

# CESSDA ERIC

Consortium of European Social Science Data Archives  
European Research Infrastructure Consortium

## GDPR and research one year on – Experiences across Europe



Webinar and Panel discussion  
27 June 2019

Scott Summers, Lecturer Business Law, University of East Anglia, UK

Oliver Watteler, GESIS - Leibniz-Institute for the Social Sciences, Germany

Anne-Mette Somby, Special Adviser Data Protection Services, Norwegian Centre for Research Data, Norway

Marlon Domingus, Data Protection Officer, Erasmus University Rotterdam, Netherlands

*Moderator: Veerle Van den Eynden, UK Data Service*



# Overview

Briefly: what is the GDPR

Experiences from the UK

Experiences from Germany

Experiences from Norway

Experiences from the Netherlands

Questions: submit via GoToWebinar

Let's ask YOU some questions first 😊

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# The General Data Protection Regulation (GDPR)

- » EU-wide data protection regulation that came into force a year ago on the **25 May 2018**
- » Enables **data subjects** to have **greater control** over their **personal data**, whilst **modernising** and **unifying** European **data protection rules**
- » Permits EU Member States – in certain areas – to make **specific domestic provisions** for **particular aspects** of the **GDPR**
- » Applies to **personal data** and data of **living persons**
- » Applies to:
  - data controller / data processor in the EU **who collects personal data** about a data subject of **any country, anywhere in the world**
  - data controller or data processor based outside the EU but collects personal data on EU citizens

# Personal, Pseudonymised, Anonymous data

## Personal data

- » **any information** relating to an **identified** or **identifiable** natural **person** ('data subject')

## Pseudonymised data

- » the personal data can **no longer be attributed** to a **specific data subject** without the **use of additional information**

## Anonymous Data

- » data that cannot identify individuals in any way: anonymisation **irreversibly destroys any way of identifying the data subject**

# Principles for processing personal data

## 1. Process **lawfully, fairly** and **transparently**

*Inform the participant of what will be done with the data, process accordingly*

## 2. Keep to the **original purpose**

*Collect data for specified, explicit and legitimate purposes; do not process further in a manner incompatible with those purposes*

## 3. **Minimise** data size

*Personal data collected should be adequate, relevant and limited to what is necessary*

## 4. Uphold **accuracy**

*Personal data should be accurate and kept up to date*

## 5. Remove data which are not used

## 6. Ensure **data integrity** and **confidentiality**

*Protection against unauthorised or unlawful processing, accidental loss, destruction or damage, using appropriate technical or organizational measures*

# Archiving and research exemption

*Processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, shall be subject to appropriate safeguards, in accordance with this Regulation, for the rights and freedoms of the data subject. Those safeguards shall ensure that **technical and organisational measures** are in place in particular in order to ensure respect for the principle of **data minimisation**. Those measures may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner*

- » Principle(s) 2. and 5. are less strict
- » 2. Purpose: further processing allowed
- » 5. Personal data may be stored for longer periods

# Six grounds for processing personal data

One of these is required in order to process a data subject's personal data:

1. Consent
2. Contract
3. Legal obligation
4. Vital interests
5. Public interest
6. Legitimate interest



# Data subject rights

- » The right to be informed
- » The right of access
- » The right to rectification
- » The right to erasure - the 'right to be forgotten'
- » The right to restrict processing
- » The right to data portability
- » The right to object
- » Rights in relation to automated individual decision-making and profiling



# Experiences UK

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# Changes in the UK

- » Data Protection Act 1998 → Data Protection Act 2018
- » From 8 to 6 data protection principles
- » Processing grounds: heavy push for 'public task' in research
- » Revisiting what 'anonymisation' means in research
- » Placing data subject's privacy at the center of any research project

# Changes in the UK

- » Privacy Impact Assessments or Data Protection Impact Assessments
- » Security – and storage – of personal data (and research data) that is collected
- » Providing greater transparency and clarity to participants
- » Who is the data controller?
- » An opportunity to highlight the importance of considering data sharing / archiving when collecting research data

# Experiences Germany

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# „Great commotion“

- GDPR entering into force- uncertainties about content and transition to new regulations
- Main obvious reason: structure of GDPR
- *“If you have been used to German data protection legislation not much change”*  
Niklaus Forgó, University of Vienna (MOOC, 2018)
- Issues adding to uncertainty (among others):
  - Privacy by design / privacy by default (Art 23)
  - „Privacy Breach Notification“ (Art 32 and 33)
  - Sanctions:
    - Right to an effective judicial remedy against a controller or processor (Art 79)
    - Fines (Art 83)!

# Issue: “Anonymization”

- “Anonymization” at the core of scientific activities in human subject research in Germany
- Federal Constitutional Court (1983) > “factual anonymity” > core idea: risk minimization
- German Data Protection Law until 2018 (Art 3, Sect 6, 3):  
“‘Rendering anonymous’ shall mean the alteration of personal data so that information concerning personal or material circumstances  
[a] cannot be attributed to an identified or identifiable natural person  
[absolute anonymous] or  
[b] that such attribution would require a disproportionate amount of time, expense and effort [factual anonymous]”
- GDPR: “Anonymous” only mentioned once in Recital 26 (GDPR)
- Clarification needed for working with data in human subject research
- For the German social science community:  
German Data Forum (data infrastructure stakeholders) took a stance  
> continue working with a kind of “factual anonymity”

# Other issues

## General

- Organization of e-mail lists: new consent
- Possible dissuasions with costs by lawyers for unclear or incomplete data protection statements

## Research

- International data exchange within and beyond the European Union
  - we still do this for scientific purposes
- More explicit consent forms also covering the data archiving after projects end
- More involvement of data protection officers or universities' legal advisors when drafting data service or archiving agreements
- Pending: discussion on handling “personal data” from authors or primary investigators in citations etc.



# Data protection at GESIS

- More request by research projects on demands for data/privacy protection  
> higher level of awareness
- Consent forms for population surveys like the German GSS
- Demanding proof of informed consent from cooperation partners in international survey programs (e.g. European Values Study 2017)
- Handling “pseudonymized” data by cooperation partners in international survey programs
- Still pending: “Data protection impact assessment“ (Art 35)

# Experiences Norway

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# Norway experiences

- NSD provides assessment for research projects processing personal data since 1981 (directive 95/46/EC)
- GDPR has resulted in a growth in the number of projects seeking assessment (approximately 60%)
- Institutions are more responsible and use more resources on meeting the demands in GDPR and training for their staff
- Researchers find the new regulation more demanding when it comes to obtaining consent and protect privacy
- Recordings – video considered personal data
- As an archive we find that the new regulation allows for data to be reused and shared more easily than before (At least in theory)

# Consent as legal basis - implications after GDPR

- Before GDPR: oral information and oral consent was practiced in qualitative studies (fieldwork), and “silent” consent
- Now: oral consent has to be recorded, and “silent” consent is not allowed
- New information sheet template (NSD)
  - Much new and mandatory information, e.g. participants rights
  - Template will ensure consent as a legal basis
  - Researchers find it difficult to use
- When impossible to ensure consent (recorded, in written document or with electronic signature) in qualitative research, then other legal basis will be used
- Consent is legal basis for most research, this is different from Finland, Sweden and Denmark where legal basis for processing personal data is “public interest” (art. 6.1 e and art. 9. 2 j)
- Public interest is most commonly used as legal basis for:
  - Data collected on the internet
  - Public registries
  - Data collected in anthropology studies/fieldwork

# Children and consent as a legal basis

- Age for consent is regulated in national legislation

Norway:

- Personal Data Act and Health laws states 18/16 years, some cases younger children can give consent (consent as the legal basis)
- For children under the age of 16 years parents have to give consent

Consequences:

- Difficult to gain consent, parents do not respond to request to participation
- Difficult to document consent
- Both parents have to give their consent
- Children are considered vulnerable – DPIA often required

# Data Protection Impact Assessment (DPIA)

- Article 35 defines when DPIA is required, what it should contain and who will implement it
- New obligation with the GDPR
- Ensure safeguards for the registered
- When likely to result in a high risk to the rights and freedoms of natural persons
- The controller shall seek the advice of the data protection officer when carrying out a DPIA

## Norway:

- NSD perform DPIA based on the research notification form from the researcher
- DPIA is performed based on a template that ensures that all relevant elements is included
- NSD has performed more than 100 DPIAs
- The DPIA will be formally approved by the institution (data controller) and the local Data Protection Officer

# Experiences Netherlands

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# Overview Privacy Legislation - The Netherlands

Name legislation	Personal Data Registration Act (WPR)	Personal Data Protection Act (WBP)	General Data Protection Regulation (GDPR)
Effective from:	1 July 1989	1 September 2001	25 May 2018
Personal Data:	Any information relating to an identified or identifiable natural person	Any information relating to an identified or identifiable natural person	Any information relating to an identified or identifiable natural person
Purpose Legislation:	Focuses on the <i>registration</i> of personal data.	Focuses on the <i>processing</i> of personal data.	Focuses on the <i>protection of natural persons</i> in relation to the processing of personal data.
Supervisor:	Registration Chamber	Personal Data Authority	Data Protection Authority
Holder / Controller:	Holder: the person authorised to determine the purpose, content and use of the registration.	Controller: the person (natural or legal) who determines the purposes and means of the processing of personal data.	Controller: the person (natural or legal) which determines the purposes and means of the processing of personal data.
Processor:	Third party processing data on behalf of the <i>holder</i> .	The person who processes personal data on behalf of the <i>controller</i> without being subject to his direct authority.	A natural or legal person, public authority, agency or other body which processes personal data on behalf of the <i>controller</i> .
DPO:	-	Data protection official (optional)	Data protection officer (mandatory for public authorities or bodies and in certain cases for the private sector.)
Public / Private:	Distinguishes public sector (regulatory duty) and private sector (obligation to register).	No distinction: both subject to reporting.	No distinction: both subject to the obligation to demonstrate that the processing of personal data complies with the GDPR.





# National Initiatives: National Coordination Point RDM

## Data stewardship



Completed

### Data Stewardship

Maarten van Bentum (UT), Mijke Jetten (RU), Nicole Koster (UT), Toine Kuiper (TUE), Jan Lucas van der Ploeg (UMCG), Gera Pronk (ISSeeTea), Martine Pronk (UU), Saskia Rademaker (HHS), Marta Teperek (TUD), Marijke Verheij (RUG), Marije van der Geest (UMCG). Namens de Adviesgroep: Henk van den Hoogen (UM), Annemie Mordant (Memic/UM), Jacquelyn Ringersma (WUR)

[Private page.](#)

The task group was being supported by Melanie Imming ([immingimpact.eu](https://www.immingimpact.eu))

## Privacy risks



Purpose: The idea is to work out a DPIA per scenario and to subsequently maintain it, so that for a majority of new research the selection of a scenario will be sufficient to be compliant.

[Short pitch](#) | [Extended version](#)

Erik van den Beld (Saxion), Marlon Domingus (EUR), Pam Dupont (Tiu), Raymond van Erkel (LEI), Jasper de Groot (UU), Mijke Jetten (RU), Cristina Montagner (RUG), Fieke Schoots (LEI), Marco Teunisse (UvA), Dick Vestdijk (HU), Raoul Winkens (UM)

Focus group: Jantien van Berkel (WUR), Mareike Boom (LEI), Martijn den Hamer (HvA), Jessica Hruday (VU), vertegenwoordiger van NETHICS, Sander Nieuwenhuis (DSW sub-committee 'Scientific integrity, data storage and reproducibility'), Jacqueline Tenkink (UU)

First meeting: 9 July 2019

## Data collaboration



Purpose: Draw up an inventory of institute transcending research projects (use cases), call attention to hindrances, map which incompatible policies causes obstacles and describe implications and solutions.

[Short pitch](#) | [Extended version](#)

Marlon Domingus (EUR), Peter Hinrich (SURF), Monic Hodes (UU), Patrick Hoetink (UT), Wouter Kool (LEI), Sonja Meeuwssen (LUMC), Judith Pijnacker (SURF), Jan Rijnders (RU), Jacquelyn Ringersma (WUR), Jolien Scholten (VU), Yan Wang (TUD), Iza Witkowska (UU)

Focus group: Toine Kuiper (TUE), Francisco Romero (RUG), Henk van der Zijden (Hanze)

[Private page.](#)

Next meeting: 24 June 2019

## Pseudonymization



Purpose: Present best practices of pseudonymization and key file management, collected by means of questionnaires and interviews.

[Short pitch](#) | [Extended version](#)

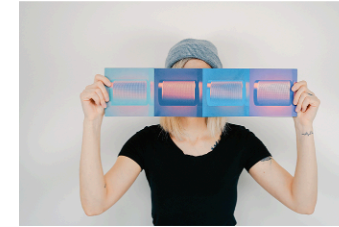
Henk van den Hoogen (UM; adviesgroep), Erik Jansen (UM), Simone van Kleef (Antonius zh), Tineke van der Meer (HU), Martiene Moester (LUMC), Jan Lucas van der Ploeg (UMCG), Francisco Romero Pastrana (RUG), Jolien Scholten (VU), Leander van der Spek (UvH)

Focus group: Derk Arts (Castor), Marlon Domingus (EUR), Laura Huis in 't Veld (DANS), Nicole Koster (UT), Karin van der Pal (LUMC), Alfons Schroten (UM/MEMIC)

[Private page.](#)

In completion phase.

## Anonymization



Purpose: Review of GDPR definition, discuss balance between open science and privacy rights, assess the re-identification risks of various types of data: consider likelihood, feasibility and impact of re-identification with such data.

[Short pitch](#) | [Extended version](#)

Yvonne Drost (UMCU), Henk van den Hoogen (UM, lid LCRDM adviesgroep), Jessica Hruday (VU), Santosh Ilamparuthi (TUD), Toine Kuiper (TUE), Jan Lucas van der Ploeg (UMCG), Joan Schrijvers (UvA), Erik Tjong Kim Sang (eScience), Niek van Ulzen (HvA), Arnold Verhoeven (UM)

Focus group: Floor Knuistingh Neven (UvA), Tineke van der Meer (HU), Alfons Schroten (UM/MEMIC), Nicole Koster (UTwente), Francisco Romero Pastrana (RUG)

[Private page.](#)

Next meeting: 18 June 2019

## Workspaces



Purpose: Propose criteria for a GDPR compliant virtual research environment as well as provide seven use cases.

[Short pitch](#) | [Extended version](#)

Jeroen Beliën (VUmc), Ymke van den Berg (SURF), Erik van den Bergh (WUR), Jan Willem Boiten (namens Adviesgroep), Lolke Boonstra (TUD), Hans Brouwers (RUG), Mark Cole (SURF), Erik Flikkenschild (LUMC), Maarten Hoogerwerf (UU), Taco Horsley (UvA), Philipp Weissert (RUG)

[Private page.](#)

In completion phase.

# Trend: Appropriate Measures for Research Scenarios (scaleable).

## *Individual research*

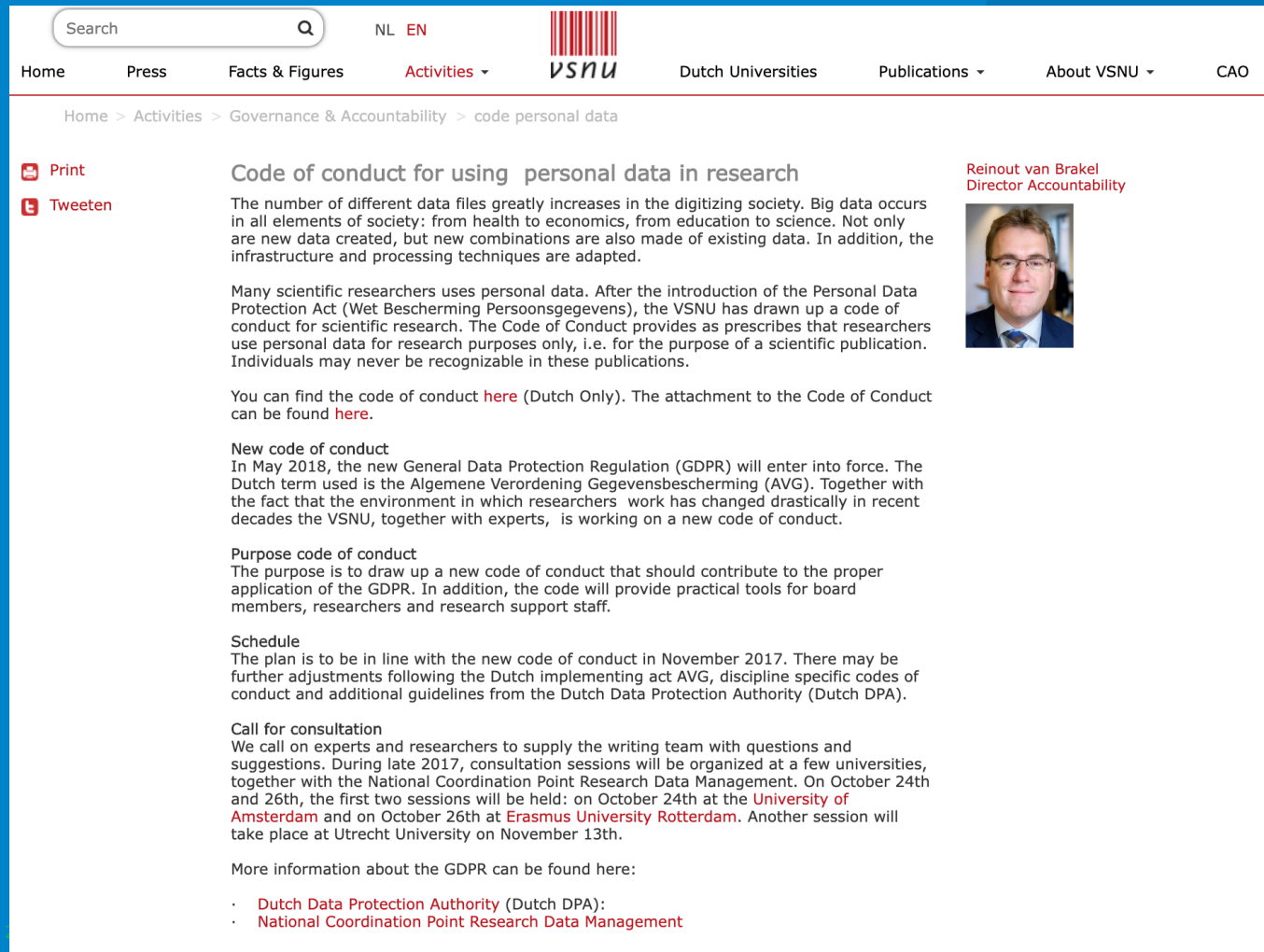
Research Scenarios and Accompanying Typical Relevant Legal Documents & Agreements							
# Research Scenario	Re-use of Personal Data (PD)	Collection of Personal Data (PD)	Re-use of Special Categories of Personal Data (SCPD) in the dataset	Collection of Special Categories of Personal Data (SCPD) in the dataset	Collaboration with third parties (Academia / Public / Private) and/or Service Providers processing (SC)PD	Cross Border Data Transfers	Relevant documents for you
1. Individual research, further processing PD, within European Economic Area and including Adequacy Decision (EEA*)	yes	yes	no	no	no	no	With data provider(s): 1. data sharing agreement or: 2. data processing agreement or: 3. non disclosure agreement
2. Individual research, further processing PD, outside EEA*	yes	yes	no	no	no	yes	With data provider(s): 1. data sharing agreement or: 2. data processing agreement or: 3. non disclosure agreement
3. Individual research, data collection & further processing PD, within EEA*	yes	yes	yes	yes	no	no	With data provider(s): 1. data sharing agreement or: 2. data processing agreement or: 3. non disclosure agreement  With data subjects: 1. consent form
4. Individual research, data collection & further processing PD, outside EEA*	yes	yes	yes	yes	no	yes	With data provider(s): 1. data sharing agreement or: 2. data processing agreement or: 3. non disclosure agreement  With data subjects: 1. consent form

# Research Scenarios - continued

## *Collaborative research:*


Research Scenarios and Accompanying Typical Relevant Legal Documents & Agreements							
# Research Scenario	Re-use of Personal Data (PD)	Collection of Personal Data (PD)	Re-use of Special Categories of Personal Data (SCPD) in the dataset	Collection of Special Categories of Personal Data (SCPD) in the dataset	Collaboration with third parties (Academia / Public / Private) and/or Service Providers processing (SC)PD	Cross Border Data Transfers	Relevant documents for you
5. Research Group, further processing PD, within European Economic Area and including Adequacy Decision (EEA*)	yes	yes	no	no	no	no	<p>With data provide(s):</p> <ol style="list-style-type: none"> <li>1. data sharing agreement or:</li> <li>2. data processing agreement or:</li> <li>3. non disclosure agreement</li> </ol> <p>With partner(s):</p> <ol style="list-style-type: none"> <li>1. joint controller agreement</li> </ol>
6. Research Group, further processing PD, outside EEA*	yes	yes	no	no	no	yes	<p>With data provider(s):</p> <ol style="list-style-type: none"> <li>1. data sharing agreement or:</li> <li>2. data processing agreement or:</li> <li>3. non disclosure agreement</li> </ol> <p>With partner(s):</p> <ol style="list-style-type: none"> <li>1. joint controller agreement</li> <li>2. standard contractual clauses</li> </ol>
7. Research Group, data collection & further processing PD, within EEA*	yes	yes	yes	yes	no	no	<p>With data provide(s):</p> <ol style="list-style-type: none"> <li>1. data sharing agreement or:</li> <li>2. data processing agreement or:</li> <li>3. non disclosure agreement</li> </ol> <p>With partner(s):</p> <ol style="list-style-type: none"> <li>1. joint controller agreement</li> </ol> <p>With data subjects:</p> <ol style="list-style-type: none"> <li>1. consent form</li> </ol>
8. Research Group, data collection & further processing PD, outside EEA*	yes	yes	yes	yes	no	yes	<p>With data provider(s):</p> <ol style="list-style-type: none"> <li>1. data sharing agreement or:</li> <li>2. data processing agreement or:</li> <li>3. non disclosure agreement</li> </ol> <p>With partner(s):</p> <ol style="list-style-type: none"> <li>1. joint controller agreement</li> <li>2. standard contractual clauses</li> </ol> <p>With data subjects:</p> <ol style="list-style-type: none"> <li>1. Consent Form</li> </ol>

# Work in progress (since 2016): National Code of Conduct for processing Personal Data





The screenshot shows the VSNU website with a search bar at the top left and navigation links for Home, Press, Facts & Figures, Activities, Dutch Universities, Publications, About VSNU, and CAO. The breadcrumb trail reads: Home > Activities > Governance & Accountability > code personal data. On the left side, there are social media sharing options for Print and Tweet. The main content area features the title 'Code of conduct for using personal data in research' and a portrait of Reinout van Brakel, Director of Accountability. The text discusses the increase in data files in the digitizing society, the introduction of the Personal Data Protection Act (Wet Bescherming Persoonsgegevens), and the development of a code of conduct for scientific research. It also mentions the new General Data Protection Regulation (GDPR) and the Dutch term Algemene Verordening Gegevensbescherming (AVG). The page includes sections for 'New code of conduct', 'Purpose code of conduct', 'Schedule', and 'Call for consultation'. At the bottom, there are links for more information about the GDPR, including the Dutch Data Protection Authority (DPA) and the National Coordination Point Research Data Management.

Search  NL EN

Home Press Facts & Figures **Activities**  Dutch Universities Publications About VSNU CAO

Home > Activities > Governance & Accountability > code personal data

 Print

 Tweet

## Code of conduct for using personal data in research

The number of different data files greatly increases in the digitizing society. Big data occurs in all elements of society: from health to economics, from education to science. Not only are new data created, but new combinations are also made of existing data. In addition, the infrastructure and processing techniques are adapted.

Many scientific researchers use personal data. After the introduction of the Personal Data Protection Act (Wet Bescherming Persoonsgegevens), the VSNU has drawn up a code of conduct for scientific research. The Code of Conduct provides as prescribes that researchers use personal data for research purposes only, i.e. for the purpose of a scientific publication. Individuals may never be recognizable in these publications.

You can find the code of conduct [here](#) (Dutch Only). The attachment to the Code of Conduct can be found [here](#).

### New code of conduct

In May 2018, the new General Data Protection Regulation (GDPR) will enter into force. The Dutch term used is the Algemene Verordening Gegevensbescherming (AVG). Together with the fact that the environment in which researchers work has changed drastically in recent decades the VSNU, together with experts, is working on a new code of conduct.

### Purpose code of conduct

The purpose is to draw up a new code of conduct that should contribute to the proper application of the GDPR. In addition, the code will provide practical tools for board members, researchers and research support staff.

### Schedule

The plan is to be in line with the new code of conduct in November 2017. There may be further adjustments following the Dutch implementing act AVG, discipline specific codes of conduct and additional guidelines from the Dutch Data Protection Authority (Dutch DPA).


### Call for consultation

We call on experts and researchers to supply the writing team with questions and suggestions. During late 2017, consultation sessions will be organized at a few universities, together with the National Coordination Point Research Data Management. On October 24th and 26th, the first two sessions will be held: on October 24th at the [University of Amsterdam](#) and on October 26th at [Erasmus University Rotterdam](#). Another session will take place at Utrecht University on November 13th.

More information about the GDPR can be found here:

- [Dutch Data Protection Authority](#) (Dutch DPA):
- [National Coordination Point Research Data Management](#)


**Reinout van Brakel**  
Director Accountability



Source: [https://www.vsnunl/en\\_GB/code-personal-data](https://www.vsnunl/en_GB/code-personal-data)

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# National Training Program: Data Support



The screenshot shows the website for 'Essentials 4 Data Support' by RDNL (Research Data Netherlands). The page features a navigation bar with 'Website RDNL', 'Home course', 'Contact', and 'Search'. The RDNL logo is prominently displayed. A dropdown menu is open under 'START THE COURSE', listing six modules: I - Definitions, II - Planning phase, III - The research phase, IV - User phase, V - Legislation and policy, and VI - Data support. Below the menu, there are three main sections: 'START THE COURSE' (Get started with Essentials 4 Data Support), 'ABOUT THE COURSE' (Mission, target group & learning objectives), and 'THREE WAYS TO GET STARTED' (Select how you want to start Essentials 4 Data Support and enrol). A circular award logo for 'Digital Preservation Awards 2016' is also visible.

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Source: <https://datasupport.researchdata.nl/en/>

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# Questions

- How are DPIAs for research being implemented across different institutions, for research (AM)
- What is the applicability of "legitimate interests" (GDPR Article 6(f)) in research using Artificial Intelligence? (M)
- What constitutes a data transfer? A researcher bringing an electronic device across a border to a third country? Publication on the web? (S)
- How can we deal properly with GDPR in the context of open data? E.g. we publish data enriched with metadata containing personal data (O)

# Questions

- Can a public authority transfer personal data to a country outside the EU for research purposes with a consent? (AM)
- How can we make non-sensitive archived scientific data that contain DOIs (for citation) with authors names included GDPR compliant? (O)
- Does the GDPR apply to personal data, collected outside the EEA and transferred to the EEA for analysis? (S)
- Is a DPIA required in scientific research only by assessing sensitive data concerning vulnerable subjects? (cf. European Data Protection Board (EDPB)WP248 bullet 4+7) (M)
- What are the implications for international partnerships for research projects or data dissemination when non-EU countries are involved (O)

# Questions

- I'm a Dutch PhD student, interviewing Syrian refugees that have settled in Italy, Germany, the UK, Norway and the Netherlands about their experiences in migrating from Syria and settling into their new home countries. I am using consent forms that record interviewees' names. I will also keep people's names and contact details so I can interview them again in 2 years time. I audio record interviews and then transcribe them. Who is in this case the data controller and data processor? What would be the legal ground for processing these personal data? Should I do a Data Protection Impact Assessment? How do I do this? (M)
- I am a postdoc researcher doing a qualitative study, interviewing women about abusive relationships. I will use pseudonyms for each woman interviewed. Respondents may still be identifiable from the story they tell. Does this constitute personal information? If so, which legal ground should I use for this research? (AM)
- I am doing an online poll survey, using Qualtrics, asking 5000 people across Europe for which political party they voted in the recent European elections, also recording their ethnicity and other demographic information. Does this qualify as processing special categories data? If so, how do I gain explicit consent for collecting this information? (M)



# Questions

- When a US entity is a processor of pseudonymized EU data and the key to re-identify the subjects exists only in the EU (so that the US entity can not re-identify the subjects), does GDPR apply to the US entity? And is the US entity required to sign a contract with the model clauses if requested by the EU entity? If so, what suggestions do you have to limit the liability and responsibility of the US entity? (S)
- For studies funded by the US National Institutes for Health (NIH), which has a data sharing policy that enables NIH to share with other researchers the submitted study data (without identifiers), is it sufficient for a US entity that receives EU data to notify subjects generally that data will be shared with NIH and future researchers, without identifying the specific researchers or research purposes? What strategies do you suggest to allow EU entities to participate in NIH studies under a sub-award with a US entity? (S)
- How is the “right to be forgotten” applied in research settings? US law requires that raw study data be maintained in order to preserve the integrity of the research. Does this justify retaining study data of EU subjects who request erasure of their data? Are there recommended practices regarding the retained data, which may contain identifiers? How does this affect the notice requirement for EU subjects? What notice language do you recommend for research subjects regarding this right? (S)
- In a multi-site study in which a US entity collects only US data and sends it to an EU entity (e.g. sponsor, lead site or processor), does GDPR apply to the US entity? Is the US entity required to sign a contract with the model clauses if requested by the EU entity? If so, what suggestions do you have to limit the liability and responsibility of the US entity? Must a notice be given to US subjects regarding their GDPR rights? If yes, may the notice specify that the rights extend to the EU entity only and/or that the subjects may exercise the rights only against the EU entity? Must the notice, if required, be incorporated into the Informed Consent or signed by the subject, or may the US entity simply provide the notice to the subject?