Plan Overview

A Data Management Plan created using DMPonline

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PRIOR DMP

1. General features of the project and data collection

1.1. Please fill in the table below. When not applicable, please fill in NA.

DMP version	23
ABR number	
METC number	
DEC number	
Acronym study title	
Name Research Folder	
Name Division	
Name Department	
Partner Organization	
Start date study	
Planned end date study	
Check date by datamanager	

1.2 Select the specifics that are applicable for your research (more than one option possible). If necessary, add text in the additional comment area.

- Observational study

2. Data Collection

2.1 Give a short description of the data for your research, including

- **the source of the data**
- **what tools you use for Data Capture**
- **the type of data, the size of the data**
- **the format of the data**

Study subjects	Data Source	Data Capture Tool	File Type	Volume (records, MB, GB, TB..)	Format
Human		OpenClinica version ...			

2.2 Do you reuse data from other researchers or from the EHR?

- No (please specify)

2.3 Describe who will have access to which data during your study.

Type of data	Who has access
Personal data	Research team
Data from other centers	Research team

2.4 Describe how you will take care of good data quality.

All data will be checked by a member of the research team and set to 'completed' in OpenClinica after this check has been performed. The hard copy source data will be stored in a folder and kept safe in a closet with a lock where only members of the research team have access to the folder.

2.5 Specify costs involved in managing and storing your data.

There are no costs for managing and storing the data.

2.6 State if intellectual property rights (IPR) are applicable on your data collection and state which agreements will be or are made.

The data collection consists of quantitative data of exercise reports that have been collected among esophageal cancer patients following preoperative exercise therapy. All data will be stored on the hard disc drive of the Hogeschool Utrecht. The Hogeschool Utrecht will own the data.

3. Legislation/ Data Protection Impact Assessment

Will you be using personal data from the EPD, DNA, body material, images or any other form of personal data as described above?

1. **No, go to 4.1**
2. **Yes, go to next question**
3. **I am not sure, go to next question**

Answer = 1 -> skip this section and go to next question
Answer > 1 -> fill in this section and check with your datamanager (read guidance!)

Yes

3.1 Describe which personal data you are collecting and why you need them.

Question not answered.

3.2 What legal right do you have to process personal data?

- An authorized datamanager processes care data for reuse on behalf of his/her function and I will receive pseudonimized research data, so I will not ever see or process direct personal data myself

3.3 Describe how you manage your data to comply to the rights of study participants.

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal

data.

Question not answered.

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

4. Data Storage and Backup

4.1 Where will you store your data and documentation during the research.

https://www.surfdrive.nl/ The data will be stored within the firewall of the UMC on the network drive in a folder protected by permission rights. The digital files will be stored in the Secured Research Folder.
Hard copy data will be stored in a folder and will be stored safely in a locked closet where only members of the PRIOR project have access to the folder.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

The data will be backed up by the UMC Utrecht backup system. A backup will automatically be made twice a day by the dIT.

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

We do not use metadata standards yet. For the data stored in Open Clinica, a codebook of the research database will be prepared.

(Verifiëren met Elja)

5.2 Describe where you registered your research project, which standards you use for filenames and how you keep track of versions.

New versions will be distinguished by indicating the version in the filmename of the master copy by adding a code after each edit, for example Version 1.1, where the first number can be considered as the number for major versions and the last number for minor versions. The most recent copy will always be used as the source and after editing, this file will be saved with the new version code in the filename. The file with the highest code number is the most recent version.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

SPSS will be used for analysis. SPSS syntax will be saved on the secured UMC Utrecht Network drive. An overview of the datasets and analyses will be made to facilitate reproduction.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The datasets that have been used for the final analysis will be preserved, together with the researchers's logfile.

7.2 Describe which archive or repository (include the link!) you will use for long-term archiving of your data collection once the project has ended and whether the repository is certified.

Closed archive will be stored at the UMCU (exacte link nog nader toevoegen na overleg Elja. Nu niet echt inzicht welke map dit is). An open archive will be hosted by Dataverse.

7.3 Give the persistent identifier (the ISBN for your data) that you will use as a permanent link to your data collection.

I will be using a DOI-code and will update this plan as soon as I have the code.

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

The data can be used to investigate which exercise intensity leads to better postoperative outcome. The data may be used for a spin off project with a larger population.

8.2 Describe the related information that will be available with the data.

Along with the publication, the codebook of the data and scripts of analysis will be available.

8.3 Describe when the data or metadata will be available, under which criteria and for how long.

Our data will be shared with third parties after approval of the principle investigator and approval of the UMC Utrecht Data Access Committee. The criteria and time period will be determined on a case-by-case basis.

8.4 Describe where you will make your data findable and available to others. A link to the data repository or a link to the data should be provided.

Deze even bespreken met Elja.