

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 [REDACTED]
Type of action: Research and Innovation Action (RA)
Call deadline: 28.09.2017

Proposal: [REDACTED]

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]
	ELSA Expert	
	ELSA Expert	

Proposal data:

Duration (months): 22

Applicants:

[REDACTED]

Project abstract: [REDACTED]

[REDACTED]

¹ Format: First name LASTNAME.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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 prejudice 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? <i>Please specify:</i>	YES	94

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:

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 assess 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.

