university of groningen

Digital Competence Centre

# Reuse of pseudonymized research data of an external organization

## Content


Introduction

Example: Research on chronically ill children and their parents 2

Workflow: Reuse of pseudonymized data from an external organisation 3

Appendix 1: Example data flow diagram 6


## Introduction

Based on a frequently occurring case involving the reuse of pseudonymized data from another organization, the Digital Competence Centre (DCC) has developed a scenario in collaboration with the Department of General and Legal Affairs (ABJZ) and the Faculty of Behavioural and Social Sciences. The scenario contains a workflow with tips and tricks that can support researchers in setting up a study with existing pseudonymized data from an external organization and with making agreements with this organization. In addition, it also explains which support staff can help and at which point in time.

In the event of a request for help, the Data Steward is the first point of contact for a researcher. The Data Steward manages a researcher's request for help and, where necessary, looks for experts who can advise on developing the data management protocol and the agreement with the external party. Together with the P&S Coordinator of your faculty and legal advisers from ABJZ, the Data Steward advises on appropriate measures regarding the processing of the pseudonymized data sources within the scope of the GDPR in the context of scientific research. In addition, they provide support in clarifying responsibilities within the research project.

This process can take a long time depending on the complexity of the research (e.g. a longitudinal project), the type of data (e.g. processing special categories of personal data), and the organization where the data has to come from (e.g. if external organization has no standard procedures for data transfer). **Allow enough time for this (two to six months).**

This scenario is specifically intended for the reuse of research data where the ground for using the data is informed consent. If you wish to reuse personal data that has been collected on different grounds, it is important to obtain advice via dcc@rug.nl or from the P&S Coordinator of your faculty at an early stage. An example of how this can go wrong can be found here.

# Example: Research on chronically ill children and their parents

A researcher from Pedagogy wishes to conduct a study into the quality of life of children with a chronic illness and their parents. They would like to use pseudonymized data collected by the UMC Utrecht (UMCU). The data contain special categories of personal data (health data). The researchers have submitted a data request to the UMCU. In addition, the UG researchers have started drafting a data-sharing agreement. They have used the NFU template, which was provided by the UMCU.

If data or bodily materials are exchanged between parties (different organizations), an agreement must usually be signed. The type of agreement depends on several factors. The service desk for Ethical, Legal and Social Issues on the use of data and human tissue in health research (ELSI) uses the following flowchart for these factors.

When following the flowchart for this case, pseudonymized data is transferred from the UMCU to the University of Groningen. These data are not yet in use under an existing licence, and are not public. There is no other form of data agreement between the parties involved in the data transfer. The University of Groningen set up the research, so they are not doing the research on behalf of the UMCU.

This means that the UG is the controller.

**Outcome:** A data-sharing agreement must be signed.

# Workflow: Reuse of pseudonymized data from an external organization

## Researcher's help request

I would like to use pseudonymized research data from another organization, and I have to sign a data-sharing agreement to do so. What do I have to do?

## Step 1: Write a project proposal and a data management plan

### Where do I start?

This example uses the NFU model for a data-sharing agreement. This is a data-sharing agreement that university hospitals in the Netherlands standardly use.

When reusing data from an external organization, it is customary for the other party to provide a template for the data-sharing agreement. It is important to know at an early stage which template is being used. This means the conditions of the agreement can already be taken into account when writing the project proposal and the data management plan.

Look at the appendices to the model (e.g. NFU model). Include the points raised in these appendices when writing the project proposal and data management plan.

Find out whether the external organization expects certain measures from researchers who want to use the data. Discuss the points of attention from the agreement (see **Appendix 1**). Include these measures in your data management plan.

Start writing a **Project proposal** and a **Data management plan**. If possible, use the templates from your faculty. These documents form the appendices to the agreement. **Appendix 1** offers a visualization of the data flow with points of attention from the agreement that must be included in the data management plan.

All agreements must be signed by the Managing Director of the Faculty. Make sure that your P&S Coordinator is involved and the Research Director is informed.

### Tips & tricks

1. Ensure the project proposal and the data management plan are concise but fully elaborated. The contract forms the legal basis of the agreement that is entered into with the external organization, but ultimately the project proposal and the data management plan form the basis of the research to be carried out and the practical agreements made between the researcher and the external organization.
2. Work out the data management plan as a manual, in which it is clear which steps have to be followed during the data transfer and who is responsible for them. This prevents mistakes and ensures that everyone knows what is expected of them.

### Where can I go for support?

1. If you are not sure whether you have the right agreement, follow the flowchart on the ELSI website and/or ask for advice (dcc@rug.nl).
2. It is a good idea to make an appointment with the Data Steward of the DCC (dcc@rug.nl) to examine whether the measures you have drawn up in

the data management plan can be accepted as appropriate measures in the context of the General Data Protection Regulation (GDPR), and the data management policy of your faculty (link) and the University of Groningen (link).

3. When creating a data management plan, it is easy to overlook certain processing operations that may pose a high risk. Data Stewards of the DCC (dcc@rug.nl) can support you in creating a data flow diagram to identify all processing operations, and clarify responsibilities properly (See **Appendix 1** for a simple example).
4. The Data Steward of the DCC can also advise on existing sets of appropriate measures (see **Appendix 1**), and possibly help to find discipline-specific best practices.
5. If needed, the DCC can already involve the P&S Coordinator or a legal adviser in the support at this stage.

## Step 2: Application for ethical review

### What should I do for this?

The NFU template states that the supplier of the data is responsible for ethically testing the data transfer (Grounds for processing the data by an external party and the exception for the processing of health data). It is important to check whether the external organization is aware of these responsibilities.

In addition, check with the external organization whether the participants have given permission for their data to be used for follow-up research (link). If the data have been collected on a different legal ground than informed consent, please discuss this with the Data Steward of the DCC.

As soon as it is clear what the project will look like, an application for ethical review must also be submitted to your Ethics Committee. How this works can be found on the intranet of your faculty (link).

It is important to indicate that you are working on the collaboration according to this scenario, and which template is being used. This means the Ethics Committee can assess on the basis of this scenario whether responsibilities have been clarified and clear measures have been laid down.

## Step 3: Signing the agreement

Once the study, provided that the agreement is signed, has been approved by the Ethics Committee, the agreement can be sent to the P&S Coordinator. The P&S Coordinator can submit this agreement to the Managing Director for signing or ask for advice from the Research Director and/or a legal adviser from ABJZ.

All agreements must be signed by the Managing Director. Make sure that the Research Director is also informed.

If the contract has been approved by the advisers at the UG, the agreement with appendices (**Project plan** and **Data management plan**) are sent to the external organization that will provide the data.

Once the contract has been signed by all parties, the P&S Coordinator will archive the agreement.

## Step 4: The data transfer

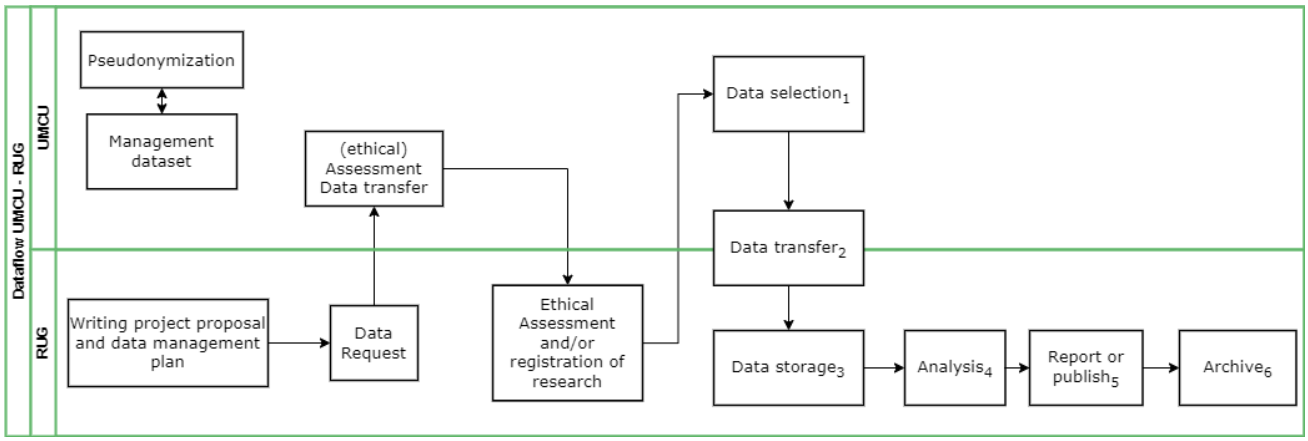
Once you have gone through all the steps, the data transfer can begin. From that time onwards, as a researcher, you have a number of obligations under the agreement. Remember that you:

1. must inform the provider in the event of a data breach. Examples of a data breach are a lost USB stick with personal data, a computer that has been hacked, or files with personal data that have fallen into the wrong hands via the recycling.
2. must comply with the conditions in the agreement when reporting on the research.
3. also must check which agreements have been laid down when archiving.

# Good luck!

# Appendix 1: Example data flow diagram

Underneath this figure are questions that can help the researcher to draw up the data management plan, and relevant links that can help in making choices regarding measures. Also take the requirements set by the external party for data protection into account.




## Figure 1 Data flow diagram

1. For which categories of persons are data processed?
   a. E.g. patients, children, employees, etc.

   Categories of personal data that are processed:

   a. What are personal data? (Click here for further explanation)
   b. What are special categories of personal data? (Click here for further explanation)

2. What transfer method is used? Is encryption used here?
   a. Data transfer (Click here for more information on secure methods of data transfer)
   b. Encryption (Click here for more information on encryption)

3. Where are data stored? Is encryption used?
   a. Storage at the UG (Click here for more information about data storage at the UG).
   b. Remember to inform the provider of the data in the event of a data breach (Article 2d of the NFU data sharing agreement).

4. Which programs are used for data analysis? Who performs the analysis? Who has access to the data?

5. Article 12 of the NFU data sharing agreement contains agreements on the recognition of the provider of the data as author in publications and the procedure that needs to be followed in that regard.

6. What agreements have been made about where the data will ultimately be archived?
   a. Check whether an exception for the destruction of the data has been agreed upon in the NFU data sharing agreement (see Article 13 of the NFU data sharing agreement for agreements for after the research).
   b. Follow the data management protocol of your faculty.