

**CLINICAL TRIAL VOLUNTEER DATA PROTECTION INFORMATION NOTICE AND CONSENT FORM**

**1. Introduction**

From time to time, a person wishing to participate in clinical trials (hereinafter referred to as “**Clinical Trial Volunteer**”) will provide personal data to UAB “BIO1” (registered office at Konstitucijos pr. 7, Vilnius, Lithuania, operational office: Santariskiu str. 2, Vilnius, Lithuania, legal entity code 304457362, (hereinafter referred to as “**BIO1**”). BIO1 will collect, process and use personal data relating to the Clinical Trial Volunteer as defined below.

The purpose of this Clinical Trial Volunteer Data Protection Information Notice and Consent Form is to inform Clinical Trial Volunteers about the processing and the transfers of their personal data within and outside BIO1, to receive Clinical Trial Volunteer’s consent for such processing, and is without prejudice to applicable local data protection/privacy laws which prevail on this Notice and Consent Form. This Notice and Consent Form describes how and for what purposes personal data relating to the Clinical Trial Volunteers will be processed in the context of BIO1. It supplements – but does not replace and is without prejudice to – any specific local notices, policies or procedures that have been distributed to or agreed on by the Clinical Trial Volunteer, if any, or that may be implemented in the future.

This Notice and Consent Form supplements data protection policies of BIO1, which set out the principles that apply to the use of personal data throughout BIO1. The policies and this Notice and Consent Form refer to all processing of Clinical Trial Volunteer’s personal information. This Notice and Consent Form may be supplemented by additional notices, policies or guidance (hereinafter – “**Additional Policies**”). Wherever such Additional Policies are in any respect inconsistent with this Notice, this Notice shall only apply to the extent that it is consistent, or may be made consistent, with that Additional Policy.

**The Data Protection Officer.** The Data Protection Officer contacts: email: [data.protection@bio1trials.com](mailto:data.protection@bio1trials.com) address: Santariskiu str. 2, Vilnius, Lithuania. Any queries in relation to Clinical Trial Volunteer’s personal data or if the Clinical Trial Volunteer would like to enforce any of the below rights shall be addressed to the Data Protection Officer via email following Section 6 of this Notice and Consent Form.

**2. Collection, processing and use of Clinical Trial Volunteer Data**

BIO1, as data controller, via automated means collects, processes and uses the following categories of personal data during the application, evaluation and selection process of Clinical Trial Volunteers:

- **personal identification data** (such as name, surname),
- **personal features** (such as gender, year of birth),
- **contact details** (such as address, phone numbers, e-mail address, both home and work etc.),
- **electronic identification details** (such as IP-address, cookies, etc.),
- **health data** (such as height and weight, information on smoking habits, information on regular medications, information on diagnosis of a chronic illness or surgery);
- **any other information provided by the Clinical Trial Volunteer to BIO1;** (all listed data together - “**Clinical Trial Volunteer Data**”).

BIO1 shall get Clinical Trial Volunteer Data from the Clinical Trial Volunteer directly.

**Terms and conditions for data processing.** Personal data may be collected, stored, maintained including transferred, both digitally and in a material medium, by any means such as email and internet connection which were selected considering the nature of the data processed, ensure safe handling and prevent unauthorised access to Clinical Trial Volunteer Data as defined by this Notice and Consent Form or Additional Policies.

**3. Purposes of collection, processing and use of Clinical Trial Volunteer Data**

BIO1 uses Clinical Trial Volunteer Data (to the extent required) for the following purposes: application, evaluation and selection of study subjects for clinical trials conducted at or by BIO1.

**Legal basis for Clinical Trial Volunteer Data processing.** BIO1 will process Clinical Trial Volunteer Data upon receipt of Clinical Trial Volunteer’s consent.

The collection of the Clinical Trial Volunteer Data by BIO1 is mandatory for all persons who wish to apply for participation as study subjects at clinical trials conducted at or by BIO1, and if it is not provided, BIO1 will be

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unable to evaluate and select particular Clinical Trial Volunteer as study subject for clinical trial conducted at or by BIO1. Where the collection of any Clinical Trial Volunteer Data is not mandatory, BIO1 will inform the Clinical Trial Volunteer of this prior to collection, as well as the implications of failing to provide Clinical Trial Volunteer Data.

### **4. Transfer of Clinical Trial Volunteer Data to third parties and service providers**

BIO1 may contract with third party service providers for application, evaluation and selection procedures, information technology support (e.g., software maintenance and data hosting, website administration). BIO1 will (i) diligently choose such third-party service providers, and (ii) ensure that such third-party service providers adopt adequate technical and organizational security measures to safeguard the Clinical Trial Volunteer Data and use the Clinical Trial Volunteer Data only as instructed by BIO1 and for no other purposes.

BIO1 may also need to make the Clinical Trial Volunteer Data available to its vendors; courts, law enforcement and/or regulatory authorities which may be located inside or outside the EEA, including in countries which do not adduce the same level of protection of personal data as in the EEA. Furthermore, BIO1 is authorized to disclose Clinical Trial Volunteer Data in case of inspections performed by competent regulatory authorities or client audits.

BIO1 will only carry out personal data transfers outside the EEA where BIO1 is confident that the level of protection applied to Clinical Trial Volunteer Data will be similar as if it had remained within the EEA. In such case where Clinical Trial Volunteer Data is transferred outside the EEA, BIO1 will apply proper protection measures (e.g., BIO1 will apply appropriate internal rules or approved Standard Contractual Clauses in order to ensure that Clinical Trial Volunteer Data is adequately protected against unauthorized processing in such countries).

### **5. Clinical Trial Volunteer Data retention period**

If you consent, your Clinical Trial Volunteer Data will be included into BIO1 database and kept for 5 years from the date when the data is entered into the database. During the retention period, you may object to further storing of your data at any time. Towards the end of the period, we may send you a repeated consent to your personal data processing. In the absence of your reply, the consent will be deemed as not received and under such circumstances we will not be able to make your proposals with a view to your participation in a clinical trial by using our internal database. After two attempts performed within a month and absence of your reply, your personal data will be deleted from our internal database.

For further information and exact storage terms for specific Clinical Trial Volunteer Data processing purposes, the Clinical Trial Volunteer should contact BIO1 Data Protection Officer.

### **6. Rights of the Clinical Trial Volunteer**

The Clinical Trial Volunteer has a right to withdraw any of his/her consents for personal data processing (at any time, without affecting the lawfulness of processing before the consent given for data processing was withdrawn), to know (to be informed) about the processing of their personal data, to access personal data held about him/her or them and obtain a copy of their personal data, to have inaccurate data corrected or to have their personal data erased and to restrict or object processing of his/her or their personal data for legitimate reasons. The Clinical Trial Volunteer has the right to data portability and to lodge a complaint with the State Data Protection Inspectorate as well as other competent authority in the country of his/her residence.

BIO1 does not take decision upon automatic processing of Clinical Trial Volunteer Data, including profiling.

For any questions related to personal data processing and protection, implementation of data subject's rights as well as applied data protection measures, the Clinical Trial Volunteer may contact BIO1 Data Protection Officer via email: [data.protection@bio1trials.com](mailto:data.protection@bio1trials.com).

### **7. Acknowledgment of Notice receipt and Consent for personal data processing**

**BY SUBMITTING YOUR PERSONAL DATA TO BIO1 YOU CONFIRM THAT: (1) YOU HAVE MADE YOURSELF ACQUAINTED WITH THIS CLINICAL TRIAL VOLUNTEER DATA PROTECTION NOTICE AND CONSENT FORM AND HAVE UNDERSTOOD IT AND THAT YOU HAD THE OPPORTUNITY TO ASK BIO1 ANY QUESTIONS ABOUT YOUR PERSONAL DATA AND THAT YOU HAVE RECEIVED ALL**

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**THE NEEDED ANSWERS IN DETAIL; AND THAT (2) YOU CONSENT TO YOUR PERSONAL DATA PROCESSING AS DESCRIBED IN THIS CLINICAL TRIAL VOLUNTEER DATA PROTECTION NOTICE AND CONSENT FORM.**

The Clinical Trial Volunteer Data Protection Information Notice and Consent Form was last updated on 25 November 2021.