

## **ETHICS SCREENING REPORT**

Call Identifier	FP7-PEOPLE-2010-RG
Proposal Acronym	DEVBCEEC
Proposal Number	268340

### **Areas Excluded From Funding Under FP7 (*Art. 6*)**

- (i) Research activity aiming at human cloning for reproductive purposes;
- (ii) Research activity intended to modify the genetic heritage of human beings which could make such changes heritable (Research relating to cancer treatment of the gonads can be financed);
- (iii) Research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer;

**If a research application, selected for funding, addresses any of the above areas the screener (-s) need to inform the moderator immediately**

Where necessary, the beneficiary(ies) shall provide the Commission with a written confirmation that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval(s) of the competent national or local authority(ies) in the country in which the research is to be carried out before beginning any Commission approved research requiring such opinions or approvals. The copy of the official approval from the relevant national or local ethics committees must also be provided to the Commission.

## STEP 1- Identification of Ethical Issues

Research involving activities marked with an asterisk

\* will be referred automatically to **Ethics Review conducted by the Ethics Review Sector of DG RTD (European Commission)**

\*\* the screening process is sufficient and the proposal only requires authorisation from a national competent body and/or the opinion of the relevant Research Ethics Committee

Note: The asterisk system is indicative only. Each proposal should be assessed on its own merit and complexity. **If justified, the Screening Panel can recommend an Ethics Review for any proposal.**

	<b>Research on Human Embryo/ Foetus</b>	<b>YES</b>	<b>NO</b>
*	Does the proposed research involve Human Embryos?		X
*	Does the proposed research involve Human Foetal Tissues/ Cells?		X
*	Does the proposed research involve Human Embryonic Stem Cells?		X
*	Does the proposed research on Human Embryonic Stem Cells involve cells in culture?		X
*	Does the proposed research on Human Embryonic Stem Cells involve the derivation of cells from Embryos?		X

	<b>Research on Humans</b>	<b>YES</b>	<b>NO</b>
*	Does the proposed research involve children?		X
*	Does the proposed research imply invasive techniques on patients (e.g. taking of tissue samples, examination of the brain, administration of new drugs)?		X
*	Does the proposed research involve persons not able to give consent and/or vulnerable populations?		X
**	Does the proposed research involve adult healthy volunteers?	X	
**	Does the proposed research involve patients?		X
**	Does the proposed research involve Human genetic analysis?		X
**	Does the proposed research involve Human biological samples?		X
**	Does the proposed research involve Human data collection?		X

	<b>Research on Animals</b>	<b>YES</b>	<b>NO</b>
*	Are those animals non-human primates?		X
**	Does the proposed research involve research on animals?		X
**	Are those animals genetically-modified laboratory animals?		X
**	Are those animals genetically-modified farm animals?		X

**	Are those animals cloned farm animals?		X
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Privacy		YES	NO
**	Does the proposed research involve processing of genetic information or personal data (e.g. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)?	X	
**	Does the proposed research involve tracking the location or observation of people?		X

Research Involving non-EU Countries		YES	NO
*	Does the proposed research involve the use of local resources (genetic, animal, plant, etc)?		X
*	Is the proposed research of benefit to local communities (e.g. capacity building, access to healthcare, education, etc)?		X
*	Does the research application comply with the relevant ethics-related EC/International legislation?	X	

Other Ethical Issues		YES	NO
Are there <b>OTHER</b> aspects of the proposed research that may raise <b>Ethical Issues that require special attention</b> ?			X
If <b>YES</b> please specify:			

## Step 2 – Use of Human Embryonic Stem Cells (hESC)

(It is necessary to complete this section **only** if there is a 'Yes' reply in **STEP 1 – Table: Research on Human Embryo/Foetus**)

	YES	NO

Have the scientific evaluators assessed whether the use of hESC is necessary in order to achieve the scientific objectives set forth in the proposal?		
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(Applicants must document that appropriate validated alternatives -in particular, stem cells from other sources or origins- are not suitable and/or available to achieve the expected goals of the proposal)

### Step 3 – Ethics Review

**Would you recommend an Ethics Review for this project?**

Yes

No

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**If YES, please justify:**

**Would you recommend the request of additional information regarding the project proposal from the applicant (-s)?**

Yes

No

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**If YES, please justify:**

### Step 4 – Screening Requirements

(Requirements become contractual obligations)

The project will survey 500 respondents in 4 countries asking about their political attitudes and collect demographic information on gender, age, income, and level of education. The applicant has noted they are experienced in conducting such surveys and *‘had to undergo specific mandatory training modules on human subject research in the United States (IRB-Process)’*. The applicant confirms that the survey will be done only in adults and this will be anonymous, but rather scan details are provided about this process. The surveys appear to be conducted by *‘professional and thus trained polling companies in the target countries’*. It must be ensured that when applying for research ethical approval from the competent local/national Ethics Committees or bodies, that detailed information must be provided on privacy/confidentiality and the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation. Copies of ethical approvals by the competent local/national Ethics Committees or bodies must be submitted to the European Commission prior to the commencement of the research.

## **Step 5 - Ethics Audit**

**(to be performed after the first year of the implementation of the project)**

(The Ethics Review Sector of DG RTD (European Commission) will undertake an Ethics Audit of selected project(s) in order to ensure compliance with ethical principles and with contractual requirements detailed above)

**Would you recommend an Ethics Audit for this project?**

**Yes**

**No**



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**If YES, please justify:**