

DISCLAIMER

The information provided in this presentation is based on a **current interpretation of the GDPR**, check the research tips and website for **updates**This presentation **should not be seen as legal advice**





GDPR IN THE RESEARCH LIFE CYCLE

PLANNING Research proposal preparation/drafting	DATA COLLECTION	DATA STRUCTURING AND ANALYSIS	PUBLICATION AND ARCHIVING
 ✓ Data ✓ Lawfulness ✓ Collaboration & partners ✓ Responsability ✓ Data transfers ✓ If necessary: processor agreements and/ or agreements for data transfer ✓ Data Protection Impact Assessment (DPIA) ✓ Research Data Management 	 ✓ Transparancy ✓ Primairy vs. secondary data collection ✓ Data subject rights & exceptions 	 ✓ Data protection ✓ Data breaches 	 ✓ Retention of personal data for research ✓ Reuse of personal data ✓ Publishing personal data ✓ Sharing personal data
 ✓ If necessary: ethical clearance ✓ Register your processing activity (dmponline.be) 	✓ Update the register if necessary	✓ Update the register if necessary	✓ Update the register if necessary





PLANNING



WHICH ASPECTS OF A RESEARCH PROJECT ARE IMPORTANT TO TAKE INTO ACCOUNT?

Data

- → Which information and type of data do you absolutely need?
- → What kind of personal data will you use (existing dataset, new dataset, acquired dataset, quantitative data, qualitative data, sensitive data, biometric data, ...)?

Lawfulness

→ On which legal ground will you process the personal data (i.e. consent, public interest, ...)?

Collaboration & partners

- → What type of collaboration takes place in your research project (none, public-public, public-private, in/outside your institution, EU/ non-EU)?
- → Which countries participate in the research?
- → Where does the storage of data take place (EU / non-EU)?

Responsabilities

→ What are the different GDPR-responsabilities of you and your partners?



WHICH ASPECTS OF A RESEARCH PROJECT ARE IMPORTANT TO TAKE INTO ACCOUNT?

Data transfer

- → Will you be sharing or transferring personal data?
- → Separate agreement or annex to data transfer/sharing agreement, consortium agreement or other type of contract

Data Protection Impact Assessment

- → Does your research constitute a potential high risk?
- → Assess the risks related to your research

Research data management

→ RDM policy of your institution

If necessary: ethical clearance from an ethics committee (≠ always advice on GDPR)

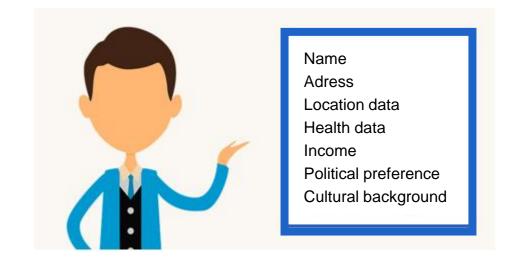
Register your processing activity in the GDPR Register of your institution



DATA

Personal data

- → Data about natural living persons from which they can be directly or indirectly identified (name, identification number, location data, online identifier, factors specific to the physical, psychological, genetic, mental, economic, cultural, social,... identity of a natural person)
- → (combinations of) indirect identifiers can also lead to identification and are therefore also personal data

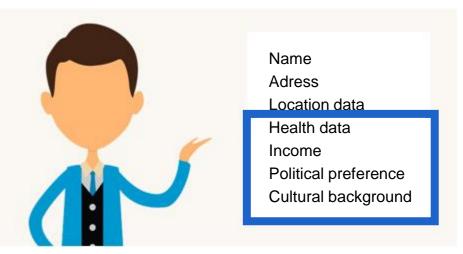


Special categories of data (sensitive data)

→ Racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, genetic data, biometric data, health data, data on sex life or sexual orientation

! Confidential data

- → All data, personal data or other that is seen as confidential in a certain context or for specific reasons
- → I.e. financial data of a company are not personal data, but might be confidential data



DATA

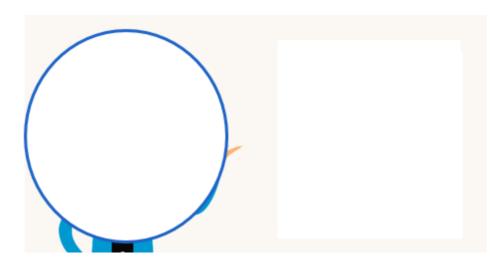
Pseudonymised data

- → Personal data (sensitive or not) that can only be associated with an identified or identifiable person by means of a non-public (secret) key
- → Data subject is are only identifiable with the use of additional information/identifiers that is kept separately
- → Pseudonymised data are still **personal data** (even if the identifiers are held by another organisation)
- → Pseudonymised data = GDPR!



- → Do not relate to an **identified or identifiable** natural person
- → Data subject is **not or no longer identifiable** (no person in any way)
- → Anonymised data ≠ GDPR
- → The handling (anonymisation) = GDPR!









Primairy data

The personal data will be collected **directly from** the data subjects within the research project

- → I.e. surveys
- → (Extra) ethics issues such as recruitment, risk of stigmatization, unexpected findings, ...
- → GDPR applies

Secondary data

The personal data will **NOT** be collected directly from the data subjects within the research project

- → I.e. the personal data was collected in a previous research (project) by the same researcher or anothher researcher and will be reused
- → I.e. the researcher is using data from a public database such as the national register
- → GDPR also applies!

! Public data (i.e. online)

- → ≠ always 'free' to use
- → GDPR might still apply



LAWFULNESS

Defining a legal ground as a condition

- → By the data controller (= research institution/researcher)
- → <u>Before</u> the processing personal data
- → One legal ground per processing/purpose

6 legal grounds for processing personal data (primary AND secondary)

- 1. Consent of the data subjects
- 2. Necessary for the performance of a contract
- 3. Legal obligations placed upon the controller
- 4. Necessary to protect the vital interests of the data subjects
- 5. Carried out in the public interest or in the exercise of official authority
- 6. Legitimate interest pursued by the controller

Just received an email from a wealthy Nigerian Prince. He told me that he doesn't have any fortune to share with me at the moment but he would appreciate if I could let him know before May 25th if I wish to continue receiving emails.

- Ciarán McGonagle (@cpmcgonagle) May 8, 2018



! Document the legal ground for processing personal data in the GDPR register (@UGent = dmponline.be)



CONSENT AS LEGAL GROUND

Consent needs to

- → be unambiguous
- → be specific
- → be **freely** given, by a clear **affirmative** action
- → Consider specific circumstances and needs of the data subjects (using pictures, translation,...)
- → be documented (written or oral statement)
- → be obtained for each separate processing activity
- → address the possibility of sharing data, future data publication
 (including storage in a repository) or long-term retention of data for reproducibility
- → outline their right to withdraw their consent, and how to do this



! Consent as **legal basis** for processing personal data ≠ **ethical consent** as an extra safeguard ('technical and organizational measures')



CONSENT AS LEGAL GROUND

Extra information for data subjects

- → Data subjects have the right to withdraw consent at any time
- → Lawfulness (legal ground consent) of the processing before the withdrawal remains unaffected

Broad consent

- → Data subjects should be able to give their consent to certain areas of research
- → Not too wide, not too narrow
- → Important if you want to reuse the data for other purposes/ research

Consent from children under the age of 18 for the processing of their personal data

→ Obtain consent from the person who holds the parental responsibility over the child



PUBLIC INTEREST AS LEGAL GROUND

Processing is **necessary** for the performance of **a task** in the **public interest** or a task assigned to the controller (host institution) in the exercise of public authority

Needs:

- → A basis (legislation) for this processing that is necessary for the performance of a task in the public interest
- → EU or national legislation

I.e. Scientific research in the public interest on the degree of participation of youth in sports, media and culture in Flanders

(Article II.18 Higher Education Codex: UGent has a triple assignment in the field of higher education, scientific research and social and scientific services)





SECONDARY DATA?

Check compatibility (legal ground of primary data collection)

- → If legal ground primary data collection = consent:
 - → Did the research participants consent to use their data in a future project?
 - → Does the purpose of your research fall within the scope of the given consent?
- → If the legal ground of the primary data collection ≠ consent: reuse for scientific purposes is compatible with the purposes for which the personal data were initially collected
 - → No 'new' legal basis required
 - → Pseudonymisation is required as a technical and organizational measure
 - → Information obligation remains, unless exception for research can be motivated

Importance

- → Publication and further processing
- → Lawfulness of processing
- → Transparency principle



COLLABORATION & PARTNERS

Who needs to comply?

- → A data controller or data processor based within the EU who processes personal data of natural persons, from any other country worldwide
- → A data controller or data processor that is based outside the EU but processes data of natural persons in the EU

Within the EU

- \rightarrow GDPR = applicable
- → Adequate data transfer mechanism under GDPR

Outside EU

- → GDPR ≠ applicable
- → Possible increased risk
- → Adequate data transfer mechanism necessary

! If you are enabling students in your research: confidentiality agreement necessary





RESPONSIBILITY?

Individual researchers

→ Are responsible and must be able to demonstrate compliance, cf. UGent Generic Code of Conduct for the processing of personal data (UGent = data controller)

Data controller (on behalf of UGent): the institution / organization that determines the purpose and means of the processing

→ Simply providing funding for research is insufficient to be the data controller in the context of research, eg FWO



RESPONSABILITY?

Joint controller (on behalf of UGent): the purpose and means of processing are determined by two or more organizations or institutions

→ Data processing agreement necessary between joint controllers

Separate controllers (on behalf of UGent): the purpose and means of the processing are determined by two or more organizations or institutions, but these are each separately responsible for processing for 1 specific processing activity

- → I.e. with clearly separable work packages in a research project
- → Data processing agreement not strictly necessary, but the separation needs to be clarified (in consortium agreement or other)



RESPONSABILITY?

Processor: the institution, organization or researcher processes personal data on behalf of another institution or organization

- → I.e. services provided by a UGent researcher for the Flemish Government
- → I.e. UGent researcher processes accountancy data for governmental institution, industry association or professional organisation, e.g. Farm Accountancy Data for Ministry of Agriculture
- → Data Processing Agreement between controller and processor necessary

Subprocessor: the institution, organization or researcher processes personal data on behalf of another organization and asks another institution, organization or researcher to perform (part of) the processing on his / her behalf

- → I.e. services by a UGent researcher and part of a survey is outsourced to another researcher / institution
- → Data Processing Agreement between processor and subprocessor necessary



DATA TRANSFER?

From EU to EU

- → Adequate data transfer mechanism under GDPR
- → But data processing agreement or clauses necessary!

From EU to non- EU

- → NO adequate data transfer mechanism under GDPR, so other adequate data transfer mechanism nessecary!
 - = Adequacy decision of the EC: check the 'white list'
 <u>https://ec.europa.eu/info/law/law-topic/dataprotection/data-transfers-outside-eu/adequacy-protection</u>
 personal-data-non-eu-countries_en
 - = Standard contractual clausules EC (non changeable!)
 - = Approved Code of conduct
 - = Derogation for special situations determined in art. 49 GDPR
- → Data processing agreement or clauses necessary!

From non- EU to EU

- → Check national (non-EU) legislation! I.e. via https://www.cnil.fr/en/data-protection-around-the-world
- → Data processing agreement or clauses or authorisation necessary!



DATA PROTECTION IMPACT ASSESSMENT (DPIA)

What?

→ Instrument to identify and assess the risks of a future processing of personal data in your research

When necessary?

- → Mandatory if data processing poses a probable high privacy risk for the data subjects
- → At the start of your research, before data collection/processing

How?

- 1. Evaluate potential high risk (@UGent embedded in GDPR Register)
- 2. UGent Word-template DPIA or soon @UGent embedded in GDPR Register





RESEARCH DATA MANAGEMENT

The bigger picture: personal data → research data

- → RDM policy of your institution
- → Privacy by design (!)
- → Create a data management plan (DMP) at the start of your research (mandatory for certain funders/ faculties)
- → If necessary get an ethical clearance by an ethics committee

Why?

- → Impact on possible risks for those involved
- → Impact on data handling and security measures during processing and storage
- → Impact on necessary (security) measures and agreements
- → Impact on the necessity of performing a data protection impact assessment (DPIA)
- → Impact on data sharing with other researchers
- → Impact on research and research outcome!



REGISTER YOUR PROCESSING ACTIVITY

Obligation under GDPR

- → Processing of personal data
- → Principle of accountability
- → @UGent: Generic code of conduct for the processing of personal data and confidential information

GDPR register at UGent

- → Incorporated in **DMPonline.be** Data Management Plans
- → Complete the GDPR template in your role as data controller on behalf of Ghent University or data processor
- → For more information check https://onderzoektips.ugent.be/en/tips/00001795/ or join a workshop





DATA COLLECTION



WHICH ASPECTS OF A RESEARCH PROJECT ARE IMPORTANT TO TAKE INTO ACCOUNT?

Transparency

- → Data subjects should be informed in a concise, transparent, intelligible and easily accessible form, using clear and plain language before the processing takes place
- → No matter the legal ground!
- → Exceptions for research (see following)

For primary data collection and reuse as secondary data

Data subject rights

- → Which rights do the data subjects have and which exceptions are there for research?
- → How can the data subjects exercise these rights?



TRANSPARENCY

Principle of transparency

- → Obligation to inform data subjects
- → Data subjects should be informed in a concise, transparent, intelligible and easily accessible form, using clear and plain language
- → Information should be adjusted to the data subjects & research participants (i.e. children)
- → For primary & secondary data!

Information for data subjects (ethical reasons)

- → The **purpose** of the research
- → What is **involved** in participating in the research
- → Describe the benefits and risks of participating in the research
- → Indicate steps that will be taken to **safeguard** their anonymity and confidentiality
- → Details of the **research**, e.g. the funding source, institution, name of the project,...
- → Explain that taking part in the study is entirely voluntary and that refusal to agree to participate will involve no penalty or loss of benefits
- → Freedom to withdraw at any moment without consequence(s)
- → Discuss what will happen to their **contribution** (including the future archiving and sharing of their data)



TRANSPARANCY: PRIMARY DATA COLLECTION

Mandatory information for data subjects under GDPR

- → The identity and contact details of the **researcher** and the **DPO**
- → The legal basis and purpose of the processing of data
- → If applicable: the fact that you will use the data for **other purposes**
- → If applicable: the fact that the data will be transferred/shared with other institutions/ researchers (recipients of the data)
- → If applicable: the fact that the data will be transferred to a third country or international organisation
- → The period of **retention or criteria** to determine period of retention
- → Information about their rights and how to exercise their rights
- → A reminder that they have the right to lodge a complaint with the supervisory authority
- → The existence of automated decision-making, including profiling

! If you plan to process this data for **another purpose**: information obligation must be fulfilled before the processing (other purpose)

Integrated in information form
In line with (informed) consent form (if applicable)



TRANSPARANCY: SECONDARY DATA COLLECTION

Mandatory information for data subjects under GDPR

- → The identity and contact details of the researcher and the DPO
- → The **legal basis** and **purpose** of the processing of data
- → If applicable: the fact that you will use the data for **other purposes**
- → If applicable: the fact that the data will be transferred/shared with other institutions/ researchers (recipients of the data)
- → If applicable: the fact that the data will be transferred to a third country or international organisation
- → The period of **retention or criteria** to determine period of retention
- → Information about their rights and how to exercise their rights
- → A reminder that they have the right to lodge a complaint with the supervisory authority
- → The existence of automated decision-making, including profiling
- → EXTRA: The categories of personal data concerned
- → EXTRA: The source of the secondary data
- → EXTRA: If applicable: that the data originate from a public source

! Within a reasonable timing (<1 month after receiving the data/ first contact/ before transfer)

! If you plan to process this data for **another purpose**: information obligation must be fulfilled before the processing (other purpose)



TRANSPARANCY: SECONDARY DATA



Exception for research (only for the use of secondary data!)

- → <u>If providing information is impossible of involves a disproportionate effort</u>
- → Motivate in the Register (@UGent: dmponline.be)
- → Other GDPR requirements still apply!



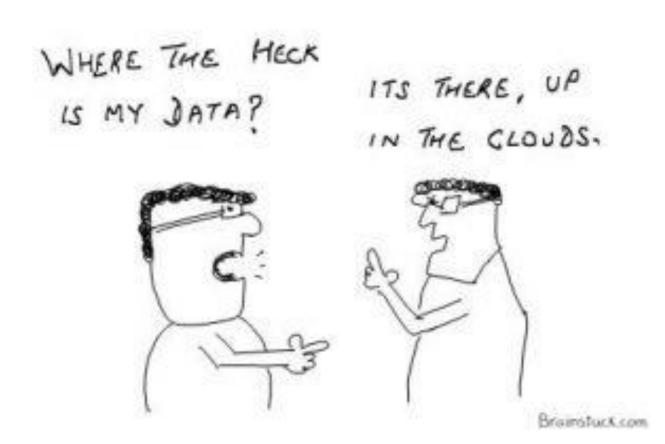
DATA SUBJECT'S RIGHTS

Data subjects have the right:

- → to be **informed** about which, how, why and when their personal data is processed
- → of access to their personal data
- → of rectification of their personal data
- → to erasure (the 'right to be forgotten')
- → to demand a restriction processing of their personal data
- → to data portability of their personal data
- → to object to (a part of) the processing
- → not to be subjected tot automatic decision making / profiling

! Verify the legal ground to see which rights can be exercised

! Inform data subjects about their rights and how they can exercise them





DATA SUBJECT RIGHTS & EXCEPTIONS

Exception on the right to erasure (the 'right to be forgotten')

- → If the exercise of the right is likely to render impossible or seriously impair the achievement of the research objectives
- → Motivate in the Register (dmponline.be)
- → Other GDPR requirements still apply!

Exception on the right of access, the right to rectification, the right to restriction of processing and the right to data portability

- → If the exercise of the right is likely to render impossible or seriously impair the achievement of the research objectives
- → Motivate in the Register (dmponline.be)
- → Other GDPR requirements and Belgian law apply!!!



DATA SUBJECT RIGHTS & EXCEPTIONS

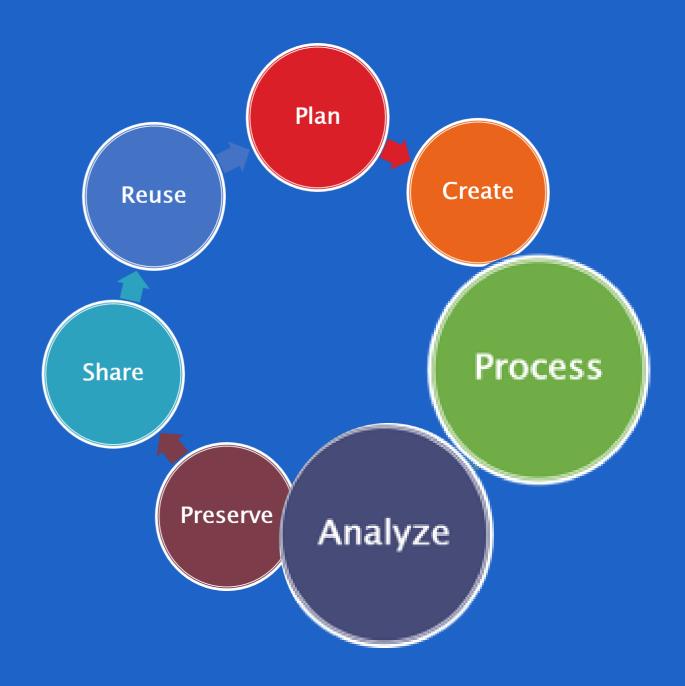
Belgian law on the protection of natural persons with regard to the processing of personal data

- → Exception regime provided based on article 89 § 2 GDPR
- → <u>If</u> the exercise of the right **of access, the right to rectification, the right to restriction of processing and the right to data portability is likely to render impossible or seriously impair the achievement of the research objectives**

Extra obligations and measures cfr. Belgian Law:

- → Motivation for the exception
- → For the processing of **genetic**, **biometric or health data**: restricted access + access list necessary
- → For primary data collection: cascade anonymous/ pseudononymous data + motivation
- → For secondary data collection or reuse of data: agreement between primary and secondary processors needed attached to GDPR Register + cascade anonymous/ pseudononymous data + motivation
- → Advise DPO necessary for anonymisation, pseudonymisation and de-pseudonymisation methods
- → Different requirements for **communication and dissemination** of data
- → Combining of multiple datasets: trusted third party (TTP)





DATA STRUCTURING AND ANALYSIS



WHICH ASPECTS OF A RESEARCH PROJECT ARE IMPORTANT TO TAKE INTO ACCOUNT?

Data protection?

- → Where is the data?
- → How is the data?
- → Who has access to the personal data?
- → Data storage
- → Destruction of data

To prevent data breach!

→ Security incident





DATA PROTECTION

Where is the data?

... on a local (UGent) server?

... in an external cloud?

Store the personal data on a safe place!

- → Use the central disk space/storage (personal disk space and shares) offered by your institution instead of storing files locally on your own IT resources (hard disk of desktop or laptop, USB stick, external hard disk,...).
- → **Do not use external cloud services** to store personal data or confidential information unless you encrypt this data
- → Be careful when saving sensitive data: risk assessment + encryption required!
- → Regularly back-up data which is not stored on the shares of your institution
- → Personal data in paper format (e.g. consent forms signed by research participants) should be kept in a secure area of a locked filing cabinet



DATA PROTECTION

How is the data...

...pseudonymised?

→ Pseudonymise personal data as soon as possible and keep the file with the personal information in a secure place

...secured?

- → Encrypt your data if necessary
- → Basic principle: do no harm
- → Make the right decisions





DATA PROTECTION

Who has access to the data?

- ... on a local (UGent) server?
- ... in an (external) cloud?

Protect your UGent account and the associated login details

Access to the raw data should be restricted!

- → Work on a trusted network
- → Use a trustworthy device (desktop, laptop, notebook, tablet, smartphone,...) which is sufficiently secured
- → Preferably work with the applications offered by your institution (for UGent offered on Athena.UGent.be
- → Install as few additional applications as possible on your devices
- → Be wary of phishing and malware infections via e-mails
- → Arrange access conditions in a consortium agreement, non-disclosure agreements, processor agreements,...

Be careful when data is "on the move" & during transmission of personal data

→ Encrypt files with personal data, avoid to transport raw data



DATA PROTECTION

How long does the data need to be stored?

... on a local (UGent) server?

... in an (external) cloud?

Destroy data in a **consistent** and **reliable** way:

- → Deleting files from hard disk -> overwrite the files or use secure erasing software
- → USB and CD/DVD -> physical destruction works best
- → Data in paper format -> shred the files or treat them as confidential waste

Tips for safely working with IT (https://www.ugent.be/intranet/nl/op-het-werk/ict/informatieveiligheid/overzicht.htm)



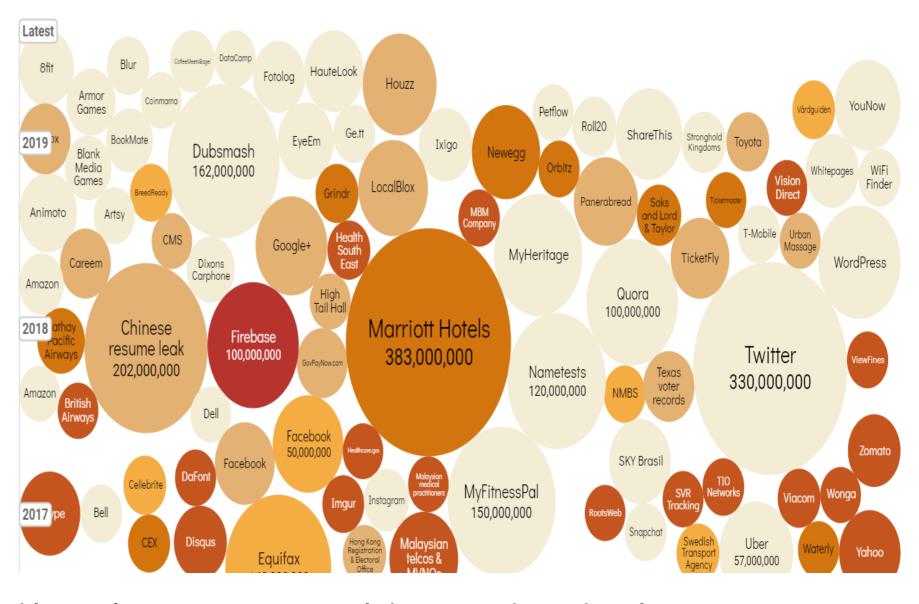
DATA BREACH?

A **security incident** that has affected the confidentiality, integrity or availability of **personal data** that results in a risk to the rights and freedoms of the data subjects

- → Not every security incident is a data breach
- → Every data breach is a possible security incident
- → It might potentially harm or threaten the rights and freedoms of natural persons

3 categories of data breaches with personal data

- → Infringement of confidentiality: unauthorized or unintended provision of or access to personal data
- → Integrity breach: unauthorized or unintentional change of personal data
- → Infringement of availability: unintentional or unauthorized loss of access to personal data or unintentional or unauthorized destruction of personal data





DATA BREACH! WHAT NOW?

Inform the DICT Helpdesk as soon as possible via helpdesk@ugent.be

- → First assessment of the infringement and potential risks
- → Possible escalation to data protection officer, information of the security officer and other necessary parties
- → Assessment of notification to supervisory authority and possible communication to stakeholders

Mandatory notification to data protection authority

- → Infringements that are likely to present a risk to the rights and freedoms of natural persons
- → Within 72 hours of being notified
- → Not by yourself, but by UGent (together with DPO)

Mandatory notification to data subjects

- → Infringements that are likely to involve high risk or high risk to the rights and freedoms of natural persons
- → As quickly as possible
- → Not by yourself, but by UGent (together with DPO)

Act fast!





PUBLICATION AND ARCHIVING



WHICH ASPECTS OF A RESEARCH PROJECT ARE IMPORTANT TO TAKE INTO ACCOUNT?

Retention of personal data

- → Principle of storage limitation
- → Exception for research
- → Retention vs. reuse

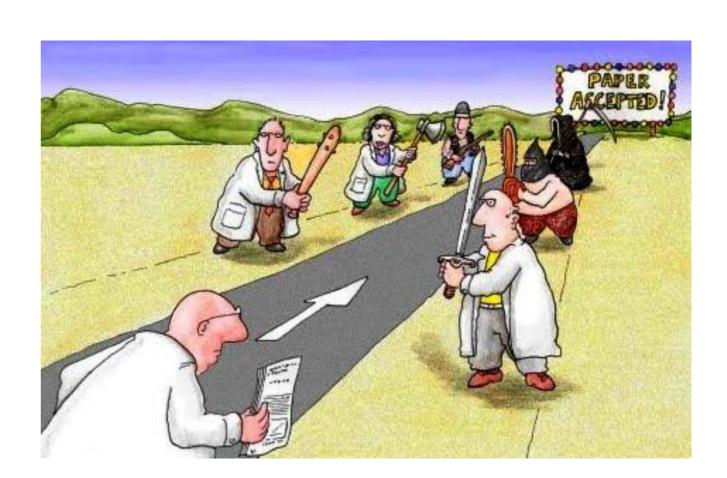
Reusing data

- → Check legal ground and compatibility
- → Transparency
- → Exception for research

Publishing personal data

Sharing personal data for publications





RETENTION OF PERSONAL DATA FOR RESEARCH

Principle of storage limitation in GDPR

→ Only as long as necessary for the data processing

Exception for research

- → Personal data may be stored for longer periods if appropriate technical and organizational measures are taken to protect the rights and freedoms of the data subject
- → F.e. pseudonymization and encryption

RDM policy Ghent University

- → Data must be kept for up to five years after the end of the project (unless contract/law determines otherwise)
- → For scientific integrity purposes

Take the appropriate **security** measures!



RETENTION VS REUSE

Retention (or storage) ≠ reuse

→ Retention or storage is for **verification and scientific integrity purposes**

Reuse of data (= secondary data)

- → Remember the principle of compatibility (lawfulness of primary data collection vs. lawfulness of secondary processing)
- → Information obligation (additional information required!)
- → Exception on the information obligation may be necessary



REUSING DATA

Further processing/ reuse of data: check compatibility (lawfulness of primary collection)

- → If legal ground primary data collection = consent: did research participants consent to use their data in a future project? Does the purpose of your research fall within the scope of the given consent?
- → If legal ground primary data collection ≠ consent: reuse for scientific purposes is compatible with the purposes for which the personal data were initially collected
 - → No legal basis separate from that which allowed the collection of the personal data required
 - → Information obligation remains, unless exception for research can be motivated

Extra information to be provided to the data subjects

- → The categories of personal data concerned
- → From which source the personal data originate + if public source

Unless: exception on obligation to inform data subjects for research

- → If providing information is impossible of involves a disproportionate effort
- → Motivate in the Register (dmponline.be)
- → GDPR applies



PUBLICATION OF PERSONAL DATA

Research participants should not be identified in published research results unless they have consented to being identified

- → Information obligation applies (except for the exception of secondary data)
- → Check requirements for consent (if consent is legal ground)
- → Ethical considerations!

If identification of the persons involved is not necessary in publication: avoid

- → Research results or output are, for example, at an aggregated level
- → The data must be pseudonymised as quickly as possible and if possible

Providing data subjects with a copy/summary of the research results or research publications will support openness and transparency



SHARING PERSONAL DATA FOR PUBLICATION

Required by some funders and journals

- → Different access categories
- → Open access: data can be used by any user
- → Restricted access: Access is limited and can only be granted upon request. Data can be shared with a user agreement/license
- → Always requires a balancing of interests between the need to provide data and the protection of personal data

Central research data management principle: as open as possible as closed as necessary

But

- → Only possible if the subjects (research participants) have given consent for data sharing!
- → **Select a trusted repository** with sufficient safeguards for sharing personal data



GDPR IN THE RESEARCH LIFE CYCLE

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WHY IS IT IMPORTANT TO KEEP TO THE RULES?

Non compliance:

- → Bad research practice
- → Reputational damage and negative media attention for the researcher, the research group and for Ghent University
- → Negative media attention
- → **Fines** of up to 20 million euros
- → Indemnification or compensation for data subjects
- → **Disciplinary measures** and **sanctions** within Ghent University (Generic code of conduct)

Compliance:

- → Good research practice
- → Sense of responsibility
- → Quality and reliability of the research and the research results
- → Confidence of citizens and data subjects in science

https://www.youtube.com/watch?v=fW8amMCVAJQ





HELP?

RDM website

https://www.ugent.be/en/research/datamanagement/privacy.htm

(Re)search tips

https://onderzoektips.ugent.be/en/

Privacy@UGent.be





IMPORTANT DOCUMENTS

GDPR

→ https://eur-lex.europa.eu/legal-content/NL/TXT/?uri=celex%3A32016R0679

Belgian law

→ http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=nl&la=N&table_name=wet&cn=201807304
6

UGent

- → Generic code of conduct for the processing of personal data https://www.ugent.be/intranet/en/regulations/code_of_conduct
- → Policy framework for research data management at Ghent University https://www.ugent.be/en/research/datamanagement



Questions?

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