TFS-Info-02c_Information on applications for MRI image data

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1. Introduction

This information sheet describes the available MRI image data, the corresponding application process and the review procedure for MRI image data applications. General information on the application procedure can be found on the info sheet TFS-Info-03 Information on use and access procedure.

2. Available MRI image data

As part of the NAKO MRI supplementary examination, a subpopulation of around 20% of all NAKO participants is examined. The sample is made up of randomly selected L2 participants from the 5 MRI study centres Augsburg, Berlin, Essen, Mannheim and Neubrandenburg as well as the 6 referring study centres Berlin-Mitte, Berlin-Süd/Brandenburg, Düsseldorf, Freiburg, Münster and Saarbrücken. All persons who have no contraindications (exclusion criteria see Bamberg et al., 2024) and who are willing to participate in the approximately one-hour whole-body MRI examination are eligible to participate.

A total of approximately 30,000 individuals participated in the baseline MRI examination (2014-2019), of whom around 19,000 underwent a second MRI examination (2019-2024). As part of the third MRI examination, approx. 12,000 participants will be invited for a third scan starting in 2024.

The MRI examinations are performed on five study-specific 3T MR systems (MAGNETOM Skyra, Siemens Healthineers, Erlangen, Germany) with identical hardware and software components. Focussing on the four organ areas brain (NEURO), musculoskeletal system (MSK), thoracoabdominal system (BODY) and cardiovascular system (CARDIO), the following MRI image data will be recorded:

	Baseline examination (2014-2019)	**First re-examination** (2019-2024)	**Second re-examination** (from 2024)
NEURO	– T1_3D_SAG (MPRAGE) – T2_FLAIR_2D_TRA – Resting_State_TRA	– T1_3D_SAG (MPRAGE) – T2_FLAIR_2D_TRA – Resting_State_TRA* – DTI_SliceAcc_TRA* – SWI_3D_TRA	– T1_3D_SAG (MPRAGE) – T2_FLAIR_2D_TRA – Resting_State_TRA§ – DTI_SliceAcc_TRA§ – SWI_3D_TRA (CAIPI)
MSK	– Hip: PD_FS_SPC – Spine: T2_TSE (cervical spine, thoracic spine, lumbar spine, COMP)	– Hip: PD_FS_SPC – Spine: T2_TSE (cervical spine, thoracic spine, lumbar spine, COMP)	– Hip: PD_FS_SPC (CS) – Spine: T2_TSE_DIXON (cervical spine, thoracic spine, lumbar spine, COMP)

* As part of the first re-examination, the resting state was performed on the first 500 participants and the DTI on the remaining participants in each MRI study centre.

§ As part of the second re-examination, the resting state is performed on the first 50% and the DTI on the second 50% of all participants.

	Baseline examination (2014-2019)	**First re-examination** (2019-2024)	**Second re-examination** (from 2024)
BODY	– T1_3DVIBE_Dixon_TRA – T2_HASTE_TRA – ME_3DVIBE (liver)	– T1_3DVIBE_Dixon_TRA – T2_HASTE_TRA – ME_3DVIBE (liver)	– T1_3DVIBE_Dixon_TRA – T2_HASTE_TRA – ME_3DVIBE (liver) – Body_DWI (liver)
CARDIO	– MRA_Tho_COR – Cine_SSFP_LAX – Cine_SSFP_SAX – MOLLI_SAX	– MRA_Tho_COR – Cine_SSFP_LAX – Cine_SSFP_SAX – MOLLI_SAX	– AdvMRA_Dixon – Cine_SSFP_LAX – Cine_SSFP_SAX – MyoMaps (T1, T2, T2S)

All acquired MRI image data is transmitted daily via DICOM data transfer to the Centre for MRI Data Management (Fraunhofer MEVIS, Bremen) and made available there after an automated image data check for the web-based recording of random results and the visual evaluation of image quality by NAKO-certified radiologists. Subsequently, all image and meta data are automatically transferred to the Greifswald Integration Centre and stored there in the long-term archives (PACS) of the Central Data Management (Integration Centre, Greifswald/Heidelberg).

Due to these established procedures and the high level of standardisation based on specific Standard Operating Procedures (SOPs), the NAKO MRI image data exhibit good to excellent image quality and a high degree of comparability both within and across individual MRI study centres (see Bamberg et al., 2024, automatic image quality assessment and subjective evaluation by certified radiologists).

3. Application

The image data from the NAKO MRI supplementary examination can be requested for scientific research purposes via the NAKO Transfer Unit. Use and access applications (and NAKO-internal notifications of use) can be submitted through the TransferHub web portal. Applicants can access the data dictionary, including the description of the study variables, upon prior registration.

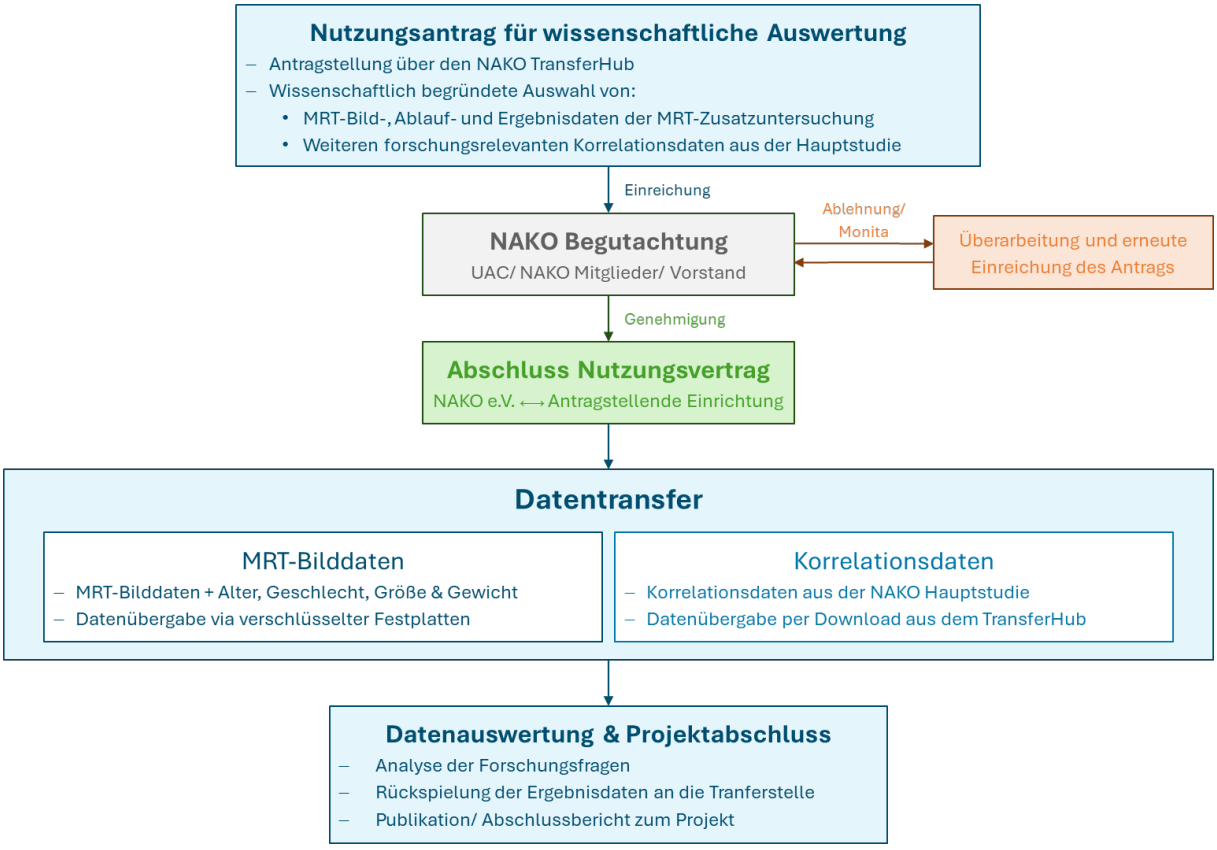
If MRI image data is required as part of a use and access application, these variables must be selected in the *Data* tab of the data dictionary under *MRI examination* > *MRI image data*. Only variables listed here can be evaluated and transferred to the applicant. In the event that use-restricted variables or non-defaced neuro datasets are requested, this requires additional justification for the necessity of these MRI image datasets. In addition to the MRI image data, variables related to the examination procedure, the contraindication query or the IF reading from the MRI supplementary examination can also be requested. Furthermore, some results data from the MRI baseline examination is already available for retrieval.

If applicants are not only interested in the MRI supplementary examination, but also in the study variables of the main study (correlation data), their selection and necessity must also be justified in the application and taken into account when compiling the variable set. At this point we refer to point 2.1.8 on the info sheet TFS-Info-03 Information on use and access procedure.

4. Application review

The detailed application review is described in the info sheet TFS-Info-03_Information_on_use and access procedure under 1.2. Only the additional review steps are described here. A schematic representation of the workflow can be found in **Figure 1**.

Figure 1: MRI image data application workflow



4.1. Review by Use and Access Committee

After the formal review of an application by the Transfer Office, the Use and Access Committee (UAC) reviews the submitted use and access applications in accordance with the requirements of the Use and Access Policy. If necessary, additional experts from the module coordinators (EG 15 MRT) are consulted regarding the use of MRI image data, and they provide an assessment of the projects. Once the assessment has been completed, the results are forwarded to the Transfer Office.

4.2. Review criteria

Use and access applications that include MRI image data are evaluated and prioritised based on specific criteria in accordance with the Use and Access Policy. These criteria extend beyond those applicable to applications concerning only study data. The review is based on the following criteria:

- Consistency and conclusiveness of the use and access application with regard to the requested data and MRI image data for the planned evaluations or analyses
- Compliance with legal and ethical standards, especially when applying for brain MRI image data for which no so-called de-facing has been performed:
    - For data protection reasons, these data can only be requested to a limited extent and the necessity must be justified accordingly.
    - In addition, it may be necessary to demonstrate how the re-identification of persons (groups) or the merging of different databases can be avoided.

- The release of this data may be subject to specific conditions or only in a modified (coarsened) form or not in connection with certain other variables.
- The review and approval is the responsibility of the MRI Core, which can consult selected experts if necessary.

5. Data transfer

If the review results in a recommendation for approval, the procedure for NAKO use and access applications is carried out as described in the info sheet TFS-Info-03_Information_on_use_and_access_procedure under 1.3.

Upon signing the use/access agreement by both the applicant institution and NAKO e.V., the NAKO Transfer Unit will compile the MRI data and deliver it to the data recipients specified in the application.

5.1. Compilation of MRI data

The MRI image data are generally so large that they cannot be provided as a download via the TransferHub, but can only be transferred by post on encrypted hard drives. If other study data has been requested in addition to the MRI image data, the latter will be made available separately via download.

5.2. Provision of data carriers for MRI data

Due to many simultaneous data compilations and transfers by the NAKO Transfer Unit, it is necessary for the data recipients to provide the NAKO Transfer Unit with a single, sufficiently large data carrier (e.g. hard drive).

Further details regarding the required size of the data carriers, the necessary encryption using VeraCrypt, as well as addresses and dispatch procedures will be communicated to applicants via email by the NAKO Transfer Unit prior to the data transfer. The general procedure for data transfer can be found in the info sheet TFS-Info-03 Information on use and access procedure under 2.1.

5.3. Processing time

An approximate processing time of six weeks is to be expected for the transfer of (image) data due to the sending and returning of the data and the compilation of the data. In the event of any deviations, the Transfer Unit will provide the necessary information accordingly.

6. Costs

The following costs must be covered by the applicant's institution for the provision of the MRI data:

- Provision of a sufficiently large data carrier (e.g. hard drive)
- Shipping costs for sending the encrypted hard drive to the Transfer Unit (insured DHL parcel)
- Shipping costs for the return shipment of the hard drive (prepaid DHL parcel label for the return shipment must be enclosed with the parcel when sending the hard drive to the Transfer Unit)