Preparatory Action on Defence Research (PADR) Programme

Guidance on

How to complete your self-assessment on "ethics, legal and societal aspects (ELSA)"

Version 1.0
19 March 2019

IMPORTANT NOTICE

These guidelines are designed to help **applicants** in **getting their proposal 'ethics, legal and societal ready' for the Preparatory Action on Defence Research (PADR) funding** (i.e. to identify and deal correctly with any of the above-mentioned issues that may arise from it). They provide guidance for assessing ethics, legal and societal aspects in **Part B** of your proposal *(see the* proposal templates *on the Funding & Tender Opportunities Portal).*

This document is however, **no more than a 'how to' guide.** It covers most of the ethics, legal and societal issues arising in research projects and gives advice on dealing with classic cases. Cases that are not covered must therefore be dealt with outside this guide.

The **ethics, legal and societal** responses completed in **Part B** of your proposal will become part of your **grant agreement** (in Annex 1, as description of the action, ethics, legal and societal requirements, etc.) and may thus give rise to binding obligations that may later on be checked **through ethics, legal and societal reviews** or **audits**.

This means the time you invest in this self-assessment is not wasted. It will actually improve your research results and:

Your proposed research will be in line with applicable international, EU and national law.

We will process your proposal more easily during the Preparatory Action on Defence Research proposal selection procedure.

You will contribute to the responsible conduct of research, thereby increasing its social acceptance.

Consider that ethics, legal and societal issues arise in many areas of research. Apart from the obvious example, the medical field, research protocols in social sciences, ethnography, psychology, environmental studies, security, defence research, etc. may involve the voluntary participation of research subjects and the collection of data that might be considered as personal. You must protect your volunteers, yourself and your researcher colleagues.

Start thinking about ethics, legal and societal aspects while designing your research protocols. Do not wait until the last minute to seek advice or check requirements under national and EU law.

Your first source should always be at your entity. We would ask you to seek advice from colleagues with expertise in the ethics, legal and societal aspects of research, such as:

- specialised ethics, legal and societal departments
- relevant managers in your university/research organisation/institutes
- medical research ethics
- ethics, legal and societal advisers in your company
- data protection officers.

They will be able to provide you with information appropriate to your specific needs and legal environment.

Consider involving/appointing an ethics, legal and societal adviser and an ELSA advisory board. From the beginning of your project, an adviser can help you deal with the above-mentioned issues and put in place the procedures to handle them appropriately.

If your research includes several ethical, legal and societal concerns or involves several significant or complex related issues *(such as participation of children, 'non-human primates (NHPs)', potential misuse or vulnerable populations, etc.)* we suggest you appoint an ethical, legal and societal adviser or an advisory board comprising several experts from different backgrounds. The Commission/Agency may also include the above suggestion as a requirement during the selection procedure.

HISTORY OF CHANGES		
Version	**Publication Date**	**Change**
1.0	19.03.2019	▪ First version

TABLE OF CONTENTS

"ELSA" review procedure

In addition to the scientific evaluation focusing on the excellence, the quality, the efficiency of implementation and the potential impact. The Ethics, Legal and Societal (ELSA) Review ensures that all research activities carried out under the PADR Programme are conducted in compliance with fundamental ethical, legal and societal principles.

A review of ethical, legal and societal aspects will be systematically carried out for proposals raising such issues.

This review will verify the respect of legislation, and the compliance with provisions of international law binding upon the Union, ethical, legal and the societal impact of the proposed action.

A group of independent experts on military ethical, legal and societal issues, including defence specific background, will conduct the review. The appropriate security clearance will be required before appointment. All experts must be validated by the Member State that has issued their security clearance.[1]

The process of the review will be as transparent as possible and ensure that it is carried out in a timely manner avoiding, where possible, the resubmission of documents.

A proposal which contravenes ethical and societal principles or any applicable legislation, or which does not fulfil the conditions set out in the work programme or in the call for proposals may be excluded from the evaluation, selection and award procedures at any time.

[1] For further details on the experts, please consult the PADR Call for Experts.

1. Legal

This section refers to the compliance with international law and EU regulations.

1.1 Compliance with the International law & EU regulations

Legal aspects checklist

Section 1.1: Law/EU regulations	YES/ NO		Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[2]
Is your research in compliance with: International humanitarian Law? (i.e. distinction, proportionality, precaution, etc.)	☐	☐	Assessment of applicable legal requirements.	Copies of legal approvals and authorisations * (*if applicable).
Convention on Prohibitions or Restrictions on the use of Certain Conventional Weapons?	☐	☐	Assessment of applicable legal requirements.	Copies of legal approvals and authorisations * (*if applicable).
Biological and toxin Weapons Convention?	☐	☐	Assessment of applicable legal requirements.	Copies of legal approvals and authorisations * (*if applicable).
EU and international export Control regulation? (including list of dual-use goods , technologies and munitions list)	☐	☐	Assessment of applicable legal requirements.	Copies of legal approvals and authorisations * (*if applicable).

How do I deal with the issues?

You should assess if your research proposal complies with the International Law and EU Regulations. (i.e. what goods and information used and produced in your research will need **export licences**? How exactly will you ensure compliance?)

What do you need to provide?

If your proposal raises one of the issues listed in the legal aspects checklist, you must if applicable, complete the **legal assessment** in **Part B** of your proposal (i.e. section

[2] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.

5.1 of the Technical Annex). Your grant proposal must include the **information** referred in the legal aspects checklist and any of the **documents** already available.

> Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

UN Security Council Resolution 1540

Treaty on the Non-Proliferation of Nuclear Weapons (NPT)

Chemical Weapons Convention

Convention on prohibitions or restrictions on the use of certain conventional weapons which may be deemed to be excessively injurious or to have indiscriminate effects.

EU export control regulation 482/2009

Export Controls for Conventional Arms and Dual-Use Goods and Technologies

The Common military list of the European Union

1.2. Misuse of research results

This section concerns research involving or generating materials, methods, technologies or knowledge that could be misused for other purposes.

Legal aspects checklist

Section 1.2: MISUSE	YES	NO	Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[3]
Does your research have a potential for misuse of research results?	☐	☐	1) Risk-assessment. 2) Details of the applicable legal requirements. 3) Details of the measures to prevent misuse.	1) Copies of authorisations (if required, i.e. export licences). 2) Copies of security clearances (if applicable). 3) Copies of ethics approvals (if applicable).

[3] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.

Is it possible for an organization or institute outside agreements (organization not bound in PADR legal framework) to adapt the results of the research?	☐	☐	1) Risk-assessment. 2) Details of the applicable legal requirements. 3) Details of the measures to prevent misuse.	1) Copies of authorisations (if required, i.e. export licences). 2) Copies of security clearances (if applicable). 3) Copies of ethics approvals (if applicable).

How do I deal with the issues?

Some questions that could be used to identify potential misuse are:

- What would happen if the materials/methods/technologies and knowledge involved or generated ended up in the wrong hands (i.e. terrorist, criminals, etc.)?
- Could the materials/methods/technologies and knowledge involved or generated serve purposes other than those intended? If so, would such use be unethical/sensitive?

You must conduct a risk-assessment and take appropriate steps to avoid misuse. There are various ways to mitigate risk, depending on the planned activity and the potential misuse you may choose to:

- Take additional security measures, e.g. physical security measures, classification of certain deliverables, compulsory security clearance for those involved in project, etc. (in the points related to EU Classified Information, it is recommended to cross-link this information with Part B section 5.2)
- Take additional safety measures, e.g. compulsory safety training for personnel, etc.
- Adapt the research design: e.g. use dummy data, etc.

You must also comply with the numerous international, EU and national laws that address concerns relating to potential misuse of materials, technologies and information *(see list below)*.

Specific cases

Biological, chemical, radiological and nuclear security-sensitive materials and explosives (CBRNE) — To avoid misuse, take appropriate measures to provide adequate security for the facility used, personnel, transfer and information. Further possible safeguards are:

- including security expertise in your research *(e.g. by appointing an independent adviser)*
- limiting the dissemination of research results
- training all staff appropriately.

In many cases, overlaps between safety and security measures will exist, but gaps need to be identified and addressed. The most frequent issue relates to research involving pathogens and the need to implement adequate biosecurity measures.

Research with a potential impact on human rights — Concerns in this field relate primarily to research on surveillance technologies, new data-gathering and data-merging technologies *(e.g. in the context of big data)*.

Risk mitigation measures may include:

- a human rights impact assessment
- involving human rights experts in your research
- training personnel and/or technological safeguards
- caution when publishing or otherwise disseminating results *(e.g. through privacy by design)*
- adapting the research design *(e.g. using dummy data)*
- classifying certain deliverables

What do you need to provide?

If your proposal raises one of the issues listed in the legal aspects checklist, you must if applicable, complete the **legal assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to the legal aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

Guidance note — Potential misuse of research results

FP7 guidance: A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU-funded research

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

1.3 Personal data

This section concerns research that involves processing of personal data, regardless of the method used *(e.g. interviews, questionnaires, direct online retrieval, etc.)*.

'Personal data' means information relating to an identified or identifiable natural person.

Legal aspects checklist

Section 1.3: PROTECTION OF PERSONAL DATA	YES	NO	Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[4]
Is your research in compliance with: **EU General Data Protection Regulation (GDPR)?**	☐	☐	1) Details of the technical and organisational measures to safeguard the rights of the research participants. For instance: For organisations that must appoint a data protection officer (DPO) under the GDPR: Involvement of the DPO and disclosure of the contact details to the research participants. For all other organisations: Details of the data protection policy for the project (i.e. project-specific, not general). 2) Details of the informed consent procedures. 3) Details of the security measures to prevent unauthorised access to personal data. 4) How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)? Explain. 5) Details of the anonymisation /pseudonymisation techniques. 6) Justification of why research data will not be anonymised/ pseudonymised (if relevant). 7) Details of the data transfers (type of data transferred and country to	1) Informed Consent Forms + Information Sheets used (if relevant).

[4] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.

				which it is transferred – for both EU and non-EU countries).	
If **YES:**	- Does it involve the processing of special categories of personal data *(e.g. genetic, health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction.)*?	☐	☐	1) Justification for the processing of special categories of personal data. 2) Why can the research objectives not be reached by processing anonymised/ pseudonymised data (if applicable)?	
	- Does it involve processing of genetic, biometric or health data?	☐	☐		1) Declaration confirming compliance with the laws of the country where the data was collected.
	- Does it involve profiling, systematic monitoring of individuals or processing of large scale of special categories of data, intrusive methods of data processing *(such as, tracking, surveillance, audio and video recording, geo-location tracking etc.)* or any other data processing operation that may result in high risk to the rights and freedoms of the research participants*?*	☐	☐	1) Details of the methods used for tracking, surveillance or observation of participants. 2) Details of the methods used for profiling. 3) Risk assessment for the data processing activities. 4) How will harm be prevented and the rights of the research participants safeguarded? Explain. 5) Details on the procedures for informing the research participants about profiling, and its possible consequences and the protection measures.	1) Opinion of the data controller on the need for a data protection impact assessment (art.35 GDPR) (if relevant).

Does your research involve further processing of previously collected personal data *(including use of pre-existing data sets or sources, merging existing data sets)***?**	☐	☐	1) Details of the database used or of the source of the data. 2) Details of the data processing operations. 3) How will the rights of the research participants be safeguarded? Explain. 4) How is all of the processed data relevant and limited to the purposes of the project ('data minimisation' principle)? Explain. 5) Justification of why the research data will not be anonymised/ pseudonymised (if relevant).	1) Declaration confirming lawful basis for the data processing. 2) Permission by the owner/manager of the data sets *(e.g. social media databases)* (if applicable). 3) Informed Consent Forms + Information Sheets + other consent documents *(opt in processes, etc.)*. (if applicable).
Does your research involve publicly available data?	☐	☐	1) Confirm that the data used in the project is publicly available and can be freely used for the project.	1) Permission by the owner/manager of the data sets *(e.g. social media databases)* (if applicable).

An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person *(art. 2(a) EU General Data Protection Regulation (GDPR)*.

> ***Examples:*** *name, address, identification number, pseudonym, occupation, e-mail, CV, location data, Internet Protocol (IP) address, cookie ID, phone number, data provided by smart meters, data held by a hospital or doctor*.

⚠ Individuals are not considered 'identifiable' if identifying them requires excessive effort.

Completely anonymised data does not fall under the data privacy rules (as from the moment it has been completely anonymised).

'Processing of personal data' means any operation (or set of operations) performed on personal data, either manually or by automatic means.

This includes "Collection (digital audio recording, digital video caption, etc.) recording, organisation, structuring & storage (cloud, LAN or WAN servers), adaptation or alteration (merging sets, amplification, etc.), retrieval & consultation, use, disclosure by transmission, dissemination or otherwise making available (share, exchange, transfer), alignment or combination, restriction, erasure or destruction."

> ***Examples:*** *access to/consultation of a database containing personal data; managing of the database; posting/putting a photo of a person on a website; storing IP addresses or MAC addresses*; *video recording (CCTV); creating a mailing list or a list of participants.*

⚠ Processing normally covers **any** action that uses data for research purposes (even if interviewees, human volunteers, patients, etc. are *not* actively included in the research).

Personal data may come from any type of research activity *(ICT research, genetic sample collection, tissue storage, personal records (financial, criminal, education, etc.), lifestyle and health information, family histories, physical characteristics, gender and ethnic background, location tracking and domicile information, etc.)*.

How do I deal with the issues?

Your research must comply with:

- applicable international, EU and national law (in particular, the GDPR, national data protection laws and other relevant legislation, *such as on clinical trials*).

Under these rules, personal data must be processed in accordance with certain principles and conditions that aim to **limit** the negative **impact** on the persons concerned and ensure **fairness**, **transparency** and **accountability** of the data processing, **data quality** and **confidentiality**.

This implies the following main obligations:

- Data processing should be subject to appropriate safeguards (see table above).
- Data should wherever possible be processed in anonymised or pseudonymised form.
- Data processing is subject to free and fully informed consent of the persons concerned (unless already covered by another legal basis, *e.g. legitimate or public interest*).
- Data processing must **NOT be performed in secret** and research participants must be made aware that they take part in a research project and be informed of their rights and the potential risks that the data processing may bring.
- Data may be processed ONLY if it is really adequate, relevant and limited to what is necessary for your research ('data minimisation principle').

⚠ Collecting personal data *(e.g. on religion, sexual orientation, race, ethnicity, etc.)* that is not essential to your research may expose you to allegations of 'hidden objectives' or 'mission creep' (i.e. collecting information with permission for one purpose and using it/making it available — online or otherwise — for another reason, without additional permission).

- Data processing operations which are more intrusive and likely to raise higher ethics risks must be subject to higher safeguards.
- For complex, sensitive or large-scale data processing or data transfers outside of the EU, you should consult your data protection officer (DPO), if you have one, or a suitably qualified expert.
- The level of data security must be appropriate to the risks for the research participants occurring in case of unauthorized access or disclosure, accidental deletion or destruction of the data.
- You are responsible for any partners, contractors or service providers that process research data at your request or on your behalf.

Generally, one of the best ways to avoid/limit data protection issues for your project is to use **anonymised** or **pseudonymised** data.

⚠ Pseudonymisation and anonymisation are not the same thing.

> 'Anonymised' means that the data has been rendered anonymous in such a way that the data subject can no longer be identified (and therefore is no longer personal data and thus outside the scope of data protection law).
>
> 'Pseudonymised' means to divide the data from its direct identifiers so that linkage to a person is only possible with additional information that is held separately. The additional information must be kept separately and securely from processed data to ensure non-attribution.

Moreover, if you have a **data protection officer** (DPO), it is generally recommended to involve them in all stages of your project, whenever it comes to data privacy issues, since this will help your proposal and grant agreement implementation (EU grants are subject to full compliance with data privacy rules).

⚠ Be aware that even if you solve all privacy-related issues, research data may still raise other ethics issues, such as the potential misuse of the research methodology/ findings or ethics harms to specific groups.

What do you need to provide?

If your proposal raises one of the issues listed in the legal aspects checklist, you must if applicable, complete the **legal assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to in the legal aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

General

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/ECText with EEA relevance.

Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, p. 89)

Guidelines on Consent under Regulation 2016/679 (wp259rev.01), Article 29 Working Party

Guidelines on Transparency under Regulation 2016/679 (wp260rev.01), Article 29 Working Party

Guidelines on Automated individual decision-making and Profiling for the purposes of Regulation 2016/679(wp251rev.01), Article 29 Working Party

Council of Europe Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data, CM/Inf (2018)15-final

Handbook on European data protection law (2018 edition), European Union Agency for Fundamental Rights and Council of Europe, European Court of Human Rights, European Data Protection supervisor

Data transfers outside the EU - International data transfers using model contracts

Electronic communications

EU Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications)

EU Directive 2006/24/EC of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communications services or of public communications networks

2. Ethics

2.1 Human beings

This section refers to any research involving work with humans beings ('research or study participants'), regardless of its nature or topic.

> ***Examples:*** *collection of biological samples, health risks linked to tests performed during the proof of concept or demonstration of a research project, medical interventions, interviews, observations, tracking or the secondary use of information provided for other purposes, e.g. other research projects, officially collected information, social media sites, etc.*

Ethics aspects checklist

Section 2.1: HUMANS		YES/ NO		Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[5]
Does your research involve human participants (i.e. volunteer, civilian/military personnel, etc.)?		☐	☐	1) Confirm that informed consent will be obtained.	1) Informed Consent Forms + Information Sheets.
If **YES:**	- Are they volunteers for the social or human research?	☐	☐	1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures.	1) Copies of ethics approvals (if required).
	- Are they persons unable to give informed consent (including /children/minors)?	☐	☐	1) Details of the procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors. 2) What steps will you take to ensure that participants are not subjected to any form of coercion?	1) Copies of ethics approvals.
	- Are they vulnerable individuals or groups?	☐	☐	1) Details of the type of vulnerability. 2) Details of the recruitment, inclusion and exclusion criteria	1) Copies of ethics approvals.

[5] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.

				and informed consent procedures. These must demonstrate appropriate efforts to ensure fully informed understanding of the implications of participation.	
	- Are they children/minors?	☐	☐	1) Details of the age range. 2) What are your assent procedures and parental consent for children and other minors? 3) What steps will you take to ensure the welfare of the child or other minor? 4) What justification is there for involving minors?	1) Copies of ethics approvals.
	- Are they patients?	☐	☐	1) What disease/condition /disability do they have? 2) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures. 3) What is your policy on incidental findings?	1) Copies of ethics approvals.
	- Are they healthy volunteers for medical studies?	☐	☐		1) Copies of ethics approvals.
Does your research involve physical interventions on the study participants (i.e. Volunteer, civilian/military personnel, etc.)?		☐	☐	1) Confirm that informed consent has been obtained.	1) Informed Consent Forms + Information Sheets.
If **YES:**	- Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, drug testing, invasive studies on the brain, TMS etc.)?	☐	☐	1) Risk assessment for each technique and overall.	1) Copies of ethics approvals.

	- Does it involve collection of biological samples?	☐	☐	1) What type of samples will be collected? 2) What are your procedures for collecting biological samples?	1) Copies of ethics approvals.

How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law.

This implies that you must ensure respect for people and for human **dignity** and fair distribution of the **benefits and burden of research,** and that you must protect the **values**, **rights** and **interests** of the research participants.

Moreover, you must obtain:

Informed consent

Participation must be entirely voluntary and you must obtain and clearly document participants' informed consent in advance.

⚠ No consent is required if national law provides for an exception (e.g. in the public interest).

Participants must be given an **informed consent form** and detailed **information sheets** that:

- are written in a language and in terms they can fully understand
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue
- explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences
- state how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently
- state what procedures will be implemented in the event of unexpected or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings).

You must ensure that potential participants have fully understood the information and do not feel pressured or coerced into giving consent.

Participants must normally give their consent in writing (e.g. by signing the **informed consent form** and **information sheets**).

If consent cannot be given in writing, for example because of illiteracy, non-written consent must be formally documented and independently witnessed.

Specific cases

Research involving children (or other persons unable to give consent, *e.g. certain elderly populations, persons judged as lacking mental capacity***)** — You must obtain informed consent from the legally authorised representative and ensure that they have sufficient information to enable them to provide this on behalf and in the best interests of the participants. Whenever possible, the assent of the participants should be obtained in addition to the consent of the parents or legal representatives. Participants must be asked for consent if they reach the age of majority in the course of the research project. Dissent should be respected.

In **social science and humanities research**, there may be situations where standard procedures for obtaining written informed consent are harmful or offensive to the participants (rather than affording them protection). In such cases, explain how alternative consent will be gained *(e.g. orally)*. If deception is to be used, retrospective informed consent should be obtained and participants must be debriefed. Deception requires strong justification and appropriate assessment of the impact and the risk incurred by both researchers and participants.

For **medical and human research** you must follow the procedures for informed consent that are described in the Declaration of Helsinki and the Oviedo Bioethics Convention *(see below)*.

Research involving children (or other persons unable to give consent) — should be carried out only if:

- studies with consenting adults would not be effective
- participants are subject to only a minimal risk and burden
- the results of the research will benefit the individual or group represented by the participant.

Social science and humanities research — often involves working with human participants and particular methodological tools *(e.g. surveys, questionnaires, interviews, standardised tests, direct observation, ethnography, recordings, experiments with volunteers, and sometimes physical interventions)*.

You must therefore clarify the ethical implications of the chosen methodologies.

Example:

Describe the sampling methods or recruitment procedures and discuss whether they could result in discriminatory practices. If such practices are inevitable given the methodology, what action should be taken to mitigate them?

For your grant proposal, you should also provide an assessment of risks, stating explicitly what kinds of harm *(psychological, social, legal, economic, environmental, etc.)* might occur, the likelihood of subjects actually incurring such harm, and the steps that you will take to minimise them.

Research entailing more than minimal risk typically involves:

- potentially vulnerable groups and people unable to give informed consent
- personal or sensitive topics, which might induce psychological stress, anxiety or humiliation
- deception
- risks to researcher safety or
- seeking respondents through the internet/social media *(e.g. using identifiable visual images or discussing sensitive issues)*.

Particular attention must be paid to vulnerable categories of individuals such as children, patients, people subject to discrimination, minorities, people unable to give consent, people of dissenting opinion, immigrant or minority communities, sex workers, etc.

If your research involves children or other individuals unable to make decisions for themselves, you must maintain an active relationship with their legal guardians and/or carers; you must not only seek their consent, but also allow them to monitor the research.

⚠ Ensure that data are kept securely and that publication (including publication on the internet) does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity.

In rare cases, there may be a need to override agreements on confidentiality and anonymity *(e.g. if maintaining confidentiality facilitates illegal behaviour such as drug dealing, child abuse, etc. that has come to light in the course of the research)*. In such circumstances, you must carefully consider disclosure to the appropriate authorities. You must inform the participants or their guardians of your intentions and the reasons for disclosure, unless this makes disclosure impracticable. You should also consider the technical aspects of collecting and storing your research data.

Data collection using electronic encoding tools (digital recorders or cameras) should be given special attention *(see also section 1.3)*. You should also discuss these issues with your organisation's data protection officer.

What do you need to provide?

If your proposal raises one of the issues listed in the ethical aspects checklist, you must if applicable, complete the **ethical assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to the ethical aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

2.2 Human cells or tissues

This section refers to research using, producing or collecting human cells or tissues.

You may obtain cells or tissues:

- from commercial sources
- as part of this research project
- from another research project, laboratory or institution
- from a biobank.

Ethics issues checklist

Section 2.2: HUMAN CELLS / TISSUES		YES/ NO		Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[6]
Does your research involve human cells or tissues?		☐	☐	1) Details of the cells or tissue types.	1) Copies of relevant ethics approvals. 2) Copies of accreditation /designation/authorisation/ licensing for using, processing or collecting the human cells or tissues (if required).
If **YES:**	- Are they available commercially?	☐	☐	1) Details of the provider (company or other).	1) Copies of import licences (if relevant).
	- Are they obtained within this project?	☐	☐	1) Details of the source of the material, the amount to be collected and the procedure for collection. 2) Details of the duration of storage and what you will do with the material at the end of the research. 3) Confirm that informed consent has been obtained.	1) Informed Consent Forms + Information Sheets.
	- Are they obtained from another project, laboratory or institution?	☐	☐	1) Country where the material is stored. 2) Details of the legislation under which material is stored. 3) How long will the material be stored and what will you do with it at the end of the research project? 4) Name of the laboratory/institution.	1) Copies of import licences (if relevant). 2) Statement of laboratory/institution that informed consent has been obtained.

[6] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.

				5) Country where the laboratory/institution is located. 6) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	
	- Are they obtained from a biobank?	☐	☐	1) Name of the biobank. 2) Country where the biobank is located. 3) Details of the legislation under which material is stored. 4) Confirm that material is fully anonymised or that consent for secondary use has been obtained.	1) Copies of import licences (if relevant). 2) Statement of biobank that informed consent has been obtained.

How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2004/23/EC).

  Under this Directive, the handling of cells and tissues is subject to specific rules *(in particular, concerning donor selection/protection; accreditation/designation/authorisation/ licensing of tissue establishments and tissue and cell preparation processes; quality management of cells and tissues; procurement, processing, labelling, packaging, distribution, traceability, and imports and exports of cells and tissues from and to third countries)*.

The main obligations are to:

- keep track of the **origin** of the cells and tissues you use, produce or collect

and to obtain:

- the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells or tissues
- free and fully informed consent of the donors.

Specific cases

Cells or tissues from clinical practice (secondary use) — For human cells or tissues which you or others have derived from clinical practice *(e.g. waste material from surgery or other operations*) provide evidence *(e.g. copies of examples of informed consent documentation)* that the donors have given informed consent for the use of their waste cells or tissues (either specifically for the research or generally, for any secondary use).

If, for the purposes of your research, you intend to collect more **additional material** than would normally be collected during the standard clinical procedure *(e.g. a larger than normal tissue sample or a sample that includes some additional adjacent material)*, you must ensure that informed consent has also been given for collecting additional material. You must also explain the need for such material in your grant proposal and show that you have obtained appropriate ethics approvals.

Secondary use for future research — If you intend to store the material for future use in other projects, you must:

- confirm that you have obtained the donor's consent for such secondary use
- state the legislation under which the material will be stored
- state how long it will be stored and what you will do with it at the end of the research.

Biobanking — Biobanks raise significant ethical issues concerning informed consent and data privacy.

'Biobanks' are repositories for the storage of biological samples (usually human) and play a significant role in biomedical research. These 'libraries' provide researchers with access to large numbers of tissue samples, genetic material and associated data.

If your project has the aim or effect of setting up a biobank, you must ensure that there is strict compliance with appropriate European and national ethical standards (in particular, regarding data privacy; *see section 1.3*).

You must confirm that informed consent has been obtained and show that you have obtained all necessary ethics approvals (or that you are exempted under national law).

⚠ No samples/data may be placed in the biobank before all appropriate consents and ethics approvals have been obtained

You will need to make a report on key aspects of the biobank's activities, including in particular:

- information on which donors will be excluded/included *(e.g. competent adults, children and minors, adults unable to provide informed consent, individuals in an emergency setting, etc.)*
- details of the material that will be 'banked', including:
  - personal (coded or fully identifiable) biosamples
  - personal information associated with a sample *(e.g. name/code, gender, age, etc.)*
  - personal data resulting from analysis of a sample *(e.g. analysis of genetic material or a genome)*
  - anonymised biosamples
  - anonymised data resulting from analysis of a sample (from which individuals could be identified) and
  - epidemiological (population level) data
- information on the standard procedures for:
  - accepting material into the biobank,
  - processes and standards for sample-quality assurance and ensuring accuracy of data and information
  - handling requests for release of samples/data from the biobank *(including fair and just financial arrangements and benefit-sharing for third countries)*.

Genetic testing — For using or storing human cells or tissues for genetic testing, you must obtain the donor's informed consent for the genetic testing, and show that you have obtained approval from the relevant ethics and data protection bodies; and any licence required under national legislation.

Transfer to/from non-EU countries — If your research project involves the transfer of cells and tissues from/to non-EU countries, you must comply with the specific provisions on import/export under Directive 2004/23/EC.

Moreover, since human cells and tissues constitute personal data, you must also comply with the rules on data transfer to non-EU countries *(see section 1.3)*.

What do you need to provide?

If your proposal raises one of the issues listed in the ethical aspects checklist, you must if applicable, complete the **ethical assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to the ethical aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

EU Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p.48).

2.3 Animals

This section refers to research involving animals.

Ethics issues checklist

Section 2.3: ANIMALS		YES/NO		Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[7]
Does your research involve animals?		☐	☐	1) Details of the species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used. 2) Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used.	
If **YES**:	- Are they vertebrates?	☐	☐		
	- Are they non-human primates (NHP) (e.g. monkeys, chimpanzees, gorillas, etc.)?	☐	☐	1) Why are NHPs the only research subjects suitable for achieving your scientific objectives? Explain. 2) What is the purpose of the animal testing? Give details. 3) Where do the animals come from? Give details.	1) Personal history file of NHP.
	- Are they genetically modified?	☐	☐	1) Details of the phenotype and any inherent suffering expected. 2) What scientific justification is there for producing such animals? Give details. 3) What measures will you take to minimise suffering in breeding,	1) Copies of GMO authorisations.

[7] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.

				maintaining the colony and using the GM animals? Give details.	
	- Are they cloned farm animals?	☐	☐	1) Details of the phenotype and any inherent suffering expected. 2) What scientific justification is there for producing such animals? Give details. 3) What measures will you take to minimise suffering in breeding, maintaining the colony and using of the GM animals? Give details.	1) Copies of authorisations for cloning (if required).
	- Are they an endangered species?	☐	☐	1) Why is there no alternative to using this species? Give details. 2) What is the purpose of the research? Give details.	1) Copies of authorisations for supply of endangered animal species (including CITES).

How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, EU Directive 2010/63/EU).

  This Directive is designed to limiting the use of animal testing for scientific purposes. It sets out EU-wide animal welfare standards (including authorisations, restrictions on the use of certain kinds of animals, standards for procedures, minimum requirements for personnel, recording and traceability, care and accommodation).

⚠ Some EU Member States have stricter rules.

This means that you must choose alternatives to animal use where possible and implement the principles of **replacement**, **reduction** and **refinement** (‘**three Rs**’).

Replacement — replacing animal use by an alternative method or testing strategy (without use of live animals).

Examples

‘Higher' animals can be replaced by 'lower' animals: microorganisms, plants, eggs, reptiles, amphibians, and invertebrates may be used in some studies to replace warm-blooded animals.

Live animals may be replaced by non-animal models, such as dummies for an introduction to dissection for teaching the structure of the animal or the human body, mechanical or computer models, audio-visual aids, or in vitro modelling.

Reduction — reducing the number of animals used.

Refinement — improving the breeding, accommodation and care of animals and the methods used to minimise pain, suffering, distress or lasting harm to animals.

Moreover, you must obtain:

- the necessary authorisations for the supply of animals and the animal experiments (and other specific authorisations, if applicable).

⚠ You must obtain all relevant national authorisations before you can start to use animals.

Specific cases

Non-human primates (NHPs) — Since non-human primates are so close to human beings, their use in experiments raises particular ethics concerns. Directive 2010/63/EU sets strict limits to their use: They may be used only for specific research purposes (of primary importance) and only if there is no alternative *(art. 8)*. Moreover, only offspring of non-human primates which have been bred in captivity or which are sourced from self-sustaining colonies may be used *(art. 10)*.

⚠ The use of great apes requires very exceptional justification and must be specifically authorised by the Commission/Agency.

Endangered species — Endangered species cannot be used, except for very important research purposes and where there is no alternative non-endangered species that will meet the scientific objective *(art. 7 Directive 2010/63/EU)*.

In this case, you should follow agreed international practices (CITES).

What do you need to provide?

If your proposal raises one of the issues listed in the ethical aspects checklist, you must if applicable, complete the **ethical assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to the ethical aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

General

EU Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

The ARRIVE Guidelines — Animal Research: Reporting In Vivo Experiments. Festing MFW, Overend P, Gaines Das R, Cortina Borja M, Berdoy M (2002), *The design of animal experiments: reducing the number of animals in research through better experimental design*, Laboratory Animal Handbooks Series, 14. London: Royal Society of Medicine Press.

Hooijmans C. *et al*. (2010), *A gold standard publication checklist to improve the quality of animal studies, to fully integrate the Three Rs, and to make a systematic review more feasible*, ATLA 38: 167-182.

For alternatives to animal testing, refer to the following website: http://ecvam.jrc.it/

Research on animals

Research on animals

Endangered species

CITES

2.4. Environment, health & safety

This section concerns research that may adversely affect:

- the environment or
- the health & safety of the researchers involved.

This may be due to any of the following:

- the experimental design of the research itself
- undesirable side-effects of the technologies used.

a) Environment

Ethics aspects checklist

Section 2.4.1: ENVIRONMENT	YES/NO		Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[8]
Does your research involve the use of elements that may cause harm to the environment, to animals or plants? *For research involving animal experiments, see section 3.*	☐	☐	1) Risk-benefit analysis. 2) Show how you apply the precautionary principle (if relevant). 3) What safety measures will you take? Give details.	1) Safety classification of laboratory. 2) Copy of GMO and other authorisations (if required).
Does your research deal with endangered fauna and/or flora /protected areas?	☐	☐		1) Specific authorisations (if required).

How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the precautionary principle and legislation on nature conservation and pollution control).

[8] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case your proposal is invited to the grant agreement preparation phase.

The precautionary principle requires that where there is plausible scientific evidence for serious risks, you must prove that a new technology will not harm the environment.

The legislation on nature conservation and pollution control includes the EU Habitats Directive 92/43/EEC, the EU Wild Birds Directive 79/409/EEC, EU Regulation (EC) No 338/97 on protection of wild fauna, the EU GMO Directive 2009/41/EC and the Cartagena Protocol on Biosafety.

This means you must assess potential risks to the environment and avoid or minimise such risks.

Moreover, you must obtain:

- the necessary environmental authorisations (if applicable).

⚠ You must obtain all relevant national authorisations before you can start your research.

What do you need to provide?

If your proposal raises one of the issues listed in the ethical aspects checklist, you must if applicable, complete the **ethical assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to the ethical aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

b) Health & safety

The health and safety of all human participants in research - as subjects, investigators or uninvolved third parties, must be a priority in all research studies.

The kinds of risk to researcher safety vary according to the nature of the discipline, the topic and the research site. Only the 'researcher in the field' can fully assess safety concerns and/or their willingness to tolerate risks.

However, research in both familiar and unfamiliar settings can involve added safety concerns. Even in familiar settings, surprising, non-routine things can happen which pose safety risks.

Moreover, in certain types of research, the risk of harm to the researcher is caused by the topic of study or by the actions of the researchers themselves. Lack of caution or failure to obey standard procedures may lead to physical or psychological harm.

⚠ Improved safety practices may impose additional cost burdens, which can be included in your estimated budget.

Ethics aspects checklist

Section 2.4.2: HEALTH AND SAFETY	YES/NO	Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[9]
Does your research involve the use of elements that may cause harm to humans during the research process, including research staff? *For research involving human participants, see section 2.1.*	☐	1) Details of the health and safety procedures.	1) Safety classification of laboratory.

How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law (in particular, the legislation on public-health control *(e.g. regulating conduct in animal epidemics, food imports, consumer protection, etc.)* and safety at work *(e.g. Directive 2006/25/EC)*).

This means you must warn and advise researchers. In some cases you must even remove them from dangerous situations.

Moreover, you should establish and follow a set of safety checks and procedures (or a more in-depth risk assessment) for each project they conduct.

You must also obtain:

- the necessary health and safety authorisations (if applicable).

[9] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case your proposal is invited to the grant agreement preparation phase.

Specific cases

Toxic chemicals and/or **explosives** — Staff should have adequate training in storing, handling and disposing of such substances. If new substances and/or formulations *(e.g. nanomaterials)* are developed, you must provide adequate risk assessments.

Radioactive material — Clear legislation exists in all EU countries on the storage, handling and disposal of radioactive materials.

The release of radioactive material into the environment is allowed only if you can show that use of alternatives (e.g. non-radioactive stable isotopes, simulants etc.) is not possible.

Research 'in the field' — Establish and abide by recognised procedures to help keep researchers and subjects safe. These should include:

- keeping careful notes of all research engagements
- ensuring projects are adequately staffed
- using mobile phones to keep in touch with the research base
- conducting full risk assessments of fieldwork sites

- formally notifying authorities of research being conducted in an area
- carrying authorised identification
- researcher preparation & training covering techniques for handling conflict, threats, abuse or compromising situations
- debriefing after field research with an assessment of fieldwork safety and
- reporting any health & safety incidents.

What do you need to provide?

If your proposal raises one of the issues listed in the ethical aspects checklist, you must if applicable, complete the **ethical assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to the ethical aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

Background documents & further reading

General environment

EU Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora (OJ L 206, 22.7.1992, p.7)

EU Directive 79/409/EEC of 2 April 1979 on the conservation of wild birds (OJ L 103, 25.4.1979, p.1)

EU Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 103, 25.4.1979, p.1)

Cartagena Protocol on Biosafety

EU Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1)

EU Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (OJ L 164, 25.6.2008, p. 19)

GMOs

EU Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on trans-boundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1)

EU Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75)

Public health & consumer protection

Consumer safety

Health & safety at work

EU Directive 2006/25/EC of the European Parliament and of the Council of 5 April 2006 on the minimum health and safety requirements regarding the exposure of the workers to risks arising from physical agents (OJ L 114, 27.4.2006, p.38)

A Code of Practice for the Safety of Social Researchers

Ethics advisers/advisory boards

A suitably experienced *ethics adviser* can help you to deal with ethical issues and putting into place the procedures to handle these appropriately if your research includes several ethical concerns.

If your research involves several significant or complex ethical issues, you should appoint an *ethics advisory board* with several experts with varied expertise.

If you appoint an ethics adviser/advisory board, it is important that they are:

- external to the project and to the host institution
- totally independent and
- free from any conflict of interest.

Your university or institution (or members of your consortium) may have experience with an ethics adviser or members of an ethics advisory board and may be in a position to suggest potential candidates.

The ethics adviser or ethics advisory board should maintain an overview of the work throughout the whole course of your project and help you to think ahead about possible problems that might arise and how they can be addressed. Their experience will help you check for compliance with ethical standards within the relevant research fields. They will also be responsible for reporting to you and to the Commission/Agency, on a regular basis, on ethics concerns as they arise and the continuing probity of your studies.

If you appoint an ethics adviser or set up an ethics advisory board, you should work with them on a regular basis throughout your project. Their oversight role should be fully integrated into your research activities and they should work closely with you and your colleagues, so they are fully aware of all the developments as your research progresses. Your ethics advisers/ethics advisory board should be an essential element in your project management structure.

What do you need to provide?

You must provide:

- the name and contact information for persons suggested
- the terms of reference for their involvement and the deliverables expected
- their declarations of no conflict of interest.

Background documents & further reading

General information on ethics

Ethics for Researchers

European Textbook on Ethics in Research (2010)

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

3. Societal

The security of the EU citizens is one of many societal values in Europe, all of which must be balanced against one another. Defence research is a tool to support security and freedom that can only be achieved within the rule of law.

Therefore, Member States are in other words bound by law to respect and to promote human dignity, freedom, democracy, equality, the rule of law and protection of fundamental rights, including the right to privacy and data protection, freedom of expression and association, good governance and security.

In light of this obligation, the impact of the research on society should be considered, both in the defence context but also beyond.

Societal aspects checklist

Section 3: SOCIETAL	YES/ NO		Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[10]
Does the application of the proposed research have the potential to influence or change currently installed societal structures and mechanisms for decision-making, accountability or responsibility?	☐	☐	1) Risk analysis of issues and corrective measures.	1) Copies of societal review report. (if applicable)
Does the research include a 'human-in-the-loop'?	☐	☐	1) Risk analysis of issues and corrective measures.	1) Copies of societal review report. (if applicable)
Does the research include a 'human-behind-the-loop'?	☐	☐	1) Risk analysis of issues and corrective measures	1) Copies of societal review report. (if applicable)
Does the research include a 'human-out-of-the-loop'?	☐	☐	1) Risk analysis of issues and corrective measures	1) Copies of societal review report. (if applicable)
Is the societal impact of the application of the proposed research reversible?	☐	☐	1) Risk analysis of issues and corrective measures	1) Copies of societal review report. (if applicable)
Is the cumulative societal impact of the application of the proposed research	☐	☐	1) Risk analysis of issues and corrective measures	1) Copies of societal review report. (if applicable)

[10] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.

proportional to its use?				
Is the long-term societal impact of the application of the proposed research proportional to its use?	☐	☐	1) Risk analysis of issues and corrective measures	1) Copies of societal review report. (if applicable)
Could the application of the proposed research trigger disproportionate countermeasures by adversaries?	☐	☐	1) Risk analysis of issues and corrective measures	1) Copies of societal review report. (if applicable)
If implemented, could the research disproportionately affect specific untargeted groups or discriminate unduly them?	☐	☐	1) Risk analysis of issues and corrective measures	1) Copies of societal review report. (if applicable)

How do I deal with the issues?

Your research must comply with:

- ethical principles
- applicable international, EU and national law.

What do you need to provide?

If your proposal raises one of the issues listed in the ethical aspects checklist, you must if applicable, complete the **societal assessment** in **Part B** of your proposal (i.e. section 5.1 of the Technical Annex).

Your grant proposal must include the **information** referred to the ethical aspects checklist and any of the **documents** already available.

⚠ Documents that are not submitted together with the proposal should be kept on file and may have to be provided later on, if requested by the Commission/Agency.

AI related research

Coordinated Plan on Artificial Intelligence

Autonomy in Future Military and Security Technologies

Mapping the Development of Autonomy in Weapon Systems

4. Other ELSA

ELSA aspects checklist

Section 4.1: OTHER ELSA ISSUES	YES/ NO		Information to be provided in Part B-5.1 of the proposal	Documents to be kept on file[11]
Do you plan to import any material – including data – from non-EU countries into EU?	☐	☐	1) Any relevant information.	1) Any relevant document.
Do you plan to export any material – including data – from EU into non-EU countries?	☐	☐	1) Any relevant information.	1) Any relevant document.
Are there any other legal, ethics and societal aspects that should be taken into consideration? *Please specify:*	☐	☐	1) Any relevant information.	1) Any relevant document.

Since the Preparatory Defence Research intends to support disruptive and innovative research, it may be that your research raises **new ethical, legal and societal "ELSA" issues and concerns** that are currently not (fully) covered by any "**ELSA**" aspects checklist Table *(**e.g. new developments in the fields of neurobiology, human-machine interaction, developments in nanotechnology, genetic enhancement, synthetic biology, artificial intelligence, the creation of androids and cyborgs, cross-cutting technology, etc**.)*. If you know of any such other "ELSA" relevant issues that apply to your project, describe them in this section and explain how you intend to address them.

In highly innovative research, with high socio-economic impact, it is necessary to apply "ethics, legal and societal" approach by design methodology.

> This allows you to alert the Commission/Agency in time and get appropriate assistance for addressing them. It also avoids the problems you would have if such issues were found out only later (in the context of an audit or investigation).

⚠ If, "ethics, legal and societal" issues arise **unexpectedly during your research**, contact your Project Officer immediately and provide detailed information on the issue and how you intend to handle it. We will ensure that you receive appropriate help and guidance.

[11] The documents to be kept on the file might be requested, upon the conclusions of the ELSA Review, and in case, your proposal is invited to the grant agreement preparation phase.