Privacy Shield

Reader General Information

Please be aware, under the Privacy Shield:

- Bioanalytical Systems Inc. is being subject to the investigatory and enforcement powers of the Federal Trade Commission (FTC)
- Under certain conditions, individuals could invoke binding arbitration
- Bioanalytical Systems Inc. is required to disclose personal information in response to lawful requests by public authorities, including to meet national security or law enforcement requirements

Complaints handling

In compliance with the Privacy Shield Principles, Bioanalytical Systems Inc. (Inotiv) 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 Inotiv via our Client Services or Quality Assurance departments at:

Inotiv Client services

Stephanie Miller
smiller@inotivco.com
Phone number 765 497-8311

Or

Inotiv Quality Assurance

Lucia Bravo
lbravo@inotivco.com
Phone number 765 497-8473

Bioanalytical Systems Inc. has further committed to refer unresolved Privacy Shield complaints to **International Centre for Dispute Resolution®, the international division of the American Arbitration Association® (ICDR/AAA)** (http://go.adr.org/privacyshield.html), an alternative dispute resolution provider located in the United States. If you do not receive timely acknowledgment of your complaint from Inotiv, or if we have not addressed your complaint to your satisfaction, please contact **Luis Martinez** at MartinezL@adr.org or at +1.212.716.5833 or Alyssa Montano at MontanoA@adr.org or at +1.212.484.3281 at **ICDR/AAA** for more information or to file a complaint. The services of **ICDR/AAA** regarding subjects and Privacy Shield complaints are provided at no cost to you.

Policy

1.1 Inotiv participation in Clinical Trials

Inotiv participation in clinical trials is limited to Bioanalysis of study samples collected from human subjects as defined in the study protocol. For that reason the following statements are true regarding Inotiv participation in clinical trials:

- All samples received for analysis at Inotiv for a clinical study must be collected under an approved clinical protocol.
- Inotiv requires a copy of the protocol or equivalent document to proceed with sample analysis.
- The protocol should be written in English; otherwise the sponsor must provide Inotiv with an English translation of the relevant sections of the protocol.
- Sponsor approval of the Inotiv Bioanalytical Workplan indicates acknowledgment to Inotiv that there is study subject written consent to have their samples tested as required by Inotiv and that if the subject opts out of the study Inotiv will be notified.
- Clinical samples collected by sponsors or their authorized third parties sent to Inotiv for analysis are key-coded at origin.
- Inotiv is not the point of origin of samples and for that reason Inotiv does not maintain nor requires the key to identify the subjects of any study.
- Inotiv does not collect any patient information during the course of sample analysis of a clinical trial.
- All final study results are reported by Inotiv to the sponsor and other authorized parties using the sample code that identified the sample at time of arrival.

1.2 EU-US Privacy Shield Program and Key coded data

The EU- US Privacy Shield Program can be found at the address https://www.privacyshield.gov

Inotiv research work is described as key-code data in the US Privacy Shield Program Supplemental Principles section 14.g:

> *Key-coded Data: Invariably, research data are uniquely key-coded at their origin by the principal investigator so as not to reveal the identity of individual data subjects. Pharmaceutical companies sponsoring such research do not receive the key. The unique key code is held only by the researcher, so that he or she can identify the research subject under special circumstances (e.g., if follow-up medical attention is required). A transfer from the EU to the United States of data coded in this way would not constitute a transfer of personal data that would be subject to the Privacy Shield Principles.*

1.3 Sample documentation containing personal information

For Clinical Studies if a sender was to include with the samples and/or sample documentation sent to Inotiv any personal information that may identify the study subjects, Inotiv will obliterate or remove the personal information when possible; such information will not be used by Inotiv. As with all other study data, any personal data received via a clinical study that may identify a patient, is maintained confidential.

The following information is classified by Inotiv as examples of "personal information":

- Names
- Geographic information, such as Zip Code
- Elements of birthdates, particularly ages over 89 years
- Personal telephone numbers
- Personal fax numbers
- Personal e-mail addresses
- Social security or other government issued subject identifier information
- Medical record prescription information
- Health plan beneficiary information
- Subject account numbers
- Subject certificate/license numbers
- Any other information that could be used to identify clinical study subjects

1.4 Inotiv and the US Privacy Shield Principles

While according to the Supplemental Principles section 14.g the US Privacy Shield Program Principles do not apply to Inotiv, it is Inotiv policy for all Inotiv employees to adhere to the Privacy Principles as follows:

Notice: Inotiv does not select or dose subjects for clinical studies, has direct or indirect contact with study subjects or maintains any information regarding subject's identities. For that reason Inotiv does not generate consent forms from study subjects. The consent forms are the responsibility of the study sponsor. However Inotiv acknowledges the importance of such documentation and the notice such documents must provide to study subjects. If at any point during the conduct of the study Inotiv employees become aware that such documentation is not in place for a give study, work will be stopped until the deficiencies are addressed by the sponsor.

Choice: Inotiv will stop sample analysis of a particular subject as soon as the sponsor notifies Inotiv of the subject's choice to opt out of the study. Any data generated to date will be handled as defined in the consent form. Sponsor will notify Inotiv of their reporting requirements.

Accountability for Onward Transfer: Inotiv will only receipt samples for analysis and will only provide study data to Pharmaceutical government regulators as well as sponsors and their authorized third party

companies according to contract and sponsor reporting requirements. However such data does not contain subject personal information as such data is not provided or maintained by Inotiv. Data will only be transferred as key-coded data.

Security: Inotiv will take reasonable precautions to protect study data from loss, misuse and unauthorized access, disclosure, alteration and destruction.

Data Integrity and Purpose Limitation: Key-coded study ID must be relevant for the purposes for which it is to be used. Inotiv will take reasonable steps to ensure that data is reliable for its intended use, accurate, complete, and current. Inotiv will maintain all clinical data collected per corporate policies on study data as required by law, until it is returned to the sponsor or a destruct approval is received from the sponsor

Access: All options selected by study participants during the course of the clinical study will be honored during the retention of the data by Inotiv. Inotiv will provide access to study data to individuals if Inotiv is notified of such requirement by the sponsor. Sponsor will provide Inotiv with specific written instructions on how to proceed with access requests.

Resource, Enforcement and Liability: Inotiv adheres to the principles as listed above and will handle any disputes according to US federal and state laws and the regulations of the US Department of Commerce.