



Healthy Brain Study bylaws

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These bylaws describe the rules for obtaining and using the Healthy Brain Study (HBS) data and biosamples, including:

- Access rights and obligations regarding data and biosamples
- Authorship rules on publications
- Inclusion of the HBS data and biosamples in grant proposals

Within this document we stratify researchers into three tiers with different rights.

Tier I: Researchers on Radboud Campus that contributed to study design and data acquisition

Tier II: All other researchers on Radboud Campus

Tier III: Publicly financed researchers from other academic institutions

Companies can apply in all tiers, but they cannot apply independently from researchers on Radboud Campus.

Step 1: Apply for data and/or biosamples

Step 2: Internal review of application

Step 3: Signing data/material transfer agreement (DTA, MTA,DMTA)

Step 4: Release of data and/or biosamples

Step 5: Publication of results

1. Apply for data and/or biosamples

1.1 What should be in proposals for data access?

Project proposals for data and/or biosample access should contain name(s), affiliation(s) and expertise of applicant(s), a Dutch title and summary in layperson terms for our Dutch website, the title of the project, a summary of your project, research question and hypothesis, methods, and which data are requested. Justification of each data item is required. A data table and a data request form is provided.

1.2 Is preregistration of the research question required?

Yes, a preregistration, preferably on the open science framework (OSF), or a registered report in a peer-reviewed journal, should be demonstrated. A preregistration makes a clear distinction between generating hypotheses and testing these hypotheses, which aids the prevention of hindsight and confirmation biases. It does not prevent researchers from presenting exploratory analyse, but it prevents presenting an exploratory finding as confirmatory. The preregistration should be done and sent to HBS (hbs-data@radboudumc.nl) before signing the data/material transfer agreement. For preregistrations, the [aspredicted.org template](https://aspredicted.org/template) available on OSF is preferred.

1.3 Who can apply when?

Tier I researchers can submit proposals on the first call. Submission deadlines will be announced on the HBS website and in the HBS newsletter. Tier II researchers can apply six months later and tier III researchers twelve months after the first call. However, together with tier I researchers, tier II and III researchers can already apply within the first six months.

1.4 What is required of researchers?

A researcher should be a bonafide researcher, which means a researcher with:

- an intention to generate new knowledge and understanding using rigorous scientific methods;
- an intention to publish the research findings in the scientific community, without restrictions other than IP and data protections, and with minimal delay, for wider scientific and eventual public benefit;



- intended activities that are consistent with legal and ethical requirements.

Furthermore, at least one of the applicants holds a PhD degree and works at an academic institution and has relevant expertise related to the analysis proposed.

1.5 Including HBS participants in additional studies

Researchers can promote their studies in our newsletter after data collection finished. Personal re-approaching of participants will only be considered when the proposal draws on the richness of the data. Proposals for new data acquisition should additionally include justification of the additional burden to the subjects.

1.6 Costs

Data release

For all other data releases a fee will be charged covering costs for data maintenance and release. The minimum fee is €1.500 for a small part of the data. For a substantial number of data items, a quote will be provided.

Biosample release

The fees of the Radboud Biobank plus the costs for data maintenance and release by the HBS project team apply.

Grant proposals

Drafts of grant proposals including the budget should be submitted to hbs-data@radboudumc.nl with at least one month before submission to the granting agency. In case of grant proposals that use HBS data, the project leader and project manager of the HBS approve and decide on the fee. An access fee that covers costs for data maintenance and release by the HBS project staff will be charged (up to 10% of the grant total if the research is fully done by HBS data and/or biosamples). Here we provide two examples to calculate the fee:

- The proposed research in a work package will be done entirely with HBS data. The fee will be 10% of the total work package costs.
- The proposed research in a work package will be done for 25% with HBS data. The fee will be 2,5% (25% of 10%) of the total work package costs.

2. Internal review of application

2.1 Who reviews proposals?

The HBS Data Access Committee (DAC) reviews all study proposals. Submission deadlines will be announced on the HBS website and in the HBS newsletter. The DAC consists of two alternating members of the HBS scientific board, which consists of researchers of Radboud Campus, representing all faculties and the Max Planck Institute for Psycholinguistics. In addition, the DAC consists of a layperson from the participant panel and a regulatory expert.

The DAC is chaired by the HBS project leader and supported by the HBS project manager. The DAC will make a decision within one month after submission deadlines, which can also ask for further clarification and/or collaboration with specific experts on campus. The DAC may ask for independent expert advice if necessary. In case of inconsistency between scientific board members, the layperson and/or regulatory expert, the chair decides.

2.2 What are the review criteria?

The DAC is asked to enable most efficient use of the HBS data in the service of excellent research. The HBS data use should be in line with the aim of the HBS as described in the [protocol paper](#) and the [information brochure](#) that subjects read and consent to (only available in Dutch).



Review criteria for data requests:

The DAC checks if the project is in line with the aim of the HBS and if the requested data are needed to answer the research question.

Review criteria for biosamples:

The DAC reviews the content and quality of the proposal, and whether proposals should be combined or rejected in case of redundancy with another proposal.

2.3 Who should check for competing proposals?

In case of application for data, it is up to the applicant to check the list of [previously granted data requests](#) on the HBS website. By filling out the data request form, the applicant acknowledges that they checked previously released data.

In case of application for biosamples, the DAC checks for competing proposals, because it is our responsibility to handle the biosamples carefully. Proposals should efficiently handle biosamples and avoid left-over samples as much as possible.

2.4 Amendment

Amendments to the data request should be sent to hbs-data@radboudumc.nl. In case the amendment consists of considerable changes, a new calculation of the costs, another internal review, and a new data/material transfer agreement may be required. Any data requested in the amendment are subject to the same obligations and terms as stated in the HBS_bylaws_v2 and the HBS_data_transfer_agreement_template_v3.

3. Signing Data/Material Transfer Agreement

3.1 Is a DTA, MTA or DMTA in place?

The relevant agreements will be provided and have to be signed by the researcher requesting the data (RECIPIENT), the head of the department in which the researcher works (RECIPIENT'S RESPONSIBLE SUPERVISOR), a representative of the HBS (PROVIDER), and the HBS project leader (PROVIDER'S RESPONSIBLE SUPERVISOR).

3.2 All processed data and samples with relevant documentation (including scripts and data/biosamples processing protocols) must be integrated back into the HBS Research Data Repository for future use according to FAIR-principles.

4. Release of data and/or biosamples

4.1 Data sharing

Open access to the full HBS resource does not comply with the EU General Data Protection Regulation, because the HBS resource contains a substantial amount of sensitive personal data. Data releases from the HBS resource cannot be shared openly. However, any researcher or reviewer can be granted access for replication studies or checks of scientific integrity.

4.2 Unsolicited findings

Researchers have the obligation to report potential unsolicited findings, such as abnormalities in the MRI or biosample data or clinical questionnaire scores higher than the cut-off, to hbs-data@radboudumc.nl.

4.3 Withdrawal of informed consent

If participants withdraw, data/ biosamples will not be released anymore, but researchers are allowed to use already released data/biosamples.

4.4 Left-over biosamples

Left-over biosamples cannot be returned. Researchers are encouraged to efficiently handle biosamples to avoid left-over samples as much as possible.

4.5 Information provided in the metafile

The metafile that will be provided with the requested data contains detailed information about the data and processing of the data. The purpose of the metafile is to inform the



researcher. Detailed information about questionnaires should only be used to understand the data, not to recreate and use a questionnaire without permission (if permission by the authors is required).

5. Publication of results

5.1 Publication of proposals

The research question, project summary, and keywords of all granted data requests will be published on our website, including links to the preregistration and publications. Researchers are obliged to send publication manuscripts or abstracts using HBS data at least 30 days before submission, and to inform the HBS about publications using HBS data (hbs-data@radboudumc.nl).

5.2 Every publication (partly) based on the HBS should refer to the HBS protocol paper: Healthy Brain Study consortium, Aarts E, Akkerman A, Altgassen M, Bartels R, et al. (2021) Protocol of the Healthy Brain Study: An accessible resource for understanding the human brain and how it dynamically and individually operates in its bio-social context. PLOS ONE 16(12): e0260952. <https://doi.org/10.1371/journal.pone.0260952>

5.3 Every single paper should acknowledge the Healthy Brain Study in a standard manner, like: "This research has been conducted using the Healthy Brain Study Resource under Release Number ...". The release number can be found in paragraph 12c of the data/material transfer agreement.

5.4 Open access policy

All publications emerging from HBS data and/or samples must be made available

Open Access upon publication. HBS accepts three routes:

- Gold: publication in a full Open Access journal registered in the Directory of Open Access Journals (DOAJ)
- Hybrid: publication in a hybrid journal. The Dutch Association of Universities has a series of agreements with major publishers that allow Dutch researchers to publish open-access in these journals at no extra cost. See on that subject: www.openaccess.nl
- Green: publication in a closed subscription journal and sharing a version of the article directly (without embargo) via an open access repository (preferably the version of record, otherwise the authors accepted manuscript or the preprint). The repository should be registered in the Directory of Open Access Repositories (OpenDOAR).