Ref. Ares(2018)3523939 - 03/07/2018



ETHICS ASSESSMENT CONSENSUS REPORT

Proposal Acronym	813986
Proposal Number	Syn2Psy
Programme	Horizon 2020
Call for proposals	H2020-MSCA-ITN-2018
Topic	MSCA-ITN-2018
Type of action	MSCA-ITN-ETN European Training Networks
Call deadline	17 January 2018
Dates of Ethics Assessment	13 – 15 June 2018

1. Identifying ethics issues

Section 1: HUMAN EMBRYOS/FOETUSES		YES/NO	Page
Does this research involve Human Embryonic Stem Cells (hESCs)?		NO	
If YES:	- Will they be directly derived from embryos within this project?		
	- Are they previously established cells lines?		
Does this research involve the use of human embryos?		NO	
If YES:	- Will the research lead to their destruction?		
Does this research involve the use of human foetal tissues / cells?		NO	
Section 2: HUMANS		YES/NO	Page
Does this research involve human participants?		YES	19, 24, 50
If YES:	- Are they volunteers for social or human sciences research?	NO	
	- Are they persons unable to give informed consent?	YES	50
	- Are they vulnerable individuals or groups?	YES	50
	- Are they children/minors?	YES	50
	- Are they patients?	YES	19, 24, 50
	- Are they healthy volunteers for medical studies?	YES	24
Does this research involve physical interventions on the study participants?		YES	24
If YES:	- Does it involve invasive techniques?	YES	24
	- Does it involve collection of biological samples?	YES	24
Section 3: HUMAN CELLS / TISSUES		YES/NO	Page
Does this research involve human cells or tissues?		YES	24-28
If YES:	- Are they available commercially?	NO	
	- Are they obtained within this project?	YES	24-28
	- Are they obtained from another project, laboratory or institution?	YES	Response of the applicant
	- Are they obtained from a biobank?	YES	24

Section 4: PERSONAL DATA		YES/NO	Page
Does this research involve personal data collection and/or processing?		YES	24-28
If YES:	- Does it involve the collection and/or processing of sensitive personal data	YES	24-28
	- Does it involve processing of genetic information?	YES	24-28
	- Does it involve tracking or observation of participants?	NO	
Does this research involve further processing of previously collected personal data (secondary use)?		YES	24-28

Section 5: ANIMALS		YES/NO	Page
Does this research involve animals?		YES	23-31
If YES:	- Are they vertebrates?	YES	23-31
	- Are they non-human primates (NHPs)?	NO	
	- Are they genetically modified?	YES	23-31
	- Are they cloned farm animals?	NO	
	- Are they endangered species?	NO	
Wt and genetically modified mice and rats.			

Section 6: THIRD COUNTRIES	YES/NO	Page
In case non-EU countries are involved, do the research related activities undertaken in these countries raise potential ethics issues? Switzerland	YES	24, 48
Is it planned to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)?	NO	
Is it planned to import any material – including personal data – from non-EU countries into the EU?	NO	
Is it planned to export any material – including personal data –from the EU to non-EU countries?	NO	
In case this research involves low and/or lower-middle income countries, are any benefit-sharing actions planned?	NO	
Could the situation in the country put the individuals taking part in the research at risk?	NO	

Section 7: 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?	YES	25, 26

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?	YES	25, 26
Section 8: DUAL USE	YES/NO	Page
Does this research involve dual-use items in the sense of Regulation 428/2009, or other items for which an authorisation is required?	NO	
Section 9: EXCLUSIVE FOCUS ON CIVIL APPLICATIONS	YES/NO	Page
Could this research raise concerns regarding the exclusive focus on civil applications?	NO	
Section 10: MISUSE	YES/NO	Page
Does this research have the potential for misuse of research results?	NO	
Section 11: OTHER ETHICS ISSUES	YES/NO	Page
Are there any other ethics issues that should be taken into consideration?	NO	

2. Research excluded from funding (human cloning and genetic heritage)

Does the proposal include research

- aiming at human cloning for reproductive purposes?

  ☐ YES

  ☒ NO

- intended to modify the genetic heritage of human beings which could make such changes heritable?

  ☐ YES

  ☒ NO

3. Use of Human Embryos (hE) and Human Embryonic Stem Cells (hESC)

Did the scientific evaluators confirm that the use of hESC is necessary in order to achieve the scientific objectives of the proposal?

☐ YES

☐ NO

☒ Not applicable

Does the proposal meet the applicable legal requirements of the country where the research will be carried out (including all the special conditions for funding: authorisations/approval of the relevant national or local ethics committee, parental consent, absence of financial inducement, etc.)?

☐ YES

☐ NO

☒ Not applicable

If the national rules of the country where the research will be carried out foresee licensing and control measures: does the proposal refer to these rules and ensure compliance?

☐ YES

☐ NO

☒ Not applicable

Do you confirm that the proposal does NOT include 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?

☐ YES

☐ NO

☒ Not applicable

If the proposed activities include the use of hESC line(s) not yet registered in the European Registry, does the proposal foresee the registration of the(se) line(s)?

☐ YES

☐ NO

☒ Not applicable

4. Analysis of the ethical dimension

Humans

Tooth extractions and associated gingival biopsies from patients and healthy volunteers, including children and vulnerable individuals, will be performed.

The Ethics Commission of the Faculty of Medicine, University of Coimbra, has approved the study and the approval has been made available to the Panel.

Human cells/tissues

The project involves use of dental stem cells and fibroblasts derived from gingival biopsies for the development of culture models and cerebral organoids.

Human iPSCs will be obtained from collaborators, companies and iPSC banks.

Data protection

Age- and gender-matched patients and controls will be recruited. Insufficient information is given regarding data collection, data processing and data protection including genetic data.

Some ESRs will get exposure to clinical research and learn about the clinical evaluation of patients with autism and psychosis, and other neurodevelopmental disorders and the selection criteria for patients, which also includes processing of personal data.

According to the applicant's response the data will be used anonymously. However, what is actually described in the response is pseudoanonymization (samples will be coded). Therefore, the requirements regarding data still stand.

Animals

Several strains of transgenic mice and rats will be used. Some experiments include transplantation of iPSC-derived neurons from human patients into mice. The European and national laws for animal experimentation have been addressed for all countries participating in animal experiments. The principle of 3Rs is well addressed.

Environment & Health & Safety

Viruses, such as AAV and rabies associated virus will be applied for lentiviral mediated transduction, which might be harmful to humans, including research staff and requires BSL2 measures.

5. Ethics recommendations

None

6. Ethics opinion

☐ '**additional information is needed'**

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

☒ **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:

Humans

1. Details on the procedures and criteria that will be used to identify/recruit research participants must be submitted as a deliverable to the REA before the commencement of the relevant work.
2. Detailed information on the informed consent procedures that will be implemented for the participation of humans must be submitted as a deliverable to the REA before the commencement of the relevant work.
3. English translations/summaries of the ethics approvals for the research with humans must be submitted as a deliverable to the REA before the commencement of the relevant work.
4. English translations of the informed consent forms and information sheet must be submitted as a deliverable to the REA before the commencement of the relevant work.
5. The applicant must clarify how consent/assent will be ensured in case of children and/or adults unable to give informed consent before the commencement of the relevant work.
6. Details on incidental findings policy must be provided to the REA before the commencement of the relevant work.

Human cells/tissues

7. For human cells/tissues obtained within another project, details on cells/tissues type and authorisation by primary owner of data must be submitted as a deliverable to the REA prior to the commencement of the relevant work.
8. For human cells/tissues obtained om a biobank, details on cells/tissues type as well as details on the biobank and access to it must be obtained and kept on file before the relevant work commences, and submitted upon request to the REA.

9. For human cells/tissues available commercially, details on cells/tissues type and provider must be obtained and kept on file before the relevant work commences and submitted upon request to the REA.

Data protection

10. The applicant must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s) as a deliverable to the REA before the relevant work commences.

11. A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be submitted to the REA before the relevant work commences.

12. For further processing of previously collected personal data, an explicit confirmation that the applicant has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be submitted before the relevant work commences.

Animals

13. The applicant must obtain the relevant authorisations (for breeders, suppliers, users, and facilities) for animal experiments. These must be kept on file and submitted to the REA upon request.

14. Copy of project specific authorisation (covering also the work with genetically-modified animals) with English translation summary must be submitted as a deliverable to the REA before the commencement of the relevant work.

15. If applicable, copies of training certificates/personal licenses of the staff involved in animal experiments must be kept on file and submitted upon request.

Environment

16. The applicant must confirm that facilities authorizations have been obtained (e.g. security classification of laboratory, GMO authorization), and are kept on file.

17. The applicant must ensure that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project before the work commences.

General

18. An independent External Ethics Advisor must be appointed to monitor ethics issues associated with the project, especially the research involving children and persons unable to give informed consent. Ethics Reports must be submitted to the REA together with the Periodic Reports.

☐ **second ethics assessment recommended** (i.e. need for a (second) in-depth analysis to take a decision and to define necessary ethics requirements)

☐ **no ethics clearance**

7. Sensitivity level

How would you judge the overall sensitivity of the proposal (reflecting how the ethics aspects of the project should be closely look at)?

☐ Normal

☒ High

8. Ethics checks

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

☐ YES

☒ NO