ETHICS CR/SR

⚠ Use this template for PADR ethics CRs/SRs for the ethics assessment.
⚠ One report per proposal.

- Instructions and footnotes in blue will have to be deleted in the final versions of the Ethics CR/SR.
- For options *[*in square brackets*]*: the option that applies must be must be kept, and the others deleted.
- For fields in [grey in square brackets]: enter the appropriate data between the brackets.

ETHICS ASSESSMENT

*[*CONSENSUS REPORT (CR)*][*SUMMARY REPORT (SR)*]*

Programme: *PADR*
Call for proposals: [**insert title: PADR - text**] ([**insert call identifier: PADR-xxxx-20XX**])
Topic: [insert short name of topic] — [insert long name of topic]
Type of action: [insert type of action]
Call deadline: [insert deadline: dd.mm.yyyy]

Proposal: [insert proposal ID]— [acronym]

Date of ethics assessment: between [dd.mm.yyyy] and [dd.mm.yyyy]

Ethics reviewers:

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

Proposal data:

Duration (months): [insert number of months]

Applicants: [insert table with list of applicants, their costs and the requested grant amount]

Project abstract: [insert project abstract]

[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?			
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?			
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)*			
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?			
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)*?		
	- Does it involve tracking or observation of participants?		
Does this research involve further processing of previously collected personal data (secondary use)?			

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?		
Does this research deal with endangered fauna and/or flora/protected areas?		
Does this research involve the use of elements that may cause harm to humans, including research staff?		

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

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

Comments on identified ethics issues *(optional)*:

Xxxx

xxxx

xxxxxx.

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:

xxxx.

xxxxx.

xxx

3. Ethics recommendations

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

RECOMMENDATIONS *(optional)*:

xxxxx

xxxx.

xxxx

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:

xxxx.

xxxx

xxx

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

REASONS *(optional)*:

xxxx.

xxxx

xxx

[☐☑] **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:

xxxx.

xxxx

xxx

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)*:

xxxx.

xxxx

xxx

6. Ethics checks

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

[☐☑] YES
[☐☑] NO

REASONS *(mandatory if YES)*:

xxxx.

xxxx

xxx

TIMING *(mandatory if YES)*: xxxx

[insert name(s)]

Ethics reviewers

HISTORY OF CHANGES		
VERSION	PUBLICATION DATE	CHANGE
0.0	13.07.2017	Initial version.
1.0	18.07.2017	CR/SR only version
2.0	03.11.2017	Final version for ELSA review CR/SR template