



# **Data Protection and Ethics Review Process:**

## **The impact of GDPR**

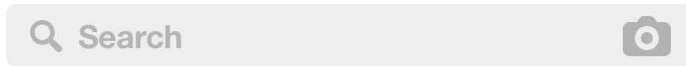


## *Ethics and Data: Why Should We Care?*

- **No human should be subject to research project without his/her knowledge and agreement;**
- **Potential high risk for data subject rights (in case of data breach) such as:**
  - Discrimination;
  - Stigmatisation;
  - Harm to the welfare and wellbeing etc.;
- **Lost of trust in science;**

# Main Ethics Concerns

Free, voluntary and informed consent?



Heads up! On May 1, 2018, we'll update our **Privacy Policy** and **Terms of Service** to make them clearer and to address some new privacy laws in Europe. Tap Accept to let us know you're okay with the updates.

[Learn more](#) [Accept](#)




- **Big Data analytics;**
- **Use of data from social media platforms;**
- **Use of data collected by commercial organisations (e.g. fitness trackers) for research purposes and vice versa;**

## Welcome to the Oath Privacy Center

- Analyze your content and other information (including emails, instant messages, posts [photos](#), [attachments](#), and [other communications](#)). You can review and control certain types of information tied to your Oath account by using [Privacy Controls](#).

## ***Main Ethics Concerns***

*Utilisation of publicly available data*




*"On Twitter, we get excited if someone follows us. In real life we get really scared and run away." Unknown via @mozusa*

- **Profound confusion between the concepts of 'being in public' and 'being public';**
- **Misconception that publicly available data poses only marginal risks.**

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# ***Main Ethics Concerns***

## *Online recruitment*

- **Uncertainty as to the real age of the participants;**
- **Possible harm for the individuals;**

## ***Main Ethics Concerns***

*Anonymisation and Pseudonymisation*

*Data Minimisation*

- **Lack of clear understanding of the process and the difference between anonymisation and pseudonymisation;**
- **Excessive collection of data and unjustified storage periods.**

# ***Main Ethics Concerns***

*Security Arrangements*

*Data Transfers*

- **Non-secure data processing arrangements;**
- **Use of non-adequate software and storage providers and changing terms of use;**
- **Restrictions for processing of data in third countries.**



## *Main Ethics Concerns*



# EU General Data Protection Regulation:

## Data Protection: ~~R~~evolution

### ARTICLE 8

#### Right to respect for private and family life

1. Everyone has the right to respect for his private and family life, his home and his correspondence.
2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

### Treaty on the Functioning of the European Union

Article 16  
(ex Article 286 TEC)

1. Everyone has the right to the protection of personal data concerning them.

- Builds on the principles of the Data Protection Directive 95/46/EC;
- Increases transparency and accountability of the data processing;
- Enhances the data protection rights of the individuals.

### Charter of Fundamental Rights of the European Union

Article 7

#### Respect for private and family life

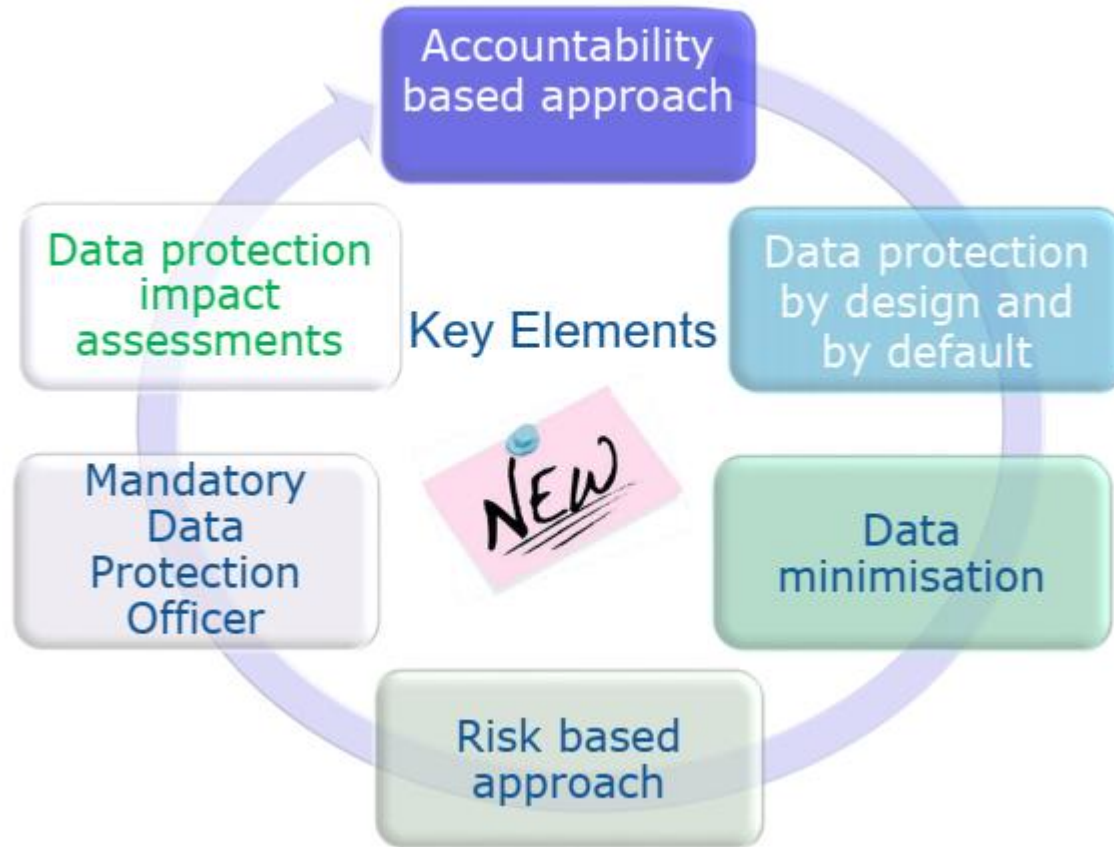
Everyone has the right to respect for his or her private and family life, home and communications.

Article 8

#### Protection of personal data

1. Everyone has the right to the protection of personal data concerning him or her.
2. Such data must be processed fairly for specified purposes and on the basis of the consent of the person concerned or some other legitimate basis laid down by law. Everyone has the right of access to data which has been collected concerning him or her, and the right to have it rectified.
3. Compliance with these rules shall be subject to control by an independent authority.

# Key GDPR Approaches



# ***GDPR and Research:***

*Key principles*

- **Processing of data for research purposes shall be subject to appropriate safeguards.**
- **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.**

# GDPR and Its Impact on the Ethics

## **Risk based approach**

**Data protection must be proportionate to the risks to data subjects.**

## *Examples of Higher Ethics Risk Indicators*

<b>Types of personal data used in the research</b>	<ul style="list-style-type: none"><li>* racial or ethnic origin;</li><li>* political opinions, religious or philosophical beliefs;</li><li>* genetic, biometric or health data;</li><li>* sex life or sexual orientation;</li><li>* trade union membership.</li></ul>
<b>Data subjects involved in the research</b>	<ul style="list-style-type: none"><li>* children;</li><li>* vulnerable persons ;</li><li>* persons who have not given their explicit consent to participate in the research project.</li></ul>
<b>Scale or complexity of data processing</b>	<ul style="list-style-type: none"><li>* large-scale processing of personal data;</li><li>* systematic monitoring of publicly assessable area on a large scale</li><li>* involvement of multiple datasets and/or service providers, or the combination and analysis of different datasets (i.e. "big data").</li></ul>

## *Examples of Higher Ethics Risk Indicators*

<b>Data processing techniques involved in the research</b>	<ul style="list-style-type: none"><li>* privacy-invasive methods or technologies (e.g. the covert observation, surveillance, tracking or deception of individuals);</li><li>* the use of camera systems to monitor behaviour or record sensitive information;</li><li>* "data-mining" (including data collected from social media networks), "web-crawling" or "social network analysis";</li><li>* the profiling of individuals or groups (particularly behavioural or psychological profiling);</li><li>* the use of "artificial intelligence" to analyse personal data;</li><li>* the use of automated decision-making which has a significant impact on the data subject(s).</li></ul>
<b>Involvement of non-EU countries</b>	<ul style="list-style-type: none"><li>* transfer of personal data to non-EU countries;</li><li>* collection of personal data outside the EU.</li></ul>

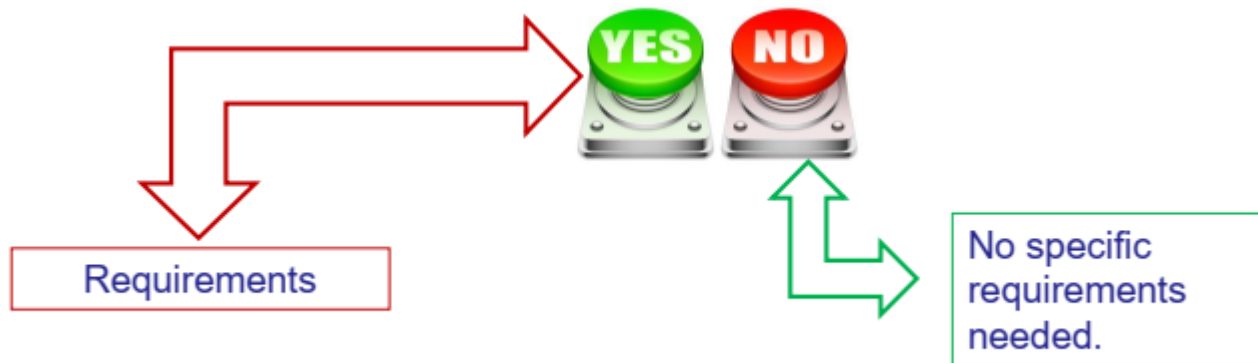


**Lawfulness, FAIRNESS and transparency  
of data processing.**

## *H2020 Ethics Framework:*

*What shall we look at?*

- **Does the research involve the collection and/or processing of personal data?**



## *General requirements*

**If personal data is processed, the following may be requested:**

- **Confirmation by the host institution that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research.**
- **If designation of a DPO is not required under the GDPR , a detailed data protection policy for the project must be elaborated.**

## *General requirements*

### **If personal data is processed:**

- Description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants.

**AND/OR**

- Description of the anonymisation/pseudonymisation techniques that will be implemented
- Description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing.

## *General requirements*

### **If personal data is processed:**

- Explanation how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation' principle).
- Explanation why the research data will not be anonymised/pseudonymised.
- Detailed information on the informed consent procedures with regard to data processing.
- Templates of the informed consent forms and information sheets.

## Key Questions

### 2. Does the research involve processing of special categories of data?

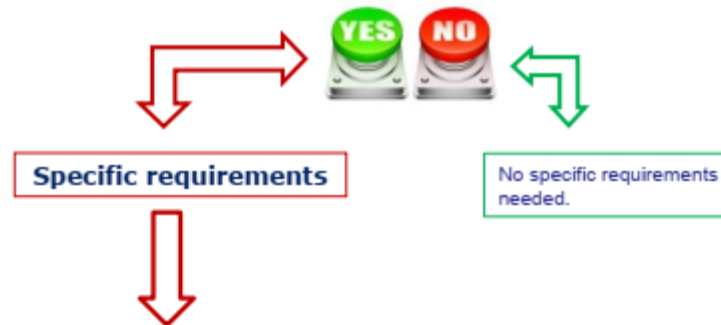
- Does the research involve the processing of genetic, biometric or health related data?



- Detailed justification for the processing of special categories of personal data.
- The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national law and submit declaration of compliance.

## Key Questions

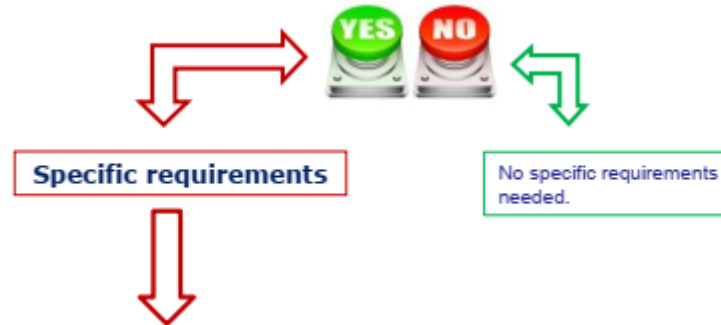
**Does the research involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods\* of data processing or any other data processing operation that may result in high risk to the rights and freedoms of the research participants?**



- Explanation how the data subjects will be informed of the existence of the profiling, its possible consequences and how their fundamental rights will be safeguarded.

## Key Questions

### 4. Does the research involve further processing of previously collected personal data?

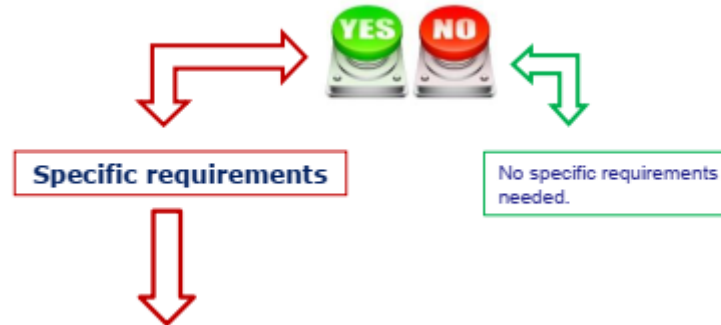


- An explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects.



## Key Questions

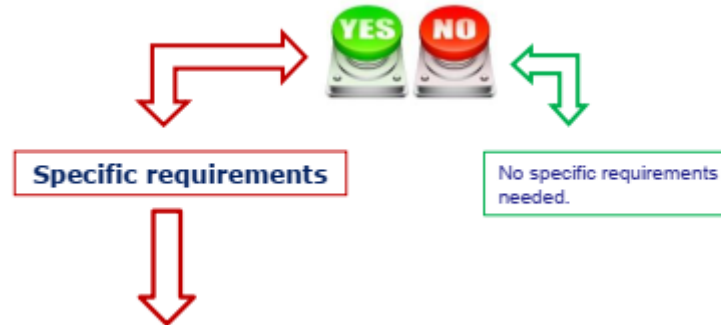
5. Is it planned to import personal data - from the non-EU countries into the EU?



- In case personal data are transferred from a **non-EU country to the EU** (or another third state), confirmation that such transfers comply with the laws of the country in which the data were collected.

## Key Questions

### 6. Is it planned to export personal data from the EU to non-EU countries?

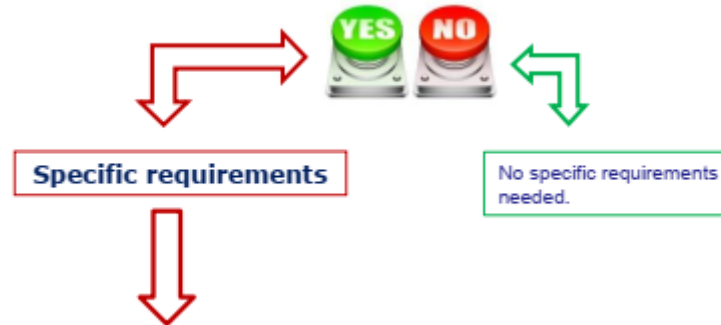


For countries, not covered by adequacy decision\*:

- In case personal data are transferred from the **EU to a non-EU** country or to an international organisation, confirmation that such transfers are in accordance with Chapter V of the General Data Protection Regulation 2016/679.

## Key Questions

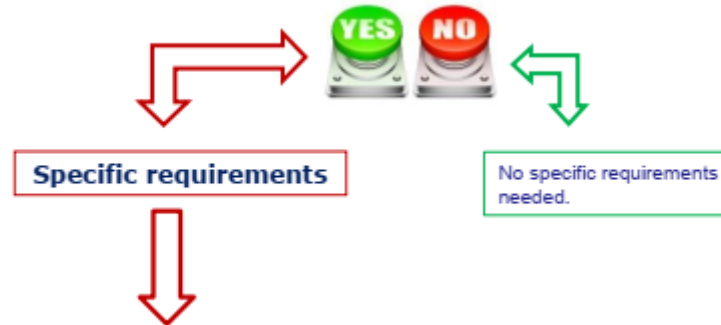
### 7. Does the research involve the processing of publicly available data?



- An explicit confirmation that the data used in the project is publicly available and can be freely used for the purposes of the project.

## Key Questions

8. Does the data processing expose the research participants to high ethics risks?



- Evaluate the ethics risks related to the data processing activities of the project. This includes also an opinion if data protection impact assessment should be conducted under art.35 GDPR. The risk evaluation and the opinion must be submitted as a deliverable.

## *General requirements*

### **Assessment of:**

- Individual ethics harms (for the research participants);
- Ethics harms to third parties (e.g. family, friends etc.)
- Group level ethics harm (for the community or the group);

### **Ethics risks to be considered (non-exclusive list):**

- Discrimination;
- Stigmatisation;
- Exposing identity and sensitive data (privacy breach);
- Security/safety risks for the research participants;
- Reputational risk and loss of position within occupational and other settings;
- Harms to the interests and wellbeing on the research participants, third parties and the community;
- Potential for misuse of data.

## *Further help:*

- Guidance 'How to complete your ethics self-assessment' (2018):

[http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/ethics/h2020\\_hi\\_ethics-self-assess\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf)

- EC Guidance Note on Ethics and Data Protection (2018):

[http://ec.europa.eu/research/participants/data/ref/h2020/grants\\_manual/hi/ethics/h2020\\_hi\\_ethics-data-protection\\_en.pdf](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-data-protection_en.pdf)

- Ethics help desk: [RTD-ETHICS-REVIEW-HELPDESK@ec.europa.eu](mailto:RTD-ETHICS-REVIEW-HELPDESK@ec.europa.eu)