

# General Terms and Conditions

## Article 1 - Applicability and Basic Definitions

1. These terms and conditions (hereinafter the "Terms and Conditions") shall regulate all contractual arrangements between Biostatistics FNUSA-ICRC (hereinafter the "Provider") and the customer as the buyer of the services (hereinafter the "Customer") supplied by the Provider, unless expressly agreed otherwise in writing.

2. The services within the meaning of paragraph 1 of this Article include data management, data analysis, consultation in project preparation (hereinafter "services").

3. The following definitions shall serve for the purpose of these terms and conditions:

a. Agreement is any agreement established upon the acceptance of the Provider's offer, pursuant to which the Provider shall render services to the Customer.

b. Website means the website available at <https://biostatistics.fnusa.cz/en/front-page-english/>.

4. Except for the present Terms and Conditions and any specific terms and conditions agreed directly between the Parties, the Agreement does not contain any other provisions which may be in conflict with the present Terms and Conditions, or any other contractual terms and conditions, especially the Customer's terms and conditions, even if the Provider has been fulfilling this Agreement without an express refusal of such terms and conditions.

## Article 2 - Purpose of Agreement

### Services

1. The Customer and the Provider agree that by ordering services through the Provider's website, a distance contract is concluded, which includes the following General Terms and Conditions.

The subject of this contract is in particular the obligation of the Provider to perform the services and the obligation of the Customer to pay the Provider a fee for the services performed. The moment of conclusion of the contract is deemed to be the sending of the completed enquiry form by the Customer (electronically).

2. The Provider accepts no responsibility for ensuring that the ordered services comply with the Customer's requirements and needs. The Customer shall clarify requirements and needs adequately in advance prior to the provision of the services.

3. The Provider shall decide on the appointment of the employees or other persons (third parties) for the provision of the work or services.

4. In the case of a request for the creation of a new database, the Customer is obliged to provide documents for the creation of the database, where must specify the individual questionnaires to be created. For each questionnaire, all fields of the questionnaire and their possible answers must also be specified. The user roles for all those who will have access to the database must also be specified within the enquiry form. Each database must comply with the GDPR and all FNUSA and FNUSA ICRC internal regulations, i.e., the data in the database is stored without any identifying information only under a pseudonymisation code that is unique for each record. Identifying information is kept separate from the data and can only be accessed by authorised users. The database must comply with the regulations of the Directive on the Protection of Personal Data and Human Subjects in Research. In the event that it is later necessary to grant access to the database to other users, this must be noted on the enquiry form, which will be created as an addendum to the existing enquiry form.

Without specifying a particular user on the enquiry form, it is not possible for that user to have access to the database. If the project manager is authorised to add users to the database without relying on the Provider, this rule does not apply.

5. In the case of a request for database management by the Provider, the Customer must specify in the request form which services Customer wants to use and how. Database management includes control of data collection during the project (correct uploading of data, complete completion of individual records), management of access rights to the database, data exports according to precisely specified requirements and possible import of instrument data. The request for database management is considered to be completed on the date of database closure. The database is currently inactive, i.e., no new records are added, the data is cleaned and ready for export.

6. In the case of a request for data analysis, the data must be transmitted by a secure way. This is either by using the FNUSA cloud, in person on an external drive or other data carrier, or by uploading to the REDCap database which has been created specifically for this purpose (available at: <https://redcap.fnusa.cz/redcap/surveys/?s=3MPE3YCT3A4FRKFA>). If data transfer is not possible in this form, the data may be in a ZIP file with a password sent via email, with the password being communicated to the Provider via a method other than via email. The data must be pseudonymised, anonymised if the analysis allows. If the data cannot be transmitted in pseudonymised form for some compelling reason, it may be transmitted non-pseudonymised, but the reason why the data is being transmitted non-pseudonymised must be clearly specified in the enquiry form. The Customer is responsible for ensuring that the data has been collected in accordance with applicable data collection regulations and GDPR rules. If during the analysis it is found that the data does not meet these

requirements, the processing of the request will be stopped and subsequently all files associated with the request will be deleted. The Customer is required to pay an invoice for the work that was done in processing the request before the data issue was discovered.

### **Article 3 – Claim request**

1. The Customer has the right to complain about the services provided by Provider within 30 days of receiving the result. The complaint is made via the complaint form (available at: <https://redcap.fnusa.cz/redcap/surveys/?s=PCPCC784LJDNYLFM>). The Provider is obliged to comment on each complaint within 30 days of receipt. If the Provider accepts the complaint, it is obliged to settle the complaint free of charge.

### **Article 4 - Prices and Terms of Payment**

1. The Customer and the Provider have agreed that the price for the services shall be determined on the basis of the Provider's valid price list, unless otherwise agreed in writing. All incidental costs and payments, such as freight, customs and bank fees, etc. shall be borne by the Customer and may not be deducted from the price of the services.

2. The Provider shall send the Customer an invoice for the services provided within 30 days of the completion of the processing of the request. This invoice is due in 30 days (unless otherwise stipulated by the internal regulation of FNUSA). The invoice is issued by the head of the Provider's department or an authorized person.

3. Payments for the services of the Provider's department within FNUSA/FNUSA-ICRC take place in the FAMA+ application as part of the so-called internal accounting.

4. As a general rule, the Provider shall send invoices electronically, to the address(es) specified by the Customer, unless agreed otherwise. The Customer shall promptly inform the Provider about any changes to the

Customer's electronic billing address. In doubts, invoices shall be deemed delivered on the date on which they are sent electronically to the last known electronic address of the Customer and/or the electronic address of the Customer's accounting department, alternatively to the Customer's electronic address which is publicly available (for example the Customer's website).

#### **Article 5 – Publications Policy**

1. If the statistical analysis is used in a publication, the Provider reserves the right to provide a written acknowledgement within that publication in one of the following versions:

a. *The authors gratefully acknowledge the Biostatistics Core Facility of FNUSA-ICRC for their support and assistance in this work.*

b. *Biostatistics CF of FNUSA-ICRC is gratefully acknowledged for the support and assistance in this work.*

If an employee of the Provider collaborates in the production of a publication with a work that corresponds to co-authorship, the Provider reserves the right to include the name of this employee in the list of co-authors.

If the Customer uses data stored or collected in the REDCap database, it is advisable to include in the publication an acknowledgement for the use of the service in the wording:

a. *Study data were collected and managed using REDCap electronic data capture tools hosted at [YOUR INSTITUTION]. REDCap (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures;*

*3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources.* (available at: <https://projectredcap.org/resources/citations/>).

#### **Article 6 - Confidentiality and Data Protection**

1. The Provider is entitled to process the data provided by the Customer including personal data; in this process, the Provider shall treat all information provided by the Customer as confidential information, in accordance with the applicable provisions.

2. Personal data of Customers are processed in connection with the subject of the Provider's activity, due to the conclusion of a contractual relationship in order to provide the Customer with a service or other fulfillment, or due to negotiations leading to such a contractual relationship, to improve the services and to respond promptly to Customer's requests.