

## Transfer of human biological material to laboratory and return of analytical data and metadata

NIPH Biobank and the **project** have concluded a Material Transfer Agreement (MTA) regulating their mutual obligations and rights. Biological material will be transferred directly from the NIPH Biobank to the **laboratory**, which is *not* a party to the MTA.

A condition for this transfer is that the laboratory agrees to perform all work in accordance with the terms of the MTA. This document provides an overview on what must be returned to NIPH Biobank when analyses are completed.

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### Biological material and analysis

The NIPH Biobank will provide biological material as described in the MTA. Samples are sent in individually labelled vials with unique laboratory numbers assigned by the biobank. The laboratory shall perform the analyses specified in the MTA.

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### Analysis report

When all analyses are completed, both the laboratory and the project must submit a completed report to the NIPH Biobank ([biobank-bioretrieval@fhi.no](mailto:biobank-bioretrieval@fhi.no)). Templates will be provided when samples are shipped. The report must include:

- Detailed information on sample processing and handling
  - Full description of analytical methods, platforms, hardware and software and their settings
  - A list of samples (with RetrievalDetail-ID) that failed to produce analytical data, including the reason for failure
  - Information on batch effects or intra/inter-run variation, if applicable
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### Return of analytical results and metadata

To ensure reliable, sustainable reuse of data in accordance with FAIR principles, the following must be returned to NIPH Biobank (when applicable):

- **Raw data** (unformatted), intermediate data (if applicable) and **quality-controlled data**, labelled with RetrievalDetail-ID
- Units of measurement for each variable
- Limits of detection (LOD) or limits of quantification (LOQ)
- Detailed information on case/control allocation, if applicable
- Detailed information on rack name and position, if applicable

**Important note regarding laboratory file formats:** Laboratory output often uses colour coding, highlights or internal flags that are lost when exporting to CSV or TXT, which can remove important analytical information. E.g. values below LOQ were previously marked in red, but this was not preserved on export and had to be replaced with indicator variables (1/0). To avoid such loss, **all formatting-based annotations must be converted into explicit, machine-readable variables** before data are returned. This includes LOQ flags (e.g., `below_LOQ = 1/0`) and internal quality flags or other visual markers.

All necessary information must be translated into specific variables (e.g. machine-readable variables) prior to transfer to NIPH. If applicable, the laboratory may enter measurement results (raw data) into the manifest file. Ensuring this preserves relevant metadata and supports high-quality, reusable datasets.

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### Data transfer

The method for transferring data will be agreed with NIPH Biobank ([biobank-bioretrieval@fhi.no](mailto:biobank-bioretrieval@fhi.no)).

Small, encrypted files may be transferred by email only if:

- the file is encrypted, and
- the password is communicated separately.

**Do not send large analytical results by email.** Guidance for transferring large datasets (e.g., GWAS, EWAS) is available here: <https://github.com/folkehelseinstituttet/mobagen/wiki/Returning-data-to-NIPH>

**Keys for linking** analytical data to project specific ID will be transferred to the project **after** the data have been returned.

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### Remaining biological material and data

After analyses and QC are completed—or when the MTA expires, whichever comes first —any remaining biological material must be destroyed. The laboratory may be asked to confirm destruction in writing. Remaining analytical data must also be deleted, unless otherwise agreed. If participants withdraw consent, the laboratory may be asked to promptly destroy the relevant material and/or data.

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### Other terms

The laboratory cannot claim ownership of inventions resulting from analysis of biological material