EUROPEAN DEFENCE AGENCY

CHIEF EXECUTIVE

Ms Emily O'Reilly
European Ombudsman
1 avenue du Président Robert Schuman
CS 30403
F-67001 Strasbourg

EDA202001008/CSD/CR 7 January 2020

Dear Ms O'Reilly,

Subject: Complaint 1529/2019/MG

I refer to your letter dated 27 November 2019, in which you propose a solution to resolve the above-mentioned complaint.

Pursuant to the proposed solution, the European Defence Agency ("EDA") should grant increased partial access to the Ethics Summary Reports (hereinafter "ESRs") on the proposals in receipt of EU funding which have been or are being implemented, including to the commercial information contained in those reports.

I am pleased to inform you that EDA's assessment is overall in line with your own assessment as regards the access to documents request in question. The points you have confirmed, notably that individual reports should not be disclosed in order to avoid possible external pressure on individual evaluators and the risk of self-censorship and that access to details of unsuccessful proposal is not to be granted in order to protect the commercial interests of those legal entities, will be most helpful in handling similar future requests.

We have carefully considered your view that successful proposals should not benefit from the same level of protection of commercial interests as they received EU funding giving the public the right to be adequately informed about the content of the proposals. As a result, we have once again reviewed the documents in question in light of your proposal that EDA should grant increased partial access to the ESRs of the proposals that received EU funding and fall under the scope of the request for access to documents of the complainant.

I am pleased to inform you that in light of your recommendation and based on this detailed review, EDA is able to grant increased partial public access to the documents in question.

The revised versions of the documents are annexed to this letter.

EUROPEAN DEFENCE AGENCY

CHIEF EXECUTIVE

I take the opportunity to commend your office on the constructive approach taken in this case and trust that EDA's position will enable you to bring this case to a satisfactory closure.

Yours sincerely,

Jorge DOMECQ

Annex : Revised expunged version of the ESRs of the successful proposals falling under the scope of the disputed request for access to documents

ETHICS ASSESSMENT

CONSENSUS REPORT (CR)

Programme: *Preparatory Action on Defence Research (PADR)*
Call for proposals: Force protection and advanced soldier systems (**PADR-FPSS-2017**)
Topic: PADR-FPSS-01-2017 – Adaptive Camouflage for the Soldier II
Type of action: Research and Innovation Action (RA)
Call deadline: 28.09.2017

Proposal: 800871 – ACAMSII

Date of ethics assessment: between 10.01.2018 and 11.01.2018

Ethics reviewers:

Names (and role, if other than evaluator) [1]		
Name SURNAME	**Role**	**Signature**
[redacted]	ELSA Expert	[redacted]
[redacted]	ELSA Expert	
[redacted]	ELSA Expert	

Proposal data:

Duration (months): 36

Applicants:

1. TOTALFORSVARETS FORSKNINGSINSTITUT
2. CENTRO TECNOLOGICO DAS INDUSTRIAS TEXTIL E DO VESTUARIO DE PORTUGAL
3. FRAUNHOFER GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.
4. Damel - Confeccao de Vestuario Lda
5. Center for Physical Sciences and Technology
6. NEDERLANDSE ORGANISATIE VOOR TOEGEPAST NATUURWETENSCHAPPELIJK ONDERZOEK TNO
7. SAFRAN ELECTRONICS & DEFENSE

Project abstract: The project will develop adaptive camouflage for soldier protection in future military conflicts occurring in a multinational context in various environments including dynamic changes. An advanced opponent might operate sensors in several wavelength bands and use sensor data fusion in order to extract further information. This new threat situation creates a strong need for multispectral adaptive camouflage for the soldier. The project is roughly divided into the following phases, separated in time with some overlap: Environmental background studies; research on materials, structures and components; textile camouflage design; integration; implementation; production; life cycle cost estimation; test and evaluation; dissemination and exploitation. Continuous dialogue with military end-users ensures relevance and compatibility with other equipment. Research will be performed on novel materials, structures, components and methods to improve the flexibility of the soldier camouflage and thereby the survivability. Both active (controlled by an operator or a computer processing sensor data) and passive (without control signal) camouflage principles will be studied. The final demonstration aims at including a combination of several active and passive technologies providing protection against radar, infrared and visible sensor threats. The consortium members complement one another and cover the whole value chain, including competence in threat analysis, military end user needs, signature expertise, sensors, materials science, textile production, optoelectronic components, camouflage pattern design, human perception, system integration, system tests in lab and field, optical and radar measurements, modelling and simulation, signature measurements, assessments, dissemination and training. The plan for dissemination and exploitation includes workshops with military stakeholders, EU, procurements agencies as well as presentations for academic, military and industrial audiences.

[1] Format: First name LASTNAME.

1. Identifying ethics issues

Please go through the table below and indicate by answering 'YES' or 'NO' if the proposed research has features which gives it an ethical dimension. (Your answer will NOT prejudge the ethics opinion — which depends *from the analysis to be carried out further down. For example, if personal data is anonymised, you should answer 'YES', but the proposal will nevertheless get 'ethics clearance' without conditions because the issue is already addressed).*

If no 'YES' is/needs to be ticked, immediately proceed to the 'ethics opinion' and give unconditional 'ethics clearance'.[1]

Section 1: HUMANS		YES/NO	Page
Does this research involve human participants?		YES	3, 33, 69
If YES:	- Are they volunteers for technical research?	YES	33, 69
	- Are they persons unable to give informed consent?	NO	
	- Are they vulnerable individuals or groups?	NO	
	- Are they children/minors?	NO	
	- Are they patients?	NO	
	- Are they healthy volunteers for medical studies?	NO	
	- Are they members of the Armed Forces?	YES	3, 29
Does this research involve physical interventions on the study participants?		NO	
If **YES:**	- Does it involve invasive techniques?	NO	
	- Does it involve collection of biological samples?	NO	

[1] When compiling the table, it is advised to consider also the following reference documents for arms control:

- Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (1993)
- Hague conventions (1899)
  - Declaration concerning the Prohibition of the Use of Projectiles with the Sole Object to Spread Asphyxiating Poisonous Gases
  - Declaration concerning the Prohibition of the Use of Bullets which can Easily Expand or Change their Form inside the Human Body such as Bullets with a Hard Covering which does not Completely Cover the Core, or containing Indentations

Section 2: HUMAN CELLS / TISSUES		YES/NO	Page
Does this research involve human cells or tissues? *(other than from Human Embryos/Foetuses, see section 1)*		NO	
If Yes	- Are they available commercially?	NO	
	- Are they obtained within this project?	NO	
	- Are they obtained from another project, laboratory or institution?	NO	
	- Are they obtained from a biobank?	NO	

Section 3: PERSONAL DATA		YES/NO	Page
Does this research involve personal data collection and/or processing?		YES	11, 69
If Yes	- Does it involve the collection and/or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*?	YES	11, 69
	- Does it involve tracking or observation of participants?	NO	
Does this research involve further processing of previously collected personal data (secondary use)?		NO	

Section 4: ENVIRONMENT & HEALTH AND SAFETY	YES/NO	Page
Does this research involve the use of elements that may cause harm to the environment, to animals or plants?	NO	
Does this research deal with endangered fauna and/or flora/protected areas?	NO	
Does this research involve the use of elements that may cause harm to humans, including research staff?	YES	69

Section 5: MISUSE	YES/NO	Page
Does this research have the potential for misuse of research results?	YES	69

Section 6: OTHER ETHICS ISSUES	YES/NO	Page
Are there any other ethics issues that should be taken into consideration? *Please specify:*	NO	

Comments on identified ethics issues *(optional)*:

2. Analysis of the ethical dimension

Please provide a detailed analysis of the ethical aspects of the proposal. Focus on how ethical issues are addressed, e.g.:

- *how the ethical issues relate to the research objectives, methodologies or potential impact;*
- *compliance with applicable legal requirements;*
- *if the applicants have the necessary authorisations.*

ANALYSIS:

The project states that human "volunteers will be used to test the produced clothing equipment", and that "no danger will be imposed on the subjects", but since the equipment has to be resistant (and adaptable) to cold and heat, the project does not mention under what kind of circumstances the test will be conducted and if the exposure to different temperatures, in combination with the presence of chemical in the textile, could cause dermatological reactions to the participants. If on one side the proposal affirms: "industry guidelines for textile tests will be followed", on the other hand the volunteers should receive full information of the potential danger they may incur. For instance, from an ethical dimension, it is not clear whether human volunteers will be allowed to withdraw from the experimentation process at any given moment, should they have sound reasons to believe their physical integrity is at risk. Also, it remains unknown whether the same volunteers will be advised by certified health specialists that their health and integrity is not at risk before granting consent.

3. Ethics recommendations

⚠ *Ethics recommendations are suggestions and advice provided to the applicant(s); they do not become contractual obligations.*

RECOMMENDATIONS *(optional)*:

1) Prepare and approve an ethical Code of Conduct (e.g. best practises for the management of ELSA in the project).

2) It is recommended that the project coordinator should be responsible for verifying that all phases of the project comply with ELSA principles contained in the Code of Conduct.

3) The document does not exclude that human volunteers will participate in the testing phase. In this case it would be recommended to specify:

- what kind of test will be conducted and under what circumstances;
- if participants will be monitored or not.

4) Medical support for volunteers should also be required after the testing phase.

4. Ethics opinion

Please select below the appropriate ethics opinion for this proposal (only one can be selected) and indicate the ethics requirement(s) you consider necessary.
If additional information is needed, request this information (by ticking the first button) before you give your ethics opinion. Once the information is received, the report will be reopened for your ethics opinion.

☐ **'additional information is needed'** (⚠ *only if the elements can easily be gathered and quickly transmitted.)*

☑ **ethics clearance** (i.e. the proposal is 'ethics ready')

REASONS *(optional)*:

☐ **conditional ethics clearance** (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

ETHICS REQUIREMENTS:

⚠ *For each requirement, also indicate:*
- *the type(s) of related ethics issues (a category(ies) of the EIT)*
- *whether it has to be fulfilled before or after grant signature (default option: after)*
- *by when the requirement must be fulfilled (e.g. number of months after the project start or timing linked to task concerned).*
- *a comment/reason (optional)*

REASONS:

5. Sensitivity level

How would you judge the overall sensitivity of the proposal (i.e. how deeply the ethics aspects of the project should be looked into)?

☐ Normal

☑ High

REASONS *(optional)*:

Because the project assumes a scenario with volunteers.

6. Ethics checks

In your opinion, would an ethics check during the project implementation be necessary?:

☑ YES
☐ NO

REASONS *(mandatory if YES)*:

In consideration of the final results that the project is aimed at achieving, and as the research has in programme some tests on human beings, a check is required to establish if all ELSA aspects are duly taken in consideration and fully respected.

TIMING *(mandatory if YES)*:

Middle and final term.

[redacted]

Ethics reviewers

[redacted]

ETHICS ASSESSMENT

CONSENSUS REPORT (CR)

Programme: *Preparatory Action on Defence Research (PADR)*
Call for proposals: Force protection and advanced soldier systems (PADR-FPSS-2017)
Topic: PADR-FPSS-01-2017 — Generic Open Soldier System Reference Architecture
Type of action: Research and Innovation Action (RA)
Call deadline: 28.09.2017

Proposal: 800783 — GOSSRA

Date of ethics assessment: between 10.01.2018 and 11.01.2018

Ethics reviewers:

Names (and role, if other than evaluator) [1]		
Name SURNAME	**Role**	**Signature**
[redacted]	ELSA Expert	[redacted]
[redacted]	ELSA Expert	
[redacted]	ELSA Expert	

Proposal data:

Duration (months): 22

Applicants:

1. Rheinmetall Electronics GmbH
2. GMV AEROSPACE AND DEFENCE SA
3. ITTI SP ZOO
4. TEKEVER ASDS
5. LARIMART S.p.A.
6. LEONARDO - SOCIETA PER AZIONI
7. SAAB AKTIEBOLAG
8. INDRA SISTEMAS SA
9. NEDERLANDSE ORGANISATIE VOOR TOEGEPAST NATUURWETENSCHAPPELIJK ONDERZOEK TNO

Project abstract: GOSSRA will produce a Generic Reference Architecture for Soldier Systems which is ready for standardization. It will be open and used in order to derive the Target Architecture for a specific Soldier System to be procured. The developed architecture will be technically validated in order to ensure its feasibility.

The Reference Architecture shall be comprehensive for the software, electronics, voice and data communication also including sensors, effectors, human interface devices and C4I. It shall be formulated according to the NATO Architectural Framework (NAF) v3 and built upon work already performed in the EDA studies STASS I and STASS II.

The GOSSRA partners consist of major European Soldier System companies which developed and delivered Soldier System in large numbers. Also, smaller companies which provided components or took part in Soldier System studies are involved. With government stakeholders from related European nations, the architecture will be acceptable to all major players with the EU.

[1] Format: First name LASTNAME.

The required NAF views have already developed in STASS I and II in agreement of the companies involved. GOSSRA will take a different approach and uses the architectures already developed by reviewing and refining them with the increased number of companies and states with respect to

- International Interoperability
- Adaptability to Missions or Mission Intensity
- Dynamic Environments
- Maintenance of State of the Art Soldier System
- Logistic and Human Resource Footprint
- Improve Soldier System Effectiveness
- Life Cycle Cost Estimation

GOSSRA will address emphasis on future developments and specifically identifies Soldier Mission and Technology Trends and Potentials.

To achieve the readiness for standardization the architecture will be transformed to a standard Architecture Tools format and formulated in a document ready for standardization.

The generated architecture will be technically validated in an experimental Environment.

1. Identifying ethics issues

Please go through the table below and indicate by answering 'YES' or 'NO' if the proposed research has features which gives it an ethical dimension. (Your answer will NOT prejudge the ethics opinion – which depends from the analysis to be carried out further down. For example, if personal data is anonymised, you should answer 'YES', but the proposal will nevertheless get 'ethics clearance' without conditions because the issue is already addressed).

If no 'YES' is/needs to be ticked, immediately proceed to the 'ethics opinion' and give unconditional 'ethics clearance'.[1]

Section 1: HUMANS		YES/NO	Page
Does this research involve human participants?		YES	14, 94
If YES:	- Are they volunteers for technical research?	YES	94
	- Are they persons unable to give informed consent?	NO	
	- Are they vulnerable individuals or groups?	NO	
	- Are they children/minors?	NO	
	- Are they patients?	NO	
	- Are they healthy volunteers for medical studies?	YES	94
	- Are they members of the Armed Forces?	YES	14
Does this research involve physical interventions on the study participants?		NO	
If **YES:**	- Does it involve invasive techniques?	NO	
	- Does it involve collection of biological samples?	NO	

[1] When compiling the table, it is advised to consider also the following reference documents for arms control:

- Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (1993)
- Hague conventions (1899)
  - Declaration concerning the Prohibition of the Use of Projectiles with the Sole Object to Spread Asphyxiating Poisonous Gases
  - Declaration concerning the Prohibition of the Use of Bullets which can Easily Expand or Change their Form inside the Human Body such as Bullets with a Hard Covering which does not Completely Cover the Core, or containing Indentations

Section 2: HUMAN CELLS / TISSUES		YES/NO	Page
Does this research involve human cells or tissues? (*other than from Human Embryos/Foetuses, see section 1*)		NO	
If Yes	- Are they available commercially?	NO	
	- Are they obtained within this project?	NO	
	- Are they obtained from another project, laboratory or institution?	NO	
	- Are they obtained from a biobank?	NO	

Section 3: PERSONAL DATA		YES/NO	Page
Does this research involve personal data collection and/or processing?		YES	18, 19, 94
If Yes	- Does it involve the collection and/or processing of sensitive personal data (*e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction*)?	YES	18,19, 94
	- Does it involve tracking or observation of participants?	NO	
Does this research involve further processing of previously collected personal data (secondary use)?		NO	

Section 4: ENVIRONMENT & HEALTH AND SAFETY	YES/NO	Page
Does this research involve the use of elements that may cause harm to the environment, to animals or plants?	NO	
Does this research deal with endangered fauna and/or flora/protected areas?	NO	
Does this research involve the use of elements that may cause harm to humans, including research staff?	NO	

Section 5: MISUSE	YES/NO	Page
Does this research have the potential for misuse of research results?	YES	94

Section 6: OTHER ETHICS ISSUES	YES/NO	Page
Are there any other ethics issues that should be taken into consideration? *Please specify:*	YES	94

Comments on identified ethics issues *(optional)*:

1) We cannot exclude that civilians may also take part in the testing phase.

2) The GOSSRA project specifically states that its implementation does not involve any ethical (or for the matter, legal and societal) aspects other than some potential experimentations including humans (at p. 94). However, one can identify more ethical issues than that judging by the overall objective of the project itself: so-called Soldier Systems.

   a) The novelty nature of Soldier Systems allowing high levels of data analysis in real time has extensive moral, philosophical, political, strategic, and legal implications. One of these implications, for example, has a very strong moral background: such as the psychological effects on the civilian population that living surrounded by "multi-intelligent" soldiers equipped with these systems in urban environments may have.

   b) Also, the extent to which these sophisticated systems may alienate the soldier from the reality of the battlefield remains to be clarified. For instance, a possible "data overload" or an excess or avalanche of data provided to the soldier may make the vast amount of information unusable in the end.

2. Analysis of the ethical dimension

Please provide a detailed analysis of the ethical aspects of the proposal. Focus on how ethical issues are addressed, e.g.:
- *how the ethical issues relate to the research objectives, methodologies or potential impact;*
- *compliance with applicable legal requirements;*
- *if the applicants have the necessary authorisations.*

ANALYSIS:

The document affirms that GOSSRA does not include any ethical, legal or societal aspects with the exception of some potential experimentations including humans. It remains unclear what kind of test will be conducted, what is the targeted group of participants and what kind of personal data will be asked and stored. Furthermore, leaving aside all the moral and ethical implications inherent to improved data-analysis, the project itself recognizes (at p. 94) one issue with regards potential experimentations including humans. And while it is true, however, that validation research activities will be strictly voluntary; that involved personnel will be provided with information on the GOSSRA project and on the scope and aims of the particular activity/exercise in which they are invited to participate; and that they will give their consent by signing an appropriate form which will be available in a language in which the participant is comfortable and can fully understand. However, nothing is said about including advice by health specialists before giving

consent. Also, nothing is said with regards to the possibility of withdrawing from the testing phase once having given initial consent.

Finally, from the point of view of gender, it is positive that the consortium affirms to be aware on the subject and to be committed in involving a higher number of women in the research.

3. Ethics recommendations

⚠ *Ethics recommendations are suggestions and advice provided to the applicant(s); they do not become contractual obligations.*

RECOMMENDATIONS *(optional)*:

1) Prepare and approve an ethical Code of Conduct (e.g. best practises for the management of ELSA in the project).

2) It is recommended that the project Steering committee should be responsible for verifying that all phases of the project comply with ELSA principles contained in the Code of Conduct.

3) The document does not exclude that "some potential experimentations including humans" can be conducted. In this case it would be recommended to specify:

   - what kind of experiment will be conducted and under what circumstances;
   - if the participants are civilians or military, and if they will be monitored or not;
   - what kind of data of the participants will be stored and how.

4) Medical support for volunteers is also recommended after the testing phase.

4. Ethics opinion

Please select below the appropriate ethics opinion for this proposal (only one can be selected) and indicate the ethics requirement(s) you consider necessary.

If additional information is needed, request this information (by ticking the first button) before you give your ethics opinion. Once the information is received, the report will be reopened for your ethics opinion.

☐ **'additional information is needed'** *(⚠ only if the elements can easily be gathered and quickly transmitted.)*

☑ **ethics clearance** (i.e. the proposal is 'ethics ready')

REASONS *(optional)*:

☐ **conditional ethics clearance** (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

ETHICS REQUIREMENTS:

⚠ *For each requirement, also indicate:*

- *the type(s) of related ethics issues (a category(ies) of the EIT)*
- *whether it has to be fulfilled before or after grant signature (default option: after)*
- *by when the requirement must be fulfilled (e.g. number of months after the project start or timing linked to task concerned).*
- *a comment/reason (optional)*

REASONS:

5. Sensitivity level

How would you judge the overall sensitivity of the proposal (i.e. how deeply the ethics aspects of the project should be looked into)?

☐Normal

☑High

REASONS *(optional)*:

Because the project assumes a scenario with volunteers. Moreover, in the future the final result will be an Open Architecture-platform, which means that the possibility for using such architecture for inappropriate purposes is quite high.

6. Ethics checks

In your opinion, would an ethics check during the project implementation be necessary?:

☑ YES

☐ NO

REASONS *(mandatory if YES)*:

An Ethical check will be indispensable to asses if a test with participation of persons will be conducted and if all phases of the project comply with ELSA.

TIMING *(mandatory if YES)*:

Middle term and final check.

[redacted]

Ethics reviewers

[redacted]

ETHICS ASSESSMENT

CONSENSUS REPORT (CR)

Programme: *Preparatory Action on Defence Research (PADR)*
Call for proposals: Unmanned Systems (PADR-US-2017)
Topic: PADR-US-01-2017– Technological demonstrator for enhanced situational awareness in a naval environment
Type of action: Research Action (RA)
Call deadline: 05.10.2017

Proposal: 801697 – OCEAN2020

Date of ethics assessment: between 17.11.2017 and 27.11.2017

Ethics reviewers:

Names (and role, if other than evaluator)		
Name SURNAME	**Role**	**Signature**
[redacted]	ELSA Expert (WEBEX)	[redacted]
[redacted]	ELSA Expert	
[redacted]	ELSA Expert	

Proposal data:

Duration (months): 36

Applicants:

The OCEAN2020 consortium consists of 42 partners from which 15 countries are represented. This large European dimension is fundamental for demonstrate the possibility to effectively pursue future collaboration on defence capabilities and programmes and the inclusiveness of small countries in the overall picture. The partners comprising OCEAN2020 consortium all possess excellence in their respective field of competence, thus providing complementary know-how for the successful carryout and completion of the project. Moreover the involved organization are the prime contractors of sub-contractors in their respective national defence programmes and are the natural interlocutor of armed forces. In OCEAN2020, all the supply and demand chain is represented:

- Large Enterprises (LEONARDO, INDRA, SAAB, CTM, SAFRAN, IDE, QINETIQ, SKYSOFT, MBDA, IDS, GMV, TERMA, ECA, FINCANTIERI, E-GEOS, HENSOLDT)
- Small and Medium Enterprises (BPTI, CYBERNETICA, BARRACUDA, SEADRONE, AUTONAUT, BLUE BEAR, PROLEXIA, SCHÖNHOFER, ANTYCIP, INFINITE VISION, INSIS, ALTUS, LUCIAD, BLACKSHAPE)
- University and Research institutes (CMRE, IOSB, TNO, VTT, CNIT, NKUA, IAI),
- End Users (Italian Navy, Lithuanian Navy, Hellenic MoD, Portuguese Navy, Spanish MoD).

OCEAN2020 will last 36 months, with a budget of – Cost 35,480,000

Project abstract:

This proposal, OCEAN2020, will demonstrate:

- Enhanced situational awareness in a maritime environment through the deployment and integration of Unmanned Systems.
- How to meet the challenges in Persistent Wide Area Surveillance and Maritime Interdiction.
- How to accomplish a project of substantial complexity in a demanding timescale through EU wide cooperation of End Users, large industries, research institutes and Small/Medium Enterprises.

OCEAN2020 will pull together the technical specialists relevant to the maritime domain covering the "observing, orienting, deciding and acting" operational tasks. The team is drawn from 14 countries across Europe.

OCEAN2020 will pave the way towards future EU Defence by integrating legacy and new technologies for unmanned systems, ISTAR payloads and effectors. Data from multiple sources will be exploited into a Recognised Maritime Picture (RMP), to secure maritime dominance. The aim is to have a common RMP shared between national CMSs and from the front line up to a future EU Maritime Operation Centre. Implementing the contents of the proposal will help EU to lead innovation in the maritime domain and reduce reliance on non-EU countries.

To be successful in reaching these goals the OCEAN2020 Consortium will solve the problems of integrating EU systems as well as integrating the individual organisations into a coherent team. The activity will culminate in demonstrations in the Mediterranean and Baltic seas that demonstrate the EU ability to meet these challenges.

OCEAN2020 represents the ambition and vision of a European maritime initiative and highlighting the strategic approach shared and undertaken by all partners.

OCEAN2020 stands for "Open Cooperation for European mAritime awareNess", being:

- European Maritime Awareness distinctive of the challenge as given under the Call
- Open Cooperation based on "shared innovation" that matches with the value chain of "research & industrial" cooperation.

1. Identifying ethics issues

Please go through the table below and indicate by answering 'YES' or 'NO' if the proposed research has features which gives it an ethical dimension. (Your answer will NOT prejudge the ethics opinion — which depends *from the analysis to be carried out further down. For example, if personal data is anonymised, you should answer 'YES', but the proposal will nevertheless get 'ethics clearance' without conditions because the issue is already addressed).*

If no 'YES' is/needs to be ticked, immediately proceed to the 'ethics opinion' and give unconditional 'ethics clearance'.[1]

Section 1: HUMANS		YES/NO	Page
Does this research involve human participants?		**YES**	
If YES:	- Are they volunteers for technical research?	YES	212
	- Are they persons unable to give informed consent?	NO	
	- Are they vulnerable individuals or groups?	NO	
	- Are they children/minors?	NO	
	- Are they patients?	NO	
	- Are they healthy volunteers for medical studies?	NO	
	- Are they members of the Armed Forces?	YES	13
Does this research involve physical interventions on the study participants?		**NO**	
If **YES:**	- Does it involve invasive techniques?		
	- Does it involve collection of biological samples?		

Section 2: HUMAN CELLS / TISSUES	YES/NO	Page
Does this research involve human cells or tissues? (*other than from Human Embryos/Foetuses, see section 1)*	**NO**	

[1] When compiling the table, it is advised to consider also the following reference documents for arms control:

- Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (1993)
- Hague conventions (1899)
  - Declaration concerning the Prohibition of the Use of Projectiles with the Sole Object to Spread Asphyxiating Poisonous Gases
  - Declaration concerning the Prohibition of the Use of Bullets which can Easily Expand or Change their Form inside the Human Body such as Bullets with a Hard Covering which does not Completely Cover the Core, or containing Indentations

If Yes	- Are they available commercially?		
	- Are they obtained within this project?		
	- Are they obtained from another project, laboratory or institution?		
	- Are they obtained from a biobank?		

Section 3: PERSONAL DATA		YES/NO	Page
Does this research involve personal data collection and/or processing?		**YES**	
If Yes	- Does it involve the collection and/or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*?	YES	212
	- Does it involve tracking or observation of participants?	NO	
Does this research involve further processing of previously collected personal data (secondary use)?		**NO**	

Section 4: ENVIRONMENT & HEALTH AND SAFETY	YES/NO	Page
Does this research involve the use of elements that may cause harm to the environment, to animals or plants?	**YES**	**59**
Does this research deal with endangered fauna and/or flora/protected areas?	**NO**	
Does this research involve the use of elements that may cause harm to humans, including research staff?	**NO**	

Section 5: MISUSE	YES/NO	Page
Does this research have the potential for misuse of research results?	**NO**	

Section 6: OTHER ETHICS ISSUES	YES/NO	Page
Are there any other ethics issues that should be taken into consideration? *Please specify:* N/A	**NO**	

Comments on identified ethics issues *(optional)*:

N/A

4. Analysis of the ethical dimension

ANALYSIS:

1. The use of unmanned systems in military operations is not without ethical concerns and issues and in the frame of this project it remains unclear:

- How data is secured and maintained;
- Who is responsible to ensure public or environment safety;
- Who is responsible/accountable in the event of an accident/mishap;

For instance, there is always a strong moral reproach when an accident or a deliberate action occurs. Potentially, the programmer of the machine could be responsible for faulty software which prompted the action or accident or, in equal terms, a civil contractor who supplied these systems for a Government. And also, a commander in the field might also be held morally and legally responsible if he deliberately failed to override the operator of the autonomous system.

2. If the project assumes live demonstrations at sea, it would be required to previously present the demonstration area to be sure that it is not one of the environmental protection zones on Baltic and Mediterranean Seas (project does not make references to applicable international sea conventions).

3. The object of the proposal, research on naval situational awareness, has many ethical implications as it involves tools for Intelligence gathering, surveillance and reconnaissance. Law and policy often lag behind the pace of technology, so that leaves the researchers with only morality and ethics as constraint between what is acceptable and not. That is why this proposal is remarkable because it assesses the potential impact its implementation might have on moral issues. It draws a clear picture considering that ethics will be addressed during the whole project from requirement phase to validation.

4. Legal issues are also taken into consideration, especially in the field of Human Rights in relation with respect for human dignity, freedom of choice, right to integrity and respect for privacy.

5. Gender equality as a standard is also addressed remarkably well, recognizing the gender gap between sexes in the field of research and reassuring that women will be represented in adequate numbers as researchers and participants and that they will have the same chance as male members to participate in the project team and project events.

5. Ethics recommendations

⚠ *Ethics recommendations are suggestions and advice provided to the applicant(s); they do not become contractual obligations.*

RECOMMENDATIONS:

Prepare an ethics Code of Conduct to be followed by Ethics Manager and Project Coordinator in order to all ELSA issues.

6. Ethics opinion

Please select below the appropriate ethics opinion for this proposal (only one can be selected) and indicate the ethics requirement(s) you consider necessary.
If additional information is needed, request this information (by ticking the first button) before you give your ethics opinion. Once the information is received, the report will be reopened for your ethics opinion.

☐ **'additional information is needed'** *(⚠ only if the elements can easily be gathered and quickly transmitted.)*

Additional information needed:

N/A

☑ **ethics clearance** (i.e. the proposal is 'ethics ready')

REASONS *(optional)*:

☐ **conditional ethics clearance** (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

ETHICS REQUIREMENTS: N/A

REASONS: N/A

7. Sensitivity level

How would you judge the overall sensitivity of the proposal (i.e. how deeply the ethics aspects of the project should be looked into)?

☑ Normal

☐ High

REASONS *(optional)*: N/A

8. Ethics checks

In your opinion, would an ethics check during the project implementation be necessary?

☑ YES
☐ NO

REASONS *(mandatory if YES)*:

Regardless of ethical issues being addressed during the whole project, from the requirement phase, throughout the design and development up to the validation phase of the project, an independent ethics check would be advisable as well.

TIMING *(mandatory if YES)*:

Mid-term and, at least, six to three months before the release of the final results.

[redacted]

Ethics reviewer(s)

[redacted]

ETHICS ASSESSMENT

CONSENSUS REPORT (CR)

Programme: *Preparatory Action on Defence Research (PADR)*
Call for proposals: Strategic Technology Foresight (PADR-STF-2017)
Topic: PADR-STF-01-2017– The European Defence Research Runway
Type of action: Coordination and Support Action (CSA)
Call deadline: 28.09.2017

Proposal: 800893 – PYTHIA

Date of ethics assessment: between 30.10.2017 and 03.11.2017

Ethics reviewers:

Names (and role, if other than evaluator)		
Name SURNAME	**Role**	**Signature**
[redacted]	ELSA Expert	[redacted]
[redacted]	ELSA Expert	
[redacted]	ELSA Expert	

Proposal data:

Duration (months): 18

Applicants: ENGINEERING -INGEGNERIA INFORMATICA SPA Italy, Zanasi and Partners Italy, Expert System France, Hawk Associates Ltd UK, Military University of Technology Poland, Bulgarian Defence Institute, Fondazione ICSA Italy, National Defence University Romania

1. Engineering Ingegneria Informatica S.p.A. ENG Italy (coordinator)
2. Zanasi & Partners Z&P Italy
3. Expert System France ESF France
4. Hawk Associates Ltd HAWK UK
5. Military University of Technology WAT Poland
6. Bulgarian Defence Institute BDI Bulgaria
7. Fondazione ICSA ICSA Italy
8. National Defence University NDU Romania]

PYTHIA will last 18 months, with a budget of – Cost 947.610 €

Project abstract: The PYTHIA project aims to devise an innovative methodology for strategic technology foresight, able to deliver frequent "predictions" on technology-related matters, including the discovery of major trends in a particular area of research and development. The PYTHIA consortium's work will be based on the following activities: 1. Review of the current methodologies for technology forecasting (e.g. Horizon Scanning and Technology Watch), including performance comparison and their overall measure of success; 2. Development of a new methodology, based on big data analytics techniques such as data and text mining, for automatically analysing large volumes of technology-related data in order to detect key technology trends. The methodology will rely on information automatically collected from a variety of public sources (e.g. technology patents, scientific publications, prototype descriptions, marketing communications and press releases, industry production & sales reports, social media, etc.); 3. Study of the cognitive factors that might affect analysts' ability to perform technology forecasts. Recommendations will be developed on how to make more accurate predictions (e.g. mitigating cognitive biases, avoiding overreliance on linear thinking, encouraging more creativity and collaborative work processes). The study will benefit from the findings of similar international projects; 4. Assessment of the impact of future technology trends on national/EU defence planning through an analysis of its key elements (i.e. defence strategy, threats and risks and EU/national interests), aimed at identifying future disruptive technologies and related themes for future

defence research; 5. Organisation of workshops involving representatives of different sectors of the EU and extra-EU civil and defence technology industry, experts on technological forecasting as well as members of the scientific community, in order to validate the PYTHIA methodology in different domains.

1. Identifying ethics issues

Please go through the table below and indicate by answering 'YES' or 'NO' if the proposed research has features which gives it an ethical dimension. (Your answer will NOT prejudge the ethics opinion — which depends *from the analysis to be carried out further down. For example, if personal data is anonymised, you should answer 'YES', but the proposal will nevertheless get 'ethics clearance' without conditions because the issue is already addressed).*

If no 'YES' is/needs to be ticked, immediately proceed to the 'ethics opinion' and give unconditional 'ethics clearance'.[1]

Section 1: HUMANS		YES/NO	Page
Does this research involve human participants?		**NO**	
If YES:	- Are they volunteers for technical research?		
	- Are they persons unable to give informed consent?		
	- Are they vulnerable individuals or groups?		
	- Are they children/minors?		
	- Are they patients?		
	- Are they healthy volunteers for medical studies?		
	- Are they members of the Armed Forces?		
Does this research involve physical interventions on the study participants?		**NO**	
If YES:	- Does it involve invasive techniques?		
	- Does it involve collection of biological samples?		

[1] When compiling the table, it is advised to consider also the following reference documents for arms control:

- Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (1993)
- Hague conventions (1899)
  - Declaration concerning the Prohibition of the Use of Projectiles with the Sole Object to Spread Asphyxiating Poisonous Gases
  - Declaration concerning the Prohibition of the Use of Bullets which can Easily Expand or Change their Form inside the Human Body such as Bullets with a Hard Covering which does not Completely Cover the Core, or containing Indentations

Section 2: HUMAN CELLS / TISSUES		YES/NO	Page
Does this research involve human cells or tissues? (*other than from Human Embryos/Foetuses, see section 1)*		**NO**	
If Yes	- Are they available commercially?		
	- Are they obtained within this project?		
	- Are they obtained from another project, laboratory or institution?		
	- Are they obtained from a biobank?		

Section 3: PERSONAL DATA		YES/NO	Page
Does this research involve personal data collection and/or processing?		**YES**	
If Yes	- Does it involve the collection and/or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*?	Yes	72
	- Does it involve tracking or observation of participants?	No	
Does this research involve further processing of previously collected personal data (secondary use)?		**NO**	

Section 4: ENVIRONMENT & HEALTH AND SAFETY	YES/NO	Page
Does this research involve the use of elements that may cause harm to the environment, to animals or plants?	**NO**	
Does this research deal with endangered fauna and/or flora/protected areas?	**NO**	
Does this research involve the use of elements that may cause harm to humans, including research staff?	**NO**	

Section 5: MISUSE	YES/NO	Page
Does this research have the potential for misuse of research results?	**NO**	

Section 6: OTHER ETHICS ISSUES	YES/NO	Page
Are there any other ethics issues that should be taken into consideration? *Please specify:* Those related to Objective 1 Predicted Methodology, and 2 Technology and Intelligence Analysis. Data and text mining, as well as the collection of information gathered from web sources, even though publicly available could contain codes or hidden information that may potentially be cracked for the purpose of the research, thus accessing to sensitive or personal information without the approval of their owners (it is worth to notice that also cracking tools are publicly available on the internet but their usage arise ethical issues, when they are not a violation of the law). Furthermore, from an ethical perspective, decisions and actions taken with information and its related technologies do affect the lives and beliefs of people, having in turn strong ethical and moral implications. For instance, is it ethically permissible for machines to decide upon the priority of a particular technological trend? Is it ethically permissible to use machines in order to make predictions (an activity based in such a human virtue as intuition)? If so, if we find it acceptable, then how (well) should they be able to discriminate between what is relevant from what is not? And while it is also true that the way that such questions are answered depends upon one's moral code and principles, one misses in the PYTHIA project some clear-cut answers to these dilemmas. Perhaps in the form of a short Code of Conduct for the user-manager. However, the establishment of a so-called Security Advisory Board should suffice to solve these delicate questions.	**YES**	4

Comments on identified ethics issues *(optional)*:

N/A.

2. Analysis of the ethical dimension

ANALYSIS:

PYTHIA takes into account the new global security situation and its geopolitical, economic, environmental and technological elements, and therefore it means that it should take into account also all ELSA-related problems. Moreover, in the proposal there is a cognitive psychology idea or approach that is connected with some specific human behaviours or people's choices, involving human ethical activity.

PYTHIA methodology will also include an evaluation of the military implications that follow from technological trends (i.e. supporting with new knowledge the production and procurement of the most needed weapons systems) "supported by contextual analysis".

The kind of research per se implies that some ethical standards are at risk to be breached even though the applicants affirm that "No ethical issues are expected to be raised by the activity carried on within this project" (page 72).

For instance, according to the methodology that will apply to the research, only open sources will be accessed and analysed, but also open sources can disclose sensitive or private information without the consent of the interested party.

Despite the statement mentioned above, the Stakeholders Management Committee is given the task to constantly monitor the compliance of the project with ethical, legal, privacy and data protections issues (page 40). As well as an independent Security Advisory Board "may" be established after the beginning of the research (page 72) while and internal Security Advisory Board is put in place (page 29).

As per the compliance with legal requirements, the aspect is taken in consideration as a potential obstacle to the impact of the project (Pages 18/19). At the early stage of the research, an assessment of the applicable laws will be conducted in order to comply with the different legal frameworks of the countries that are part of the initiative.

Along the document, there is no mention of the legally required authorisations to access classified information but given that the applicants are Agencies, Universities and Institutions working already in the security field, there is no doubt about their clearance. The problem may arise for external or contracted partners that will take part in the project.

3. Ethics recommendations

⚠ *Ethics recommendations are suggestions and advice provided to the applicant(s); they do not become contractual obligations.*

RECOMMENDATIONS:

1. Prepare an ethics Code of Conduct (e.g. best practises for the management of ELSA in the project)

2. A clear ELSA reporting strategy throughout the implementation of the project should also be taken into account (e.g. at the beginning and at the end phases of the project)

4. Ethics opinion

Please select below the appropriate ethics opinion for this proposal (only one can be selected) and indicate the ethics requirement(s) you consider necessary.
If additional information is needed, request this information (by ticking the first button) before you give your ethics opinion. Once the information is received, the report will be reopened for your ethics opinion.

☐ **'additional information is needed'** *(⚠ only if the elements can easily be gathered and quickly transmitted.)*

Additional information needed:

No additional information is needed

☐ **ethics clearance** (i.e. the proposal is 'ethics ready')

REASONS *(optional)*:

N/A

☑ **conditional ethics clearance** (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

ETHICS REQUIREMENTS:

Appoint an independent and preferably external Advisory Board for ELSA at an early stage of the project (e.g. 3 experts with at least one senior independent ELSA expert)

REASONS:

N/A

5. Sensitivity level

How would you judge the overall sensitivity of the proposal (i.e. how deeply the ethics aspects of the project should be looked into)?

☑ Normal

☐ High

REASONS *(optional)*:

Normal: N/A

Normal: N/A.

6. Ethics checks

In your opinion, would an ethics check during the project implementation be necessary?:

☑ YES

☐ NO

REASONS *(mandatory if YES)*:

A mid-term and/or final review on how ELSA have been managed throughout the development of the project is/are deemed necessary in particular for the handling of personal data and privacy.

[redacted]

Ethics reviewer(s)

[redacted]

Ethics Summary Report

Call Reference	PADR-STF-2018
Proposal Number	831739
Acronym	SOLOMON

Ethics Issues

Humans

Does this research involve human participants?	**Yes**
Are they volunteers for social or human sciences research?	**Yes**

Comments

Although the consortium acknowledges the need for inclusion of human participants in the ethics issues table, the information provided on ethical safeguards in the Ethics Section is generic and minimal.

Involvement of human participants will take place in various settings. However, given the limited information provided it is difficult to delineate and understand the specific study settings (e.g. validation tests) that will involve human subjects.

Settings that will require attention to ensure standards regarding human participants in research are met will be (at least):

a. Stakeholder and User Groups and validation tests (p 4, 5, 6, 7, 18, 19, 24, 33, 34, 35): Individuals participating in these tests need to be fully informed about the nature of the project, their role and consent to their participation.

A clear breakdown and description of these activities should be provided together with recruitment strategies as well as number of participants enrolled in the validation test to justify the inclusion of human subjects in research. Further, confirmation and clarification on these issues is required.

Critical issues in all the studies involving human study subjects are:

- Full information on the nature of the research;
- Free consent to participate in the study;
- The right to withdraw at any time;
- Transparency on financial interests and identification of the sponsors of the study;
- Approval by a local ethics committee, if applicable.

Protection of personal data

Does this research involve personal data collection and/or processing?	**Yes**
Does it involve tracking or observation of participants?	**Yes**
Does this research involve further processing of previously collected personal data (secondary use)?	**Yes**

Comments

The consortium recognizes the need to address data protection and privacy issues arising during the course of the project in the Ethics Issues Table and the Ethics Section. However, the framework for ensuring data protection is not convincingly described. For example, in the Ethics Section under 5.1 the General Data Protection Regulation (Regulation (EU) 2016/679) is correctly identified as relevant legal framework while on p 42 under 3.2.2.4 reference to Directive 95/46/EC is provided. Furthermore, although informed consent is mentioned as a legal base for processing no informed consent sheets have been provided. No sensitive personal data will be processed. It is unclear if a Data Protection Officer (DPO) will be nominated for the project. If not, it is recommended that a DPO should be nominated.

Information on the following issues is also missing:

1. What kind of personal data will be recorded during what part of the research?
2. How will the informed consent be obtained when using online tools during dissemination activities?
3. What data security and data safety standards will be applied to ensure adequate protection and accuracy of the data?
4. How will the rights of the data subjects (e.g. rectification, right to be forgotten) and data protection principles (e.g. data minimisation) be upheld?

Therefore, a clear breakdown of what personal data will be recorded, informed consent procedures for online activities, implementation of data protection standards and information on how upholding the rights of the data subjects will be upheld need to be provided.

Misuse

Does this research have the potential for malevolent/criminal/terrorist abuse?	Yes

Comments

The aspect of potential misuses (e.g. knowledge on vulnerabilities) was addressed in the Ethics Section and adequate safeguards based on a prior risk assessment like information and personnel security measures were presented. Task 1.4 will also look into security impacts of the generated knowledge and develop relevant safeguards. Copies of the risk assessment together with a detailed description of the established safeguards at the various project partners should be provided.

Other ethics issues

Are there any other ethics issues that should be taken into consideration?	Yes

Please specify

The consortium falls short in addressing ethics issues in relation to military ethics. As the project will not only develop tools to identify elements constituting the current EU defence industry value system but also develop methodologies to assess supply risks of technologies and components as well as foresight tools and road maps it might have impacts on how military ethics standards regarding new weapons and technologies are incorporated in the European defence architecture. No information on how these issues will be addressed in SOLOMON were provided. Future outlooks, trajectories and road maps should include an assessment on the ethical status of individual technologies. Risk assessment should include military ethics and fundamental rights as risk categories and finally, dissemination e.g. especially in a training context should address how military ethics and fundamental rights affect the military supply chain value creation. Early engagement in these areas will be crucial to avoid potential science-society disconnects and make European publicly funded defence research sustainable and accepted.

Therefore, similar to the privacy by design context, military ethics and fundamental rights considerations should be added and implemented to WP2, 3, 4, and 5. Adequate expertise in the form of an independent ethics advisor, capable of carrying out such assessments, must be recruited into the project.

Ethics recommendations

A DPO should be nominated.

Ethics Opinion

Conditional ethics clearance (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

Post-Grant Requirements

Humans

1. The procedures and criteria that will be used to identify/recruit research participants must be included in the first ELSA related deliverable.
2. The informed consent procedures that will be implemented for the participation of humans must be included in the first ELSA related deliverable.
3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be included in the first ELSA related deliverable.
4. If applicable, copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans must be included in the first ELSA related deliverable.

Protection of personal data

1. Detailed information on the procedures for data collection, storage, protection, retention, and destruction, and confirmation that they comply with national and EU legislation must be kept on file.
2. In case of further processing of previously collected personal data, information on the legal base of such processing must be kept on file.

Other ethics issues

An independent Ethics Advisor competent in military ethics must be appointed to monitor the ethics issues involved in this project and how they are handled. The Advisor must be consulted at least on the issue of risk assessment regarding implications on military ethics. A report by the Ethics Advisor must be integrated in the relevant deliverable of the ELSA aspects management (Task 1.4).

Misuse

Risk assessment and details on measures to prevent misuse of research findings must be submitted in the relevant deliverable of the ELSA aspects management (Task 1.4).

Ethics Checks

In your opinion, would an ethics check during the project implementation be necessary?	**YES**

An Ethics Check should be conducted. The Check should verify that adequate measures as noted above have been implemented.

Ethics Summary Report

Call Reference	PADR-EF-2018
Proposal Number	831726
Acronym	TALOS

Ethics Issues

Humans

Does this research involve human participants?	**Yes**

Comments

The information provided in the proposal on demonstration trials (p 7) remains vague and the exact nature of the demonstration trials and whether it will involve the enrollment of human study subjects is unclear and needs to be clarified.

In case human participants are included, they need to be fully informed about the nature of the research, their role in the research setting, the research sponsor and consent to their participation. In addition, safety risks should be fully explained.

Furthermore, in case safety risks exist, adequate insurance provisions should be foreseen to cover any adverse effects from the participation in the research and participants should be fully informed about any potential risks.

Protection of personal data

Does this research involve personal data collection and/or processing?	**Yes**
Does it involve tracking or observation of participants?	**Yes**
Does this research involve further processing of previously collected personal data (secondary use)?	**Yes**

Comments

The consortium correctly identifies the need for protection of personal data processed during the course of the project. Assurance regarding adherence to GDPR and applicable laws is provided (pp. 7, 126) and the nomination of an IPR and Data manager competent in personal data protection is foreseen. However, limited details on the legal base (e.g. legitimate interest or consent), the codification-anonymisation procedures, the data safety and security measures and the exact nature of the personal data were provided. This will be covered in the Data Management Plan.

Third countries

In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues?	**Yes**

Specify the countries involved:

[redacted]

Is it planned to import any material – including personal data – from non-EU countries into the EU?	**Yes**

Specify material and countries involved

[redacted] the EU fibres developed by TALOS (see section 3.1.4 WP4:ST4.1.4, page 44). [redacted] These two components require end-users certificate but it will not be an issue for lab development as foreseen in the lifetime of the project. [redacted]

Comments

Technologies will be purchased from third countries and imported into the EU. It is indicated that off-the-shelf equipment as well as equipment requiring end-user certificates will be imported. Adequate approvals for such purchases must be in place and copies of such approvals (e.g. export authorisations, IPR permissions) should be kept on file.

Environmental protection and safety

Does this research involve the use of elements that may cause harm to the environment, to animals or plants?	**Yes**
Does this research involve the use of elements that may cause harm to humans, including research staff?	**Yes**

Comments

Regarding risks to environment

Before any field tests an environmental risk assessment must be conducted and, if relevant, risk mitigation plans must be developed and reported. The outcome of the environmental risk assessment should be included in the Periodic Report.

Regarding risks to occupational health and safety of researchers

General assurance that national legislation, local guidelines and other standards (e.g. EN 60825) in mitigating such risks will be complied with was provided. Outdoor test conducted in Italy must comply with Decreto Legislativo 81/08 "TESTO UNICO SULLA SALUTE E SICUREZZA SUL LAVORO" regarding laser safety. Further details on the relevant standards and laws (e.g. Directive 2006/25/EC) and how they are related to the individual activities of laser development and testing need to be provided.

More information should be provided regarding the use of Thulium and, if any, the prescriptions necessary to deal with those components/systems which include it (such as the need for particular storing and/or the need for some personal protective equipment as part of D2.1 Legal and safety aspects (M3).

Misuse

Does this research have the potential for malevolent/criminal/terrorist abuse?	**Yes**

Comments

To ensure that the technology does not fall into the hands of terrorists and criminals, information and personnel security measures are mentioned. In addition, physical security measures and, if relevant, transfer security measures need to be implemented to restrict physical access to the laser in the laboratories and during field tests.

Other ethics issues

Are there any other ethics issues that should be taken into consideration?	**Yes**

Please specify

Military Ethics - Compliance to the Laws of Armed Conflicts

General: Discrimination between combatants and non-combatants

minimizing collateral damage

The usage of the technology creates challenges (e.g. reflection, scattering) in the context of discriminating combatants and non-combatants, especially in the context of asymmetric warfare and protection of civilian populations in urban settings. An ethics risk assessment of this issue should be conducted and potential risk mitigation measures identified that might support further development of the technology.

Specific Issues - Blinding

In the definition of scenarios the issue of blinding by lasers needs to be addressed and adequate safeguards be specified to ensure the developed technology is not in violation of Protocol IV of the 1980 Convention on Certain Conventional Weapons.

A risk assessment should be produced in the context of deliverable D 6.11 Legal evaluation of the operational rules that focuses on ensuring that the technology will be in compliance with current standards in military ethics. Recommendations arising from this assessment should be included into the project design.

Ethics recommendations

It is recommended that the Data Manager also acts as Data Protection Officer (DPO) of the consortium.

Ethics Opinion

Conditional ethics clearance (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

Pre-Grant Requirements

Environmental protection and safety

1. Before any field tests an environmental risk assessment must be conducted and, if relevant, risk mitigation plans must be developed and reported. The outcome of the environmental risk assessment should be included in the Periodic Report.

2. More information should be provided regarding the use of Thulium and, if any, the prescriptions necessary to deal with those components/systems which include it (such as the need for particular storing and/or the need for some personal protective equipment as part of D2.1 Legal and safety aspects (M3).

3. The applicant must demonstrate that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project. This must be confirmed before signature of the grant agreement.

Post-Grant Requirements

Humans

In case human research participants are involved in the field studies, the following requirements apply:
1. The procedures and criteria that will be used to identify/recruit research participants must be kept on file.
2. The informed consent procedures that will be implemented for the participation of humans must be kept on file.
3. Templates of the informed consent/assent forms and information sheets (in language and terms intelligible to the participants) must be kept on file.

Protection of personal data

1. Detailed information on the procedures for data collection, storage, protection, retention, and destruction, and confirmation that they comply with national and EU legislation must be kept on file.
2. In case of further processing of previously collected personal data, relevant authorisations must be kept on file.

Third countries

1. Adequate approvals for purchases from Third Countries must be in place and copies of such approvals (e.g. export authorisations, IPR permissions) should be kept on file.

Misuse

1. In addition to information and personnel security measures, physical and transfer security measures should be in place and reported in the Periodic Report to ensure that access to the technology by malevolent actors is limited.

Other ethics issues

1. A risk assessment should be produced in the context of deliverable D6.11 Legal evaluation of the operational rules that focuses on ensuring that the technology will be in compliance with current standards in military ethics. Recommendations arising from this assessment should be included into the project design.

2. The Ethical and Legal Manager should have prior expertise in military ethics and law of armed conflicts.

Ethics Checks

In your opinion, would an ethics check during the project implementation be necessary?	YES

Most of the ethics issues are subject to progress and development of the project, deliverables included (D.1.3, D. 1.15, D.2.1, D.611), therefore ethics checks (M18 and 36) should be performed.

ETHICS ASSESSMENT

CONSENSUS REPORT (CR)

Programme: *Preparatory Action on Defence Research (PADR)*
Call for proposals: Force protection and advanced soldier systems (PADR-FPSS-2017)
Topic: PADR-FPSS-01-2017 — ULTRALIGHT MODULAR BULLET PROOF INTEGRAL SOLUTION FOR DISMOUNTED SOLDIER PROTECTION
Type of action: Research and Innovation Action (RA)
Call deadline: 28.09.2017

Proposal: 800876 — VESTLIFE

Date of ethics assessment: between 10.01.2018 and 11.01.2018

Ethics reviewers:

Names (and role, if other than evaluator) [1]		
Name SURNAME	**Role**	**Signature**
[redacted]	ELSA Expert	[redacted]
[redacted]	ELSA Expert	
[redacted]	ELSA Expert	

Proposal data:

Duration (months): 36

Applicants:

1. ASOCIACION DE INVESTIGACION DE LA INDUSTRIA TEXTIL
2. CENTRO TECNOLOGICO DAS INDUSTRIAS TEXTIL E DO VESTUARIO DE PORTUGAL
3. BRASSER PAUL
4. FUNDACION TECNALIA RESEARCH & INNOVATION
5. PETRO CERAMIC SpA
6. FY-COMPOSITES Oy

Project abstract: Protective clothing aims at protecting soldiers from ballistic threats. The demands of these systems, are often strict and contradictory, as they demand requirements in terms of both optimal comfort and maximum level of protection. Thus, the design and development of an effective protective clothing is a complex problem.

With this background, the main objective of VESTLIFE is to develop a new lightweight and modular bulletproof integral solution, which integrates a CBRN detection system. The garments will include an increased coverage area whilst maintaining comfort, plus a weight reduction, thus ensuring optimum balance between protection and comfort.

In this sense, VESTLIFE addresses the main issues present in existing commercial solutions: behaviour and weight. The objectives of VESTLIFE are to reduce between 25% and 35% the weight of current panel solutions and, at the same time, to improve ballistic protection behaviour (5-10% increase of speed penetration requirement and 15-20% depth of trauma reduction: Back Face Signature (BFS)). These will be achieved via the combination of soft and hard plates, developed with innovative textile and ceramics-based materials and structures, which will also require effective collaboration between both R&D centres and industrial partners.

[1] Format: First name LASTNAME.

1. Identifying ethics issues

Please go through the table below and indicate by answering 'YES' or 'NO' if the proposed research has features which gives it an ethical dimension. (Your answer will NOT prejudge the ethics opinion — which depends *from the analysis to be carried out further down. For example, if personal data is anonymised, you should answer 'YES', but the proposal will nevertheless get 'ethics clearance' without conditions because the issue is already addressed).*

If no 'YES' is/needs to be ticked, immediately proceed to the 'ethics opinion' and give unconditional 'ethics clearance'.[1]

Section 1: HUMANS		YES/NO	Page
Does this research involve human participants?		YES	37, 55, 56, 62
If YES:	- Are they volunteers for technical research?	YES	55, 56
	- Are they persons unable to give informed consent?	NO	55, 56
	- Are they vulnerable individuals or groups?	NO	
	- Are they children/minors?	NO	
	- Are they patients?	NO	
	- Are they healthy volunteers for medical studies?	YES	55
	- Are they members of the Armed Forces?	YES	37, 55, 56, 62
Does this research involve physical interventions on the study participants?		NO	
If **YES:**	- Does it involve invasive techniques?	NO	
	- Does it involve collection of biological samples?	NO	

[1] When compiling the table, it is advised to consider also the following reference documents for arms control:

- Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction (1993)
- Hague conventions (1899)
  - Declaration concerning the Prohibition of the Use of Projectiles with the Sole Object to Spread Asphyxiating Poisonous Gases
  - Declaration concerning the Prohibition of the Use of Bullets which can Easily Expand or Change their Form inside the Human Body such as Bullets with a Hard Covering which does not Completely Cover the Core, or containing Indentations

Section 2: HUMAN CELLS / TISSUES		YES/NO	Page
Does this research involve human cells or tissues? (*other than from Human Embryos/Foetuses, see section 1)*		NO	
If Yes	- Are they available commercially?	NO	
	- Are they obtained within this project?	NO	
	- Are they obtained from another project, laboratory or institution?	NO	
	- Are they obtained from a biobank?	NO	

Section 3: PERSONAL DATA		YES/NO	Page
Does this research involve personal data collection and/or processing?		YES	51, 55, 56
If Yes	- Does it involve the collection and/or processing of sensitive personal data *(e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)*?	YES	51, 55, 56
	- Does it involve tracking or observation of participants?	NO	
Does this research involve further processing of previously collected personal data (secondary use)?		NO	

Section 4: ENVIRONMENT & HEALTH AND SAFETY	YES/NO	Page
Does this research involve the use of elements that may cause harm to the environment, to animals or plants?	NO	28
Does this research deal with endangered fauna and/or flora/protected areas?	NO	
Does this research involve the use of elements that may cause harm to humans, including research staff?	NO	

Section 5: MISUSE	YES/NO	Page
Does this research have the potential for misuse of research results?	YES	96

Section 6: OTHER ETHICS ISSUES	YES/NO	Page
Are there any other ethics issues that should be taken into consideration? *Please specify:* _____ _____	YES	55, 56

Comments on identified ethics issues *(optional)*:

All data connected with creation of body maps may reveal certain data related to health such as heart rate and body temperature.

The project VESTLIFE does include a reference to ethical issues that is, however, somewhat short as it only deals with potential misuse of research results and data protection (p. 96).

There is a strong core ethical subject with regards to volunteer participation during the research and the possibility to withdraw once activities have started. Moreover, with regards also to the "potential foreseen risks and benefits" of such research activities, the project does not mention if those include medical or health risks and benefits. (p. 55-56).

Nevertheless, this shortcoming seems to be mitigated by the obligation of the partners to responsibly manage the conduct of operational work according ethical and legal standards (p. 63).

2. Analysis of the ethical dimension

Please provide a detailed analysis of the ethical aspects of the proposal. Focus on how ethical issues are addressed, e.g.:

- *how the ethical issues relate to the research objectives, methodologies or potential impact;*
- *compliance with applicable legal requirements;*
- *if the applicants have the necessary authorisations.*

ANALYSIS:

Ethical and gender balance aspects are taken in consideration.

VESTLIFE project approaches ethical issues in a specific section (p. 55) and does recognize explicitly that its activities and results may arise and involve ethical, legal and societal aspects. Also the project will have a data management plan to which all partners will commit.

As for legal issues, they may arise from the eligibility of applicable law to the different phases of the project as they will be conducted in countries adopting non homogeneous legislations.

Likewise, the risk of a potential misuse of research results is addressed. Furthermore, even though VESTLIFE System will be tested by end users "only for ergonomics, comfort and operability... but not in ballistic red conditions or under an enemy attack", it is not possible to completely exclude possible lasting physical or psychological consequences on participants to the testing phase.

The objective of the project itself obeys to a certain moral public obligation of States and Armed Forces to provide personnel with protective gears. However, from a more practical point of view, the project deals with ethical issues only with reference to potential misuse and data management. Nevertheless, it is laudable that the project identifies as one of its main "specific and operative objectives" to "assure the fulfilment of ethical, legal and societal aspects in the new developments along the whole project duration" (p. 2-3).

Finally, as for fire behaviour or use of toxicological substances, there is not a specific paragraph aimed at addressing the problem, nonetheless the presence in the consortium of partners who work on the subject leads to understand that the issue should be taken in consideration.

3. Ethics recommendations

⚠ *Ethics recommendations are suggestions and advice provided to the applicant(s); they do not become contractual obligations.*

RECOMMENDATIONS *(optional)*:

1. Prepare and approve an ethical Code of Conduct (e.g. best practises for the management of ELSA in the project).
2. The Project Coordinator should be responsible for ELSA contained in the Code of Conduct. Also, the Project Management Board should include ELSA discussion in the Agenda of the Technical Committee Meetings.
3. With regards to human participants in research activities or results, Managers of the VESTLIFE project should be requested to verify if the Informed Consent Form (ICF) includes both the consent and the possibility of withdrawing from the testing phase should the participant not feel safe nor comfortable.
4. Medical support for volunteers is also recommended after the testing phase.
5. In order to address any legal issues that may arise from the eligibility of applicable law to the different phases of the project, as they will be conducted in countries adopting non homogeneous legislations, it is recommended to perform a preliminary analysis of possible discrepancies among applicable rules. It is also recommended that the analysis is included in a deliverable of the project.

4. Ethics opinion

Please select below the appropriate ethics opinion for this proposal (only one can be selected) and indicate the ethics requirement(s) you consider necessary.
If additional information is needed, request this information (by ticking the first button) before you give your ethics opinion. Once the information is received, the report will be reopened for your ethics opinion.

☐ **'additional information is needed'** *(⚠ only if the elements can easily be gathered and quickly transmitted.)*

Additional information needed:

☑ **ethics clearance** (i.e. the proposal is 'ethics ready')

REASONS *(optional)*:

N/A

☐ **conditional ethics clearance** (i.e. clearance is subject to conditions, i.e. ethics requirements. The requirements must either be fulfilled before grant signature or become part of the grant agreement)

ETHICS REQUIREMENTS:

⚠ *For each requirement, also indicate:*
- *the type(s) of related ethics issues (a category(ies) of the EIT)*

- *whether it has to be fulfilled before or after grant signature (default option: after)*
- *by when the requirement must be fulfilled (e.g. number of months after the project start or timing linked to task concerned).*
- *a comment/reason (optional)*

REASONS:

5. Sensitivity level

How would you judge the overall sensitivity of the proposal (i.e. how deeply the ethics aspects of the project should be looked into)?

☐ Normal

☑ High

REASONS *(optional)*:

Because the project assumes scenarios with human volunteers.

6. Ethics checks

In your opinion, would an ethics check during the project implementation be necessary?:

☑ YES

☐ NO

REASONS *(mandatory if YES)*:

In order to guarantee that ethical, legal and/or societal/gender equality issues that may arise during the implementation of the project are taken care of responsibly.

TIMING *(mandatory if YES)*:

Middle time and final phase.

[redacted]

Ethics reviewers

[redacted]