



## Safe Harbor Privacy Policy

### **PRIVACY STATEMENT:**

Octagon Research Solutions (Octagon) is committed to respecting the privacy of individuals. This includes protecting the confidentiality of records that could identify individuals and to safeguard personal information, which also includes sensitive personal information, individually identifiable health information, and protected health information, both in paper and electronic formats, contained in and processed at Octagon's facilities from loss, misuse, unauthorized access, disclosure, alteration, and destruction. Octagon has implemented several privacy policies to ensure that personal information will be processed appropriately and in a manner consistent with any applicable privacy and confidentiality laws and regulatory requirements and standards, including, but not limited to, the principles of International Conference on Harmonization (ICH) good clinical practice (GCP) (2.11), Safe Harbor, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 CFR Part 164, and 21 CFR Parts 11, 50, and 56.

### **SAFE HARBOR OVERVIEW:**

The European Union's (EU) comprehensive privacy legislation, the Directive on Data Protection (95/46/EC, the "Directive") became effective in October 2008. The privacy legislation of Switzerland (Federal Act on Data Protection, FADP) became effective in June 1992. Both privacy legislations require that transfers of personal information take place only to countries that provide an "adequate" level of privacy protection. In order to bridge the differences in approaches to privacy employed by the United States (US), the EU, and Switzerland, the US Department of Commerce has made separate agreements with the European Commission (June 2000) and the Federal Data Protection and Information Commission of Switzerland (December 2008) on a set of data protection principles and frequently asked questions (the "Safe Harbor Privacy Principles") to enable US companies to satisfy the requirement that adequate protection be given to personal information transferred from the EU or Switzerland to the US.

### **SCOPE:**

This policy applies to all personal information in any format including electronic, paper, or verbal, transferred from the EU or Switzerland to Octagon. Information regarding Safe Harbor, as well as Octagon's certification status, can be found at <http://www.export.gov/safeharbor/index.asp>.

### **DEFINITIONS:**

**Personal Information:** Any information or set of information that identifies, or could reasonably be used 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:** Any personal information specifying medical or health conditions; personal sexuality; racial or ethnic origin; political opinions; religious, ideological, or philosophical beliefs; or trade union-related views, activities, or membership; information on social security measures; or information on administrative or criminal proceedings and sanctions, which



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are treated outside pending proceedings. Additionally, Octagon will treat as sensitive any personal information received from a third party where the third party identifies and treats it as sensitive.

### **SAFE HARBOR PRIVACY PRINCIPLES:**

This policy is based upon the Safe Harbor Privacy Principles. Octagon has voluntarily self-certified to, is committed to, and adheres to the Safe Harbor Privacy Principles in order to meet the requirements for the protection of personal information transferred from the EU or Switzerland to the United States.

#### **Notice:**

Octagon will inform individuals about the purposes for which Octagon collects and uses personal information about them, how to contact Octagon with any inquiries or complaints, the types of non-agent third parties to which Octagon discloses the personal information, and the choices and means Octagon offers individuals for limiting the use and disclosure of their personal information. The notice will be provided in clear and conspicuous language when individuals are first asked to provide personal information to Octagon, or as soon thereafter as practicable, but in any event before Octagon uses such personal information for a purpose other than that for which it was originally collected or processed by Octagon or discloses it for the first time to a non-agent third party.

#### **Choice:**

Octagon will provide individuals the opportunity to choose (opt out) whether their personal information is to be disclosed to a non-agent third party or to be used for a purpose that is incompatible with the purposes for which it was originally collected or subsequently authorized by the individual. Individuals will be provided with clear and conspicuous, readily available, and affordable mechanisms to exercise choice.

For sensitive personal information, Octagon will provide individuals the opportunity to affirmatively or explicitly choose (opt in) whether their sensitive personal information is to be disclosed to a non-agent third party or to be used for a purpose that is incompatible with the purposes for which it was originally collected or subsequently authorized by the individual.

#### **Onward Transfer (Transfers to Third Parties):**

Octagon will apply the Notice and Choice privacy principles when disclosing personal information to any non-agent third party. Octagon may use agents (third parties that perform tasks on behalf of and under the instructions of Octagon) to process personal information. In these cases, Octagon will only transfer personal information to the agent after obtaining assurances from the agent that they will safeguard personal information consistently with this policy. This may include ascertaining that the agent has certified to the Safe Harbor Privacy Principles, is subject to the Directive for the EU or the FADP for Switzerland or another adequacy finding, or enters into a written agreement with the agent requiring that the agent provide at least the same level of privacy protection as required by the relevant Safe Harbor Privacy Principles. Where Octagon has knowledge that an agent is processing



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personal information inconsistent with this policy, Octagon will take reasonable steps to prevent or stop such processing.

### **Access:**

Octagon will provide individuals with reasonable access to their personal information to be able to correct, amend, or delete personal information where it is demonstrated to be inaccurate or incomplete, except where 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.

### **Security:**

Octagon will take reasonable precautions to protect personal information from loss, misuse, unauthorized access, disclosure, alteration, and destruction.

### **Data Integrity:**

Octagon will process personal information only in ways that are relevant and consistent with the purposes for which it was originally collected or subsequently authorized by the individual, and will take reasonable steps to ensure that the personal information is reliable for its intended use, accurate, complete, and current.

### **Enforcement:**

Octagon has put in place processes to ensure and verify compliance with this policy including:

- Readily available and affordable independent recourse mechanisms by which an individual's complaints and disputes can be investigated and resolved and damages awarded where the applicable law or private sector initiatives so provide.
- Follow up procedures for verifying that the attestations and assertions that Octagon has made to adhere to the Safe Harbor Privacy Principles are true and that privacy practices have been implemented as presented.
- Obligations to remedy problems arising out of a failure of Octagon to comply with the Safe Harbor Privacy. Sanctions will be sufficiently rigorous to ensure compliance by Octagon.

Octagon will provide an annual statement verifying self-certification to ensure appearance on the list of Safe Harbor participants.

### **Annex:**

The EU and Switzerland recognize that certain U.S. government bodies (e.g., Federal Trade Commission, Department of Transportation) are empowered to investigate complaints and to obtain relief against unfair or deceptive practices as well as redress for individuals in case of non-compliance with the Safe Harbor Privacy Principles.



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### **LIMITATION ON APPLICATION OF THE SAFE HARBOR PRIVACY PRINCIPLES:**

Adherence by Octagon to the Safe Harbor Privacy Principles 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, provided that, in exercising any such authorization, an organization can demonstrate that its non-compliance with the principles is limited to the extent necessary to meet the overriding legitimate interests furthered by such authorization, or (c) if the effect of applicable privacy legislation (e.g., the Directive or Member State law for the EU; the FADP or Swiss/cantonal data protection measures for Switzerland) is to allow exceptions or derogations, provided they are applied in comparable contexts.

### **DISPUTE RESOLUTION OR QUESTIONS ABOUT THIS POLICY:**

Any questions, complaints, access requests, comments regarding this policy, or the reporting of any inappropriate disclosure or use of personal information, should be directed to Octagon's Privacy Officer.

Octagon will investigate and attempt to resolve any complaints and/or disputes regarding the processing of personal information in accordance with the principles of this policy. For complaints and/or disputes that cannot be resolved between Octagon and the complainant, Octagon has agreed to cooperate and comply with the European Data Protection Authorities for the EU or the Federal Data Protection and Information Commissioner for Switzerland established dispute resolution procedures to resolve disputes pursuant to the Safe Harbor Privacy Principles.

### **CHANGES TO THIS SAFE HARBOR PRIVACY POLICY:**

Octagon will regularly review this policy to ensure that it provides an appropriate level of protection for personal information. Octagon reserves the right to amend this policy from time to time, consistent with the requirements of the Safe Harbor Privacy Principles. Appropriate notice will be given concerning such amendments, including the timely posting on Octagon's website. Please check back periodically for updates to this policy. This policy was last updated on 22 May 2009.

### **CONTACT INFORMATION:**

Octagon Research Solutions, Inc.

Attn: Privacy Officer

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Wayne, PA 19087 USA

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