

GDPR in research - what does it mean for research institutions?

Original

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Tilburg University

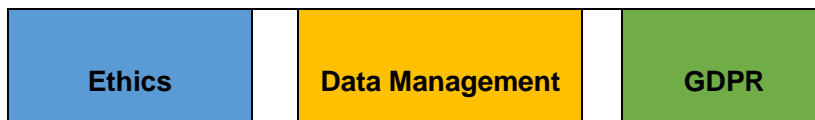
Application Form

Research Ethics - Data Management - Data Processing Register

Instruction

This document covers ethics, data management and the data processing register in an integrated form. First there is some general information that all researchers should fill in. Part 1 is mainly about ethics, Part 2 mainly about data management and Part 3 mainly about the GDPR requirements. Each question is color coded, so you can easily see which questions you can skip if you do not need to apply for ethical clearance or if the GDPR does not apply to your study. Please note that all researchers have to create a data management plan for the study they are planning to execute. This is not a GDPR related requirement, but part of the Research Data Management Policy of Tilburg University.

Color codes per question:



Most questions are necessary for two or more purposes and have two or three color codes.

Questions per category

Ethics:

- Questions 3 up to and including 9;
- Both checklists;
- Questions 12, part 1 and part 3.

Data management:

- Questions 3a up to and including 3d, 3f;
- Questions 4 up to and including 5a, b and d;
- Question 6 and 7b;
- Question 8, part 1;
- Question 9;
- Both checklists if you gather data from persons (also with web scraping, but not with machine generated algorithms);
- Questions 11 up to and including 17.

GDPR – Processing Register:

- Questions 3b up to and including 3d;
- Questions 4b up to and including 4d;
- Questions 5, 6, 7, 8 part 1, 9b, 9c, 9e;
- Both checklists if you gather data from persons (also with web scraping, but not with machine generated algorithms);
- Questions 11,12 13 part 2, 14, 15 part 1, 16;
- Questions 18 up to and including 27.

General information

Ethics	Data Management	GDPR
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Note: Language of application can be English or Dutch.

Project title	
Date	
Version	

Ethics	Data Management	GDPR
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1. Declaration of compliance and accuracy

By ticking the box below, the applicant declares that all information provided is correct and that all information is provided that is required to evaluate the ethical and data management aspects of the study.

 Yes

Ethics	Data Management	GDPR
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2. Details applicant

Note: The person mentioned here should be a staff member who will be responsible for all aspects of the study. When studies are conducted under supervision (student research, PhD research), the name of the responsible supervisor should be listed. When studies are conducted with external parties, the TiU staff member should be listed here.

Main applicant (responsible for the study)	
Name	
Department	
Email address	

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Phone number	
Name co-applicant if applicable (e.g., student)	
Department	
Email address	
Phone number	
(please continue below if more co-applicants are involved in the study)	



Planned start and end date of the study

Note. (1) No study for which approval is needed can commence without committee approval; (2) approval cannot be obtained after the study; (3) obtained approval will expire on the end date of the study.

Planned start date	
Planned end date	

PART 1

3. Study Proposal

Ethics	Data Management
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a. Theoretical background (max. 750 words)

<Insert text here>

Ethics	Data Management	GDPR
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b. Research question (max. 500 words)

<Insert text here>

Ethics	Data Management	GDPR
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c. Design (How will the data be collected? What is the nature of the study (experimental, observational, archive study, interview study, ...) (note that details about participants are provided in Question 5)

What method(s) do you use for the data collection? (Tick all that apply)

- Structured individual interviews
- Semi-structured individual interviews
- Structured group interviews
- Semi-structured group interviews
- Observations
- Literature study
- Survey(s)
- Lab experiment(s)
- Experiment(s) in real life (interventions)
- Physiological data, eye tracking
- Secondary analyses on existing datasets
- Other:

[Click here to enter text.](#)

How will the data be collected?

- Online
 - Mturk
 - Qualtrics
 - Survey Monkey
 - Other, please specify:

[Click here to enter text.](#)

- Paper-and-pencil
- Phone (speech)
- Via a mobile application or wearables, please specify:

[Click here to enter text.](#)

- Face-to-face
- Within an online group
- Within a real life group
- Other:

[Click here to enter text.](#)



d. Procedure and materials (give a detailed description of the nature of the measurements and an explanation of what the participants is requested to do, describing the actual or potential invasiveness; specify to what extent participants are fully informed about the purpose of

Tilburg University

the study prior to participation; pay special attention to which personal data will be collected (personal data are data that refer directly or indirectly to an identifiable natural person, such as a name, phone number, or IP address or data that involve sensitive topics such as health, religion, or ethnicity)

<Insert text here>

Ethics

e. Where will the study take place and how long will the data collection take, on average, per participant?

<Insert text here>

Ethics

**Data
Management**

f. Explain the feasibility of the study in terms of the available infrastructure (for example, can sufficient participants be found and can instruments be administered to these participants at the proposed data collection site?)

<Insert text here>

Ethics

**Data
Management**

g. How will the data be analyzed (e.g., content analysis, statistical analysis)?

--

5. Participants

Ethics	Data Management	GDPR
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a. Give a description of the sample (students, general population, vulnerable population such as patients, target population such as pregnant women, age group; please also specify if you collect background characteristics such as age, gender, and address).

<Insert text here>

Ethics	Data Management	GDPR
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b. Do participants give informed consent?

- Yes
 No, please explain:
Click here to enter text.

Ethics	GDPR
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c. Are the participants capable of giving informed consent (tick where applicable)?

- Yes
 No

Ethics	GDPR
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If not, who will give informed consent? Note that consent should be given by legal representatives for participants younger than 16 years (who may be asked to assent).

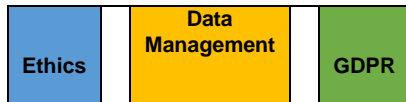
<Insert text here>

Ethics	Data Management
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d. Is there any remuneration (financial or otherwise) for the participants? Specify the remuneration if applicable (course credit, financial reward (indicate amount), other...).

Choose an item.
Click here to enter text.

6. Potential ethical threats during the data collection



Give a description of the data collection process with special emphasis on potential ethical issues, such as sensitive questions, long interviews or questionnaires, incomplete disclosure (deception), as well as a description of how these issues are to be dealt with. These ethics considerations are particularly important when dealing with vulnerable groups, such as minors, aged people, refugees, critically ill patients, etc. If applicable, special attention should be paid to any mental or physical burden.

<Insert text here>

7. Privacy and confidentiality



a. What are the privacy risks and how will *privacy* risks be mitigated?

<Insert text here>



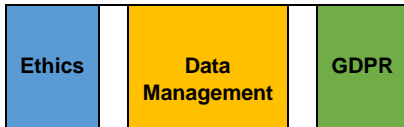
What kind of personal information is obtained about participants?

<Insert text here>



Indicate how this is explained to the participants (should also be part of the informed consent letter)

<Insert text here>



b. What are the risks to guarantee confidentiality and how will *confidentiality* be ensured? Confidentiality applies to the treatment of the data; e.g., who has access to identifiable data, what will be done to make sure that only authorized individuals have access to these data, what are potential limitations to these procedures? Also indicate how this is explained to the participants (should be part of the informed consent letter).

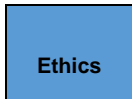
<Insert text here>

8. Finances and contract



Is there an external party involved in financing the study, such as companies, NWO, or the European Science Foundation?

Choose an item.

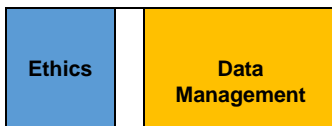


If so, indicate the ethical requirements that they impose on the study that go beyond the framework employed by TiU and explain how you deal with them:

Click here to enter text.

9. Additional materials

You are required to submit the following documents (as separate attachments):



a. The text used to recruit participants for the study (if applicable);



b. The written information about the study that is provided to the participant (information letter), including the rights of the participant regarding the GDPR (in Dutch: Algemene Verordening Gegevensbescherming);

Tilburg University



b. Informed consent forms including active consent on participation in the study for all parties involved. Please be aware that if you plan on using the data again you should also get consent on re-use of the data.;



c. The text of the debriefing material (at the end of the data collection);



d. Evidence of approval from external institution to conduct the study (if applicable).

<Insert text here>



Checklist information letter

Please check each box to confirm that the information letter contains the required elements

- Title (Title of the study, if necessary simplified, abbreviated or translated)
- Introduction

What does the study entail

- Purpose
- Background
- Nature
- Duration

What does participating in the study entail

- Procedures
- Expected duration
- Disadvantages/consequences/risks
- Possible advantage for the participant

Information about the participation

- Voluntariness of participation.
- Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation.
- Confidentiality protection and limitations
- Applicable insurance guarantees (only if there is additional insurance to the standard insurance)
- Period of time to which the consent applies (normally the length of the study)
- Re-use of specified data in the current, future or other research, where applicable
- Deliberation time (if applicable)
- Processing results
- Period of time that data will be stored and encrypted (10 years)
- Incentives for participation (traveling expense, pp hours)
- Approval Ethical Review Board (ERB)
- Request for participation
- Closing / whom to contact in case of question or additional information (name and telephone number/ email address researchers)
- Appendices: Informed Consent



Checklist informed consent

Mentally competent participants and minors of 16 years or older

Please check each box to confirm that the informed consent contains the required elements

- Title (Title of the study, if necessary simplified, abbreviated or translated)
- Confirmation that the information is read
- Confirmation that there was room for questions
- Reminder on voluntariness of participation. Right to decline to participate and withdraw from the research once participation has begun, without any negative consequences, and without providing any explanation
- Permission processing of anonymous/coded data as mentioned in the information letter
- Permission for storing the research data for a period of ten years
- Permission participation in the study
- Date, name, signature participant (self-written, so not preprinted)
- Date, name, signature researcher (self-written, so not preprinted)
- Give the participant a copy of the signed informed consent form

Addition/correction for mentally incompetent adults:

- Date, name, signature legal representative, relation to participant

Addition/correction for minors younger than 16 years:

- Date of birth participant
- Date, name, signature (if possible both) parents/guardians

PART 2.

By filling in this part of the form, you are complying with the Research Data Management (RDM) policy of Tilburg University, stating that all research conducted at the University should be documented in a Data Management Plan (DMP). In addition, a DMP includes a pre-DPIA (Data and Privacy Impact Assessment), which makes it visible whether there are certain risks and whether you are obliged to conduct a DPIA. You comply with all DMP, DPIA and Pre-DPIA requirements by completing this part. In the data management part of the form a distinction is made between digital and non-digital data.

11. Data Collection

Can you describe the data you will be creating/collecting?

Checklist (not all may apply):

- How will data be collected?

Data Management	GDPR
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<Insert text here>

- What type of data will be collected? (measurements, observations, models, software....)

Data Management	GDPR
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<Insert text here>

- In what file formats?

Data Management	GDPR
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<Insert text here>

- Is there currently sufficient storage capacity during the project? Please explain.

Data Management	GDPR
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Choose an item.
Click here to enter text.

Data Management	GDPR
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- Is there currently sufficient backup capacity during the project? Please explain. If no or insufficient storage or backup capacities are available then explain how this will be taken care of.

Choose an item.
[Click here to enter text.](#)

Data Management	GDPR
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- Describe how often and where backups of data will be made and who is responsible for this.

<Insert text here>

Data Management	GDPR
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- Will any data be collected that may lead to the identification of participants? If so, explain how.

Choose an item.

Data Management	GDPR
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- Which tools or software are needed to create/process/visualize the data?

<Insert text here>

Data Management	GDPR
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- Are these tools or software products contracted by the university?

Please state the details of the contract here. If there is no contract, please state the details of your data representative here. [Click here to enter text.](#)

Data Management	GDPR
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- Will pre-existing data be used? If so, what is the source of the data

<Insert text here>

12. Data Storage and Back-up

Checklist (not all may apply):

Ethics	Data Management	GDPR
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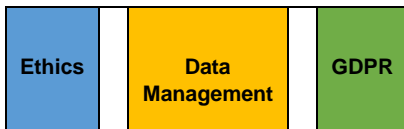
- How will the raw data be stored and backed up during the research?

- On the home PC of the researcher
- On the M-drive of TiU
- On the O-drive of TiU
- In a cloud service: [Choose an item. Click here to enter text.](#)
Have you agreed upon a processor agreement with this service (if so, this agreement has to be archived in the central planon system)? [Choose an item.](#)

Data Management	GDPR
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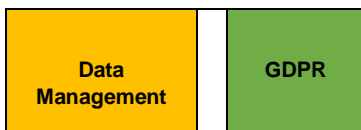
- How will the processed data be stored and backed up during the research?

- On the PC of the researcher
- On the M-drive of TiU
- On the O-drive of TiU
- In a cloud service: [Choose an item.](#)
Have you agreed upon a processor agreement with this service? [Choose an item.](#)



- How will the privacy of participants be protected during data storage? Will names and other identifiers be stored in another place than the other data? If not, how will the privacy be protected?

- Names and other identifiers are pseudonymized, but there will be a key file
- Identifiers are stored in the data file but the file is encrypted
- Other:
[Click here to enter text.](#)



- Which storage medium will you use for your storage and backup strategy?

- Portable personal storage media (CDs, DVDs, USBs, portable hard drives)
- Network storage (M-drive, O-drive)
- Other:
[Click here to enter text.](#)



- Are the data backed up at different locations?

Choose an item.
[Click here to enter text.](#)



- Who will have access to the raw data *during* the data collection?

<Insert text here>



- Who will have access to the raw data *after* the data collection (long-term storage)? Are there restrictions on this access? Do data need to be anonymized or pseudonymized?

<Insert text here>

13. Data Documentation

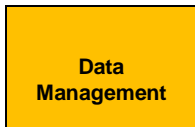
How will your data be documented to help future users to understand and reuse it?

Checklist (not all may apply):



- What standards will be used for documentation and metadata (description of the data)? If there is not a standard already available for your data, outline how and what metadata will be created.

<Insert text here>



- How will your data be documented during your research and for long-term storage?

<Insert text here>



- Are the data, or a part of these, available for reuse according to the [Open Access](#) principles after completing the project? If so, please describe in a concrete manner when and how the data will be made available. If not, please explain why the data are not suitable and/or available for reuse.

<Insert text here>



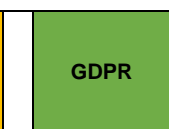
- Are there any conditions for the reuse of the data?

<Insert text here>

14. Data Sharing and Reuse

How will you share the data?

Checklist (not all may apply):



- If you allow others to reuse your data, how will the data be shared? In case the dataset cannot be shared, the reasons for this should be mentioned (e.g. ethical, rules of personal data, intellectual property, commercial, privacy-related, security-related).

<Insert text here>

Tilburg University



- How will the privacy of participants be protected?

<Insert text here>



- Are there any sharing requirements (e.g., funder data sharing policy)?

<Insert text here>



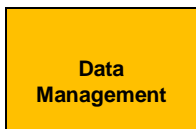
- What will be the audience for reuse? Who will use it now? Who will use it later?

<Insert text here>



- Where do you intend to publish the data and when?

<Insert text here>



- How long will the data be stored?
Note. The university policy is to store data for 10 years. Medical data should be stored 15 years. Contact details should be removed as soon as possible after completion of the project.

Informed consent forms should be stored up to 10 years. Please note that the term is for integrity reasons, when sharing the data they must be completely anonymized. If the data is reused, it must be anonymized as well, unless it is a longitudinal study.

<Insert text here>

15. Data Preservation and Archiving

Which data should be preserved, and/or shared (make sure to check the data management policy)?

Checklist (not all may apply):

Data Management

GDPR

- Which criteria will you use to decide which data has to be archived for preservation and long-term access? Which data has to be destroyed?

<Insert text here>

Data Management

- What file formats?

<Insert text here>

Data Management

- Which data repository will be used for archiving the data?

<Insert text here>

The following questions (16 and 17) only refer to non-digital data and can be skipped if all data from the proposed project will be digital.

Data Management

GDPR

16. (only to be answered in case of non-digital data storage of the main data of a study) What kind of data will need to be stored during the study (paper surveys, transcripts, photocopies of original documents)? Do these data need

special protection to secure privacy and confidentiality? Where will these data be stored? Who will have access to the data?

<Insert text here>

Data
Management

17. (only to be answered in case of non-digital data storage of the main data of a study) What kind of data will need to be stored over the required term, set for long term preservation of data?

<Insert text here>

PART 3. REGISTER

By filling in this part of the form you are complying to the GDPR regulation that all research with personal data should be registered in the register of TiU. *Note.* All research involving personal data that is conducted at TiU should be registered in a central database. In order to comply with legal requirements (the “GDPR”), the following questions need to be answered.

GDPR

18. Which personal data are to be processed? Examples are first name, last name, address, e-mail address, administration number (ANR), as well as fingerprints, medical information, or other sensitive data. Tick all that apply.

No personal data will be processed, this is the end of the questionnaire.

General

- Contact data limited (e.g. name, email)
- Contact data full (e.g. address, gender, age, birthdate, phone)
- Nationality, birth place, birth country
- Student number/Employee number
- Experiences (work, education)
- Finances
- Visual materials (pictures, video)

Special data

- Racial or ethnic origin
- Religious or philosophical beliefs
- Political opinions
- Health data
- Sex life or sexual orientation
- Trade union membership
- Genetic data
- Medical data
- Biometric data
- Criminal records

Sensitive data

- Copy identification card
- R&D meeting
- Study results

Other:

[Click here to enter text.](#)

GDPR

19. Who/which party will manage the data collection under the responsibility of the main applicant? Do not list names of persons but their functions/roles, such as student-assistant or principal researcher. Tick all that apply.

- Principal researcher
- Fellow researchers
- Student-assistant
- External parties (such as hired interviewers)
- Other, please specify:

[Click here to enter text.](#)

GDPR

20. Who/which party will have access to the personal data from the database/system? Note that when conducting surveys or experiments, names of participants are often stored separately from the rest of the data.

This question only refers to the data parts with personal data. Do not list names of persons but their functions/roles. A distinction is made between information sheets with details of the participants (such as names), raw data (as collected) and pseudonymized data (data from which personal identifiers have been removed)

Information sheets

- Not applicable
- Principal researcher
- Fellow researchers
- Student-assistant
- External parties (such as hired interviewers)
- Other, please specify:
[Click here to enter text.](#)

Raw data

- Not applicable
- Principal researcher
- Fellow researchers
- Student-assistant
- External parties (such as hired interviewers)
- Other, please specify:
[Click here to enter text.](#)

Pseudonymized data

- Not applicable
- Principal researcher
- Fellow researchers
- Student-assistant
- External parties (such as hired interviewers)
- Other, please specify:
[Click here to enter text.](#)

GDPR

21. Who/which party is responsible for the *data storage*? Note that data stored on the network are managed by the IT Department. Do not list names of persons but their functions/roles.

- Principal researcher
- IT department TiU
- Other, please specify:
[Click here to enter text.](#)

GDPR

22. Are there any external parties (processors) involved in this study regarding data collection, data storage, archiving and/or other data-related activities? If so, please describe and name them here and state the website(s) of the processor(s) and / or external controller(s).

Note. A processor is a person or organization to whom or which the responsible party has outsourced the processing of personal data, such as a cloud service. The external party should comply with the GDPR. Some services, such as Surfdrive, comply with these regulations. If an external party is not known to be GDPR compliant, the applicant should ensure that there is a contract to ensure appropriate processing by the external party. This party should take appropriate technical and organizational measures to protect personal data against loss or any form of unlawful processing (e.g. unnecessary collection of data or further processing).

The model processor agreement and procedure is available via intranet at or can be requested from one of the Data Protection Representatives (see).

Data collection

- Not applicable
- Yes: Click here to enter text.

Data storage

- Not applicable
- Yes: Click here to enter text.

Archiving

- Not applicable
- Yes: Click here to enter text.

Other data-related activities

- Not applicable
- Yes: Click here to enter text.

GDPR

23. (Only applicable if there is an external party that requires a processor agreement) Have you agreed upon and centrally archived a processor agreement with the above mentioned processors? Please specify.

<Insert text here>

GDPR

24. What is the legal base for which the processing activity takes place?

Note. Personal data cannot be processed according to the GDPR unless there is a legal base for processing. This question refers to the legal basis for processing personal data. There are several possibilities, three of which are particularly relevant for research at TiU: (1) consent (participants sign a consent form to process their personal data); (2) Legitimate interest as scientific researcher (“gerechtvaardigd belang”) (for example, this applies to the use of public data from social media where consent is not needed); (3) permission (when an external party

provides the applicant with personal data and the external party has obtained consent to use these data).

- (1) consent (participants sign a consent form to process their personal data);
- (2) Legitimate interest as scientific researcher (“gerechtvaardigd belang”) (for example, this applies to the use of public data from social media where consent is not needed);
- (3) permission (when an external party provides the applicant with personal data and the external party has obtained consent to use these data)

GDPR

25. If applicable, does the applicant receive personal data from or provide personal data to a third party and which of the organizations determines the purpose and means of the processing?

Note. This happens when an applicant receives data from an external party and the external party determines what will happen with the data (e.g., the applicant receives data on which specific analyses have to be conducted). Then it is mandatory to make specific agreements regarding the delineation of the processing. The model processor agreement is available from Legal Affairs.

- No
- Yes, data will be sent to:
 - the project group, including [Click here to enter text.](#)
 - co-researcher(s) from other universities of institutions. Please state their names, contact details and countries: [Click here to enter text.](#)
 - other persons responsible for processing the data. Please state their names, contact details and countries: [Click here to enter text.](#)
- Yes, data access will be provided to:
 - the project group, including [Click here to enter text.](#)
 - co-researcher(s) from other universities of institutions. Please state their names, contact details and countries: [Click here to enter text.](#)
 - other persons responsible for processing the data. Please state their names, contact details and countries: [Click here to enter text.](#)

GDPR

26. If applicable, to which third parties (controllers and processors) are the data provided by default? What is the purpose and the basis of this provision?

Note. Examples are tax authorities, pension funds, health insurers etc. Third parties with an independent processing responsibility are always external and determine their own purpose and resources for the processing. If the data is provided to another controller, then an agreement should be concluded about privacy and security guarantees. This can be done in the agreement that already exists with that other party or in a data exchange agreement for the study for which this clearance is asked.

<Insert text here>

GDPR

27. Is a Data Protection Impact Assessment (DPIA) needed? Tick all that apply. Please note that if two or more boxes are ticked a DPIA is required.

Note. A DPIA is a systematic estimate of the impact of a certain system on the data protection of the persons concerned. Such an assessment is required if the applicant intends to collect a huge data set or an extremely sensitive data set, which warrant a separate analysis of the risks of the projects. Based on this estimate, recommendations can be made to minimize this impact as much as possible or even eliminate it completely.

>> Continue on the next page

- Evaluation or scoring, including profiling and predicting, especially from “aspects concerning the data subject's performance at work, economic situation, health, personal preferences or interests, reliability or behavior, location or movements”. An example: building behavioral or marketing profiles based on usage or navigation of websites.
- Automated-decision making with legal or similar significant effect: processing that aims at taking decisions on data subjects producing “legal effects concerning the natural person” or which “similarly significantly affects the natural person”. For example, the processing may lead to the exclusion or discrimination against individuals. Processing with little or no effect on individuals does not match this specific criterion
- Systematic monitoring: processing used to observe, monitor or control data subjects, including data collected through “a systematic monitoring of a publicly accessible area”. This type of monitoring is a criterion because the personal data may be collected in circumstances where data subjects may not be aware of who is collecting their data and how they will be used. Additionally, it may be impossible for individuals to avoid being subject to such processing in frequent public (or publicly accessible) space(s).
- Sensitive data: this includes special categories of data (for example information about individuals' political opinions), as well as personal data relating to criminal convictions or offences. This criterion also includes data which may more generally be considered as increasing the possible risk to the rights and freedoms of individuals, such as electronic communication data, location data, financial data (that might be used for payment fraud).
- Data processed on a large scale: a. very large datasets concerning many thousands or millions of people; b. the volume of data and/or the range of different data items being processed; c. the duration, or permanence, of the data processing activity; d. the geographical extent of the processing activity.
- Datasets that have been matched or combined, for example originating from two or more data processing operations performed for different purposes and/or by different data controllers in a way that would make it possible to deduce the personal identities of subjects.
- Data concerning vulnerable data subjects, such as minors and patient groups.
- Innovative use or applying technological or organizational solutions, like combining use of finger print and face recognition for improved physical access control, etc.
- Data transfer across borders outside the European Union, taking into consideration, the potential risks of data transfers to such countries.
- When the processing in itself “prevents data subjects from exercising a right or using a service or a contract”. This includes processings performed in a public area that people passing by cannot avoid.

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Is a DPIA required for this study? Please note that if two or more boxes of the previous question were ticked, a DPIA is required.

- No
- Yes, but no DPIA has been conducted yet.
- Yes and has already been carried out. Please, specify the details:
[Click here to enter text.](#)

END