. An Agreement may be formed through the execution of a written contract by both parties, by MolecularMD's express or implied acceptance of a purchase order, work order, scope of work, or by any other means of offer and acceptance of a contract.
- 4.2 Consent:** Any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to them.
- 4.3 EEA:** European Economic Area. The EEA includes the member states of the European Union (EU) plus Iceland, Liechtenstein, Norway and Switzerland.
- 4.4 EU Data Protection Authorities (EU DPAs):** Authorities tasked with the protection of data and privacy in the European Union.
- 4.5 EU:** European Union
- 4.6 FDPIC:** Swiss Federal Data Protection and Information Commissioner, authorities tasked with the protection of data and privacy in Switzerland.
- 4.7 Genetic Data:** Personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question.
- 4.8 ICDR-AAA:** International Centre for Dispute Resolution-American Arbitration Association
- 4.9 IRM:** Independent Recourse Mechanism
- 4.10 Personal Data and/or Personal Information (PI):** Any information relating to an identified or identifiable natural person ('data subject'); 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. Any information provided by clients or collected by MolecularMD: (1) that identifies an individual, or when used in combination with other information identifies an individual; or (2) from which identification or contact information of an individual person can be derived. PI can be in any media or format, including computerized or electronic records as well as paper-based files. PI does not include the name, business telephone number, business cell phone number, business address, business email address, or internal identification number of individual MolecularMD employees.
- Specific Personal Information that MolecularMD collects includes, but is not limited to: (1) a first or last name or initials; (2) a home or other physical address, including street name and name of city or town; (3) an email address or other online contact information, such as an instant messaging user identifier or a screen name that reveals an individual's email address; (4) a telephone number; (5) a social security number, tax ID number or other government-issued identifier; (6) an Internet Protocol ("IP") address or host name that identifies an individual; (7) a persistent identifier, such as a customer number held in a "cookie" or

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processor serial number, that is combined with other available data that identifies an individual; (8) birth dates or treatment dates; or (10) coded data that is derived from PI. Additionally, to the extent any other information (such as, but not limited to, case report form information, clinical trial identification codes, personal profile information, IP addresses, other unique identifier, or biometric information) is associated or combined with PI, then such information also will be considered PI.

4.11 Processing: Any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

4.12 Protected Health Information (PHI): A subset of Personal Information that includes individually identifiable health information. Individually identifiable health information is that which can be linked to a particular person. Specifically, this information can relate to:

- The individual’s present or future physical or mental health or condition;
- The provision of health care to the individual; or,
- The past, present, or future payment for the provision of health care to the individual.

For the purposes of this policy, all PHI is considered both sensitive information and Personal Information.

4.13 Sensitive Information: A subset of Personal Information that due to its nature has been classified by law or this policy as deserving additional privacy and security protections. Sensitive Information consists of:

- All government-issued identification numbers (including US Social Security numbers, Canadian Social Insurance numbers, driver's license numbers, and passport numbers);
- All financial account numbers (bank account numbers, credit card numbers, and other information if that information would permit access to a financial account);
- Individual medical records and biometric information, including any information on any worker, client or patient's health, disability, disease or product interests;
- Reports of individual background checks, educational transcripts, and all other data obtained from a U.S. consumer reporting agency and subject to the Fair Credit Reporting Act; and,
- Data elements revealing race, ethnicity, national origin, religion, trade union membership, sex life or sexual orientation, and criminal records or allegations of crimes.


For the purposes of this policy, all sensitive information is considered Personal Information.

4.14 Services: The functions that MolecularMD performs for, or on behalf of, a client.

4.15 USCIB: United States Council for International Business

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5 Requirements

5.1 Roles and Responsibilities

Roles	Responsibilities
Data Protection Officer (may be referred to as Privacy Officer)	<ul style="list-style-type: none"> • Inform and advise the organization and its employees of their obligations • Monitor compliance with GDPR (including training, audits) • Advise on data privacy impact assessments • Acts as the point person for the regulators
Trial Sponsor	<ul style="list-style-type: none"> • Provide documented instructions on the processing of any Personal Information transferred to MolecularMD
All Employees	<ul style="list-style-type: none"> • Maintain knowledge of the requirements of this Policy and the corresponding legal and regulatory requirements • Promptly report any breach of confidentiality of Personal Information to their supervisor and to the Data Protection Officer
Management	<ul style="list-style-type: none"> • Promptly and thoroughly investigate allegations of any use or disclosure of Personal Information • Report breaches of confidentiality of Personal Information to the relevant regulatory authorities in compliance with the regulations in effect for that jurisdiction

Table 1

- 5.1.1 MolecularMD shall appoint a Data Protection Officer to be responsible for developing and implementing all required policies and procedures. The designated officer will be indicated on AI-0005, *Organizational Chart*.
- 5.1.2 MolecularMD must monitor and stay informed of the legal and regulatory requirements for its Processing of Personal Information and shall comply with applicable privacy or security laws and regulations.
- 5.1.3 The Data Protection Officer will train all staff on appropriate procedure(s) in the event of a breach of confidentiality.

5.2 Personnel Training


- 5.2.1 All MolecularMD employees will be trained on this Policy and are required to maintain knowledge of the requirements.

5.3 Confidentiality

- 5.3.1 MolecularMD must maintain all PI in strict confidence. MolecularMD shall make the Personal Information available only to its employees and onsite contractors who have a need to access the Personal Information in order to perform the Services. MolecularMD shall not disclose, transmit, or make available the Personal Information to third parties (including subcontractors), unless such disclosure, transmission, or making available has been explicitly authorized in the Agreement or in writing as authorized in the Agreement. In no event may MolecularMD provide Personal Information or any other client information to a third party unless that entity has agreed in writing to the terms contained within this Policy.

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5.3.2 When MolecularMD ceases to perform Services for any client, MolecularMD shall return all PI (along with all copies and all media containing the PI) to client or shall securely destroy all PI as requested by the client. For specific records within the PI that MolecularMD is required by regulation to maintain, MolecularMD shall ensure the continued confidentiality and security of the PI and shall not actively Process the PI (other than storage) after termination of the relationship.

5.3.3 Any Personal Information collected or accessed in the performance of the Services contracted shall be limited to that which is necessary to perform such Services or to fulfill any legal requirements.

5.4 Client Notification

5.4.1 MolecularMD shall notify the client as soon as becoming aware of any of these events:

- A request for access to any PI received from an individual who is (or claims to be) the subject of the data;
- A request for access to any PI received from any government official (including any data protection agency or law enforcement agency);
- An inquiry, claim or complaint regarding the processing of the PI received;
- Any breach of confidentiality of any PI related to that client; and,
- Any other requests with respect to PI received from client employees or other third parties, other than those set forth in the agreement.

5.5 Website(s) Data Collection and Data Subject Notification

5.5.1 MolecularMD collects Personal Information outside of Services performed/provided.

5.5.2 MolecularMD website(s) shall provide a link to this Privacy Policy.

5.5.3 MolecularMD gathers Personal Information about MolecularMD.com and associated site users. We may ask for Personal Information (name, address, email address, etc.), such as when responding to a question via email that requires a response.

5.5.4 MolecularMD.com will not obtain personally identifying information from site visitors unless the data subject chooses to provide it to us.

5.5.5 We will not voluntarily sell, give away, or trade names, addresses or any personally identifiable information about our site users (without their expressed permission) to any third parties.

5.5.6 We will not otherwise release such information unless not doing so endangers the website or is required by law or in the courts.


5.5.7 The data subject is promptly informed of any data breach.

5.6 Computer Systems

5.6.1 MolecularMD shall have an effective process to administer access rights. The process shall include the following controls: (1) users and system resources shall only be given the access necessary to perform their required functions (FRM-0456, *Computer and Network Access Set-Up*); (2) access rights shall be updated based on personnel or system changes; and, (3) access rights shall be periodically reviewed at an appropriate frequency based on the risk to the application or system. MolecularMD shall also use effective authentication methods appropriate to the level of risk.

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- 5.6.2 MolecularMD shall define physical security zones and implement appropriate preventative and detective controls in each zone to protect against the risks of physical penetration by malicious or unauthorized people, damage from environmental contaminants, and electronic penetration through active or passive electronic emissions.
- 5.6.3 MolecularMD shall secure its computer networks using multiple layers of access controls to protect against unauthorized access. Specifically: (1) group network servers, applications, data, and users into security domains; (2) establish appropriate access requirements within and between each security domain; and, (3) implement appropriate technological controls to meet those access requirements consistently, including (for example) firewalls.
- 5.6.4 MolecularMD shall secure access to the operating systems and applications. MolecularMD shall secure remote access to and from its systems by disabling remote communications at the operating system level if no business need exists and/or tightly controlling access through management approvals, robust controls, logging, and monitoring access events and subsequent audits.
- Protect against the risk of malicious code by using anti-virus products on clients and servers; using an appropriate blocking strategy on the network perimeter; filtering input to applications; and creating, implementing, and training staff in appropriate computing policies and practices.
 - Control and protect access to paper, film, and computer-based media to avoid loss or damage. In particular, for all media containing Sensitive Information, MolecularMD shall ensure safe and secure disposal of such media, and secure all media in transit or transmission to third parties.
- 5.6.5 Sensitive Information may not be stored on any portable computer devices or media (including, without limitation, laptop computers, removable hard disks or flash drives, personal digital assistants (PDAs) or computer tapes) unless the Sensitive Information is encrypted, or the hard drive that contains the Sensitive Information on the portable computer device or media is fully encrypted.

5.7 General System Controls

- 5.7.1 MolecularMD shall ensure that systems are developed, acquired, and maintained with appropriate security controls.
- 5.7.2 MolecularMD shall identify systems and applications that warrant security event monitoring and logging, and reasonably maintain and analyze log files.
- 5.7.3 MolecularMD shall extend security responsibilities for outsourced operations through: (1) appropriate due diligence in service provider research and selection; and, (2) contractual assurances regarding confidentiality, security responsibilities, controls, and reporting.
- 5.7.4 MolecularMD shall establish a disaster recovery/business continuity plan that addresses ongoing access to the Personal Information as well as security needs for back-up sites and alternate communication networks. See POL-0013, *MolecularMD Business Continuity Planning*, and SOP-0078, *Business Continuity Plan*.

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5.7.5 MolecularMD shall maintain reasonable and appropriate insurance coverage in relation to the risks associated with the Processing.

6 Privacy Shield Principles

The privacy principles in this policy have been developed based on seven (7) Privacy Shield principles of notice, choice, onward transfer, security, data integrity, access, and enforcement.

6.1 Notice


- 6.1.1 Where MolecularMD collects Personal Information directly from individuals in the EEA and/or Switzerland, it will inform them of the purpose for which it collects and uses the Personal Information and the types of non-agent third parties to which MolecularMD discloses or may disclose that Information and the choices and means for limiting the use and disclosure.
- 6.1.2 Where MolecularMD receives Personal Information from its clients, subsidiaries, affiliates or other entities in the EEA and/or Switzerland, it will use and disclose such information in accordance with the notices provided by such entities and the choices made by the individuals to whom such Personal Information relates.
- 6.1.3 The independent dispute resolution body designated to address complaints and provide appropriate recourse free of charge to the data subject is the EU DPAs independent recourse mechanism (IRM) for dispute resolution or the Swiss Federal Data Protection and Information Commissioner (FDPIC).

6.2 Choice

- 6.2.1 Where MolecularMD collects Personal Information directly from individuals in the EEA and/or Switzerland, it will offer individuals the opportunity to choose (opt-out) whether their Personal Information is (1) to be disclosed to a non-agent third party, or (2) to be used for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual.
- 6.2.2 For Sensitive Information, MolecularMD will give individuals the opportunity to affirmatively and explicitly (opt-in) consent to the disclosure of the information to a non-agent third party or the use of the information for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual.
- 6.2.3 Where MolecularMD receives Personal Information from its clients, subsidiaries, affiliates or other entities in the EEA and/or Switzerland, MolecularMD's customers are responsible, pursuant to the contractual agreements with MolecularMD, for providing choice to individuals as to whether their Personal Information may be disclosed to third parties by MolecularMD or used for a purpose that is incompatible with the purpose(s) for which the information was originally collected or subsequently authorized by the individual. MolecularMD shall inform its customers about the need to (1) provide notice to individuals about MolecularMD's privacy practices; (2) obtain consent from individuals with respect to such practices, where required by applicable law, and (3) inform individuals about the possibility that MolecularMD may disclose their Personal Information to various categories of third parties, as specified in the Onward Transfer section of this Policy.

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6.2.4 MolecularMD does not process Personal Information specifying medical or health conditions, racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership or sexual orientation, except where required by law.

6.3 Accountability for Onward Transfer (Transfer to Third Parties)

6.3.1 MolecularMD shall only transfer Personal Information about individual to third party where the third party has a contract with MolecularMD that provides that such data may only be processed for limited and specified purposes consistent with the consent provided by the data subject and that it provides at least the same level of privacy protection as is required by these privacy principles.

6.3.2 In the event that MolecularMD transfers Personal Information to third party, it will notify individuals and provide an opt-out opportunity or obtain an opt-in if the transfer involves Sensitive Information, unless such transfers are otherwise permitted under the Privacy Shield principles.


6.3.3 Where MolecularMD has knowledge that third party is using or disclosing Personal Information in a manner contrary to this Policy, MolecularMD will take reasonable steps to prevent or stop the use or disclosure.

6.3.4 MolecularMD is potentially liable in cases of onward transfer to third parties of data received pursuant to the Privacy Shield Framework and has responsibility for the processing of personal information it receives under the Privacy Shield and subsequently transfers to a third party acting as an agent on its behalf. MolecularMD shall remain liable under the Principles if its agent processes such personal information in a manner inconsistent with the Principles, unless it can be proven that it is not responsible for the event giving rise to the damage.

6.4 Security

6.4.1 MolecularMD shall have documented and implemented appropriate operational, technical and organizational measures to protect Personal Information against accidental or unlawful destruction, alteration, unauthorized disclosure or access. MolecularMD will regularly test or otherwise monitor the effectiveness of the safeguards' controls, systems and procedures. MolecularMD will periodically identify reasonably foreseeable internal and external risks to the security, confidentiality and integrity of the Personal Information, and ensure that there are safeguards in place to control those risks. MolecularMD shall monitor its employees and contractors for compliance with its security program requirements. See POL-0003, *Facility Access and Security*, and SOP-0133, *Software, System, & Network Access Security*.

6.4.2 Prior to allowing any employee or contractor to Process any Personal Information, MolecularMD shall: (1) conduct an appropriate background check of the individual; (2) require the individual to execute an enforceable confidentiality agreement (FRM-0010, *Employee Confidentiality Information Agreement*, FRM-0363, *HIPAA Confidentiality Agreement*); and, (3) provide the individual with appropriate privacy and security training.

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6.4.3 If the Processing involves the transmission of Personal Information over a network, MolecularMD shall have implemented appropriate supplementary measures to protect the Personal Information against the specific risks presented by the Processing. Sensitive Information may only be transmitted in an encrypted format.

6.5 Data Integrity and Purpose Limitation

6.5.1 Where MolecularMD collects Personal Information directly from individuals in the EEA and/or Switzerland, MolecularMD takes reasonable steps to ensure that the Personal Information is relevant for the purposes for which the information is to be used and that the information is reliable for its intended use and is accurate, complete and current. MolecularMD depends on its customers to update and correct relevant Personal Information whenever necessary. Personal Information will be retained in a form identifying or making identifiable the data subject only for as long as it serves a purpose of processing.

6.5.2 Where MolecularMD receives Personal Information from its clients, subsidiaries, affiliates or other entities in the EEA and/or Switzerland, MolecularMD's customers are responsible, pursuant to their contractual relationships with MolecularMD, for taking reasonable steps to ensure that the Personal Information is reliable for its intended use, accurate, complete and current.

6.6 Access

6.6.1 Upon request, MolecularMD will grant individuals reasonable access to Personal Information that it holds about them. In addition, MolecularMD will take reasonable steps to permit individuals to correct, amend, or delete information that is demonstrated to be inaccurate or incomplete, as long as the rights of persons other than the individual would not be violated.

6.7 Recourse, Enforcement, and Liability

6.7.1 MolecularMD has established annual review and audit program to monitor adherence to this policy. See SOP-0002, *Periodic Review*, and SOP-0009, *Quality Assurance Auditing*. MolecularMD will investigate any breach of this policy that has been reported to MolecularMD.


6.7.2 In addition, MolecularMD provides a statement, at least once a year, signed by the appointed Data Protection Officer or an authorized designee, verifying the adherence to the Privacy Shield Principles.

6.7.3 In circumstances where MolecularMD collects Personal Information directly from individuals in the EEA and/or Switzerland, individual may submit complaints concerning the processing of their Personal Information by MolecularMD directly with MolecularMD. The complaint is recorded and managed in accordance with SOP-0115, *Complaint Management*.

6.7.4 In circumstances where MolecularMD receives Personal Information from its clients, subsidiaries, affiliates or other entities in the EEA and/or Switzerland, individual should submit complaints concerning the processing of their Personal Information by MolecularMD in accordance with the customer's relevant dispute resolution mechanism (if available). MolecularMD will participate in the customer's dispute resolution process at the request of the individual.

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6.7.5 MolecularMD will investigate and attempt to resolve complaints and disputes regarding use and disclosure of Personal Information by reference to the principles contained in this policy.

6.7.6 MolecularMD has chosen the EU Data Protection Authorities (EU DPAs) and the Swiss Federal Data Protection and Information Commissioner (FDPIC) to serve as an independent recourse mechanism (IRM) for dispute resolution arising from collection, use, and retention of Personal Information transferred from EU member countries or Switzerland to companies in the United States and has subscribed to USCIB, acting as a trusted third party on behalf of the European Union (EU) Data Protection Authorities.

6.7.7 Per the requirements of Privacy Shield, MolecularMD is subject to the investigatory and enforcement powers of the Federal Trade Commission (FTC). Under certain conditions, individuals may invoke binding arbitration for dispute resolution.

6.8 Privacy Shield Supplemental Principles


6.8.1 MolecularMD is committed to complying with the supplemental principles as they may apply to the data processing performed by MolecularMD.

7 Contact Information

Questions or comments regarding this Policy shall be submitted to MolecularMD using any of the contact information below. In compliance with the Privacy Shield Principles, MolecularMD commits to resolve complaints about our collection or use of your personal information. EU and Swiss individuals with inquiries or complaints regarding our Privacy Shield policy should first contact MolecularMD at:

By mail: MolecularMD
 Data Protection Officer
 1341 SW Custer Drive
 Portland, OR 97219
 By Tel: 001-503-459-4974
 By Fax: 001-503-459-4976
 By Email: dataprotectionofficer@molecularmd.com

MolecularMD has further committed to refer unresolved Privacy Shield complaints to the EU Data Protection Authorities (DPAs) or the Swiss Federal Data Protection and Information Commissioner (FDPIC) as an independent recourse mechanism. If you do not receive timely acknowledgment of your complaint from us, or if we have not addressed your complaint to your satisfaction, please visit <https://edpb.europa.eu/about-edpb/board/members> if you are in the EU to find the contact information for your DPA or <https://www.edoeb.admin.ch/edoeb/en/home/data-protection/handel-und-wirtschaft/transborder-data-flows/transfer-of-data-to-the-usa.html> if you are in Switzerland to obtain more information or to file a complaint. The services of the DPAs or FDPIC are provided at no cost to you.

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8 Document History

Rev	Author	Description of Change
001	Kevin Hawkins	Initial release of document.
002	MaiLy Le	Incorporated Safe Harbor Privacy Principles. Added section 6 & 7.
003	Jessica Horowitz	Added reference to POL-0017, <i>Organizational Chart</i> in section 5 and added step 5.1.6. Added section 6.7.6, and updated Section 4, <i>Definitions, Acronyms, Abbreviations</i> as appropriate.
004	Jessica Horowitz	Updated Section 1, <i>Purpose</i> to comply with U.S.-EU Safe Harbor and U.S.-Swiss Safe Harbor requirements. Updated Section 3, <i>Related Documents</i> to update titles for POL-0013 and SOP-0078 and remove reference to the superseded POL-0004. Added EEA to Section 4, <i>Definitions, Acronyms, Abbreviations</i> . Removed reference to POL-0017, <i>Organizational Chart</i> throughout document. Added reference to AI-0005, <i>Organizational Chart</i> , to Section 3 and Step 5.1.1 Updated Step 5.5.4 to remove reference to superseded POL-0004 and list the updated document titles for POL-0013 and SOP-0078. Added reference to Switzerland in Step 6.7.6.
005	Kevin Hawkins	Revision of references and processes from Directive 95/46/EC to Regulation 2016/679. Revision of references and processes from Safe Harbor Frameworks to Privacy Shield Frameworks. Inclusion of website personal data handling. Updated roles and responsibilities to FRM-0020A standard.
006	Kevin Hawkins	Edits required for Privacy Shield
007	Kevin Hawkins	Add the MolecularMD facility addresses as a covered entities in the Scope section