

# **SAFE HARBOR PRIVACY POLICY**

## **INTRODUCTION**

MED Institute Inc. (hereinafter the "Company") is committed to respecting the privacy of all individuals including the privacy of clinical research subjects. The Company upholds an internal Global Compliance Program and Code of Conduct and values the confidence of its employees, customers, clinical trial participants, business partners and others. Mindful of the commitment to honesty and ethical behavior, the Company strives to collect, use and disclose personal information, including health and medical information, only in a manner consistent with the laws of the countries in which it conducts business. This Safe Harbor Privacy Policy ("the Policy") sets forth the privacy principles the Company follows with respect to the transfer of personal information between the European Economic Area (EEA) which includes the Member Countries of the European Union (EU) plus Norway, Iceland and Liechtenstein, and the European Free Trade Association (EFTA) which includes all aforementioned Member Countries and Switzerland, to the United States.

## **PURPOSE**

The Company's purpose for collecting and transferring clinical data is solely for clinical research. Clinical research information is processed in a manner that does not contain any individual identifiers in accordance with accepted industry pattern and practices. Absence of individual identifiers prevents unauthorized third parties from access to personal data.

## **SAFE HARBOR**

The United States Department of Commerce and the European Commission have agreed on a set of data protection principles and frequently asked questions (the "Safe Harbor Principles") to enable United States companies to satisfy the requirements under the European Union Directive 95/46 of the European Parliament and of the Council of 24 October 1995 that adequate protection be given to personal information transferred from the EU to the United States. The EEA has also recognized the U.S. Safe Harbor as providing adequate data protection (OJ L 45, 15.2.2001, p.47). Consistent with its commitment to protect personal privacy, the Company adheres to the Safe Harbor Principles.

## **SCOPE**

This applies to all personal information received by the Company from the EEA and EFTA, in any format including electronic, paper, or verbal.

## **DEFINITIONS**

For purposes of this Policy, the following definitions shall apply:

**"Agent"**: means any third party that collects or uses personal information under the instructions of, and solely for, the Company or to which the Company discloses personal information for use on their behalf.

**"Personal Information"**: means any information or set of information that identifies or is used by, or on behalf of, the Company to identify an individual. Personal information does not include information that is encoded or anonymized, or publicly available information that has not been combined with non-public personal information.

**"Sensitive Personal Information"**: means Personal Information that reveals race, ethnic origin, sexual orientation, political opinions, religious or philosophical beliefs, trade union membership, or that concerns an individual's health. In addition, the Company will treat as "sensitive personal information" any information received from a third party where that third party treats and identifies the information as sensitive.

## **PRIVACY PRINCIPLES**

The Privacy Principles in this Policy are based on the seven Safe Harbor Principles.

**Notice**: Where the Company collects personal information directly from individuals in the EU, it will inform them in writing of the type of personal information collected, the purposes for which it collects and uses the personal information, and the types of non-agent third parties to which the Company discloses or may disclose that information, and the choices and means, if any, the Company offers individuals for limiting the use and disclosure of their personal information. Notice will be provided in clear and conspicuous language when individuals are first asked to provide personal information to the Company, or as soon as practicable thereafter, and in any event before the Company uses or discloses the information for a purpose other than that for which it was originally collected.

Within the course of clinical trial activities, data collected are coded so that personal identifiers are removed. The Company uses accepted industry patterns and practices which are compliant with applicable existing U.S. Federal

regulations, to recruit and inform study participants about the respective clinical trial research. Investigators and their affiliated Institutions where the clinical trials are conducted may also provide additional information in accordance with accepted industry pattern and practices.

Where the Company receives personal information from their affiliates, or other entities in the EU, they 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.

**Choice:** The Company will offer any individuals submitting personally identifiable information advance notice in writing of the use of said information. Individuals will be offered the opportunity to choose (opt-out) whether their personal information is (a) to be disclosed to a non-agent third party, or (b) to be used for a purpose other than the purpose for which it was originally collected or subsequently authorized by the individual.

For sensitive personal information, individuals will be given the explicit and affirmative (opt-in) choice for that information to be disclosed to a third party or used for a purpose other than that for which it was originally collected or subsequently authorized by the individual through the exercise of the opt-in choice.

The Company will exercise its best efforts to conform all data security policies and procedures to the respective national and international data protection and confidentiality regulations governing the performance of clinical research. The Company will provide individuals with reasonable mechanisms to exercise their choices.

**Data Integrity:** The Company, its affiliates and authorized agents will use personal information only in ways that are compatible with the purposes for which it was collected or subsequently authorized by the individual. The Company will take reasonable steps to ensure that personal information is relevant to its intended use, accurate, complete and current.

It is the Company's policy to maintain the highest level of security in data processing. Computer systems, equipment, networks, programs, data and documentation are secured to the maximum extent reasonably practicable through the use of state-of-the-art technology.

**Transfers to Agents:** The Company will obtain assurances from their agents in writing that they will safeguard personal information consistently with this Policy. Examples of appropriate assurances that may be provided by agents may include: a contract obligating the agent to provide at least the same level of protection as is required by the relevant Safe Harbor Principles, being subject to another European Commission adequacy finding. If the Company becomes

aware that an agent is using or disclosing personal information in a manner contrary to this Policy, the Company will immediately take reasonable steps to prevent or stop the use or disclosure.

Authorized agents working on behalf of the Company are required to properly execute confidentiality agreements in connection with handling confidential information containing personal data in accordance with applicable laws, including but not limited to, the European Data Protection Directive [EC/95/46].

**Access and Correction:** Upon request, the Company will grant individuals reasonable access to personal information that it holds about them. In addition, the Company will take reasonable steps to permit individuals to correct, amend, or delete information that is demonstrated to be inaccurate or incomplete. All inquiries regarding access requests related to personal data information in the possession of the Company should be submitted to MED Institute, Incorporated, Corporate Compliance Officer, 1400 Cumberland Avenue, Indiana, USA 47906.

**Security:** The Company maintains a high level of security through implementation of state-of-the-art controls. Computer networks, programs, data and documentation are maintained to the highest industry standards. Access to data, equipment and documentation is restricted to authorized staff. The Company will take reasonable precautions to protect personal information in its possession from loss, misuse, unauthorized access, disclosure, alteration and destruction.

**Enforcement:** The Company will ensure adherence to this Policy through annual compliance audits of its relevant privacy practices conducted under the direction of the Global Corporate Privacy Office. Any employee the Company determines is in violation of this Policy will be subject to disciplinary action up to and including termination of employment.

**Dispute Resolution:** Any questions or concerns regarding the use or disclosure of personal information should be directed to the Corporate Compliance Officer. The Company will investigate and attempt to resolve complaints in accordance with the principles contained in this Policy. For complaints that cannot be resolved between the Company and the complainant, the Company has agreed to participate in the procedures of the panel established by the European Data Protection Authorities to resolve disputes pursuant to the Safe Harbor Principles.

**Training:** The Company has provided its employees with appropriate training, and will conduct annual re-training, to ensure that all individuals who process personal information are fully aware of their responsibility with respect to data protection.

**Limitation on Application of Principles:** Adherence by the Company to these Safe Harbor Principles may be limited (a) to the extent required to respond to a

legal or ethical obligation, and (b) to the extent expressly permitted by an applicable law, rule, or regulation.

**Changes to the Safe Harbor Privacy Policy:** This Policy may be amended from time to time, consistent with the requirements of the Safe Harbor Principles. A notice will be posted on the following web site: [www.medinst.com](http://www.medinst.com) for sixty (60) days if this Safe Harbor Privacy Policy is changed in a material way.

**Contact Information:** Questions or comments regarding this Policy should be submitted to:

MED Institute, Incorporated  
Corporate Compliance Officer  
1400 Cumberland Avenue  
West Lafayette, IN 47906

Telephone: 1-765-463-7537  
Facsimile: 1-765-497-0641

**Effective: August 16, 2005**