ETHICS SCREENING REPORT

Call Identifier	**FP7-SEC-2013-1**
Proposal Acronym	**SIIP**
Proposal Number	**607784**

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 REA 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 REA 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 REA.

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.**

	Research on Human Embryo/ Foetus	YES	NO
*	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?		
*	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

	Research on Humans	YES	NO
*	Does the proposed research involve children?		X
*	Does the proposed research involve persons not able to give consent?		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	

	Research on Animals[1]	YES	NO
*	Are those animals non-human primates?		X
**	Does the proposed research involve research on animals?		X

[1] The type of animals involved in the research that fall under the scope of the Commission's Ethical Scrutiny procedures are defined in the Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes Official Journal L 358 , 18/12/1986 p. 0001 - 0028

**	Are those animals transgenic small laboratory animals?		X
**	Are those animals transgenic farm animals?		X
**	Are those animals cloned farm animals?		X

	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 (ICPC Countries[2]) [3]	YES	NO
*	Is any material used in the research (e.g. personal data, animal and/or human tissue samples, genetic material, live animals, etc) : a) Collected and processed in any of the ICPC countries?		X
*	b) Exported to any other country (including ICPC and EU Member States)?		X

	Dual Use	YES	NO
*	Research having direct military use		X
*	Research having the potential for terrorist abuse		X

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

[2] In accordance with Article 12(1) of the Rules for Participation in FP7, 'International Cooperation Partner Country (ICPC) means a third country which the Commission classifies as a low-income (L), lower-middle-income (LM) or upper-middle-income (UM) country. Countries associated to the Seventh EC Framework Programme do not qualify as ICP Countries and therefore do not appear in this list.

[3] A guidance note on how to deal with ethical issues arising out of the involvement of non-EU countries is available at:
ftp://ftp.cordis.europa.eu/pub/fp7/docs/developing-countries_en.pdf

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?		X

(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**

If YES, please justify:

Step 4 – Screening Requirements

(Requirements become contractual obligations)

1. Copies of approvals/notifications by the competent local/national Ethics Committees/authorities must be submitted to the EC/REA prior to the commencement of the relevant research.
2. When applying for approval/notification from the competent local/national Ethics Committees/authority clear and detailed information must be provided on the source of the personal data to be used.
3. When submitting the application to the competent local/national ethical boards/bodies/administrations for authorization/opinion/notification, detailed information must be provided on the source of personal data and whether or not ethical approval has been obtained to cover their use in the present study
4. When applying for approval/notification from the competent local/national Ethics Committees/authorities, detailed information must be provided on the procedures that will be used for the recruitment of participants (e.g. number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants etc) and the nature of the material that will be collected.
5. When applying for approval/notification from the competent local/national Ethics Committees/authorities, detailed information must be provided on the informed consent

procedures that will be implemented. Copies of examples of Informed Consent Forms and Information Sheets must be included. These must be in language and terms understandable to the participants. Participants must have the right:

- To know that participation is voluntary
- To ask questions and receive understandable answers before making a decision
- To know the degree of risk and burden involved in participation
- To know who will benefit from participation
- To withdraw themselves and their data from the project at any time
- To know how their data will be collected, protected during the project and destroyed at the end

6. When applying for approval/notification from the competent local /national Ethics Committees/authorities, 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
7. The applicants must provide detailed information on the procedures that will be implemented for data collection, storage, access, sharing policies, protection, retention and destruction, as well as a detailed description of security measures that will be implemented to prevent improper use, improper data disclosure scenarios and 'mission creep' (i.e.: unforeseen collection/usage of data not needed within the project). This should be reported to EC/REA as a deliverable in the first reporting period.

Would you request additional information (not referred to in the Screening Requirements) that needs to be provided to the REA prior to the Ethics Review? Comment: *The REA will be responsible to transmit any additional information to the European Commission*

☐ **Yes** ☒ **No**

If YES, please justify:

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**

If YES, please justify:

Ethics Experts' Signatures:

Date: 14.03.2013