European Commission

THE EU RESEARCH & INNOVATION PROGRAMME

2021 – 2027

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HORIZON EUROPE RESEARCH ETHICS

Research and Innovation

amazing-galloping-horses.webp

TRUST TAKES YEARS TO BUILD, SECONDS TO BREAK, AND FOREVER TO FIX.

European Commission

Structure today

- Legal Basis

Horizon Europe

- Operational issues

Ethics Appraisal Process

- Specific issues and ANNEX

The Ethics and Integrity life line – The policy and operational framework

The ERA PACT

HORIZON EUROPE REGULATION and SPECIFIC PROGRAMME

Ethics Appraisal and research financing in ethics and integrity

The HE Grant Agreement

The responsibilities of the beneficiaries

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THE PACT

1. VALUES AND PRINCIPLES FOR RESEARCH AND INNOVATION

(1) Agree on a common set of values and principles for research and innovation in the Union as set out below, and apply them in their internal research and innovation systems, in close collaboration with stakeholders. These values and principles should also be promoted by the Member States and the Union in their interactions with third countries in order to achieve a level playing field and common framework conditions.

Upholding values

(a) Ethics and integrity of research and innovation: researchers, research processes and the research and innovation system overall should comply with strict ethics and integrity rules and practices, which are the foundation of responsible and trustworthy research free from undue influence, a prerequisite for achieving excellence, and underpin the responsibility of researchers to guard against biases and methodological shortcuts;

(b) Freedom of Scientific research

……

https://ec.europa.eu/info/news/commission-adopts-proposal-pact-research-and-innovation-europe-2021-jul-16_en

Ethics in Horizon Europe

HORIZON EUROPE SPECIFIC PROGRAMME STRENGTHENING THE EUROPEAN RESEARCH AREA

….Ethics and integrity, to further develop a coherent Union framework in adherence with the highest ethics standards and the European Code of Conduct for Research Integrity,……,

providing the training opportunities in these areas

Horizon Europe Specific Programme https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021D0764&from=EN

REGULATION (EU) 2021/695 ESTABLISHING HORIZON EUROPE

Article 19
‘Actions carried out under the Programme shall comply with **ethical principles** and **relevant Union, national and international legislation**, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.’

https://ec.europa.eu/info/research-and-innovation/funding/funding-opportunities/funding-programmes-and-open-calls/horizon-europe_en

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General Ethics obligations

Article 19 (4) Horizon Europe Regulation

Legal entities participating in an action **shall obtain all approvals or other mandatory documents** from the relevant national, local ethics committees or other bodies, such as data protection authorities, before the start of the relevant activities. Those documents **shall be kept on file** and provided to the Commission or the relevant funding body upon request.

Model Grant Agreement (MGA) Article 14

The action must be carried out in line with the **highest ethical standards** and the applicable EU, international and national law on ethical principles.

Activities raising ethical issues must comply with the additional requirements formulated by the ethics panels (including after checks, reviews or audits; see Article 25).

Before starting an action task raising ethical issues, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities.

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf

The EUROPEAN CODE for Research Integrity
A reference document

The Code is a reference in the Horizon Europe Regulation

and in

the HE Grant Agreement

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Ethics and Integrity in Horizon Europe

- Integrity and ethics in research are key components and a prerequisite for **achieving excellence** in research and innovation.
- **The key goal is to build and sustain trust in science and innovation, and to encourage and enable** researchers and innovators use the ethics by design approach to bring meaningful added value: the development of knowledge, technology and applications that improve people's lives, prospects and possibilities.
- **Ethics is not be 'red tape' for research, but empowers researchers** to do the right thing for our society and to build trust grounded in our values and fundamental rights such as human dignity and privacy protection and security.

Guiding principles

Article 19 - Regulation (EU) 2021/695 establishing Horizon Europe:

‘Particular attention shall be paid to:

- the principle of proportionality
- the right to privacy
- the right to the protection of personal data
- the right to the physical and mental integrity of a person
- the right to non-discrimination
- the need to ensure protection of the environment
- the need to ensure high levels of human health protection’

Activities not eligible for funding
(Article 18 HE regulation 2021/695; Article 14 Model Grant Agreement)

- Activities must **focus exclusively on civil applications** and **must not**:
  - aim at human cloning for reproductive purposes;
  - intend to modify the genetic heritage of human beings which could make such changes heritable (except for research relating to cancer treatment of the gonads, which may be financed);
  - intend to create human embryos solely for the purpose of research, or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer;
  - lead to the destruction of human embryos.
- No funding shall be granted for research activities that are prohibited in all the Member States.
- No activity shall be funded in a Member State where such activity is forbidden.

Horizon Europe - Changes to the Ethics Issues Table

1. ~~Human embryos & foetuses~~ **Human Embryonic Stem Cells (hESC) and Human Embryos (hE)**
2. Human participants
3. **Human cells / tissues**
   - **Does your research involve the use of human embryonic or foetal cells or tissues (other than hESC)?**
4. Personal data
5. Animals
6. Non-EU countries
7. Environment & Health and Safety
8. **Artificial Intelligence – NEW!**
9. Other ethics issues
10. **Crosscutting issue: potential misuse of results***
11. ~~**Exclusive focus on civil applications**~~
12. ~~**Dual use**~~

Artificial intelligence – NEW!
Scientific & ethics evaluation

Trustworthy Artificial Intelligence

- **Due diligence** is required regarding the **trustworthiness of all AI-based systems/techniques** used or developed in projects funded under Horizon Europe.

- Scientific Experts to answer a specific question:
  - Do the activities proposed involve the use and/or development of AI-based systems and/or techniques?
  - If so, scientific experts' must assess the **technical robustness*** of the proposed AI-system as part of the excellence criterion
- The ethics experts **take into account the assessment on the technical robustness** when performing their ethics evaluation

(*) Technical robustness refers to technical aspects of AI systems and development, including resilience to attack and security, fullback plan and general safety, accuracy, reliability and reproducibility.

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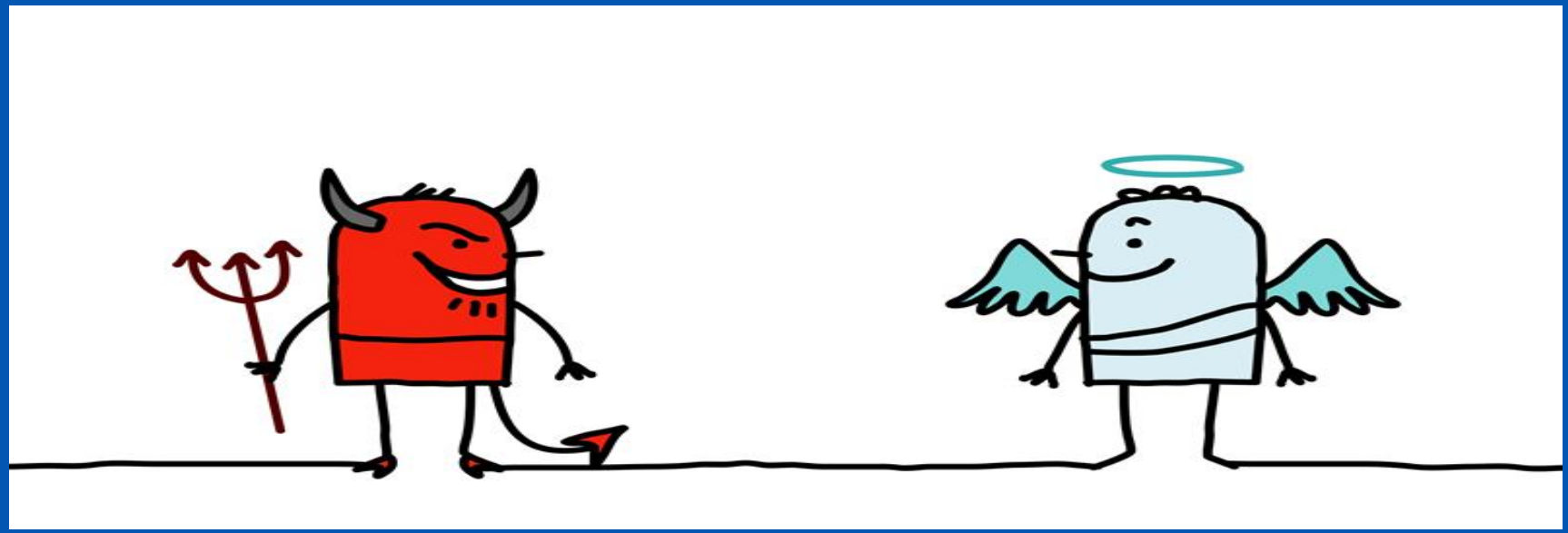
Ethics Appraisal

Horizon Europe overview

The responsibility of the applicant



Do not fight your angel….

Time : a rare commodity

"All these privacy regulations are just common sense and ethics. Who's got time for that?"

START: What researchers should do

"…. **to seek advice from colleagues with expertise in the ethics of research**: specialised ethics departments, relevant managers in your university/research organisation, hospital research ethics committees, ethics advisors in your company, data protection officers, etc. They will be able to provide you with the necessary information targeted at your specific needs and legal environment."

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.“

ETHICS BY DESIGN

Consider that ethics issues arise in many areas of research. **Apart from the obvious**, **the medical field**, research protocols in social sciences, ethnography, environmental studies, security research, etc. might involve the voluntary participation of research subjects and the collection of data that might be considered as personal.

You must protect your volunteers and also protect yourself (and your researcher colleagues)

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ETHICS TO DO LIST

The researchers must do:

Identify all potential ethical issues ;

Handle all ethics aspects of the proposal;

Explain in sufficient detail how the ethics issues will be addressed .

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HE Ethics in brief, reference material; guidance notes

programme-guide_horizon_en.pdf (europa.eu)

HE Ethics training and Ethics by Design in AI

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

III. ETHICS APPRAISAL - HORIZON EUROPE

Application

- Ethics Issues Table (1a)
- Ethics **Self-Assessment** (1b-1d)

Shortlisted PROPOSALS

- Before Grant agreement!
- **Ethics Screening** of all proposals (2)
- **Ethics Assessment** of proposals raising complex and/or serious ethics issues (3)

Ongoing RESEARCH PROJECTS

- **Ethics Checks and Review** for selected projects (4)

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Ethics Issues Table

2. HUMANS			Page
Does this activity involve human participants?		○ Yes ○ No	
If **YES**:	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	○ Yes ○ No	
	Are they healthy volunteers for medical studies?	○ Yes ○ No	
	Are they patients for medical studies?	○ Yes ○ No	
	Are they potentially vulnerable individuals or groups?	○ Yes ○ No	
	Are they children/minors?	○ Yes ○ No	
	Are they other persons unable to give informed consent?	○ Yes ○ No	
Does this activity involve interventions (physical also including imaging technology, behavioural treatments, etc.) on the study participants?		○ Yes ○ No	
If **YES**:	Does it involve invasive techniques?	○ Yes ○ No	
	Does it involve collection of biological samples?	○ Yes ○ No	

Step 2: Self-assessment

If any YES in the Ethics issues Table…

Go to the "How-to complete your ethics self assessment"

→ Ethics Self-assessment

HE Regulation (Article 19 (2)):

- 'Legal entities participating in an action shall provide:

(a) an ethics self-assessment identifying and detailing all the foreseeable ethics issues related to the objective, implementation and likely impact of the activities to be funded, including a confirmation of compliance (…) and a description of how it will be ensured.'

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Step 2: ‘How-to complete your ethics self assessment’

Section 2: HUMANS		YES/ NO		Information to be provided in the proposal	Documents to be kept on file and provided on request
Does your activity involve human participants?		☐	☐	Please provide information in one of the subcategories below	
If **YES:**	Are they volunteers for nonmedical studies (e.g. social or human sciences research)?	☐	☐	1) Details on recruitment, inclusion and exclusion criteria and informed consent procedures. 2) Details on unexpected findings policy.	1) Copies of ethics approvals (if required by law or practice). 2) Informed consent forms and information sheets.
	Are they healthy volunteers for medical studies?	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed	1) Copies of ethics approvals. 2) Informed consent forms and information sheets.

ETHICS SELF-ASSESSMENT

If you have entered any issues in the ethics issue table, you must perform an ethics self-assessment in accordance with the guidelines 'How to Complete your Ethics Self-Assessment' and complete the table below

Ethical dimension of the objectives, methodology and likely impact
Explain in detail the identified issues in relation to: – objectives of the activities (e.g. study of vulnerable populations, etc.) – methodology (e.g. clinical trials, involvement of children, protection of personal data, etc.) – the potential impact of the activities (e.g. environmental damage, stigmatisation of particular social groups, political or financial adverse consequences, misuse, etc.)
Compliance with ethical principles and relevant legislations
Describe how the issue(s) identified in the ethics issues table above will be addressed in order to adhere to the ethical principles and what will be done to ensure that the activities are compliant with the EU / national legal and ethical requirements of the country or countries where the tasks are to be carried out. It is reminded that for **activities performed in a non-EU countries**, they should also be allowed in at least one EU Member State.

Ethics Panels are usually risk averse if you are not ready

GET READY for the ethics review: there is never enough time 5 minutes before the deadline

ETHICS BY DESIGH

ASK: usually the answers are in the same building you are (if all fails Google and trust official sources)

Better incomplete and acknowledging that empty and indifferent

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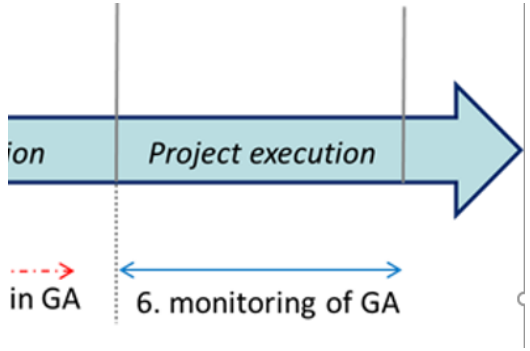
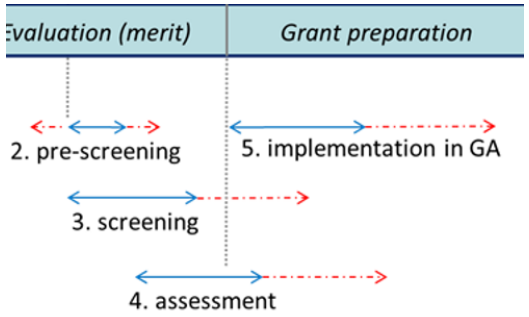
Ethics Appraisal Outcomes

Clearance



Ethics Assessment for serious and complex cases – ethics requirements in the GA and monitoring

Clearance with possibly ethics Advisor/board and Ethics Review



Rejection

What are serious and/or complex ethics issues?

- **Examples**:
  - Research involving untested forms of **human bio-engineering, human-machine integration or human-animal chimeras**
  - Research that includes **children/minors/people unable to give informed consent**, with **no clear justification** for their participation or benefit to them
  - Research that includes **vulnerable participants** in first in-human or early-stage clinical studies for new therapeutics (including new chemical entities, biologics, gene therapies), medical applications and procedures
  - Research that deploys or develops medical devices, particularly implanted devices, that aim to or have the potential to bring about **involuntarily behaviour change** or therapeutic ‘adherence’

What are serious and/or complex ethics issues?

- **Examples**:
  - Research that appears to **take advantage of differences in standards or the absence of legislative protection** for research participants, local researchers and other local staff, data protection and privacy, animals, the environment or the public, particularly in lower-income settings.
  - Research resulting in the **transfer of special category data to countries with inadequate data protection regimes**, without the knowledge or explicit consent of the data subjects.

- *https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/guidelines-on-serious-and-complex-cases_he_en.pdf*

Ethics appraisal - Key procedural changes…

Horizon 2020

Pre-screening / Screening

→ Formulation of Ethics Requirements = contractual obligations in Grant Agreement

Horizon Europe

Pre-screening/Screening for Flagging of ethics issues

Ethics Issues → **Flagged, but no contractual requirements in the GA** . Ethics advisor or board can be requested

…and similarities

Ethics Assessment for proposals **raising complex/serious ethics issues** (including **hE and hESC**)

Independent ethics advisor or board can be required

PROJECT Ethics Checks , Reviews and Audits can be initiated by the EC

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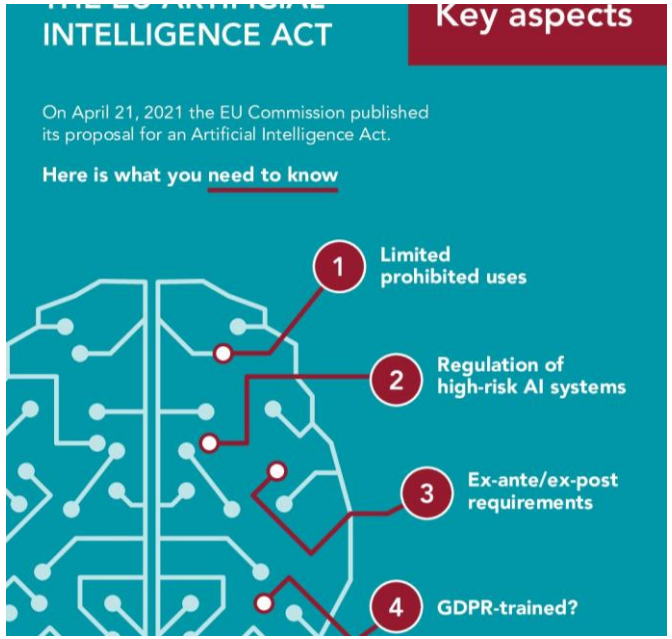
Challenges

Support to the researchers

Ethics Committees support and work loads

Education and training

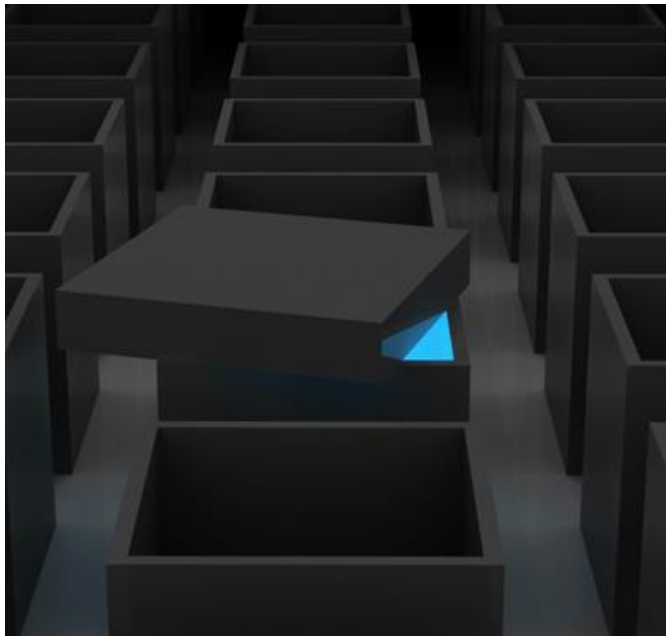
Who is ready? Ethics of emerging technologies (AI)



The EU AI ACT

Structures and Committees at local level

New committees- new roles



Learn to work outside silos

the AI black Box

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Artificial intelligence

- **Unethical applications**. E.g. violating physical or mental integrity, create addiction, risk damaging social processes and public institutions (e.g. by social scoring or contributing to misinformation)
- Key ethical requirements:
  - ➔People must be made aware that they are interaction with an AI system, its abilities and limitations, risks and benefits
  - ➔Mechanisms for human oversight, transparency and auditability must be ‘built in’ the AI system
  - ➔AI-system must be designed to avoid bias in input data and algorithmic design
  - ➔Compliance with data protection and privacy principles, e.g. data minimisation, must be demonstrated
  - ➔…

Artificial intelligence

Self-assessment: Could the AI system/technique stigmatise or discriminate against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?

→ Explain how potential bias, discrimination and stigmatization will be avoided.

→'**Ethics by design' methodology**: concrete steps for each phase in the development process. E.g.:

- Check for algorithmic bias during the detailed development phase. Data could be processed in a biased way, and therefore algorithms should be checked for this. (E.g. by using counterfactual evaluation methods)
- Ensure that interface design honours principles of universal accessibility, and avoid the introduction of functional biases in the detailed development phase that make the system unequally functional for different end-users.

Artificial intelligence

Self-assessment: Could the AI system/technique stigmatise or discriminate against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?

→ Explain how potential bias, discrimination and stigmatization will be avoided.

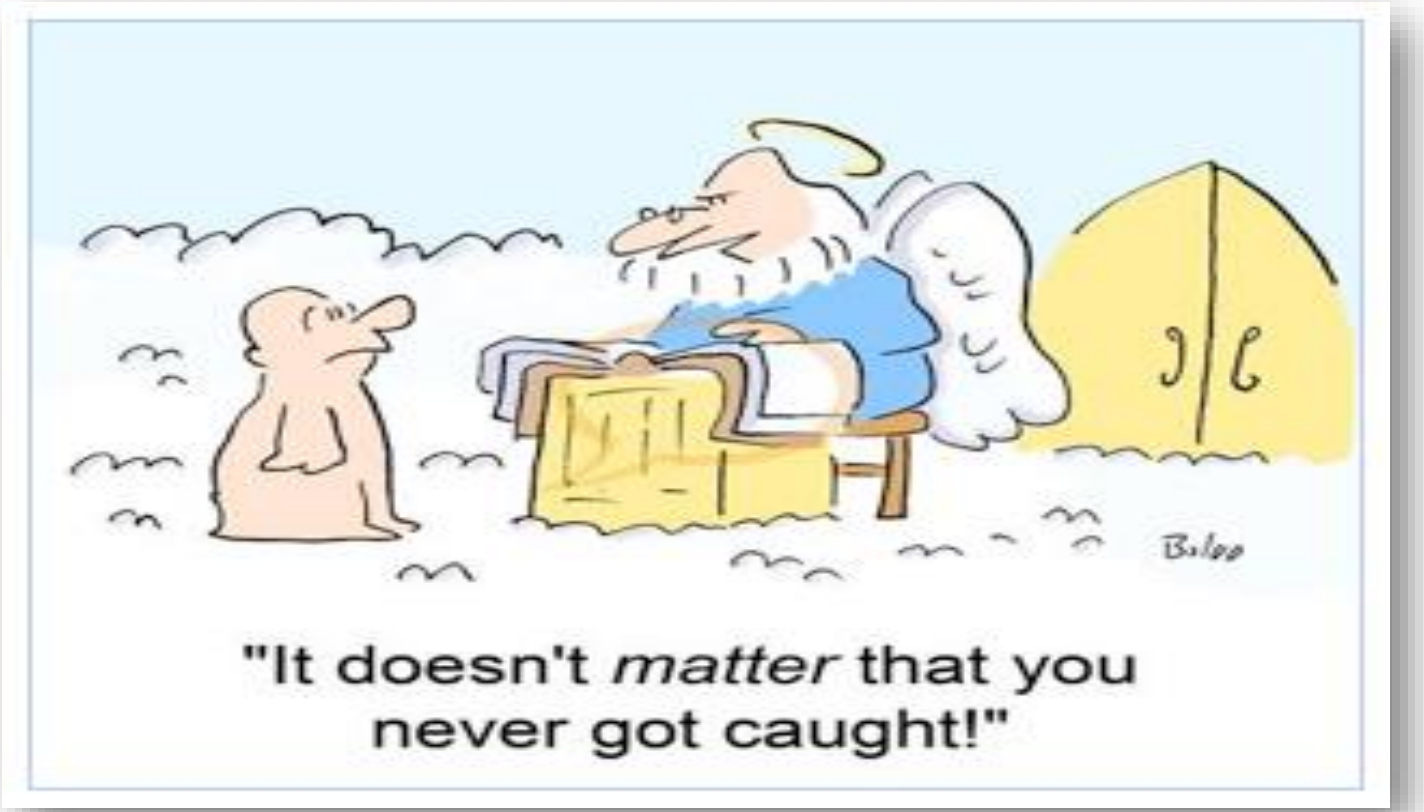
→'**Ethics by design' methodology**: concrete steps for each phase in the development process. E.g.:

- Check for algorithmic bias during the detailed development phase. Data could be processed in a biased way, and therefore algorithms should be checked for this. (E.g. by using counterfactual evaluation methods)
- Ensure that interface design honours principles of universal accessibility, and avoid the introduction of functional biases in the detailed development phase that make the system unequally functional for different end-users.

On Line General Course and AI Ethics By Design

HE Ethics training and Ethics by Design in AI

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



If you think Ethics is expensive , try misconduct….

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Thank you!

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 # HorizonEU

http://ec.europa.eu/horizon-europe

General process issues

ANNEX

Activities not eligible for funding
(Article 18 HE regulation 2021/695; Article 14 Model Grant Agreement)

- Participants declare in their proposal (part A) that no activities excluded from funding are proposed.
- Scientific evaluators are asked to confirm this.

!!! If not the case (i.e. ineligible activities in the proposal), proposals are not immediately rejected, but processed according to their score.

BUT:

- Removal of activities not eligible for funding is reflected in the score.
- Modification OR rejection of proposals is decided at GAP stage, taking into account opinion of scientific experts (e.g. feasibility of reaching projects' objectives with other methods)

Use of human embryonic stem cells & human embryos - Scientific evaluation & Ethics assessment

- Research on human stem cells, both adult and embryonic, may be financed depending both on the contents of the scientific proposal and the legal framework of the Member States involved*.
- **Scientific experts** give their opinion on whether the proposal involves the use of **hESC** and **hE.** This is independent of, and serves to verify, the applicants' answers in the ethics issues table.
- If scientific evaluators consider that the proposal involves hESC, they have to state whether the use of hESC is, or is not, **necessary to achieve the scientific objectives** of the proposal and the reasons why.

The scientific experts' answer to the questions on hESC/hE will be used by the ethics experts in charge of the ethics assessment (mandatory for all proposals involving hESC or hE)

Dual use & Exclusive focus on civil applications

No longer to be assessed by ethics reviewers !!

- Applicant declarations (Part A of the proposal): '*we declare that the proposal has exclusive focus on civil applications*' + '*if the proposal involves dual-use items or other items for which authorization is required, we will comply with the relevant regulatory framework*.'
- For **dual use**, the declaration by the applicant is sufficient (no further checks in evaluation or grant management).
- For **exclusive focus on civil applications** aspects: verified by scientific evaluators.
  - → Guidance note on research focusing exclusively on civil applications
  - → Commission Recommendation on internal compliance programmes for controls of research involving dual-use items under Regulation (EU) 2021/821

The approach to follow for the question on 'exclusive focus on civil applications' is the same as the process for activities not eligible for funding. Opinion of experts indicating if removing the activities that do not have an exclusive focus on civil applications would lead to lower evaluation scores, and final decision during GAP.

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Cross-cutting issue: misuse

- The Security Issues Table (application form Part A) covers **misuse from the security perspective**.

  E.g. research activities that could generate knowledge, materials and technologies that could be adapted for criminal/terrorist activities; or result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery.

- **Misuse not related to the security dimension** will be considered under the **Ethics Issues Table** and analysed as part of the relevant ethics sections (humans, personal data, animals, environment, health and safety, artificial intelligence) or as 'other ethics issue'.

Cross-cutting issue: misuse

- **Misuse not related to the security dimension:**
  - E.g. the development of surveillance technologies that could curtail human rights and civil liberties.
  - E.g. research that involves minority or vulnerable groups or develops social, behavioural or genetic profiling technologies that could be misused to stigmatise, discriminate against, harass or intimidate people.

→ Guidance note on potential misuse of research results

3. Ethics Screening: Possible outcomes

Ethics issues?

NO? ➔ ETHICS CLEARANCE

YES? ➔ Serious and/or complex ethics issues?

1. **NO**: Beneficiaries further deal with ethics issues in accordance with national and European legislation – **no further analysis or requirements** in the Ethics Summary Report ➔ **ETHICS CLEARANCE**

2. **NO**: Beneficiaries further deal with ethics issues in accordance with national and European legislation BUT **need to appoint external independent ethics advisor or board** ➔ **CONDITIONAL ETHICS CLEARANCE**

3. **YES**: ➔ **ETHICS ASSESSMENT**

Ethics Assessment

- An **in-depth analysis** of the ethics issues for:

    1. All proposal involving **hE and/or hESC** (directly to assessment)

    2. Proposals raising **serious and/or complex ethics issues**

- Panel of at least 5 external experts

- **Key goal: to identify additional measures that must be implemented during grant preparation or later during grant implementation,** for ethics issues not satisfactorily addressed in the proposal.

- **!** Ethics requirements in proportion to the severity of the ethics issues, according to a risk-based approach.

4. Ethics Assessment: Possible outcomes

1. **ETHICS CLEARANCE** → GA is finalized

2. **CONDITIONAL ETHICS CLEARANCE**

   →The Ethics Summary Report contains **ethics requirements that need to be fulfilled**

   →Before GA and/or contractual obligations included in GA

   →**Ethics work package & Ethics deliverables** *(e.g. information on consent procedures, copies of ethics approvals, …)* as part of project reporting and monitoring

3. ***Second ethics assessment or more information needed*** → GA is postponed

4. **NO ETHICS CLEARANCE (after second assessment)** → Proposal cannot be funded

5. Implementation

!!! No ethics requirements =/= no ethics obligations

- The **applicant declarations** and **ethics self-assessment** become part of the description of the action (Annex 1 of the grant agreement) and create obligations for the beneficiaries.
- The **Ethics Summary Report (EthSR)** will remind applicants/beneficiaries of the ethics issues raised by their proposal: Applicants/beneficiaries are **responsible** for complying with ethics standards and rules as applicable to their project. They must keep all relevant documents on file and submit individual documents on request

➔ **Risk-based & trust-based approach**

Ethics summary report after screening

− General requirement applicable to all grants

The beneficiaries must ensure that all ethics issues related to activities in the grant are addressed in compliance with ethical principles, the applicable international and national law, and the provisions set out in the Grant Agreement. This includes the ethics issues identified in this report and any additional ethics issues that may emerge in the course of the grant. In case any substantial new ethics issues arise, beneficiaries should inform the granting authority. For each ethics issue applicable, beneficiaries must follow the guidance provided in the How to complete your ethics self-assessment

5. Implementation

!!! **No ethics requirements =/= no ethics obligations**

Proposals ‘cleared’ after screening without ethics requirements may still:

- have to **appoint an independent ethics advisor or ethics board**
- be subject to an **ethics check or ethics review**

External independent ethics advisor or board

- **Mandate**:
  - to advise the beneficiary on how to deal with ethics issues and to report to the Commission/Agency/Funding Body.
  - ! Not responsible for ethics management and compliance, and remain independent from the beneficiary.
- The choice between a single **external independent** ethics advisor and an ethics board (with a minimum of three experts) reflects **the size of the grant and the seriousness/complexity of the ethics issues**.
- Ethics requirements also offer the possibility to request the appointment of an **'ethics mentor',** when there is lower ethics risk/ no need for an independent advisor/board.

Guideline on Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

6. Monitoring: Ethics Checks & Reviews

- During the lifetime of the project, to:
  - **assist the beneficiaries** to deal with the ethics issues raised by their research and if necessary
  - to take preventive or/and corrective measures
- **When are Ethics Reviews* requested?**
  - For projects raising serious / complex ethics issues
  - Compliance with ethics requirements needs to be checked during the implementation
  - Decision by the Project officer in the EC/Agency (i.e. documents provides are unsatisfactory)
  - ! All documents 'to be kept on file' may be requested !

6. Monitoring

- An **Ethics Check:**
  - internal check by the project officer or ethics officer who may be supported by ethics experts.
- An **Ethics Review:**
  - more elaborate and in-depth procedure carried out by up to 5 external ethics experts (formerly know as 'Ethics Check' in H2020)
- Depending on the **size** of the grant and the **seriousness/complexity** of the ethics issues.

What are serious and/or complex ethics issues?

3.1 Human embryonic stem cells (hESCs), human embryos (hEs), human cells and tissues

For all research activities involving human embryos or human embryonic stem cells, an **ethics assessment is mandatory**, the provision of Statement by the Commission on ethics/stem cell research – Art. 19 apply, and the funding of hESC or hE proposals requires and must be approved by the Horizon Europe Programme Committee.[7]

The ethics issues pertaining to the use in research of other categories of human tissues/cells may be considered "serious and/or complex" if these are, for example:

- **collected** within the project **from vulnerable groups** (e.g. children, unconscious patients, or patients otherwise lacking capacity to consent, prison populations) or involve **foetal or embryonic tissue** (other than hESC) collected within the project or
- used in **organoid research concerned with neurological conditions** or applications; or involving human multi-organoid complexes or related to the development of **synthetic/artificial reproductive cells or organs** (e.g. development of ova, in vitro gametogenesis (IVG)), or involving gastruloids or embryoids.

What are serious and/or complex ethics issues?

!!! Established fields of scientific research, such as **medicine and clinical practice**, are subject **to legal regulation and well-established norms and principles** through which serious and complex ethics issues can be identified and addressed

➔ If the activities are standard practices, with a clear legal/ethics framework, the related ethics issues should be **addressed by at local, regional and national level**.

!! The seriousness and complexity of the ethics issues are assessed on a **proposal-by-proposal basis**.

ANNEX PART IV; EXAMPLES -SPECIFIC AREAS

- Research with human participants, including SSH
- Artificial intelligence
- Research involving non-EU countries

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Research involving humans

Key principles and points of attention

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Human participants

- Humans must be considered as ‘research participants’ whenever they are:

  - **recruited, observed, actively engaged, or in any other way may be influenced, manipulated, or directed by the research**.

  - Regardless of the nature, methods, or topic of the proposed research activities (e.g. collecting biological samples, using personal data, medical interventions, interviews, observations, tracking etc.), ethical issues may arise in any research involving humans.

Key principles

1. Respect for human dignity and autonomy
2. Protection of the rights and interests of the research participants
3. Fair distribution of benefits and burdens

→**Informed Consent**

→**Proportionality**

→**Confidentiality**

Ethics issues in social sciences & humanities?

Potential harm to human participants (and researchers!)

- E.g. psychological distress, social exclusion, security risks, …

→Conduct a risk assessment and determine steps to minimise it

→Adapt consent and information procedures where necessary

Incidental findings

- E.g. violence, child abuse, security threats, …

→Plan ahead by drafting a **policy** for dealing with incidental/unexpected findings

→Inform participants about the **limits of confidentiality**

→Be aware of the **legal context** in which research is conducted

Ethics issues in social sciences & humanities?

Internet and social media research

- → Consult the relevant **terms and conditions of the platforms** they will be using to obtain your data
- → Ascertain **whether the data are really public** (open platforms vs password-protected fora)
- → Take all relevant precautions **to avoid collecting data from children or vulnerable adults** through social media and online questionnaires without appropriate authorisations
- → Consider the **potential sensitivity of the data and whether users** could be harmed if their data are exposed to new audiences
- → Consult the institutional **DPO**

Ethics issues in social sciences & humanities?

Exception to Informed Consent?

E.g. Research involving deception or covert research

- Researchers deliberately lie or trick the participants regarding the true purpose of the study or does not reveal capacity as researcher
- Used if disclosing its real purpose would lead participants to modify their behaviour, thereby distorting the research objective

→provide **strong justification** for the choice of method

→ensure that the use of deception **will not harm the participants** and that revealing the real nature of the research will not lead to discomfort or anger

→**debrief** participants and retrospectively obtain their informed consent

→obtain **ethics approval** for the study by a **competent committee**

Ethics issues in social sciences & humanities?

- Traditionally, ethics review processes and rules are designed to address ethics issues stemming from the biomedical sciences. **Not well-adapted** to the needs and ethics problems stemming from **Social Sciences and Humanities (SSH) research**.
  - E.g. Lack of **'ethics infrastructure'** to provide authorizations/approvals for SSH research**.**

  ➔ Based on the principle of **proportionality** and according to practice, ethics review may be performed, **for example**, by:
  - The University committee of the co-ordinator, or of another research partner
  - Approval obtained by the relevant ministry or from other relevant authority in the country
  - Ethics review by the European Commission

Points of attention

- Do not underestimate **the time needed** to develop informed consent procedures and forms that are appropriate for the research methodology & participants
  - Avoid complex and legalistic consent: make available comprehensible materials
  - Tailor the consent process to the target population
  - Do not create unjustified expectations in participants
  - Consider **new approaches to consent**: E.g. Co-creation, digital tools, …

Further reading

- Guidance note —Research on refugees, asylum seekers & migrants
- Ethics in Social Science and Humanities
- Research Ethics in Ethnography/Anthropology

ARTIFICIAL INTELIGENCE

LEARNING TOGETHER

European Commission

Artificial intelligence: Ethics by Design

- **Why?** Various ethical concerns raised by the development and use of AI-based applications:
  - Discrimination & bias. *E.g. selection and recruitment tools, clinical decision support tools, etc.*
  - Safety & Liability. *E.g. Self-driving cars, etc.*
  - Transparency and the algorithmic ‘black box’
  - Privacy & data protection. *E.g. surveillance, facial recognition, etc.*

- “Ethics by Design” = addressing ethical issues during development

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Artificial intelligence

- Trustworthy and Ethical Artificial Intelligence, respects key values:

1. Human agency and oversight
2. Privacy and data protection
3. Fairness, diversity and non-discrimination
4. Accountability
5. Transparency
6. Societal and environmental well-being

Artificial intelligence

- **Unethical applications**. E.g. violating physical or mental integrity, create addiction, risk damaging social processes and public institutions (e.g. by social scoring or contributing to misinformation)
- Key ethical requirements:
  - ➔People must be made aware that they are interaction with an AI system, its abilities and limitations, risks and benefits
  - ➔Mechanisms for human oversight, transparency and auditability must be ‘built in’ the AI system
  - ➔AI-system must be designed to avoid bias in input data and algorithmic design
  - ➔Compliance with data protection and privacy principles, e.g. data minimisation, must be demonstrated
  - ➔…

Artificial intelligence

Self-assessment: Could the AI system/technique stigmatise or discriminate against people (based on sex, race, ethnic/social origin, age, disability, sexual orientation, religion, political affiliation, etc.)?

→ Explain how potential bias, discrimination and stigmatization will be avoided.

→'**Ethics by design' methodology**: concrete steps for each phase in the development process. E.g.:

- Check for algorithmic bias during the detailed development phase. Data could be processed in a biased way, and therefore algorithms should be checked for this. (E.g. by using counterfactual evaluation methods)
- Ensure that interface design honours principles of universal accessibility, and avoid the introduction of functional biases in the detailed development phase that make the system unequally functional for different end-users.

Artificial intelligence

The ethics risk assessment and risk mitigation measures must cover the development, deployment and post-deployment phases.

Not only the development, also the use of AI-based systems or techniques in your research!

E.g. AI-based data analytics

➔ During acquisition and implementation of AI-based application, you must assess and monitor the system to ensure compliance.

Further reading

- Ethics guidelines for trustworthy AI (Independent High-Level Expert Group on AI)
- Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment (Independent High-Level Expert Group on AI)
- Guidelines on ethics by design/operational use for AI — *to be published soon*

Data and Privacy Decision tree

Personal Data transfers?

- Covered under the **PERSONAL DATA** section, but **the same principles** apply!

➔Privacy and data protection laws of non-EU country (! Data sovereignty provisions)

➔General Data Protection Regulation (Chapter V)

➔EU Member States derogations under the national legislation, e.g. pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data.

Personal Data transfers?

- **4** possible 'legal basis' for data transfers:
  1. Explicit consent
  2. Adequacy decision
  3. Data transfer agreement with standard contractual clauses
  4. Binding corporate rules (approved by data protection authority)

  + some exceptions (E.g. 'specific justification' situations (Article 49 GDPR))

- !! Use anonymized data whenever possible. Pseudonymise to minimize risks
- !! Remote access to a server in non-EU country is also a data transfer
- !! Forbid onward transfers & agree on data retention

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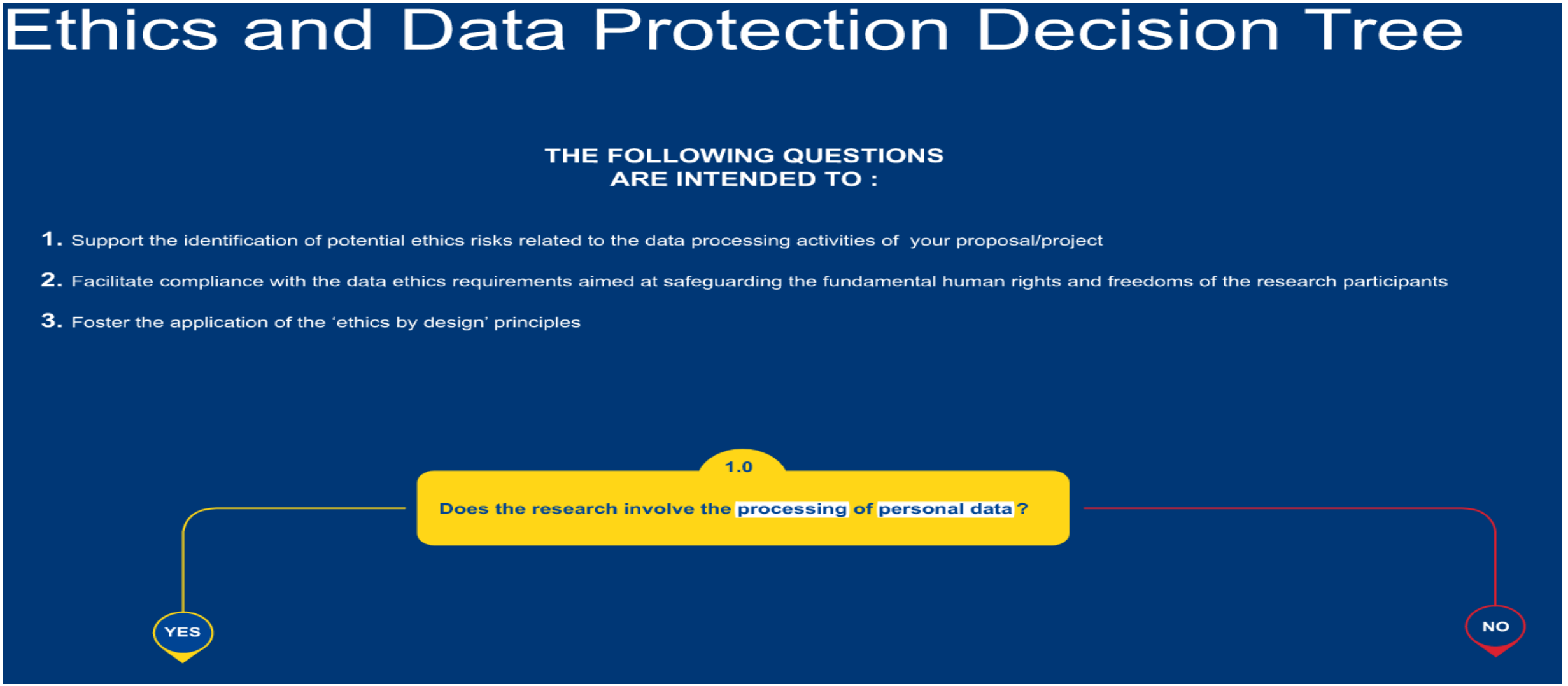
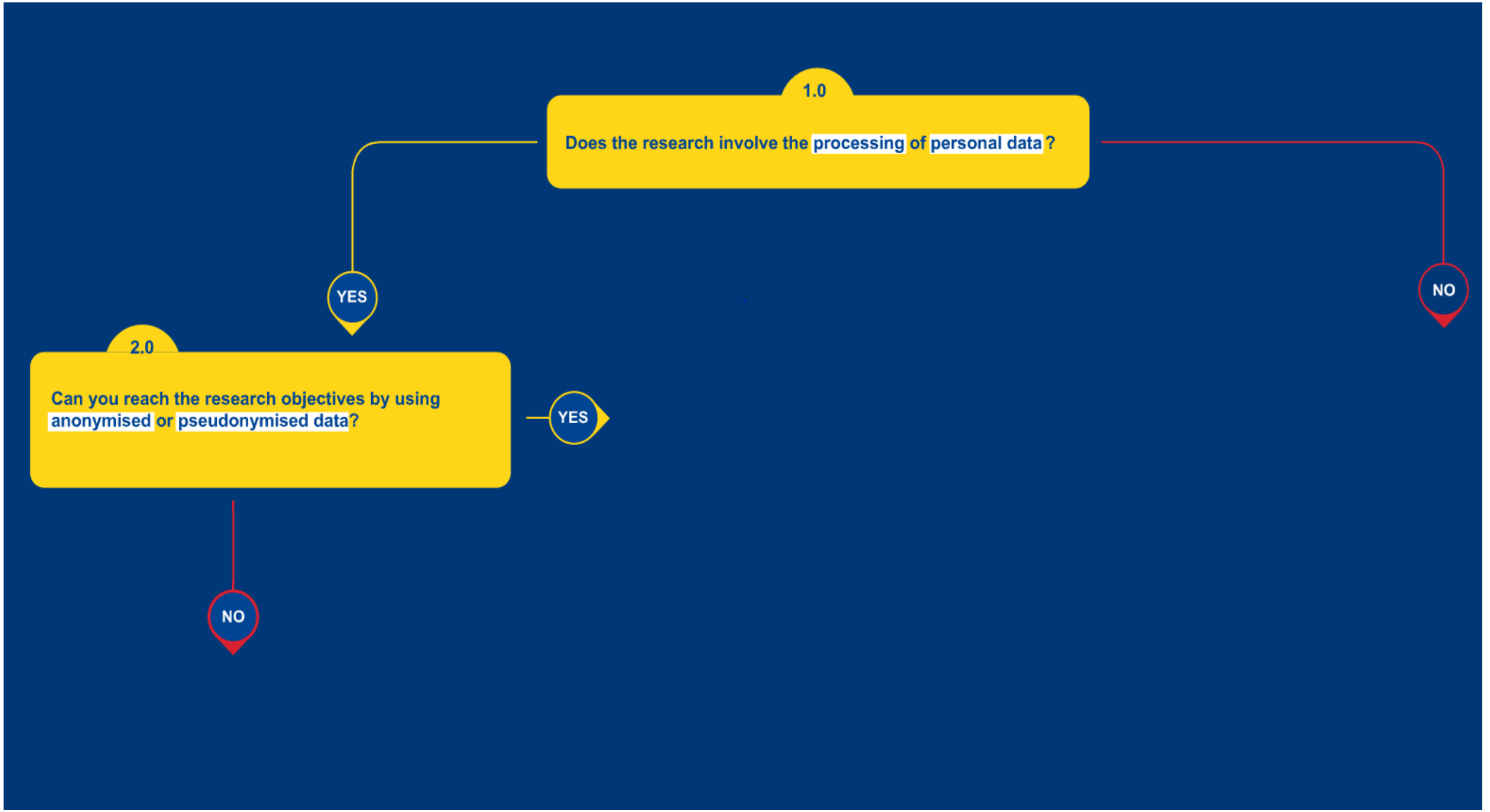
Further reading

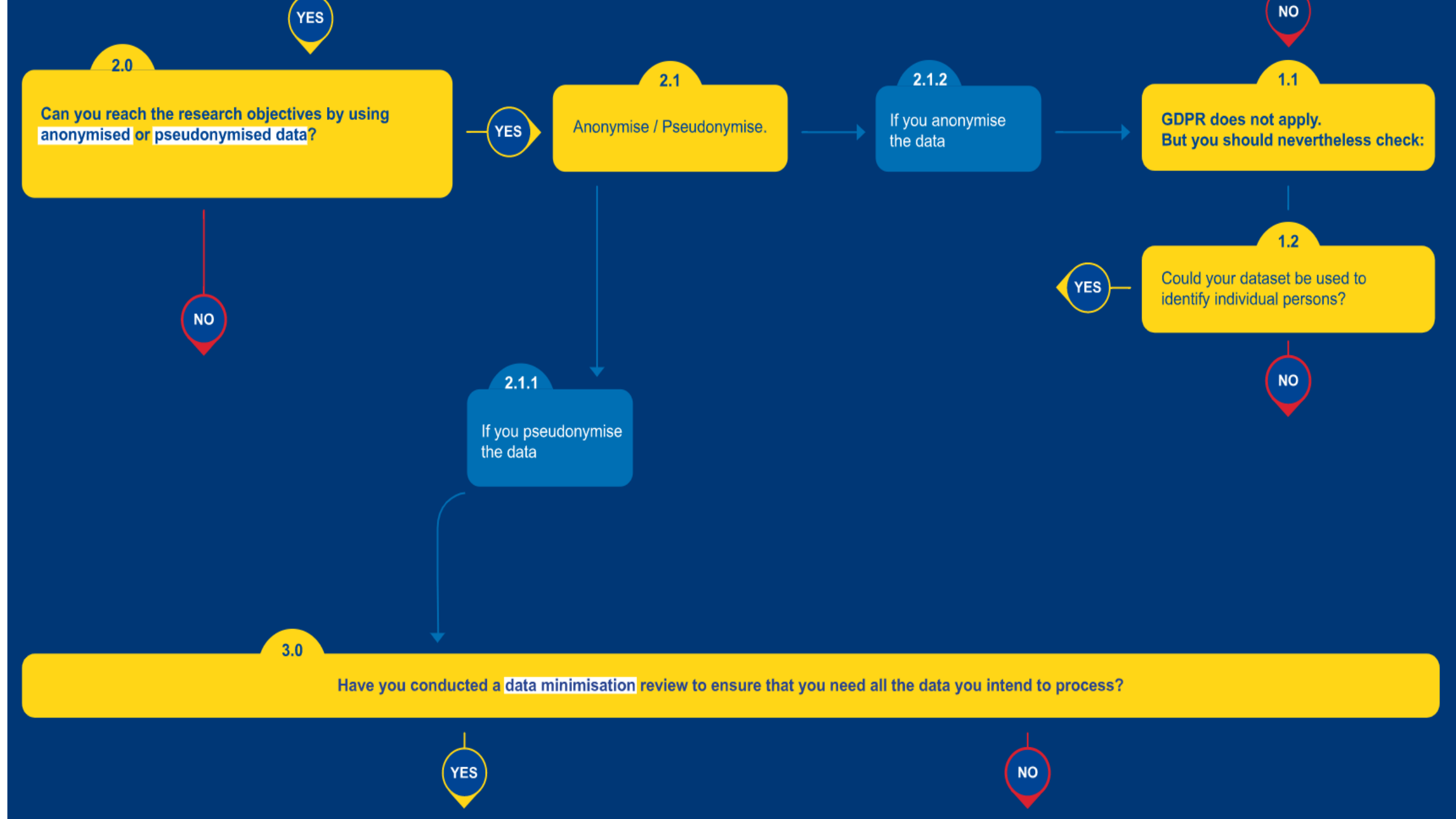
- https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection_en
- EDPB Guides and recommendations:
  - EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research Adopted on 2 February 2021 https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf
  - EDPB Guidelines on the processing of personal data for scientific research purposes *(currently under preparation, due in 2021).*

DATA PROTECTION HELP TOOL

https://ec.europa.eu/assets/rtd/ethics-data-protection-decision-tree/index.html




1.0
Does the research involve the processing of personal data?
YES
NO
2.0
Can you reach the research objectives by using anonymised or pseudonymised data?
YES
NO


YES
2.0
Can you reach the research objectives by using anonymised or pseudonymised data?
NO
YES
2.1
Anonymise / Pseudonymise.
2.1.2
If you anonymise the data
NO
1.1
GDPR does not apply.
But you should nevertheless check:
1.2
Could your dataset be used to identify individual persons?
YES
NO
2.1.1
If you pseudonymise the data
3.0
Have you conducted a data minimisation review to ensure that you need all the data you intend to process?
YES
NO

4.0

Do you have or will you obtain the informed consent of the people whose data will be used in your project?

YES

NO

4.2

- Explain how the principle of fair data processing and research ethics principles, according to which no person should be involved in research without their knowledge, will be met.
- Explain how you will address the ethics issues arising from the use of personal data concerning individuals who have not given explicit consent for their data to be used in your project.
- Explain the source and origins of the data.
- Confirm that you have lawful basis for the data processing and explain what technical and organisational measures are in place to safeguard the rights of the data subjects.

5.0

Does your project involve the processing of data concerning children or vulnerable adults?

YES

NO

15.0

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

YES

15.1

Specific requirements :

- Evaluate the ethics risks related to the data processing activities of the project and describe the measures you will implement to mitigate the risks for the research participants;
- Consult the Data Protection Officer (if any) at your institution on the data processing and data protection provisions;
- Provide the opinion of the data controller on the need for a data protection impact assessment (art.35 GDPR) (if relevant).

End

EXAMPLE OF RESOURCES

SHAPING THE ETHICAL DIMENSIONS OF SMART INFORMATION SYSTEMS

https://www.project-sherpa.eu/ethics-by-design/

TECHNOLOGY ETHICS AND HUMAN RIGHTS

https://www.sienna-project.eu/

ETHICS FOR TECHNOLOGIES WITH HIGH SOCIO-ECONOMIC IMPACT

https://www.techethos.eu/project/

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Issues for the Scientific Evaluation

Scientific evaluation

- **Human Embryonic Stem Cells (hESC)** and **Human Embryos (hE)**? Are they involved? Is their involvement necessary to achieve scientific objectives?

  → Taken into account by ethics evaluators

  → Mandatory Ethics Assessment

- **Artificial intelligence**? Is it technically robust?

  → Assessed in the excellence criterion

  → Taken into account by ethics evaluators

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Scientific evaluation

- **Do no significant harm** (DNSH) principle ('Taxonomy Regulation' 2020/852)
  - → assessed in the excellence criterion
  - → taken into account by ethics evaluators
  - → Full webinar: https://ec.europa.eu/research/participants/docs/h2020-funding-guide/other/event210421.htm

- Exclusive focus on **civil applications**?

!! The assessment of the exclusive focus on civil applications will no longer be performed under the ethics appraisal process.

  - →Declaration in application (and Security Self-assessment**)**
  - →Security review procedure

European Commission

FOCUS ON CIVIL APPLICATIONS & DUAL-USE

Research and innovation activities carried out under Horizon Europe shall have an exclusive focus on civil applications.(Article 7, HE Regulation)

Activities involving dual-use goods (in the sense of Regulation 428/2009) or dangerous materials and substances must comply with applicable EU, national and international law.

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