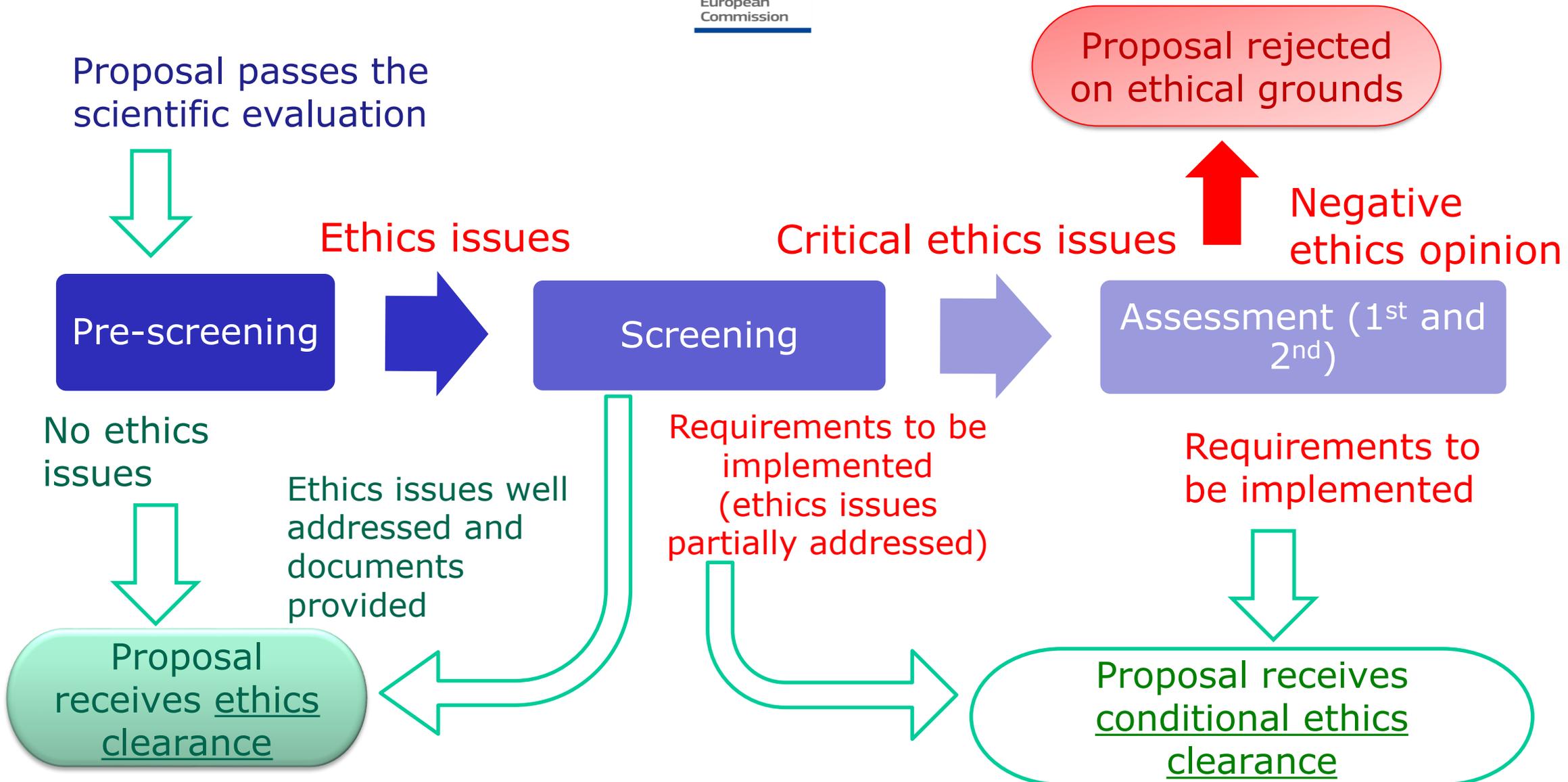




# Data Protection for H2020 projects: How to Ensure Ethics Compliance

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# Horizon2020 Ethics Review Process



# Complying with ethics and data protection requirements in H2020 funded projects



# Does your research involve the or processing of personal data?



**GDPR does not apply.**

Depending on the effort involved to identify people from the data and the safeguards to prevent this, you may be processing personal data.

← If Yes

Are you using a dataset that could be used to identify individual persons?

Explain how you are going to mitigate the related ethics risks

← If Yes

Could the dataset or the way you plan to use it have adverse implications for the group as a whole, or for specific groups within the dataset?

Explain how these will be addressed

← If Yes

Does the use of the dataset raise any further ethics issues, for example with regard to its origin or the manner in which it was obtained?

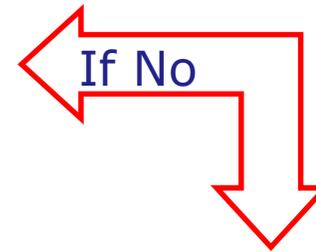
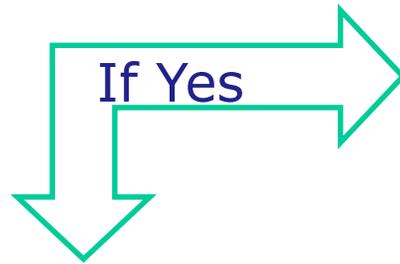
← If Yes

Are there any ethics issues arising from the use of the dataset?

If your project is processing personal data...



## Can you reach the research objectives by using anonymised/pseudonymised data?



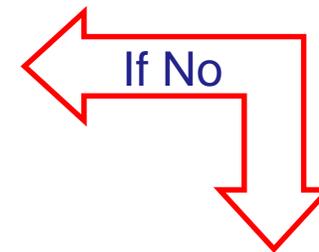
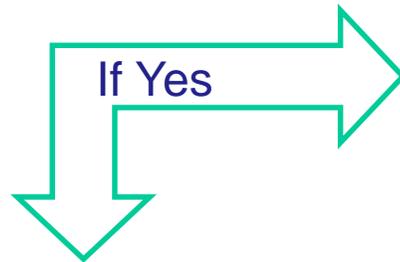
Anonymise/pseudonymise.

Explain why the research objectives cannot be reached by using anonymised/pseudonymised data.

If your project is processing personal data...



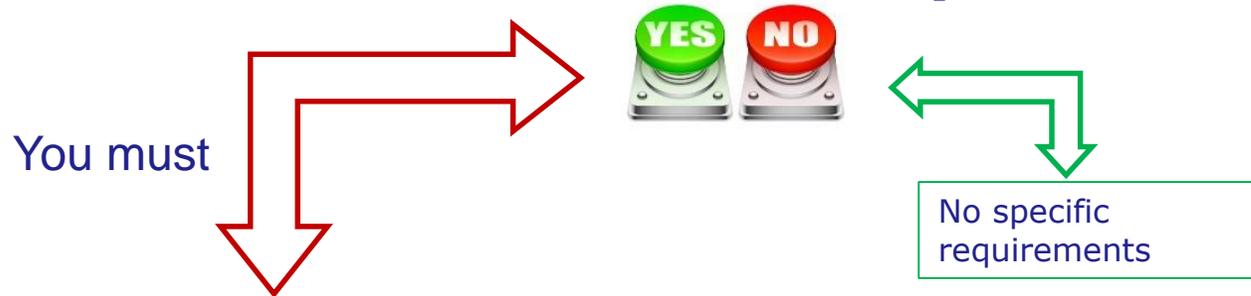
## Have you conducted a data minimisation review to ensure that you need all the data you intend to collect?



Explain how the data you are processing is adequate, relevant and limited to what is necessary in relation to the purposes of your research.

Conduct data minimisation review and explain how the data you are processing is adequate, relevant and limited to what is necessary in relation to the purposes of your research.

## Does the research involve processing of special categories of data (e.g. genetic, biometric or health related data, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?



Provide justification for the processing of special categories of personal data.

Analyse the potential risks to the rights and freedoms of research participants/data subjects and describe the measures that will be implemented to mitigate these risks in your proposal

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.



## If personal data is processed, you must provide:

1. 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.



- Explain that you are not obliged to appoint DPO under GDPR (all ethics requirements are your contractual obligations under the Grant Agreement). If your organisation does not have DPO you still have to provide project specific data protection policy;
- Provide the details of the DPO to EC only, and not to the research participants;
- Describe very vaguely that you are going to comply with GDPR (instead of providing tailored data protection policy).

## If personal data is processed, you must provide:

2. Description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants. This must include also:

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

3. Detailed information on the informed consent procedures with regard to data processing and templates of the informed consent forms and information sheets.



- Confuse pseudonymisation with anonymisation;
- Describe vaguely the security measures (e.g. stored safely by the project partner);
- State that you are processing data based on public interest and IC is not relevant. If this is the case, demonstrate fairness of the data processing.

## Does the research involve privacy-intrusive techniques, technologies or methods?



Provide details of the methods used for tracking, surveillance or observation of participants.

Provide details of the methods used for profiling.

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

Explain how will harm be prevented and the rights of the research participants safeguarded.

Assess the ethics risk related to the data processing activities

Provide the opinion of the data controller on the need for a data protection impact assessment (art.35 GDPR) (if relevant).

Consult the Data Protection Officer at your institution on the data processing and protection provisions.

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



Provide declaration confirming the lawful basis for the data processing.

Provide details of the database used or of the source of the data.

Provide details of the data processing operations.

Explain how will the rights of the research participants be safeguarded (e.g description of the appropriate technical and organisational measures).

Provide the permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).

Provide templates of the Informed Consent Forms + Information Sheets + other consent documents (if applicable).

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



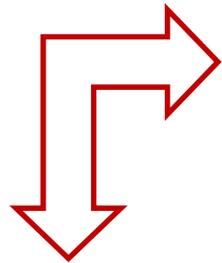
Provide explicit confirmation that the data used in the project is publicly available and can be freely used for the purposes of the project.

Provide permission by the owner/manager of the data sets (e.g. social media databases) (if applicable).

Check if your intended use of the data conforms to any terms and conditions published by the data controller.

## Is it planned to export personal data from the EU to non-EU countries\*?

For countries not covered by adequacy decision\* you must



Are all partners and/or service providers (e.g. survey tools, data analytics, cloud storage etc.) with access to or otherwise processing the research data are based in the EU?



No specific requirements

Confirm that such transfers are in accordance with Chapter V of the General Data Protection Regulation 2016/679.

Provide details on the type of personal data to be imported.

Explain how will the rights of the research participants be safeguarded (e.g. description of the appropriate technical and organisational measures).

\*Norway, Liechtenstein, Iceland; Andorra; Argentina; Canada(commercial organisations); Switzerland; Faeroe Islands; Guernsey; Israel; Isle of Man; Japan; Jersey; New Zealand; United States (under Privacy Shield); Eastern Republic of Uruguay

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

For countries not covered by adequacy decision\* you must



Provide details on the type of personal data to be imported.

Confirm that such transfers comply with the laws of the country in which the data were collected.

## 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 and describe the measures and safeguards you will implement to mitigate the risks.

Consult the Data Protection Officer at your institution on the data processing and protection provisions.

Provide the opinion of the data controller on the need for a data protection impact assessment (art.35 GDPR) (if relevant).



## **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 data;*
- *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.*

## HORIZON2020 Ethics Review Process: Some tips

- ✓ *Start thinking (and discussing) about ethics while designing your research protocols. Do not wait until the last minute to seek advice or check what is required under national and European legislation.*
- ✓ *As regards personal data, ask yourself: am I processing data in a FAIR manner?*



## Further help:

Guidance 'How to complete your ethics self-assessment':

[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)

Note on Ethics and Data Protection (2018):

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