ELSI HEALTH - RI

Implementatie Gedragscode Gezondheidsonderzoek – Coreon

DMP templates knooppunten (UMCs) – mapping met paragraaf 1.1 Gedragscode

Knooppunt	*Coreon* **Gedragscode Gezondheidsonderzoek - § 1.1 Onderzoeksprotocol en datamanagementplan**							
	Doelstelling en methodologie	Overzicht verwerking gegevens en verwerkings-stappen	Groepen, categorieën betrokkenen die deelnemen aan onderzoek	Gegevens verwekt, bijzondere, direct identificerende persoons gegevens	Passende waarborgen gegevens, toegang, beveiligde omgeving	Deelnemers hoe benaderd en geïnformeerd, toestemming, uitzondering toestemming	Verwerkings-verantwoordelijkheid welke partijen betrokken, welke rol	Omgang met rechten deelnemers. 1. Beheer archivering 2. Bewaartermijn 3. Hergebruik ,FAIR
Amsterdam *F01 Data Management Plan - RDM – Amsterdam UMC (Versie 2)*	*Summary of the project;*	1.10;1.16-1.26;	Protocol	1.1; 1.2	1.30; 1.31;	1.5;	1.32;	1) 1.27; 2)-5; 3) 1.8; 1.10; 1.11; 1.12; 1.13; 2.3; 4.2; 5;
Eindhoven *06Feb Draft Data management Plan_Arise_2023*	Protocol	5.1;	4.1;	4.2;	4.1;	5.2	4.3;	1) 3;5.3; 2) 3;5.5; 3) 2;3;5.3;5.4;
Groningen *80H1.01 TPL Data Management Plan (Versie 5)*	2.2 Step 1;	2.3 Step 2;	2.2 Step 1	2.4 Step3b	2.3 Step 2c	2.3 Step 2c	2.2 Step 1	1) 2.4 Step 3 2) 2.4 Step 3 3) 2.6 Step 5
Leiden *DMP_Template_LUMC*	Protocol	1.5	1.1;	Protocol	1.5	1.2; 1.3, protocol	4.10; 4.11;	1) Ch 3 (storage) + 4 (archiving) 2) 4.5; 3) Ch 5 (publishing data); 2.3; 2.4; 2.5 (metadata & documentation)
Maastricht *DMP_UM_MUMC*	Protocol	3	2	Protocol	4	Protocol	2	Protocol
Nijmegen *Radboudumc_Data_Management_Plan_v10*	Protocol	2.5	2.5	2.5	3.6. 3.7	2.5	2.4	1) 5.1 2) 5.2 3) 5.3
Rotterdam *ErasmusMC_DMP_mensgebonden_Template_v3*	1.7, 1.8	4.1, 4.4.1	3.1,	4.3.2, 4.12, 4.13	3.9, 4.14-4.16,	3.2-3.9	2.2, 2.3, 2.4	1)5.2-5.8, 7.1-7.7 2) 7.3 3) 4.3,6.11-6.4.9
Utrecht *DMP Template_UMCU*	1	2.1,2.3,	3.1,	3.2,	3.3,	3.2	2.6	1) 4.1 2) 7.2 3) 8.1-8.5
Voorbeeld antwoorden		Type of data New data	Population of research	Permission to re-use data (Non) sensitive data	Participants rights Safeguarding personal data	Legal basis and informed consent Participants rights	Involvement external parties Ownership & IP	Storage location Folder structure

Zorg dat het onderzoeksprotocol en datamanagementplan ingaan op:

- • De doelstellingen en methodologie van het onderzoek, respectievelijk de verzameling en verwerking van gegevens en lichaamsmateriaal;
- • Een schematisch overzicht van de verwerking van gegevens en/of lichaamsmateriaal, en de verschillende verwerkingsstappen die worden voorzien. (Dit is weliswaar geen formele vereiste in de regels voor gegevensbescherming, maar maakt vaak beter duidelijk hoe de verwerking is georganiseerd en welke partijen voor welke (delen van) verwerkingen verantwoordelijk zijn. Het wordt daarom sterk geadviseerd);
- • De groepen (categorieën) betrokkenen van wie gegevens en/of lichaamsmateriaal worden verwerkt: wie (welke groepen of populaties) nemen deel aan het onderzoek?;
- • De soorten (categorieën) gegevens en/of lichaamsmateriaal die worden verwerkt. Met name: worden er bijzondere persoonsgegevens verwerkt? Worden er ook direct identificerende persoonsgegevens verwerkt? (Zie hoofdstuk 2);
- • Passende waarborgen: hoe worden alleen de voor het onderzoek noodzakelijke gegevens en lichaamsmateriaal verwerkt, op zo'n manier dat sprake is van minimale gegevensverwerking? Worden gegevens gecodeerd of gepseudonimiseerd? Hoe is de toegang tot de gegevens geregeld? In welke beveiligde omgeving(en) worden gegevens verwerkt? (zie hoofdstuk 2);
- • De algemene voorwaarden voor verwerking en hoe daaraan invulling wordt gegeven. Hoe worden deelnemers benaderd en geïnformeerd over het onderzoek? Wordt deelnemers om toestemming gevraagd (en zo ja, hoe)? Of is er een uitzondering van toepassing (en zo ja, welke)? Of worden er alleen geanonimiseerde gegevens verwerkt? (Zie hoofdstuk 3 en hoofdstuk 5);
- • De verdeling van verwerkingsverantwoordelijkheid: welke partijen zijn betrokken bij de verwerking en in welke rol? (Zie hoofdstuk 10);
- • De omgang met rechten van deelnemers: welke rechten zijn van toepassing? Is er een kans op individuele bevindingen en hoe wordt daarmee omgegaan? (Zie hoofdstuk 6);
- 1 Het beheer en de archivering van gegevens en lichaamsmateriaal: wie is daarvoor verantwoordelijk? Welk beheerreglement is van toepassing? (Zie hoofdstuk 8);
- 2 De bewaartermijn van verzamelde gegevens en/of lichaamsmateriaal: welke bewaartermijn wordt aangehouden en waarop is die gebaseerd? (Zie hoofdstuk 8);
  • 3 De mogelijkheden en afspraken over hergebruik, uitgifte van en/of toegang tot gegevens en lichaamsmateriaal voor toekomstig onderzoek. Wordt hergebruik voorzien? Hoe wordt invulling gegeven aan de FAIR-beginselen voor datamanagement? Hoe wordt besloten over verzoeken om
  • hergebruik, uitgifte of toegang? (Zie hoofdstuk 9)

Voorbeeld antwoorden

Onderstaande voorbeelden zijn slechts voorbeelden. Ze kunnen niet gezien worden als samenvatting van de richtlijnen uit de COREON Gedragscode Gezondheidsonderzoek.

4.1 **Which type(s) of data will be collected, (re)used and/or generated during this project?**
Data from humans include health care data and images from the Electronic Health Record (in Dutch: Elektronische Patiëntendossier), data collected from human subjects through questionnaires or interviews, data derived from human biological material, data reuse from previous research involving humans or external databases, etc. Biological material from humans includes all kinds of biological material, such as blood, tissue, cells, hairs, nails, saliva, urine, faeces, etc.

4.4 **New data**
New data includes the data that is generated or collected in the context of this project. The prospective collection of data for standard care purposes is not considered new data. Research Support Office – [Institute] Data Management Plan Manual (human-related research) v3.1 – Aug 2023 17

Example answers: “We will generate DNA sequence data.” “We will collect new data on quality of life.

3.1 **What is the population of your research?**

☐ Patients
☐ Healthy Volunteers
☐ Adults
☐ Minors
☐ Mentally incompetent adults
☐ Other:

4.3.2 **Permission to reuse data**
When asking permission to reuse pre-existing data, be sure to be informed about the content of the informed consent form of the previous study. Make sure that only the data from participants who have agreed on reusing the data for further research is shared with you for reuse. It is also important to ask about the terms of use, for example whether it is allowed to combine the preexisting data with other (new or other pre-existing) data.

Example answer: “To obtain the data, a data request procedure via DANS has been followed and finalized. Permission was received from [name, function, department, organization]. Data will only be shared if participants gave permission to reuse their data for further research on the informed consent form. There are no restrictions on combining the data with other research data.”

4.12/ 4.13 **(Non-)Sensitive type of information of participants (Personal data)** Personal data is any information relating to an identified or identifiable living individual, including BSN, name, email/IP/home address, date of birth and health data. Therefore, research data almost always contains personal data and therefore falls under the General Data Protection Regulation Law (GDPR), also known in Dutch as the Algemene Verordening Gegevensbescherming (AVG), which is under the supervision of the Dutch Data Protection Authority (in Dutch: Autoriteit Persoonsgegevens). The GDPR/AVG also defines special categories of personal data, such as data concerning health, race/ethnicity, genetics and sexuality. The use of data from a special category of personal data is subject to stricter rules. In health research, the use of health data is usually already covered in the subject information sheet and/or informed consent form. If data from other special categories of personal data will be used, it must be explicitly mentioned in the subject information sheet and/or informed consent form. According to the GDPR/AVG, personal data may only be collected if it is adequate, relevant and limited to what is necessary for the purpose (source: Autoriteit Persoonsgegevens).

Example answers:
“Patient ID will be collected to be able to trace back to the patient.”
“Contact details (name and email address) are required to send surveys.”
“Age in years and gender are required to describe the study population.”
“Clinical data XXX is required to answer the research question.”

3.9 **Participant rights**
People have several rights to control their personal data according to the Dutch Data Protection Authority (in Dutch: Autoriteit Persoonsgegevens), and this also applies to research participants.
- The right to be informed in a transparent manner about the processing of the data and the participants’ rights (e.g., via the subject information sheet) (AVG Articles 12-14)
- The right of access to a copy of the data and to information about the data processing (e.g., when a participant requests to receive their personal data that was collected during the study) (AVG Article 15)
- The right to rectify the accessed information (AVG Article 16)
- The right to object (e.g., when a participant refuses to participate or refuses their data or biological material to be reused for scientific research, or when withdrawing consent) (AVG Article 21)
- The right to erasure of the collected data (e.g., partially when withdrawing consent) (AVG Article 17; see comment down below)
- The right to restrict processing, for example in combination with the one of the rights of rectification, objection or erasure (AVG Article 18, 19)

- The right to data portability (AVG Article 20)
- The right not to be subject to a decision based solely on automated processing (AVG Article 22) If you can guarantee that personal data is exclusively collected for scientific research or statistical analyses, AVG articles 15, 16 and 18 may not be applicable (GDPR/UAVG Article 44; EU-GDPR table of contents). Concerning the right to erasure: the GDPR/AVG states that data should be deleted when a person asks for it. However, an exception has been made for data processing in research and archiving (GDPR/AVG Article 89(1)). The Code of Conduct (Gedragscode Gezondheidsonderzoek) prescribes that this exception may be used if erasing the data threatens to make the research impossible or to severely hinder the research. Therefore, in case of withdrawal of consent, the data that have been collected up to the moment that the participant stops participating can be used for research. Read more about the research exemption in CESSDA's data management expert guide.

Example answer: "Participants are informed about the processing of their data and their rights through the subject information sheet. When a participant refuses to participate, their data will not be collected. When a participant withdraws consent, the data collected up to the moment of withdrawal will be used (according to GDPR/AVG Article 89(1)), but no further data will be collected

4.16 **Safeguarding personal data**
Example answers:
"Our project is registered in PaNaMa and the tasks for filling in the required information for the GDPR processing registry have been completed. We have also performed a DPIA in PaNaMa and took the required mitigating measures (please specify if not already listed in your answer)."
"We have completed a full DPIA to assess the privacy risks of this project and took the required mitigating measures (please specify if not already listed in your answer)."
"All project team members have signed a non-disclosure agreement (please explain if external project members are involved)."
"Participants will be asked to provide informed consent."
"We will be using Castor to collect only these data variables that are necessary to answer our research question and no directly identifying personal data. As for the data values, we will limit the use of free text fields and use pre-defined answer options in order to limit unnecessary level of detail. Date variables that are only needed to perform calculations within Castor will not be exported, in order to limit potentially identifiable data in the output files. Email addresses will only be accessible to authorized users and will not be exported. The Castor study is only accessible using 2 factor authentication. The data in the Castor study that was collected by the [Institute] is only accessible by members of our research team; other sites (except the initiating centre in this multicentre study) do not have access to our data."
"We will be using a data extraction from the Health Data Platform and will request only these data variables for these patients that meet our inclusion and exclusion criteria that are necessary to answer our research question. We will only ask for a certain level of detail which suffices to answer our research question, and we will make use of categorisation and aggregation where possible."
"We will be using eLabJournal to collect our research data. No unnecessary personal data will be included. Access is limited to members of our research group, and 2 factor authentication is required.

3.5 **Legal basis and Informed Consent**
Generally, informed consent of the participants is required for all types of research involving human subjects, if personal data will be collected, processed and/or analysed. For WMO studies the model PIF-ICF of the CCMO could be used as a template for the subject information sheet (in Dutch: Proefpersonen Informatie Formulier, PIF) and the informed consent form (ICF). For nWMO studies the respective local templates from the nWMO review committee should be used. For more information about informed consent, see the SOP on informed consent. In case of questions, it is strongly advised to carefully read the Frequently Asked Questions (FAQs) of the Privacy Knowledge Office (PKO). When still in doubt regarding informed consent issues after reading the provided information, consult your Privacy Contact Person (PCP).
If informed consent is present partly or indirectly (e.g., when using existing research data and participants have given consent for the previous study and for reusing their data for future studies) then describe the situation in the text box. In exceptional cases, there are good reasons for not asking informed consent for a study in which personal data will be collected, processed and/or analysed (WGBO Article 458). This MUST be properly documented with valid arguments using PKO's template (which can also be found in PaNaMa under the Dossier tab in section E, folder E11) and this MUST be approved by the PI. It is highly recommended to ask the Privacy Contact Person (PCP) for advice. For more information, read the Frequently Asked Questions (FAQs) of the PKO. Describe the situation in the text box.

Example answers:
"Informed consent is impossible to obtain for this study. The arguments on which this statement is based, are properly documented using the template of the Privacy Knowledge Office (PKO). PKO has given positive advice regarding this matter."
"Informed consent is not required because all the data in this study is truly anonymous and cannot lead to identification of the participants."
"Informed consent is not required for processing and analysing of the biological data, because already existing human cell lines were purchased."

2.2 **Involvement of external parties** In case the [Institute] collaborates with external parties in any form of data gathering, processing or (re)use as part of the project, an agreement between the [Institute] and the other party is required. Please make sure that the person who signs the agreement is authorised. For more information about agreements, see the SOP on agreements. Below you will find descriptions of some common situations in which you will need one or more agreements related to the collaboration or to the data.
Consortium agreements
A consortium agreement is a contract that enables multiple parties to actively collaborate in a research project. Details of the terms and conditions under which the collaboration takes place are documented in the consortium agreement. This includes the sharing of obligations, decision making procedures, intellectual property rights, costs and benefits (sources: ZonMw and RVO / Horizon 2020). Possibly, the conditions for sharing the data are described as well in the consortium agreement; if not, then separate Data Transfer Agreements are required. Consult Legal affairs via their legal portal to assist in drawing up and checking consortium agreements. In some cases, the Privacy Knowledge Office (PKO) will be involved as well for privacy-related aspects.
Multicentre research - [Institute] is initiating centre
As an initiating centre in a multicentre study, the participating centres will probably offer an agreement to the [Institute] (e.g., a Data Transfer Agreement or DTA). Consult Legal affairs via their legal portal to check these agreements, before signing.

Multicentre research - [Institute] is participating centre
As a participating centre in a multicentre study, an agreement between the [Institute] and the initiating centre is required (e.g., a Data Transfer Agreement or DTA). Because the [Institute]will probably be the centre that supplies data to the initiating centre, the agreement has to be drawn up by the [Institute]and be offered to the initiating party. You may want to use the standard DTA template and consult the Privacy Contact Person of your department. If necessary, contact legal support.
Clinical Trial
A Clinical Trial Agreement (CTA) is a contract between two or more parties that are involved in the financing, set up and execution of a clinical trial. The involved parties could be a sponsor (i.e., a company providing funding or a drug or device for the clinical trial) and a research institute (e.g., a University Medical Centre or a consortium). Read more about Clinical Trial Agreements on the CCMO website. For support with drawing up a CTA, first check with the research contract manager of your own department (theme office) if they can file the support request for you. Consult Legal affairs via their legal portal . In case you are starting a clinical trial and you have questions, or you would like to involve a data management officer to provide data management support during your clinical trial, we suggest to first contact the research support personnel from your own department. If there is no local research support at your department or they cannot help you any further, then contact the Clinical Trial Center (CTC). The CTC provides support with setting up and conducting clinical research, against payment
Reuse of pre-existing data
In case pre-existing data is reused for this project, it is possible that the supplying party offers an agreement (e.g., a Data Transfer Agreement or DTA). If signing a DTA is required in order to access the data, Consult Legal affairs via their legal portal to check the agreement, before signing.
Data processing
In case a third party is involved in this project which will process data from the [Institute], it is important to offer a Data Processing Agreement (DPA) to the third party. Consult your Privacy Contact Person (PCP) to help drawing up Data Processing Agreements.
Other parties with other purposes
In case other third parties are involved in this project, the party which supplies the data should draw up an agreement and offer it to the receiving party. Consult Legal affairs via their legal portal to assist in drawing up and checking agreements before signing.

2.4 **Ownership and intellectual property**
Example answers:
“The data is under the responsibility of the Principal Investigator and the study results are owned by the {Institute].”
“Intellectual property rights are described in the consortium agreement.

5.3 **Exact storage location**
The exact storage location is needed to be able to find the data in case the “responsible” person is not available.
Example answers: “The data is stored in a folder called “Project X” at \\storage.erasmusmc.nl\ MyDocs”
“The data is stored in a folder called “Project Y” in the DRE called “dws-XXXX-XYZ”

5.7 **Folder structure, file naming conventions and version control**

Example answers:

“The folder structure will be organised logically for our research project and will contain ReadMe text files that include information on how the (meta)data and documentation are organised in the folder structure.”

“We will mark the files with version numbers. Correct version control will be regulated by using a version control table. Every month, versions are reviewed, and previous versions will be archived in an archive-folder.”

“We will mark the files with explicit dates (YYYYMMDD) at the end of the file name. Every month, previous versions will be archived in an archive-folder.”

“We will use eLabJournal, which includes version control.”

“We will use Git for version control.