

Proposal No. «xxx »	Acronym: «xxxx»
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## Ethics Review Report

*For Central Review*

REVIEW DATE

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### 1. Identification of the issues raised by the Full Project Proposal (panel's assessment)

- |  |   |
|--|---|
| <input type="checkbox"/> Children            | <input type="checkbox"/> Animals                      |
| <input type="checkbox"/> Adults              | <input type="checkbox"/> Genetically-modified Animals |
| <input type="checkbox"/> Patients            | <input type="checkbox"/> Non-human Primates           |
| <input type="checkbox"/> Vulnerable Adults   |   |
| <input type="checkbox"/> Human Intervention* | <input type="checkbox"/> Developing Countries         |
| <input type="checkbox"/> Human Tissues       | <input type="checkbox"/> Data Protection              |
|  | <input type="checkbox"/> Privacy                      |
| <input type="checkbox"/> Foetal Tissues      |   |
| <input type="checkbox"/> hESC                | <input type="checkbox"/> Dual Use                     |
|  | <input type="checkbox"/> Improper Use                 |

\* such as clinical trials and research involving invasive techniques on persons (e.g. taking of tissue samples, examinations of the brain...)

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### 2. Ethical issues

a) Were the **ethical**\* aspects of the proposed research well described in relation to its objectives?

Yes

No

*Please enter your comments*

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b) Were the **ethical**\* aspects of the proposed research well described in relation to its methodology?

Yes

No

*Please enter your comments*

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c) Were the **ethical**\* aspects of the proposed research well described in relation to the possible implications of its results?

Yes

No

*Please enter your comments*

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d) Do the applicants clearly indicate how the proposal meets the national legal and ethical requirements of the country where the research will be performed?

Yes

No

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e) Do the applicants include a timeframe for approval of the proposed study by a relevant authority at national level (local ethics committee and/or competent national authority?)

Yes

No

*Please specify:*

\* the scientific evaluation should not be revisited

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### 3. Overall Assessment

a) The proposal adequately identifies and addresses the relevant ethical issues. Specific requirements, if any, are provided in the 'Requirements' section

Yes

No

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b) The proposal addresses the ethical issues only in general terms but there are aspects which require substantial clarification. These are highlighted in the 'Requirements' section

Yes

No

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### 4. Requirements

(Requirements become contractual obligations)

Would you recommend a supplementary Ethics review?

(Only for Full Project Proposals that fall under category 3b above)

Yes

No

*If YES, please justify:*

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### 5. Would you recommend an Ethics Audit?

(IMI JU will undertake an Ethics Audit of selected project(s) in order to ensure compliance with the contractual requirements detailed above)

Yes

No

*If YES, please justify:*

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### 6. Recommendations

(Recommendations are suggestion and advice provided to the applicants. Recommendations do not become contractual obligations)