



European
Commission

Ethics Appraisal and Societal Impact in H2020

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Unit B4 – Safeguarding Secure Societies

Research
Executive
Agency

ARTICLE 13 - PROPOSALS

"A proposal which contravenes **ethical principles** or any applicable legislation, or which does not fulfil the conditions set out in Decision No 2013/743/EU, in the work programme, in the work plan or in the call for proposals **may be excluded** from the **evaluation, selection and award procedures at any time.**"

ARTICLE 14 - ETHICS REVIEW

1. The Commission shall systematically carry out **ethics reviews** for proposals raising ethical issues. That review shall verify the respect of **ethical principles and legislation** and, in the case of research carried out outside the Union, that the same research would have been allowed in a Member State.
2. The Commission shall make the process of the **ethics review** as transparent as possible and ensure that it is carried out in a timely manner avoiding, where possible, the resubmission of documents.



ARTICLE 18 – GRANT AGREEMENT

The grant agreement shall, where appropriate, contain provisions ensuring the **respect of ethical principles**, including the establishment of an independent ethics board and the right of the Commission to carry out an ethics audit by independent experts.

ARTICLE 23 - IMPLEMENTATION OF ACTIONS

Participants shall comply with **national legislation, regulations and ethical rules** in the countries where the action will be carried out. Where appropriate, participants shall seek the **approval of the relevant national or local ethics committees** prior to the start of the action.

ARTICLE 34 - ETHICS

The beneficiaries must carry out the action in compliance with:

- (a) ethical principles (including the highest standards of **research integrity** and including, in particular, **avoiding fabrication, falsification, plagiarism** or other **research misconduct**) and
- (b) **applicable international, EU and national law.**

Funding will not be granted for activities carried out outside the EU if they are **prohibited** in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

The beneficiaries must process personal data under the Agreement in compliance with applicable **EU and national law on data protection** (including **authorisations or notification requirements**).



All proposals submitted for funding following a call for proposals are evaluated on their **scientific merit**.

All proposals must describe **ethical issues** raised & how they will be addressed so as to **conform to national, European and international regulations**

A proposal may be **rejected** from funding on **ethics grounds**.

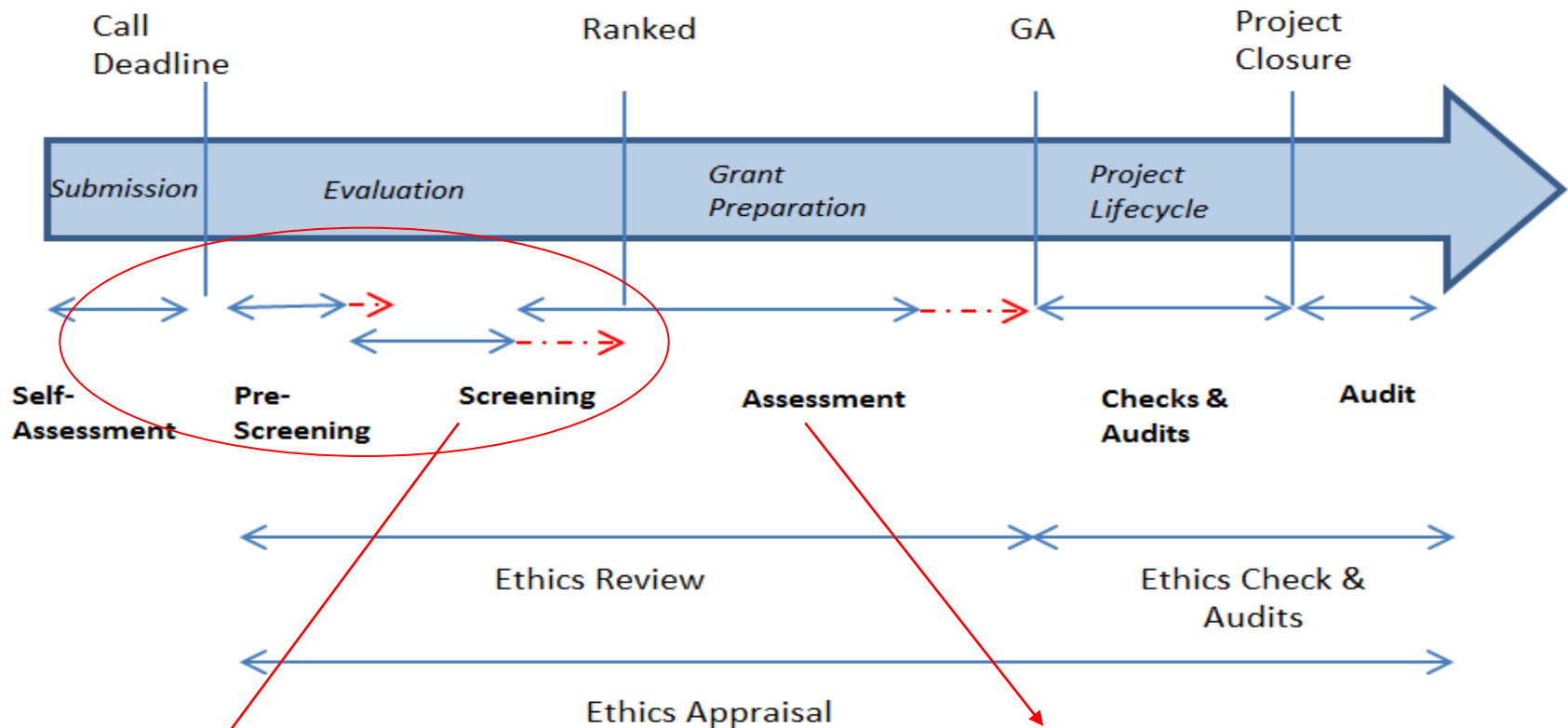
- Activities raising ethical issues must comply with the **'ethics requirements'** set out in Annex 1.
- **Before** the beginning of an activity raising an ethical issue, the coordinator must submit to the *EU* a copy of:
 - (a) any **ethics committee opinion** required under national law and/or
 - (b) any **notification or authorisation** required under **national law**.

These documents should be in English, if not - the coordinator must also submit an English summary.

- The coordinator must submit a declaration by **each beneficiary concerned** that all the submitted documents cover the action tasks.
- If a beneficiary **breaches** any of its **obligations**, the grant may be reduced and the Agreement or participation of the beneficiary may be **terminated**.



Ethics appraisal



Stage 1 — **Ethics screening**, starting with the **pre-screening** (on the basis of your 'ethics selfassessment') to see if it raises 'ethical issues' and whether they are adequately handled.

Stage 2 — **Ethics assessment**; for proposals raising serious ethical issues (e.g. severe intervention on humans, lack of appropriate ethics framework in the country where the research will be conducted, etc.) a more detailed analysis is made.

Each **applicant** is **responsible** for:

- identifying any potential ethical issues
- handling ethical aspects of their proposal
- detailing how they plan to address them in sufficient detail already at the proposal stage.

The Ethics part of each proposal (part A in SEP, part B section 6) should include description of issues and arrangements!





4 - Ethics issues table

1. HUMAN EMBRYOS/FOETUSES ⁱ		Page
Does your research involve Human Embryonic Stem Cells (hESCs) ?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve the use of human embryos?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve the use of human foetal tissues / cells?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
2. HUMANS		Page
Does your research involve human participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve physical interventions on the study participants?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does it involve invasive techniques?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
3. HUMAN CELLS / TISSUES		Page
Does your research involve human cells or tissues? If your research involves human embryos/foetuses, please also complete the section "Human Embryos/Foetuses" [Box 1].	<input type="radio"/> Yes <input checked="" type="radio"/> No	
4. PROTECTION OF PERSONAL DATA ⁱⁱ		Page
Does your research involve personal data collection and/or processing?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve further processing of previously collected personal data (secondary use)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
5. ANIMALS ⁱⁱⁱ		Page
Does your research involve animals?	<input type="radio"/> Yes <input checked="" type="radio"/> No	

6. NON-EU COUNTRIES		Page
Does your research involve non-EU countries?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Do you plan 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.)?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Do you plan to import any material - including personal data - from non-EU countries into the EU? If you consider importing data, please also complete the section "Protection of Personal Data" [Box 4].	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Do you plan to export any material - including personal data - from the EU to non-EU countries? If you consider exporting data, please also complete the section "Protection of Personal Data" [Box 4].	<input type="radio"/> Yes <input checked="" type="radio"/> No	
If your research involves low and/or lower middle income countries , are benefits-sharing measures foreseen?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Could the situation in the country put the individuals taking part in the research at risk?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
7. ENVIRONMENT PROTECTION		Page
<small>vi Directive 2001/18/EC - vii Directive 2009/41/EC - viii Regulation EC No 1946/2003 - ix Directive 2008/56/EC - x Council Directive 92/43/EEC - xi Council Directive 79/409/EEC - xii Council Regulation EC No 338/97</small>		
Does your research involve the use of elements that may cause harm to the environment, to animals or plants?	<input checked="" type="radio"/> Yes <input type="radio"/> No	36
Does your research deal with endangered fauna and/or flora and/or protected areas?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research involve the use of elements that may cause harm to humans, including research staff?	<input checked="" type="radio"/> Yes <input type="radio"/> No	37
8. DUAL USE ^{xiii}		Page
Does your research have the potential for military applications?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
9. MISUSE		Page
Does your research have the potential for malevolent/criminal/terrorist abuse?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
10. OTHER ETHICS ISSUES		Page
Are there any other ethics issues that should be taken into consideration? Please specify	<input type="radio"/> Yes <input checked="" type="radio"/> No	

- **CONSULT ETHICS ASSESSMENT GUIDELINE!**
For guidance incl. documents to be provided

ATTACH THE REQUIRED DOCUMENTS

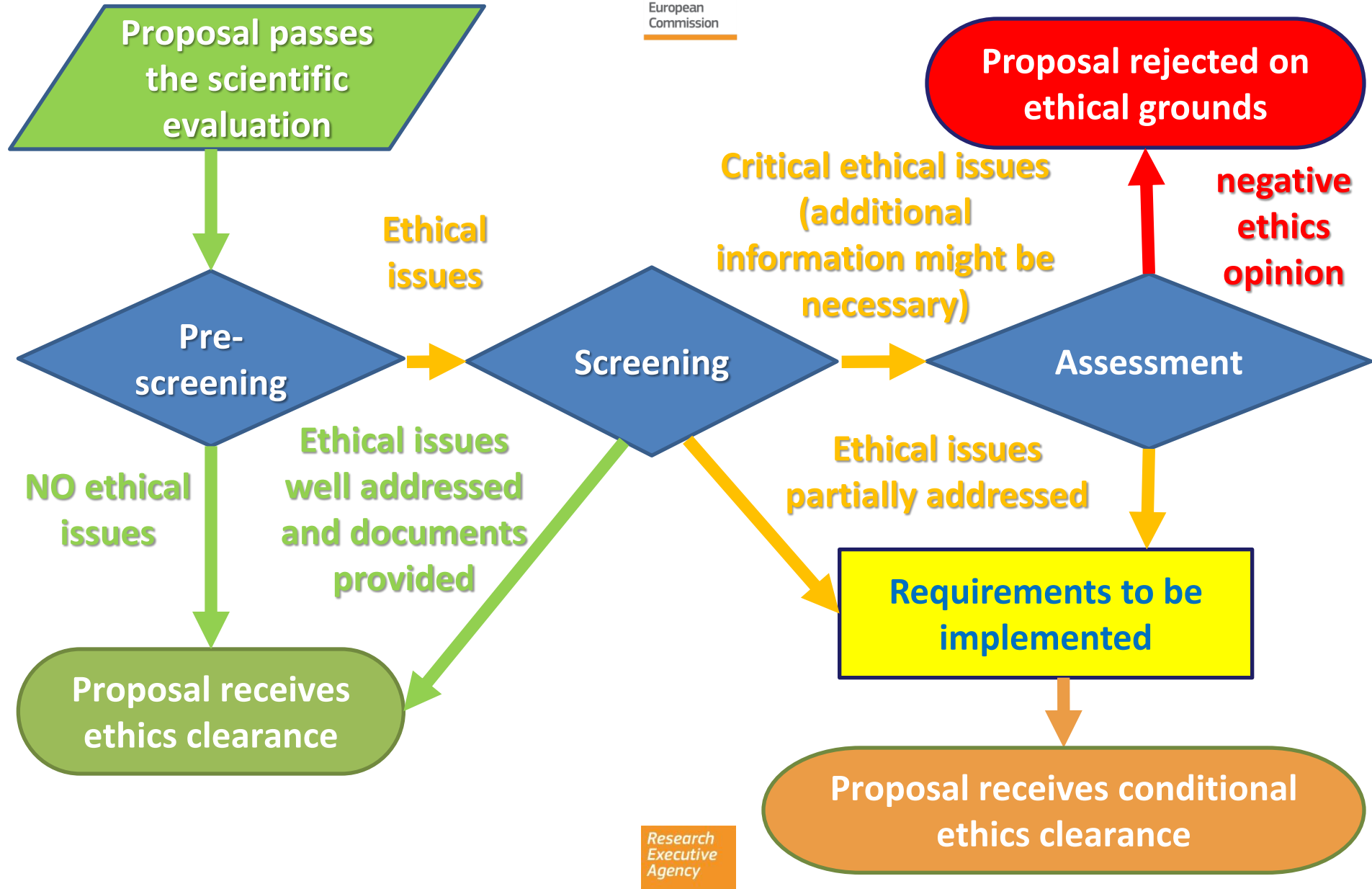


Indicate pages in the proposal

I confirm that I have taken into account all ethics issues described above and if any ethics issues apply, I have attached the required documents.



Ethics review



Conditional ethics clearance

Clearance subject to conditions that must be included as 'ethics requirements' in Annex 1 to the grant agreement.

These conditions may include:

- regular reporting to the Commission/Executive Agency;
- the appointment of an independent ethics advisor or ethics board that may be tasked to report to the service/Executive Agency on the compliance with the ethics requirements;
- an Ethics Check or Audit and their most suitable time frame;
- submission of further information/documents.
- necessary adaptation of the methodology to comply with the ethical principles and relevant legislations

- When some or all of the research activities are carried out **outside the EU**, the applicants must confirm that the proposed research is **compatible with the Union and International legislation** and could have been legally conducted in one of the EU Member States. This compatibility can be confirmed by an appropriate **EU national ethics structure**.
- If there are no appropriate national structures to give a positive opinion for the proposed activities, the conclusions of the **Ethics Review** will be the binding opinion.
- The signature of the Grant can only take place **after the Ethics Review** and when the conditions that should be fulfilled before the signature are met.

Data privacy: Data privacy is the right of any individual to expect that his/her personal information directly or indirectly collected are **processed securely** and are **not disseminated without their written consent**.

Data protection: Data protection is the framework of security measures designed to guarantee that data are handled in such a manner as to ensure that they are safe from unintended, unwanted or malevolent use. Data protection is the technical mechanism to ensure data privacy.

Mission/Function Creep: is used in the security context for a type of misuse concern, where an experiment, a technology or information/data is used beyond the approved initial plan and thereby could harm fundamental ethical values or civil rights (surveillance, people tracking tools etc)

Dual use: technologies relevant to both civilian and military application – exclusive civilian application focus (robotics, use of listed chemical/biological agents etc) (Council Decision 2006/971/EC)

Misuse/Malovelent use: research involving or generating materials, methods or knowledge that could be misused for unethical purposes (toxic chemicals, radioactive material, manuals for the production for toxic materials, critical infrastructural vulnerabilities)

Three Explanatory notes published in the Participant Portal on:

- The control of "export" for "dual-use items", including technology transfers, under Council Regulation (EC) No 428/2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items
- Potential misuse of research
- Exclusive focus on civil applications



- biometric passports/visas
- systems for facial recognition in real-time in an unrestricted environment
- 3D facial recognition algorithms
- iris and facial recognition
- video surveillance systems in railways, airport, urban areas, commercial, retail, banks, parking, traffic control etc.)
- «smart» systems / technologies
- mobile electronic tags
- automatic number plate recognition
- exposure of volunteers to electro-magnetic field tests
- research tests that could endanger human safety or breach fundamental rights
- use of animals / testing

Issues to be elaborated in the proposal (1)



- **Explain** in the ethical section **how you will comply** with the procedures, safeguards, monitoring and reporting exercises etc.
- Consider the ethical aspects **during the development phases of a system** (e.g. during tests, field trials, experiments, demonstrations) to ensure "Privacy Enhancing Technologies"
- Apply **ethics/safety standards and rules** also to **own staff** involved in the trials (as for volunteers) and ensure that appropriate **health and safety procedures** conform with national legislations are applied to staff involved in the project

Issues to be elaborated in the proposal (2)



- Ensure ethics/data protection experts in the consortium;
 - an **Ethics Advisory Board** may be established or an **external independent Ethics expert** may be appointed. The Ethics Board should include relevant **external, independent ethical expertise**, in addition to the ethics experts members of the consortium, to monitor the ethical concerns
 - a **data controller** shall be appointed when there are concerns on **data protection and privacy**, in compliance with Directive 95/46/EC and article 29 working group n° 8/2010 opinion
- Provide a detailed description of the **security measures** and legal and operational safeguards that will be implemented to prevent any potential **improper/malevolent use** of the system and any potential **mission creep scenarios**

Issues to be elaborated in the proposal (3)



- Consult experts if you do not have internal expertise in the consortium, set up a **Security Advisory Board** and keep the REA/Commission informed of any development
- Address the **costs** adequately in the budget
- Detail in the Technical Annex the start date of and the involved participants in the activities ("Tasks") raising potential ethical issues.
- State whether the **approvals/notifications** have already been sought before the competent authorities or the calendar and relevant WPs envisaged to fulfill those tasks
- On data protection issues, consult the **Vademecum** on national notification procedures and applicable law and other guidance publicly available and anticipate the notifications duties under national law

Issues to be elaborated in the proposal (4)



Consult the ethics assessment guideline

Section 4: PROTECTION OF PERSONAL DATA ²	Information to be provided	Documents to be provided
Does your research involve personal data collection and/or processing?		
- Does it involve the collection and/or processing of sensitive personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	<p>Details of the data safety procedures</p> <p>Details of procedures for data collection, storage, protection, retention, transfer if any, destruction or re-use.</p> <p>Explicit confirmation of compliance with national and EU legislation.</p>	<p>Copies of relevant Ethics Approvals for the collection and/or processing of personal data.</p> <p>Informed Consent Forms or other consent documents</p> <p>Notification to, or authorisation from, the relevant Data Protection Authority/Officer.</p> <p>Copy of authorization to merge the data sets in order to create a novel data set.</p>

Societal impact



Societal Impact Table

Does your research meet the need of society?		Page
1. Does the proposed research address documented societal security need(s) (e.g. life, liberty, health, employment, property, environment, values)?	<input checked="" type="radio"/> Yes <input type="radio"/> No	22
2. Does the research output meet these needs? Will this be demonstrated? Will the level of societal acceptance be assessed?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
3. Does the research address threats to society? (e.g. crime, terrorism, pandemic, natural and man-made disasters etc.).	<input type="radio"/> Yes <input checked="" type="radio"/> No	
4. Does the proposed research address in an appropriate way these threats?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Does your research benefit society?		Page
5. Do segment(s) of society benefit from the proposed research?	<input checked="" type="radio"/> Yes <input type="radio"/> No	26
6. Does society as a whole benefit from the proposed research?	<input type="radio"/> Yes <input type="radio"/> No	
Does your research have negative impact on society?		Page
7. Are there other European societal values that are enhanced by the proposed research e.g. public accountability and transparency; strengthened community involvement; human dignity; good governance; social and territorial cohesion; sustainable development etc.?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
8. If implemented, could the research have a negative impact on the rights and values enshrined in the Treaties (e.g. freedom of association, freedom of expression, protection of personal dignity, privacy and data protection.	<input type="radio"/> Yes <input checked="" type="radio"/> No	
9. If implemented, could the research impact disproportionately upon specific groups or unduly discriminate against them?	<input type="radio"/> Yes <input checked="" type="radio"/> No	
10. Will specific measures be taken to ensure that the research outcomes comply with the European Charter of Fundamental Rights and to mitigate against any of the negative impacts described above?	<input checked="" type="radio"/> Yes <input type="radio"/> No	

The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

Try to avoid any situation that may create confusion with respect to **fabrication, falsification, plagiarism** or other **research misconduct**:

- Provide the appropriate citation and references
- Avoid using the same text in different proposals or ongoing projects - if is the case provide the appropriate explanation/citation
- Ask your partners/consultants about the provenience of the text they provide to you



RTD-ETHICS-REVIEW-HELPDESK@ec.europa.eu

http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm#

http://ec.europa.eu/research/participants/data/ref/h2020/mga/gga/h2020-mga-gga-multi_en.pdf

http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/pse/h2020-guide-pse_en.pdf

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:083:0389:0403:en:PDF>

<http://ec.europa.eu/justice/policies/privacy/docs/wpdocs/others/2006-07-03-vademecum.doc>

<https://clientsites.linklaters.com/Clients/dataprotected/Overview/Pages/Index.aspx>

http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#fp7