# Implementation of the Data Seal of Approval

The Data Seal of Approval board hereby confirms that the Trusted Digital repository PROFILES Registry complies with the guidelines version 2014-2017 set by the Data Seal of Approval Board.
The afore-mentioned repository has therefore acquired the Data Seal of Approval of 2013 on August 9, 2016.

The Trusted Digital repository is allowed to place an image of the Data Seal of Approval logo corresponding to the guidelines version date on their website. This image must link to this file which is hosted on the Data Seal of Approval website.

Yours sincerely,

The Data Seal of Approval Board

# Assessment Information

Guidelines Version:                             2014-2017 | July 19, 2013
Guidelines Information Booklet:                 DSA-booklet_2014-2017.pdf
All Guidelines Documentation:                   Documentation

Repository:                                     PROFILES Registry
Seal Acquiry Date:                              Aug. 09, 2016

For the latest version of the awarded DSA       http://assessment.datasealofapproval.org/seals/
for this repository please visit our website:

Previously Acquired Seals:                      None

This repository is owned by:                    **Integraal Kankercentrum Nederland**
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# Assessment

## 0. Repository Context

### Applicant Entry

*Self-assessment statement:*

The PROFILES registry preserves and disseminates the data that are collected in the PROFIEL studies. The PROFIEL studies are done with help of the PROFIEL data manager system, which was developed to facilitate research in the social sciences in the Netherlands and abroad. This is done by providing scientific researchers with accessible data collection and data. The PROFILES registry is open to academics anywhere in the world for scientific purposes, free of charge. It is a public good, with maximum scientific and societal payoff.

PROFILES has an extensive cooperation with CentERdata. CentERdata has received the Data Seal of Approval in 2010 for the LISS panel and has helped with the Data Seal of Approval assessment of PROFILES. CentERdata takes care of (part of the) guidelines 7, 9, 11, 12, and 13.

### Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

# 1. The data producer deposits the data in a data repository with sufficient information for others to assess the quality of the data, and compliance with disciplinary and ethical norms.

*Minimum Required Statement of Compliance:*

3. In progress: We are in the implementation phase.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

The PROFILES Registry Data Archive preserves and disseminates the data which are collected in the PROFIEL studies. These panels are the core element of the PROFILES project, which was founded to facilitate research in the social sciences in the Netherlands and abroad. This is being done by providing scientific researchers with accessible data collection and data.

In 2008, the Netherlands Organization for Scientific Research (NWO) granted a proposal - Building an infrastructure for multidisciplinary and longitudinal data collection of the physical and psychosocial impact of cancer and its treatment: Patient Reported Outcomes Following Initial treatment and Long term Survivorship (PROFILES) -  (see NWO, 2008).

The PROFILES Registry Data Archive is managed by Tilburg University - School of Social and Behavioral Sciences (TSB) -, as well as Netherlands Comprehensive Cancer Organisation (IKNL), through a cooperation. TSB specializes in scientific research in the social sciences area. IKNL specializes in clinical registration of cancer diagnoses and treatments nationwide.

The management of PROFILES includes a Board of Overseers, which is represented by academic experts in different disciplines. PROFILES is currently performing sub-studies to examine data quality in the PROFILES studies.

For more information on the organization see:

http://www.profilesregistry.nl/Registry

http://www.profilesregistry.nl/Advisory

The organization, legal framework and processes involved with creating the PROFILES data are also described in the Preservation and Dissemination Policy of the PROFILES Registry Data Archive, available at http://www.profilesregistry.nl/Policy.

Further, PROFILES uses working methods which are in accordance with the guidelines developed by the Association of Universities in the Netherlands (VSNU) in Code of Conduct for use of personal data in scientific research.

The aim of the archive is to provide reliable and easily accessible information, including data and metadata, on mainly quality of life of cancer survivors. The data are disseminated via the website www.profilesregistry.nl, where one can access the metadata and data (see http://www.profilesregistry.nl/dataarchive). Here all public can view information on each study. The research objectives of the study and information and affiliation of the creator/reseacher are presented, as well as information on data collection (questionnaire, questions linked to the variables, mode, field, work date, universe/population, response, other field work relevant information), codebooks and metadata on dataset and variables (name, label, type, related question items, possible computations). After subscribing (free, academic users) one can download the data.

PROFILES requests all researchers who use the PROFILES data to inform her on new scientific publications based on the data. These publications are linked to the referred studies on the website. (see http://www.profilesregistry.nl/dataarchive/publications). One can view the publications from the study view, or vice versa, one can view the related study via the publication view. (For example: http://www.profilesregistry.nl/dataarchive/publications/view/36 and http://www.profilesregistry.nl/dataarchive/study_units/view/11).

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 2. The data producer provides the data in formats recommended by the data repository.

*Minimum Required Statement of Compliance:*

3. In progress: We are in the implementation phase.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

PROFILES provides her datasets in SPSS, which is among the most commonly used statistics software packages in the social sciences. PROFILES checks each dataset which is ingested in the PROFILES Data Archive. For this, there is an internal protocol of a second viewer, who checks the codebooks and datasets using a standardized check list. Further, when the data files are entered in the EASY system of DANS, they are checked before admission to the system.

When data is submitted to PROFILES in a different format than SPSS it is converted to SPSS. The PROFILES registry application is designed to support various data formats, so in the future we can decide to disseminate multiple formats.

For more information on the ingest procedure, see chapter 6.2 in the Preservation and Dissemination Policy of the PROFILES Data Archive, available at http://www.profilesregistry.nl/Policy.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 3. The data producer provides the data together with the metadata requested by the data repository.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

The data in the PROFILES Data Archive are entered via a web form, which includes standard fields on the study, field work, questionnaire and the dataset. The metadata elements we use correspond to the DDI standard, specifically the DDI 3.1 version. The system names correspond one-to-one to DDI terminology, but for the external interface some terms have been 'translated' for the research community.

The fields include, among other:

• Collection Event

• Concept / Concept Scheme

• Data Collection

• Funding Information

• Group

• Organization / Organization Scheme

• Other Material

• Question Construct / Control Construct Scheme

• Question Item / Multiple Question Item / Question Scheme

• Representation

• Study Unit

• Variable / Variable Scheme.

See for example http://www.profilesregistry.nl/dataarchive/study_units/view/35.

The data which are archived in and disseminated via the PROFILES Registry Data Archive are also deposited in the online archiving system EASY of Data Archiving and Networked Services (DANS). Data Users have access to the metadata via the EASY system, but are referred to the PROFILES Registry Data Archive for accessing the actual data files and more detailed metadata. While the PROFILES Registry Data Archive contains metadata until question item and variable level, the EASY system of DANS, contains metadata on a study level. The metadata fields in the EASY system are guided as much as possible by the specifications of Qualified Dublin Core (see http://dublincore.org/documents/dcmi-terms/). Obligatory fields include: Title, Creator, Date created, Description, Access rights, Date available, Audience (the latter only in Standard).

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 4. The data repository has an explicit mission in the area of digital archiving and promulgates it.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

Organisation

The PROFILES Registry Data Archive is a product of the Netherlands Comprehensive Cancer Organisation and Tilburg University. Both organisations have combined responsibility and own intellectual property rights. CentERdata is the IT company that has build the PROFILES Registry Data Archive and a service contract is in place to ensure that the PROFILES Registry Data Archive stays up-to-date.

Mission

The PROFILES Registry Data Archive preserves and disseminates the data which are collected in the PROFIEL studies. The PROFIEL studies were founded to facilitate research in the social sciences in the Netherlands and abroad. This is being done by providing scientific researchers with accessible data collection and data. The data is open to academics anywhere in the world for scientific purposes, free of charge. It is a public good, with maximal scientific and societal payoff.

Scope and Objectives

The data which are collected in the PROFIEL studies are made available online for all scientific researchers via the PROFILES Registry Data Archive (see http://www.profilesregistry.nl). The aim of the archive is to provide reliable and easily accessible information, including data and metadata, on mainly quality of life of cancer survivors. In addition to its own archiving and (meta)data dissemination system, the PROFIEL studies archives its data in EASY, the online archiving system of the Dutch Data Archiving and Networked Services (DANS), to ensure long-term availability of the data.

Succession planning

The future of the PROFILES Registry Data Archive is guaranteed by the Netherlands Comprehensive Cancer Organisation. In case all funding of the PROFILES Registry Data Archive stops, the Netherlands Comprehensive Cancer Organisation guarantees basic funding that is needed to keep the system in the air and to do required updates. There is a written agreement on this matter. The datasets that are depositid in the PROFILES Registry Data Archive will also remain available through the EASY database of DANS. The data sets are depositied in the EASY database for archiving, but are only downloadable through the PROFILES Registry Data Archive. The entry in the EASY database refers to the PROFILES Registry Data Archive for downloads. There is a written agreement with DANS on this matter.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 5. The data repository uses due diligence to ensure compliance with legal regulations and contracts including, when applicable, regulations governing the protection of human subjects.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

The PROFILES Registry Data Archive is a product of the Netherlands Comprehensive Cancer Organisation and Tilburg University. Both organisations have combined responsibility and own intellectual property rights. PROFILES complies with applicable laws and regulations including the Dutch Data Protection Act (Wet Bescherming Persoonsgegevens). Furthermore, PROFILES uses working methods which are in accordance with the guidelines developed by the Association of Universities in the Netherlands (VSNU) in Code of Conduct for use of personal data in scientific research (VSNU, 2005). The PROFIEL studies is registered with the Dutch Data Protection Agency (Authoriteit Persoonsgegevens) under No: m1433221.

The Client Researchers who use the infrastructure for data collection for their study are required to sign an agreement. .

Academic researchers who wish to download and use the data of the PROFIEL studies, are required to sign a statement before receiving access to the data. This statement contains the following rules:

The undersigned hereby undertakes to carry out work on the PROFILES data, in accordance with the following conditions:

1.      He/she undertakes to keep confidential any information in the PROFILES data concerning individual persons, households, enterprises or institutions which comes to his/her knowledge during the work on the data.

2.      He/she undertakes not to distribute data of the PROFILES to others without written permission from PROFILES.

3.      He/she undertakes to use the PROFILES data for purely scientific (i.e. non-commercial) research only.

4.      He/she provides a copy of all publications based on the data to PROFILES.

5.      He/she includes the following acknowledgement: In this paper use is made of data of PROFILES (Patient Reported Outcomes Following Initial treatment and Long-term Survivorship)" and refers to the European Journal of Cancer publication : van de Poll-Franse LV, Horevoorts N, van Eenbergen M, Denollet J, Roukema JA, Aaronson NK, Vingerhoets A, Coebergh JW, de Vries J, Essink-Bot ML, Mols F; Profiles Registry Group. The Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship registry: scope, rationale and design of an infrastructure for the study of physical and psychosocial outcomes in cancer survivorship cohorts.Eur J Cancer. 2011 Sep;47(14):2188-94. Epub 2011 May 27

6.      He/she refers to the European Journal of Cancer publication in the situation when normative data are being used: van de Poll-Franse LV, Mols F, Gundy CM, Creutzberg CL, Nout RA, Verdonck-de Leeuw IM, Taphoorn MJ, Aaronson NK. Normative data for the EORTC QLQ-C30 and EORTC-sexuality items in the general Dutch population. Eur J Cancer. 2010 Dec.

7.      He/she includes a member of the PROFILES research group as co-author.

8.      PROFILES does not grant exclusivity on the data or the subject. In the situation when  proposals with a comparable subject will be submitted, PROFILES will try to find agreement between the different parties.

9.      This statement shall remain valid, even after conclusion of the work of the PROFILES data.

If a data user does not comply with the statement, we follow the following procedure:

1. The person is first personally contacted and addressed on the issue

2. Case by case, we evaluate which consequences are necessary (e.g. if a third person has received the data, he

needs to sign his own statement).

3. If the person does not cooperate to the found solution, we exclude the person from further use of the data (account is blocked).

On data disclosure risks:

To anonymize the data the key identifier has been encrypted, so that it cannot be connected to the originaladministration ID. We obviously disseminate no name and address details, geographical information (postal codes, counties, or provinces), nor too small origin categories. If a researcher requires any such data, we evaluate case by case in which terms this could be possible.

All datasets are controlled on personal information as part of the data quality check before publishing. When a dataset contains variables with a specific disclosure risk, we either only publish the metadata of these variables or we aggregate or recode the data such that the information becomes more general and does not lead to the individuals anymore. For example, if a study contains information which could lead to identifying the respondent (for example in open answer fields), we will take actions to anonymize these pieces of data (for leave out the open answer question etc.). Furthermore, the panel management system and our procedures maintain a strict division of roles and disclosure (eg. panel administrators see personal data but no survey data, researchers precisely reversed, etc.).

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 6. The data repository applies documented processes and procedures for managing data storage.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

The processes for managing the data storage of the PROFILES Registry Data Archive are described based on the OAIS model in the Preservation and Dissemination Policy of the PROFILES Registry Data Archive. This document is available at  http://www.profilesregistry.nl/Policy

In short, data is stored on several servers and back-ups are made every night. The rooms in which the servers are located, are locked and only accessible by authorised personnel. Servers are kept up-to-date and receive maintenance or are replaced when needed. System administrators receive a text message in case there is a problem on a server. In the event of a total system crash, a recovery can be done from the system back-up stored at VANCIS.

Before data is archived it goes through several processes to ensure that it is stored correctly. Processing starts with ingestion with a Submission Information Package (SIP), It is then cleaned for archving. Cleaning steps are documented in a log file. the Archival Information Package (AIP) is created. A description of the metadata is availabled through a codebook. The data is anonymised and uploaded on the archive (Dissemination Infomation Package, DIP). After checks the data set is made available for download. If for a reason a new version of the DIP is needed a version number is added to the file and changes are documented.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 7. The data repository has a plan for long-term preservation of its digital assets.

*Minimum Required Statement of Compliance:*

> 3. In progress: We are in the implementation phase.

## Applicant Entry

*Statement of Compliance:*

> 3. In progress: We are in the implementation phase.

*Self-assessment statement:*

> **Currently data is deposited in SPSS format. However, the PROFILES Registry Data Archive is build to support various data formats. If in the future developments lead to the need for new or other data formats the PROFILES Registry Data Archive is able to support these, or will be adapted to support these. For the necessary updates we have a serivce contract with CentERdata, the software developer of the PROFILES Registry Data Archive.**

> The strategy to reduce the risk of obsolescence is also based on storing multiple copies on different storage media on different sites. Once one of the sites collapses, this can be repaired by restoring the data from the other sites. To prevent sites from collapsing, all servers involved are placed in climate controlled professional server rooms. Preservation (planning functional entity) is further secured by backing up the data. All servers on which PROFILES data are stored are backed up on a daily base. The backups are encrypted and stored on a different location. CentERdata is responsible for the backups. These backups are done by Vancis, the Dutch super computer center. Through this the archival storage function is implemented. A System Administrator of CentERdata is responsible for the operations of the server park. This includes the tasks of the administration functional entity. Also the updates of the software packages are done by this system administrator.

> In addition to its own system, PROFILES archives the published data files and codebooks in the EASY system of DANS, including study level metadata as is contained in the EASY system. Currently, DANS creates persistent identifiers, in this case URNs, for the PROFILES data files when they are ingested by the EASY system. These can be viewed on the website of the EASY system.

## Reviewer Entry

*Accept or send back to applicant for modification:*

> Accept

*Comments:*

> This is clear.

## 8. Archiving takes place according to explicit work flows across the data life cycle.

*Minimum Required Statement of Compliance:*

3. In progress: We are in the implementation phase.


## Applicant Entry

*Statement of Compliance:*

3. In progress: We are in the implementation phase.

*Self-assessment statement:*

The complete work flow throughout the data life-cycle, from collecting the data to data dissemination, is described in the Preservation and Dissemination Policy of the PROFILES Registry Data Archive. This document is available at http://www.profilesregistry.nl/Policy


The work flow of the ingest phase of the data life-cycle, in which the data are entered into an archive, can be divided into two parts. Ingesting the data into the PROFILES Data Archive, and ingesting the data into the EASY system of DANS. We describe both here below.


When a questionnaire has been fielded in the PROFILES studies, the concerned PROFILES Project Leader processes the raw data into a SIP. All data processing steps are documented in and run by using an SPSS syntax file to ensure a full audit-trail to the original data file and a reconstruction of the data processing.


For preparing the SIP, PROFILES Project Leaders follow a procedure which is documented in the form of a checklist, containing data and metadata requirements and quality checks. For each Submission Information Package (SIP), there is an internal second-reader-control before the SIP is delivered to the Data Archive Employee. When the Data Archive Employee  receives the SIP, he controls the concerned data and metadata before ingest in the PROFILES Registry Data Archive. Before the SIP is transformed into an AIP and accepted into the PROFILES Registry Data Archive, the Data Archive Employee  follows a Data Entry Check-list, which defines the controls to carry out on the data and metadata in submission. There are also several systematic checks within the data-entry forms used for entering (meta)data into the PROFILES Data Archive, which prevent entering incorrect or duplicate (meta)data.


The data which are archived in and disseminated via the PROFILES Registry Data Archive are also deposited in the online archiving system EASY of Data Archiving and Networked Services (DANS). DANS stores the data in a permanent and sustainable manner, according to the guidelines of the international Data Seal of Approval. These data are systematically entered into the EASY system by a Data Archive Employee of PROFILES.

When these data have been uploaded to the EASY system, a dedicated DANS employee controls the data and if necessary contacts the PROFILES Data Archive Employee before the data are ingested into the DANS EASY system. DANS and PROFILES have a license agreement for  archiving in the EASY system .

For data access, the option 'Other access: no access via EASY' is given. This means that Data Users have access to the metadata via the EASY system, but are referred to the PROFILES Registry Data Archive for accessing the actual data files. For more information on this license agreement and to download the rules of the license, please view http://www.dans.knaw.nl/en/content/dans-licence-agreement-deposited-data

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

OK!

## 9. The data repository assumes responsibility from the data producers for access and availability of the digital objects.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

The data that is disseminated on the PROFILES Registry Data Archive are collected by PROFILES itself. Therefore there has been no need for contractual agreements and enforcements.

With regard to crisis management, multiple copies of the data and of the system itself are stored on different storage media on different sites. Once one of the sites collapses, this can be repaired by restoring the data from the other sites. To prevent sites from collapsing, all servers involved are placed in climate controlled professional server rooms. Preservation (planning functional entity) is further secured by backing up the data. All servers on which PROFILES data are stored are backed up on a daily base. The backups are encrypted and stored on a different location. CentERdata is responsible for the backups. These backups are done by Vancis, the Dutch super computer center. Through this the archival storage function is implemented. A System Administrator of CentERdata is responsible for the operations of the server park. This includes the tasks of the administration functional entity. Also the updates of the software packages are done by this system administrator.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

OK

## 10. The data repository enables the users to discover and use the data and refer to them in a persistent way.

*Minimum Required Statement of Compliance:*

3. In progress: We are in the implementation phase.

## Applicant Entry

*Statement of Compliance:*

3. In progress: We are in the implementation phase.

*Self-assessment statement:*

Access to the PROFILES data is simple and open to every academic researcher, both in the Netherlands and abroad.

An extensive set of metadata on the whole life-cycle of the research project are freely accessible to the public on the website (www.profilesregistry.nl/dataarchive), including information on the study objectives, details on data collection, the entire questionnaire and metadata on the data file and individual variables. Also information on publications related to the data is provided when available. On the website one can use several ways to search within the database, such as free keyword search, browsing lists of studies, or a topic or concept based search.

Currently, DANS creates persistent identifiers, in this case URNs, for the PROFILES data files when they are ingested by the EASY system. These can be viewed on the website of the EASY system. We are working on implementing persistent identifiers to the PROFILES Registry Data Archive too.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 11. The data repository ensures the integrity of the digital objects and the metadata.

*Minimum Required Statement of Compliance:*

3. In progress: We are in the implementation phase.

## Applicant Entry

*Statement of Compliance:*

3. In progress: We are in the implementation phase.

*Self-assessment statement:*

To enable controlling on the integrity of data files, of all uploaded files (data files, codebooks, images etc), a MD5 and SHA1 checksum are calculated when the file is uploaded to the server. It is possible to check the integrity of the data file by recalculating the checksum of the current files on the server and compare those values with the checksum determined during upload of the file. This checksums are currently calculated by the system but by default not externally displayed. There is also a history of versions logged which can be looked up if needed. Upon request the checksums can be provided to the Data User to view and control the integrity of the data file he has downloaded.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

OK

## 12. The data repository ensures the authenticity of the digital objects and the metadata.

*Minimum Required Statement of Compliance:*

3. In progress: We are in the implementation phase.

## Applicant Entry

*Statement of Compliance:*

3. In progress: We are in the implementation phase.

*Self-assessment statement:*

The administrative information on the PROFILES Registry Data Archive database events and requests are logged by the application and can be used to verify past events. To access the data archival system, one must be uniquely logged in. Data Users who are logged in, gain limited rights to operate within the system, mainly to download the published datasets and to view and edit parts of their personal account information. Internally, PROFILES employees have to register for accessing the system and depending on the tasks, a specific role is allocated to the employee. The access rights within the system are dependent on this role. Each handling within the system is logged and can be trailed back to the individual user.

The data deposited in the PROFILES Data Archive are data collected and managed within the PROFILES panel. When data files are created at the end of the data collection process, all data processing steps are documented in SPSS syntax files, which are stored by CentERdata. Data file names include an extension which stands for the version number (x.x) and for each time anything is altered in a data file this receives a new version number. This procedure, including the file name which is saved, is included in the syntax files.

As part of the SIP, a metadata document, a codebook, is created. The file name of this document follows the same versioning procedure as that of the data file.

Old versions of data files remain stored, but only the newest version of any file, such as the data file or codebook, is disseminated at a given moment.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

On the whole OK

## 13. The technical infrastructure explicitly supports the tasks and functions described in internationally accepted archival standards like OAIS.

*Minimum Required Statement of Compliance:*

3. In progress: We are in the implementation phase.

## Applicant Entry

*Statement of Compliance:*

3. In progress: We are in the implementation phase.

*Self-assessment statement:*

CentERdata has developed its own system for data archiving and dissemination, called Questasy. This system is the technical basis of the PROFILES Registry Archive and all questionnaires in the panel are disseminated via this system. Questasy is based on version 3 of the Data Documentation Initiative (DDI). Version 3 of the DDI introduces a life-cycle approach of documenting survey projects and distinguishes between the metadata of questions (data collection) and variables (dataset). See the DDI Alliance website for more information (http://www.ddialliance.org).

Questasy is a web application built using a PHP framework and uses a relational database to store data. The LISS Questasy server is also harvestable via an OAI-PMH implementation. Questasy source code is available for free to scientific, academic, and governmental non-profit organizations. More information on Questasy can be found at the following sources:
http://www.ddialliance.org/sites/default/files/QuestasyDocumentingAndDisseminatingLongitudinalDataUsingDDI3.pdf

http://www.iassistdata.org/downloads/iqvol3312amin.pdf

http://www.centerdata.nl/sites/default/files/bestanden/factsheet_ddi.pdf

According to the OAIS model (Open Archival Information System), the data processing can be divided into six functional entities and related interfaces: ingest, data management, archival storage, access, preservation planning and administration. These different tasks are recognized related to the PROFILES Registry Data Archive and described applying the OAIS functional model in the Preservation and Dissemination Policy of the PROFILES Data Archive, available at http://www.profilesregistry.nl/Policy. In addition, PROFILES carries out and describes tasks included in the pre-ingest process, namely data collection.

In developing data dissemination protocols and procedures, close collaboration is aimed at through CentERdata with CESSDA (Council of European Social Science Data Archives) and DANS (Data Archiving & Networked Services).

**Reviewer Entry**

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 14. The data consumer complies with access regulations set by the data repository.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

The metadata of the PROFILES studies can be freely accessed by all via the profilesregistry.nl website. To access and download the data files, one must sign a statement and comply to the following conditions of use:

The undersigned hereby undertakes to carry out work on the PROFILES data, in accordance with the following conditions:

He/she undertakes to keep confidential any information in the PROFILES data concerning individual persons, households, enterprises or institutions which comes to his/her knowledge during the work on the data.

1.

He/she undertakes not to distribute data of the PROFILES to others without written permission from PROFILES.

2.

He/she undertakes to use the PROFILES data for purely scientific (i.e. non-commercial) research only.

3.

He/she provides a copy of all publications based on the data to PROFILES.

4.

He/she includes the following acknowledgement: In this paper use is made of data of PROFILES (Patient Reported Outcomes Following Initial treatment and Long-term Survivorship)" and refers to the European Journal of Cancer publication : van de Poll-Franse LV, Horevoorts N, van Eenbergen M, Denollet J, Roukema JA, Aaronson NK, Vingerhoets A, Coebergh JW, de Vries J, Essink-Bot ML, Mols F; Profiles Registry Group. The Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship registry: scope, rationale and design of an infrastructure for the study of physical and psychosocial outcomes in cancer survivorship cohorts.Eur J Cancer. 2011 Sep;47(14):2188-94. Epub 2011 May 27

5.

He/she refers to the European Journal of Cancer publication in the situation when normative data are being used: van de Poll-Franse LV, Mols F, Gundy CM, Creutzberg CL, Nout RA, Verdonck-de Leeuw IM, Taphoorn MJ, Aaronson NK. Normative data for the EORTC QLQ-C30 and EORTC-sexuality items in the general Dutch population. Eur J Cancer. 2010 Dec.

6.

He/she includes a member of the PROFILES research group as co-author.

7.

PROFILES does not grant exclusivity on the data or the subject. In the situation when  proposals with a comparable subject will be submitted, PROFILES will try to find agreement between the different parties.

8.

This statement shall remain valid, even after conclusion of the work of the PROFILES data.

9.

If a person requests to access restricted data, we evaluate case by case in which terms this could be possible. For example only on-site access at PROFILES could sometimes be granted. If a data user does not comply with the rules, we follow the following procedure:

1. The person is first personally contacted and addressed on the issue

2. Case by case, we evaluate which consequences are necessary (e.g. if a third person has received the data, he

needs to sign his own statement).

3. If the person does not cooperate to the found solution, we exclude the person from further use of the data (account is blocked).

For more about the rules and conditions, see

http://www.profilesregistry.nl/RulesConditions

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 15. The data consumer conforms to and agrees with any codes of conduct that are generally accepted in the relevant sector for the exchange and proper use of knowledge and information.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

PROFILES's working methods are in accordance with the guidelines developed by the VSNU (Association of Universities in the Netherlands) in its 'Gedragscode voor gebruik van persoonsgegevens in wetenschappelijk onderzoek' (Code of Conduct for use of personal data in scientific research, 2005, VSNU). PROFILES will also at all times comply with applicable laws and regulations including the Dutch Data Protection Act (Wet Bescherming Persoonsgegevens).

Data users comply to the code of conduct in the statement which they need to sign to access the data files:

The undersigned hereby undertakes to carry out work on the PROFILES data, in accordance with

the following conditions:

He/she undertakes to keep confidential any information in the PROFILES data concerning individual persons, households, enterprises or institutions which comes to his/her knowledge during the work on the data.

1.

He/she undertakes not to distribute data of the PROFILES to others without written permission from PROFILES.

2.

He/she undertakes to use the PROFILES data for purely scientific (i.e. non-commercial) research only.

3.

He/she provides a copy of all publications based on the data to PROFILES.

4.

He/she includes the following acknowledgement: In this paper use is made of data of PROFILES (Patient Reported Outcomes Following Initial treatment and Long-term Survivorship)" and refers to the European Journal of Cancer publication : van de Poll-Franse LV, Horevoorts N, van Eenbergen M, Denollet J, Roukema JA, Aaronson NK, Vingerhoets A, Coebergh JW, de Vries J, Essink-Bot ML, Mols F; Profiles Registry Group. The Patient Reported Outcomes Following Initial treatment and Long term Evaluation of Survivorship registry: scope, rationale and design of an infrastructure for the study of physical and psychosocial outcomes in cancer survivorship cohorts.Eur J Cancer. 2011 Sep;47(14):2188-94. Epub 2011 May 27

5.

He/she refers to the European Journal of Cancer publication in the situation when normative data are being used: van de Poll-Franse LV, Mols F, Gundy CM, Creutzberg CL, Nout RA, Verdonck-de Leeuw IM, Taphoorn MJ, Aaronson NK. Normative data for the EORTC QLQ-C30 and EORTC-sexuality items in the

general Dutch population. [Eur J Cancer.](#) 2010 Dec.

6.

He/she includes a member of the PROFILES research group as co-author.

7.

PROFILES does not grant exclusivity on the data or the subject. In the situation when proposals with a comparable subject will be submitted, PROFILES will try to find agreement between the different parties.

8.

This statement shall remain valid, even after conclusion of the work of the PROFILES data.

9.

During the process of analysing the data researchers of PROFILES can be consulted and one of the researchers is included as a co-author. In this way PROFILES can keep an eye on the right interpretation of the data.

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

## 16. The data consumer respects the applicable licences of the data repository regarding the use of the data.

*Minimum Required Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

## Applicant Entry

*Statement of Compliance:*

4. Implemented: This guideline has been fully implemented for the needs of our repository.

*Self-assessment statement:*

Data users are required to sign a statement before accessing the data.

Information on this statement is available at

http://www.profilesregistry.nl/RulesConditions

This agreement remains valid even after the completion of work on the data.

If a data user does not comply with the statement, we follow the following procedure:

1. The person is first personally contacted and addressed on the issue

2. Case by case, we evaluate which consequences are necessary (e.g. if a third person has received the data, he

needs to sign his own statement).

3. If the person does not cooperate to the found solution, we exclude the person from further use of the data (account is blocked).

## Reviewer Entry

*Accept or send back to applicant for modification:*

Accept

*Comments:*

OK!