NÁRODNÁ KANCELÁRIA HORIZONTU

ETIKA A BEZPEČNOSŤ V HE

(ako sú v HE uchopené horizontálne témy ako etika a bezpečnosť ?)

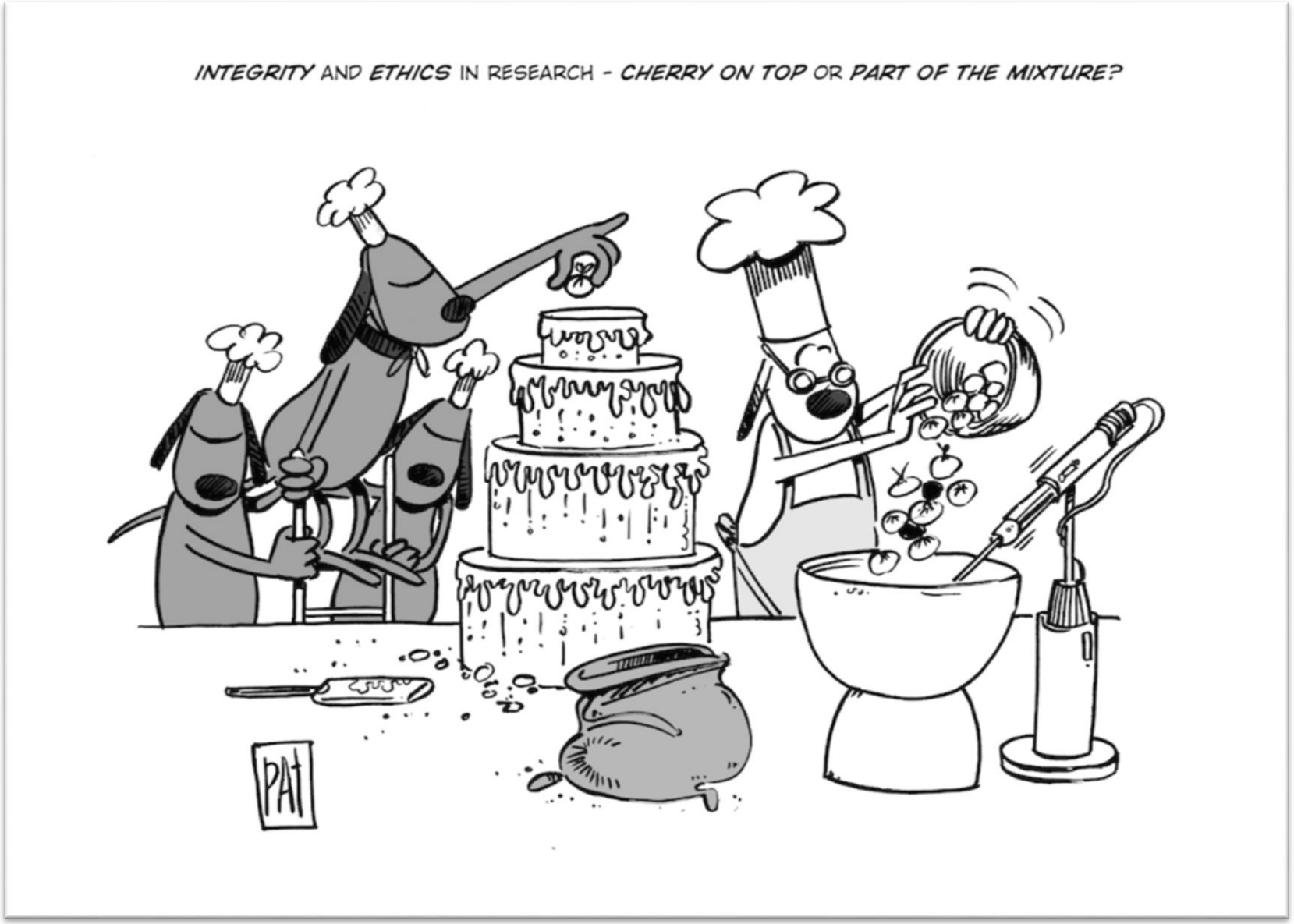
Soňa Ftáčniková
NCP pre výskumnú etiku a integritu v HE

CENTRUM VEDECKO-TECHNICKÝCH INFORMÁCIÍ SR
EURÓPSKA ÚNIA
Európsky fond regionálneho rozvoja
OP Integrovaná infraštruktúra 2014 – 2020
MINISTERSTVO ŠKOLSTVA, VÝSKUMU, VÝVOJA A MLÁDEŽE SLOVENSKEJ REPUBLIKY
SK4ERA
Investícia do Vašej budúcnosti

PREČO JE HODNOTENIE ETICKÉHO ROZMERU INTEGRÁLNOU SÚČASŤOU HODNOTENIA PROJEKTOV HE

1. Uistiť verejnosť, že výskum v HEU spĺňa **najvyššie etické štandardy**

2. Napomôcť excelentnosti v HEU
excelentný výskum = etický výskum


INTEGRITY AND ETHICS IN RESEARCH - CHERRY ON TOP OR PART OF THE MIXTURE?
PAT

VYLÚČENÉ Z FINANCOVANIA

Výskumné aktivity:
- zamerané na klonovanie ľudských bytostí za účelom reprodukcie

- sledujúce cieľ modifikovať genetické dedičstvo ľudstva, keď by sa tieto modifikácie stali dedičnými

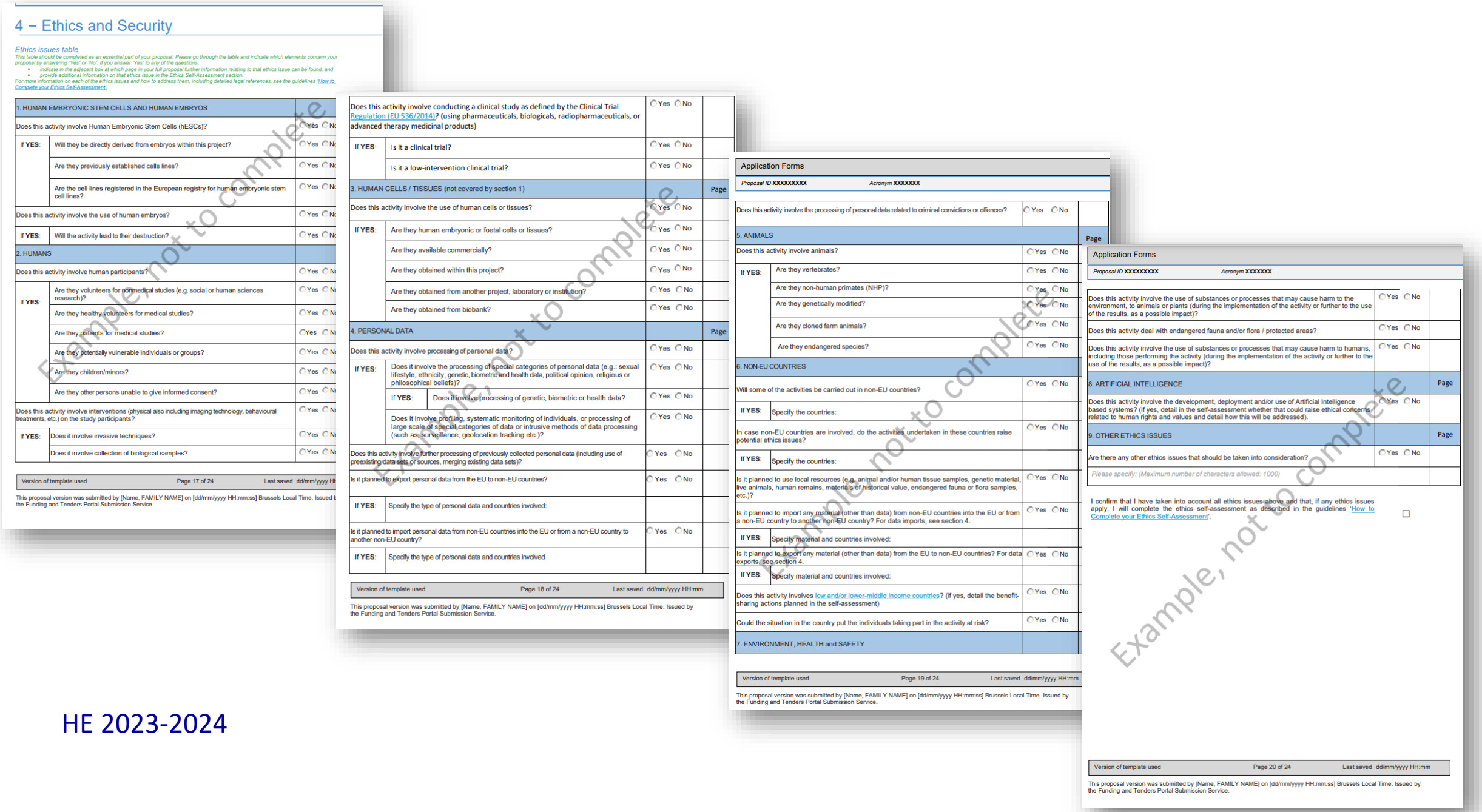
- sledujúce vznik alebo zničenie ľudského embrya, len pre účely výskumu alebo pre účely získania kmeňových buniek,

Výskumné aktivity a inovácie zamerané výlučne na civilné ciele

ETICKY CITLIVÉ OBLASTI v HE
(subjekty/objekty výskumu)

ETHICS SELF-ASSESSMENT

1. Ľudské embryá a embryotické kmeňové bunky
2. Ľudské subjekty
3. Ľudské tkanivá a bunky
4. Osobné dáta
5. Zvieratá
6. Nečlenské krajiny EU
7. Životné prostredie, zdravie a bezpečnosť
8. **Umelá inteligencia**
9. **Potenciálne zneužite výsledkov výskumu / Dual use (security panel)/misuse (security+ethics panel)**
10. Iné etické problémy/otázky (oblasť neurológie, nanotechnológie, androidy, kyborgy...)



4 – Ethics and Security

Ethics issues table

This table should be completed as an essential part of your proposal. Please go through the table and indicate which elements concern your proposal by answering 'Yes' or 'No'. If you answer 'Yes' to any of the questions,

- *indicate in the adjacent box at which page in your full proposal further information relating to that ethics issue can be found, and*
- *provide additional information on that ethics issue in the Ethics Self-Assessment section.*

For more information on each of the ethics issues and how to address them, including detailed legal references, see the guidelines 'How to Complete your Ethics Self-Assessment'.

1. HUMAN EMBRYONIC STEM CELLS AND HUMAN EMBRYOS		
Does this activity involve Human Embryonic Stem Cells (hESCs)?		○ Yes ○ No
If **YES**:	Will they be directly derived from embryos within this project?	○ Yes ○ No
	Are they previously established cells lines?	○ Yes ○ No
	Are the cell lines registered in the European registry for human embryonic stem cell lines?	○ Yes ○ No
Does this activity involve the use of human embryos?		○ Yes ○ No
If **YES**:	Will the activity lead to their destruction?	○ Yes ○ No
2. HUMANS		
Does this activity involve human participants?		○ Yes ○ No
If **YES**:	Are they volunteers for biomedical 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

Does this activity involve conducting a clinical study as defined by the Clinical Trial Regulation (EU 536/2014)? (using pharmaceuticals, biologicals, radiopharmaceuticals, or advanced therapy medicinal products)		○ Yes ○ No
If **YES**:	Is it a clinical trial?	○ Yes ○ No
	Is it a low-intervention clinical trial?	○ Yes ○ No
3. HUMAN CELLS / TISSUES (not covered by section 1)		Page
Does this activity involve the use of human cells or tissues?		○ Yes ○ No
If **YES**:	Are they human embryonic or foetal cells or tissues?	○ Yes ○ No
	Are they available commercially?	○ Yes ○ No
	Are they obtained within this project?	○ Yes ○ No
	Are they obtained from another project, laboratory or institution?	○ Yes ○ No
	Are they obtained from biobank?	○ Yes ○ No
4. PERSONAL DATA		Page
Does this activity involve processing of personal data?		○ Yes ○ No
If **YES**:	Does it involve the processing of special categories of personal data (e.g.: sexual lifestyle, ethnicity, genetic, biometric and health data, political opinion, religious or philosophical beliefs)?	○ Yes ○ No
	If **YES**: Does it involve processing of genetic, biometric or health data?	○ Yes ○ No
	Does it involve profiling, systematic monitoring of individuals, or processing of large scale of special categories of data or intrusive methods of data processing (such as, surveillance, geolocation tracking etc.)?	○ Yes ○ No
Does this activity involve further processing of previously collected personal data (including use of preexisting data sets or sources, merging existing data sets)?		○ Yes ○ No
Is it planned to export personal data from the EU to non-EU countries?		○ Yes ○ No
If **YES**:	Specify the type of personal data and countries involved:	
Is it planned to import personal data from non-EU countries into the EU or from a non-EU country to another non-EU country?		○ Yes ○ No
If **YES**:	Specify the type of personal data and countries involved	

Does this activity involve the processing of personal data related to criminal convictions or offences?		○ Yes ○ No
5. ANIMALS		Page
Does this activity involve animals?		○ Yes ○ No
If **YES**:	Are they vertebrates?	○ Yes ○ No
	Are they non-human primates (NHP)?	○ Yes ○ No
	Are they genetically modified?	○ Yes ○ No
	Are they cloned farm animals?	○ Yes ○ No
	Are they endangered species?	○ Yes ○ No
6. NON-EU COUNTRIES		
Will some of the activities be carried out in non-EU countries?		○ Yes ○ No
If **YES**:	Specify the countries:	
In case non-EU countries are involved, do the activities undertaken in these countries raise potential ethics issues?		○ Yes ○ No
If **YES**:	Specify the countries:	
Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?		○ Yes ○ No
Is it planned to import any material (other than data) from non-EU countries into the EU or from a non-EU country to another non-EU country? For data imports, see section 4.		○ Yes ○ No
If **YES**:	Specify material and countries involved:	
Is it planned to export any material (other than data) from the EU to non-EU countries? For data exports, see section 4.		○ Yes ○ No
If **YES**:	Specify material and countries involved:	
Does this activity involves low and/or lower-middle income countries? (if yes, detail the benefit-sharing actions planned in the self-assessment)		○ Yes ○ No
Could the situation in the country put the individuals taking part in the activity at risk?		○ Yes ○ No
7. ENVIRONMENT, HEALTH and SAFETY		

Does this activity involve the use of substances or processes that may cause harm to the environment, to animals or plants (during the implementation of the activity or further to the use of the results, as a possible impact)?		○ Yes ○ No
Does this activity deal with endangered fauna and/or flora / protected areas?		○ Yes ○ No
Does this activity involve the use of substances or processes that may cause harm to humans, including those performing the activity (during the implementation of the activity or further to the use of the results, as a possible impact)?		○ Yes ○ No
8. ARTIFICIAL INTELLIGENCE		Page
Does this activity involve the development, deployment and/or use of Artificial Intelligence based systems? (if yes, detail in the self-assessment whether that could raise ethical concerns related to human rights and values and detail how this will be addressed).		○ Yes ○ No
9. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration?		○ Yes ○ No
Please specify: (Maximum number of characters allowed: 1000)		

I confirm that I have taken into account all ethics issues above and that, if any ethics issues apply, I will complete the ethics self-assessment as described in the guidelines 'How to Complete your Ethics Self-Assessment'. ☐

HE 2023-2024

Prístup založený na požiadavkách primeraných etickému riziku

Application forms

Proposal ID

Acronym

Ethics Self-Assessment

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 advisor
Ethics board

Ethics self-assesment
Je súčasťou GRANT AGREEMENT
Annex 1

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-complete-your-ethics-self-assessment_en.pdf

Application forms

Proposal ID

Acronym

Declarations

Field(s) marked * are mandatory to fill.

1) We declare to have the explicit consent of all applicants on their participation and on the content of this proposal. * ☐

2) We confirm that the information contained in this proposal is correct and complete and that none of the project activities have started before the proposal was submitted (unless explicitly authorised in the call conditions). ☐

3) We declare:
- to be fully compliant with the eligibility criteria set out in the call
- not to be subject to any exclusion grounds under the EU Financial Regulation 2018/1046
- to have the financial and operational capacity to carry out the proposed project.

☐

4) We acknowledge that all communication will be made through the Funding & Tenders Portal electronic exchange system and that access and use of this system is subject to the Funding & Tenders Portal Terms and Conditions. ☐

5) We have read, understood and accepted the Funding & Tenders Portal Terms & Conditions and Privacy Statement that set out the conditions of use of the Portal and the scope, purposes, retention periods, etc. for the processing of personal data of all data subjects whose data we communicate for the purpose of the application, evaluation, award and subsequent management of our grant, prizes and contracts (including financial transactions and audits). ☐

6) We declare that the proposal complies with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Appropriate procedures, policies and structures are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct. ☐

7) We declare that the proposal has an exclusive focus on civil applications (activities intended to be used in military application or aiming to serve military purposes cannot be funded). If the project involves dual-use items in the sense of Regulation 428/2009, or other items for which authorisation is required, we confirm that we will comply with the applicable regulatory framework (e.g. obtain export/import licences before these items are used). ☐

8) We confirm that the activities proposed do not
- aim at human cloning for reproductive purposes;
- intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or
- 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 (for example, for obtaining stem cells)

These activities are excluded from funding. ☐

9) We confirm that for activities carried out outside the Union, the same activities would have been allowed in at least one EU Member State ☐

The coordinator is only responsible for the information relating to their own organisation. Each applicant remains responsible for the information declared for their organisation. If the proposal is retained for EU funding, they will all be required to sign a declaration of honour.

False statements or incorrect information may lead to administrative sanctions under the EU Financial Regulation.

Declarations

These declarations can be filled in by any coordinator contact(s). All declarations are mandatory.

1) We declare to have the explicit consent of all applicants on their participation and on the content of this proposal.	☐
2) We confirm that the information contained in this proposal is correct and complete and that none of the project activities have started before the proposal was submitted (unless explicitly authorised in the call conditions).	☐
3) We declare: – to be fully compliant with the eligibility criteria set out in the call – not to be subject to any exclusion grounds under the EU Financial Regulation 2018/1046 – to have the financial and operational capacity to carry out the proposed project.	☐
4) We acknowledge that all communication will be made through the Funding & Tenders Portal electronic exchange system and that access and use of this system is subject to the Funding & Tenders Portal Terms & Conditions.	☐
5) We have read, understood and accepted the Funding & Tenders Portal Terms & Conditions and Privacy Statement that set out the conditions of use of the Portal and the scope, purposes, retention periods, etc. for the processing of personal data of all data subjects whose data we communicate for the purpose of the application, evaluation, award and subsequent management of our grant, prizes and contracts (including financial transactions and audits).	☐
6) We declare that the proposal complies with ethical principles (including the highest standards of research integrity as set out in the ALLEA European Code of Conduct for Research Integrity, as well as applicable international and national law, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols. Appropriate procedures, policies and structures are in place to foster responsible research practices, to prevent questionable research practices and research misconduct, and to handle allegations of breaches of the principles and standards in the Code of Conduct.	☐
7) We declare that the proposal has an exclusive focus on civil applications (activities intended to be used in military application or aiming to serve military purposes cannot be funded). If the project involves dual-use items in the sense of Regulation 2021/821, or other items for which authorisation is required, we confirm that we will comply with the applicable regulatory framework (e.g. obtain export/import licences before these items are used).	☐
8) We confirm that the activities proposed do not – aim at human cloning for reproductive purposes; – intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or – 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 (for example, for obtaining stem cells) These activities are excluded from funding.	☐
9) We confirm that for activities carried out outside the Union, the same activities would have been allowed in at least one EU Member State	☐
10) *[Additional option for LUMP SUM Grants:* For Lump Sum Grants with a detailed budget table: We understand and accept that the EU lump sum grants must be reliable proxies for the actual costs of a project and confirm that the detailed budget for the proposal has been established in accordance with our usual cost accounting practices and in compliance with the basic eligibility conditions for EU actual cost grants (see *AGA — Annotated Grant Agreement, art 6*) and exclude costs that are ineligible under the Programme. Purchases and subcontracting costs must be done taking into	☐

This proposal version was submitted by [Name, FAMILY NAME] on [dd/mm/yyyy HH:mm:ss] Brussels Local Time. Issued by the Funding and Tenders Portal Submission Service.

The European Code of Conduct for Research Integrity - ALLEA

Fabrikácia

je vytváranie výsledkov, zaznamenávanie vymyslených dát alebo podávanie vykonštruovaných správ.

Falšovanie

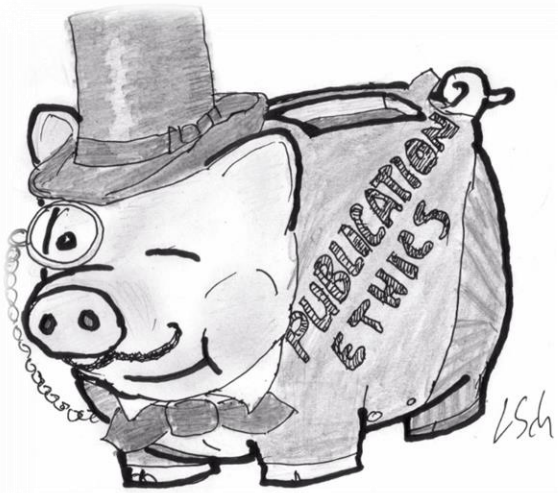
je manipulovanie výskumu alebo zámerná zmena a vynechanie nevhodných faktov, údajov a dát.

Plagiátorstvo

je prisvojenie si nápadov inej osoby, výsledkov výskumu alebo slov, bez patričného uznania.
Je to neprijateľná forma neetického správania a porušenia pravidiel vzhľadom k iným výskumným pracovníkom aj keď možno nenarušuje podstatu vedeckého výskumu tak závažne ako FF.

FFP = vlastne akademický ekvivalent pre klamanie, podvádzanie a krádež

Pochybné vedecké postupy – QRP

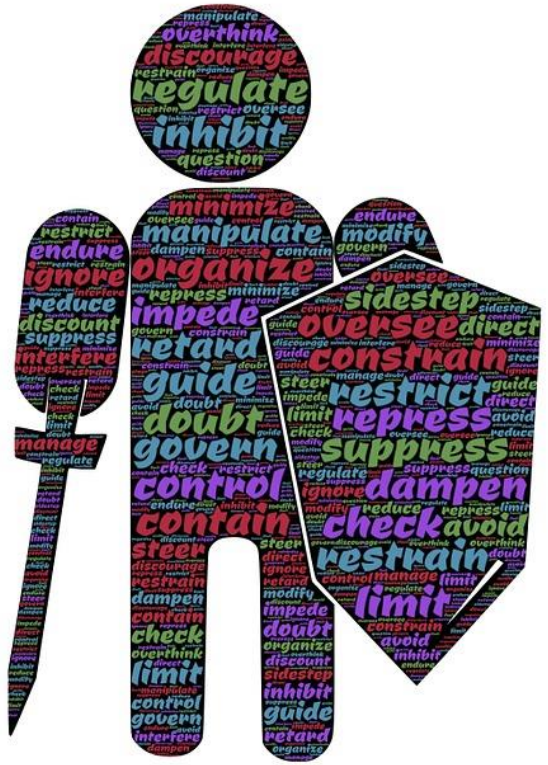

PUBLICATION
ETHICS


PAPER MILL


DOCUMENT
PLAGIARISM


JOURNAL

SECURITY
v projektoch HE



1. EU classified information (EUCI)		Yes/No	Page
Does the activity involve information and/or materials requiring protection against unauthorised disclosure (EUCI)?			
If YES:	- Is the activity going to use classified information as background information?		
	- Is the activity going to generate EU classified foreground information as results?		
Does the activity involve non-EU countries?			
If YES:	- Do participants from non-EU countries need to have access to EUCI?		
	- Do the non-EU countries concerned have a security of information agreement with the EU		
2. Misuse		**Yes/No**	**Page**
Does the activity have the potential for misuse of results?			
If YES:	- Does the activity provide knowledge, materials and technologies that could be channelled into crime and/or terrorism?		
	- Could the activity result in the development of chemical, biological, radiological or nuclear (CBRN) weapons and the means for their delivery?		
3. Other security issues		**Yes/No**	**Page**
Does the activity involve information and/or materials subject to national security restrictions?			
If Yes, please specify (max 1000 characters):			
Are there any other security issues that should be taken into consideration?			
If Yes, please specify (max 1000 characters):			

Security Issues Table

EU classified information - nutná ochrana EU Decision 2015/444 and the Implementing rules on classified grants

Guidelines on the classification of information in Horizon Europe projects; Classification of information in Digital Europe projects and Classification of information in EDF projects.

Project Security Officer (PSO)
Security Advisory Board

Security self-assessment

Security Aspects Letter (SAL)
Security Classification Guide (SCG),
sú súčasťou GRANT AGREEMENT
Annex 1

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/how-to-handle-security-sensitive-projects_en.pdf

Dôveryhodná umelá inteligencia
v Horizon Europe

+

Technická robustnosť bude hodnotená v procese odborného vedeckého hodnotenia

Všetky etické aspekty súvisiace s vývojom a použitím systémov a techník umelej inteligencie budú hodnotené etickým panelom

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/ethics-by-design-and-ethics-of-use-approaches-for-artificial-intelligence_he_en.pdf

Právny predpis – prvý svojho druhu na svete – určuje podmienky pre používanie systémov AI v EÚ (EP marec 2024)

Užitočné linky
všeobecné, etika a integrita

- EU Charter of Fundamental Rights
- ALLEA European Code of Conduct for Research Integrity
- Global Code of Conduct for Research in Resource-poor Settings

- How to handle security-sensitive projects
- Guidelines on the classification of information in Horizon Europe projects
- HE Programme security instruction (PSI)
- Guidance note on research focusing exclusively on civil applications

Užitočné linky
etika podľa oblasti

- GDPR - Decision tree | reviewed (europa.eu)
- Guidance note on potential misuse of research results
- Guidance note on research focusing exclusively on civil applications
- Guidance note on research on refugees, asylum seekers and migrants
- Ethics and data protection
- Ethics in Social Science and Humanities
- Research Ethics in Ethnography/Anthropology
- Guidelines on ethics by design/operational use for Artificial Intelligence

Užitočné linky
bezpečnosť

- How to handle security-sensitive projects
- Guidelines on the classification of information in Horizon Europe projects
- HE Programme security instruction (PSI)
- Guidance note on research focusing exclusively on civil applications

Ďakujem za Vašu pozornosť

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