

Data Request Policy

Purpose and Scope

This Data Request Policy defines how data collected in the St. Anne's University Hospital Brno (FNUSA), can be obtained for secondary research purposes. This policy includes the necessary procedures, as well as the criteria, conditions, and limitations for requesting data exports from studies. The goals of this policy are to clarify the accessibility of data from studies and to provide a common process for making data requests.

Ethics Requirements and Review Procedures

In some special cases, ethical review will be demanded. Cases are considered individually. If an ethical review is demanded, then it needs to be formally written and delivered before the data request. The data request will be processed only after all required documentation is delivered. It is recommended that requests for data be discussed with the data specialist (DS) before submitting any application.

Confidentiality

All information held by the study is confidential. All applicants who request data from the study will be required to sign a Terms and Conditions which fully details what the applicant can and cannot do with the data. This document will also describe among others the rules of written acknowledgements and process review of any publications which utilize the data obtained from the study.

Data Export Request Procedure

The REDCap software solution, in the form of a web form, was chosen to manage the data requests. REDCap is an official internal tool used within the FNUSA and the ICRC. This application allows the creation of a workflow. The system is configured to automatically send email notifications to all participants in the approval process, asking for their statement. The management of the whole process, from submission to closure, is implemented as a separate project within REDCap.

All requests for data by a third party need to be assessed by a data protection officer (DPO) and a legal department before initiating a data export.

All requests for data to be exported from the study must be submitted to the DS, by filling (data request) online form. The DS will evaluate the request to determine the formal aspects and completeness of the request fulfilment. In the case of an incomplete request, the DS will return it to the applicant for editing.

Once the online form is sufficiently filled out by the applicant, the DS will confirm receipt of the application and begin the review process. The DS will evaluate the feasibility of the given data export and send it further for examination by the statistician. The statistician will comment statistical methods stated in the request and will send it for further examination to the principal investigator (PI). PI will examine the relevance of the request, which PI can approve, return for additions or propose rejection. In case of returning for addition, the request will be forwarded back to the DS. In other cases, the

request will be sent to the head. The head will examine decisions of other members in the review process and can approve, reject or return for additions. In case the head demands an addition, the request will be sent back to DS for further examination. If the head rejects the application, the head must state the reasons for its decision. All stakeholders are asked about potential conflicts of interest during the approval process. If there is a Head conflict of interest, a second Head reviews the request. Conflicts of interest arise in the following circumstances:

- If the applicant is also a participant in the approval process.
- If a person involved in the approval process is listed as an author or co-author.

Each participant in the permitting process will endeavour to process the application as soon as possible, but no later than 10 days after notification of the need to make statement.

Request Requirements

All requests for data exports from the study must be made through an online form, and include the following information:

- Date of request and Study data name
- Information about the applicant (such as name, email, position, research background, list of publications)
- Type of request (whether it is a new request or data expansion request)
- Project name
- Information about who is expected to provide statistical analysis and interpretation
- Project Description
- Expected Outcomes
- List of researchers planned to be involved (Name, Position, Employer, if the researcher will be handling data) supplemented with specification of Researchers' roles and responsibilities
- Confirmations
- Type of data requested and exact selection of variables

Support information should be discussed with the DS for a given study before submitting any application to ensure that the requested resources are appropriate and available.

Review Criteria

The review process will evaluate the application and a determination will be made based on the following factors, and potentially others as appropriate to the request:

- All relevant approvals have been obtained.
- The availability of sufficient resources to fulfil the stated objectives.
- The specified use of the requested data, and any results derived from it.
- Any overlap, conflict, or duplication of effort involving other projects, programs, or partners which are using data obtained from the project.

Data Export

Data exports which have been approved will be handled by the DS in compliance with the Data Security Policy. Only data which has been finalized in the study, and moved from the live database to the archive will be available for export. Each export must be secured with a unique pseudonymisation key. Export involves splitting the data file into two separate files:

1. The pseudonymised data:
 - that does not contain any identifying information, i.e., the data must not contain first name, last name, date of birth, initials, address or any contact information
 - with a unique identifier specific to the export
2. Data with pseudonymisation keys which must meet the following criteria and policies:
 - Contain the original study-specific identifier and the corresponding export-specific unique identifier.
 - Access to these keys is restricted and they are kept separate from the pseudonymised data file and the original data file.

Data Transfer

The DS shall ensure that the transmission of data is carried out in accordance with the following rules:

- Data are transferred in a pseudonymised format (pseudonymisation keys are never included in the transfer).
- Exported data will be transferred using the FNUSA cloud (with a limit of 1.5 GB - <https://cloud.fnusa.cz>). For larger datasets, collaboration with biostatistics or bioengineering teams will be provided.
- The transferred files will be password protected. The password will be communicated via a secure communication channel other than the file link. If non-pseudonymised data need to be transferred, the procedure must be discussed with the DPO.
- All researchers handling the data must be named in the data request.

DS and Applicant will electronically sign a document confirming the successful sending and receiving of data.

Project Completion

Results of all outcomes selected in the request form must be provided. In case new variables have been created, the right is reserved to add them to the given study database. For each new variable, the name of the variable, the exact definition, the variables used for the calculation, and the methods and treatments are required.

Applicant commits that acquired data will not be used for any other outcomes and projects except ones selected in the request form. Violation will be sanctioned.