Imagine for Margo & Fondatioun Kriibskrank Kanner & KickCancer

EUROPEAN SCIENCE FOUNDATION	*FIGHT KIDS CANCER* SUPPORTING A PROGRAMME FOR INNOVATIVE RESEARCH

Ethics self-assessment guideline to the Fight Kids Cancer Competitive Call

Fight Kids Cancer Competitive Call

Critical Deadlines: Full Proposals to be submitted by 1st of April 2020 16:00 (4pm) Brussels time

Information about your application, including the personal information provided on the forms, will be processed and stored electronically by the European Science Foundation (ESF) Secretariat and representatives of the Call's Funders. In accordance with the selection process, the Information contained in your application may be passed on to external reviewers in confidence. Reviewers will be asked to destroy information after the review and selection process is complete.

Your application and personal information will be stored by the ESF electronic system for programme management purposes but will not be shared with other organisations outside the FKC partnership. We will use details provided in the application for correspondence about the call and may also use this information for future analyses of the performance of the programme.

By submitting your application to the FKC Programme you have indicated your acceptance of these data protection terms and conditions.

General statements

As a general reminder, your research must comply with:

- Ethical principles;
- Applicable international, EU and national laws.

Regarding this research call, several specific issues regarding ethics will need to be answer carefully using a two steps process:

1) To fill the online ethics issues checklist
2) To provide the needed information and documents if your project is selected

The ethics issues checklist is structured in 9 sections, which are the following:

1) Human Embryonic Stem Cells
2) Human beings
3) Human cells & tissues
4) Protection of personal data
5) Animals
6) Third countries
7) Health & safety
8) Misuse of research results
9) Other ethics issues

1. Human Embryonic Stem Cells

Research using human stem cells (both adult and embryonic) may be financed – depending on both the content of the scientific proposal and national/EU laws. No funding will be granted for research activities that are prohibited in all eligible countries (see Annex A). No activity will be funded in a country where such activity is forbidden.

Section 1: Human Embryonic Stem Cells (hESCs)		YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research involve Human Embryonic Stem Cells (hESCs)?						
If **YES**:	Will they be directly derived from embryos within this project?				*Research not eligible for funding*	*Research not eligible for funding*
	Are they previously established cells line?				1) Origin and line of cells. 2) Details of the licensing and control measures by the competent authorities of the country involved.	1) Copies of Ethics Approval. 2) Declaration that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) both for hESCs and human-induced

						pluripotent stem cell (hiPSC) lines. 3) Declaration confirming that the 6 specific conditions (see below) for research activities involving human embryonic stem cells are met.

You must make sure that the following **6** conditions are met:

- Cells were **NOT** derived from embryos specially created for research or by somatic cell nuclear transfer;
- The project uses existing cultured cell lines only;
- Cell lines were derived from supernumerary non-implanted embryos resulting from in vitro fertilisation;
- Informed consent has been obtained for using donated embryos for the derivation of the cell lines;
- Personal data and privacy of donors of embryos for the derivation of the cells are protected;
- **NO** financial inducements were provided for the donation of embryos used for derivation of the cell line.

2. Research involving work with humans' beings ("research or study participants).

Working with humans' beings implies that you must ensure respect for people, human dignity and fair distribution of the benefits and burden of research as well as protect the values, rights and interests of the research participants. It also implies that you must obtain the necessary ethics approvals and a free and fully informed consent of the research participants. Moreover, the grant proposal will also to comply with the principles laid down in the Declaration of Helsinki, the Oviedo Bioethics Convention and the EU Regulation No 536/2014 on clinical trials on medicinal products for human use. Regarding personal date, please refer to section 4.

Section 2: Humans		YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Do you research involve human participants?					1) Confirm that informed consent has been obtained	1) Informed Consent Forms + Information Sheets
If **YES**:	Are they persons unable to give informed consent (including children/minors)?				1) Details of the procedures for obtaining approval from the guardian/legal representative and the agreement of the children or other minors	1) Copies of ethics approvals

					2) What steps will you take to ensure that participants are subjected to any form of coercion? 3) Details of the age range 4) What are your consent procedures for children and other minors? 5) What steps will you take to ensure the welfare of the child or other minor?	
	Are they patients?				1) Details of the recruitment, inclusion and exclusion criteria and informed consent procedures 2) What is your policy on incidental findings	1) Copies of ethics approvals
Does your research involve physical interventions on the study participants?						
If **YES**:	Does it involve invasive techniques (e.g. collection of human cells or tissues, surgical or medical interventions, invasive studies on the brain, etc.)?				1) Risk assessment for each technique and overall	1) Copies of ethics approvals
	Does it involve collection of biological samples?				1) What type of samples will be collected? 2) What are your procedures for collecting	1) Copies of ethics approvals

					biological samples?	

What do we mean by informed consent?

Participants must be entirely voluntary, do not feel pressured or coerced into giving convent and must be given an informed consent form and detailed information sheets before given its consent. Regarding research involving children, the informed consent must be obtained from the legally authorised representative. This representative must receive sufficient information to enable them to provide the informed consent on behalf and in the best interests of the participants. In addition, whenever possible, the assent of the participants should be obtained in addition to the consent of the parents/legal authorised representative.

These documents must be:

- Written in a language and in terms they can fully understand;
- Describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue;
- Explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time without any consequences;
- State how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently;
- State what procedures will be implemented in the event of unexpected or incidental findings.

3. Human cells & tissues

Human cells & tissues may be obtained from commercial sources, as part of the research project, from another research project or institution and from a biobank. In particular, it must comply with the EU Directive 2004/23/EC relative to the handling of cells and tissues. Under this directive, the research project must keep track of the origin of the cells/tissues used, produced or collected but also obtain the necessary accreditation/designation/authorisation/licensing for using, producing or collecting the cells/tissues and a free and fully informed consent of the donors.

Section 3: Human Cells/Tissues	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Do you research involve human cells & tissues (other than hESCs, see section 1)?				1) Details of the cells or tissues types	1) Copies of relevant ethics approvals 2) Copies of accreditation, designation, authorisation, licensing for using, processing or collecting the human cells or tissues (if required)

If **YES**:	Are they available commercially?				1) Details of the provider	1) Copies of import licences (if relevant)
	Are they obtained within this project?				1) Details of the source of the material, the amount to be collected and the procedure for collection 2) Details of the duration of storage and what you will do with the material at the end of the research 3) Confirm that informed consent has been obtained	1) Informed consent forms and information sheets
	Are they obtained from another project or institution?				1) Country where the material is stored 2) Details of the legislation under which material is stored 3) How long will be the material be stored and what will you do with it at the end of the research project? 4) Name of the institution 5) Country where the institution is located 6) Confirm that material is fully anonymised or that consent for secondary	1) Copies of import licences (if relevant) 2) Statement of the institution that informed consent has been obtained

					use has been obtained	
	Are they obtained from a biobank?				1) Name of the biobank 2) Country where the biobank is located 3) Details of the legislation under which material is stored 4) Confirm that material is fully anonymised or that consent for secondary use has been obtained	1) Copies of import licences (if relevant) 2) Statement of biobank that informed consent has been obtained

4. Protection of personal data

By personal data, we mean information relating to an identified or identifiable natural person. According to the Article 2(a) of the EU General Data Protection Regulation (GDPR), and identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Individuals are not considered 'identifiable' if identifying them requires excessive effort. Completely anonymised data does not fall under the regulation (as from the moment it has been completely anonymised).

International, EU and national law requires that data processing should be subject to appropriate safeguards, wherever possible be processed in anonymised/pseudonymised form, done with the free and fully informed consent of the persons concerned and follow the data minimisation principle.

Anonymised: data has been rendered anonymous in such a way that the data subject can no longer be identified.

Pseudonymised: Split the data from its direct identifiers so that linkage to a person is only possible with additional information that is held separate. The additional information must be kept separately and securely from processed data to ensure non-attribution.

Section 4: Protection of personal data	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Do your research involve processing of personal data?				1) Details of the technical and organisational measures to safeguard the rights of the	1) Informed consent forms and information sheets used (if relevant)

					research participants. For organisations that must appoint a data protection officer (DPO) under the GDPR: involvement of the DPO and disclosure of the contact details to the research participants. For the others, details of the data protection policy for the project 2) Details of the informed consent procedures 3) Details of the security measures to prevent unauthorised access to personal data 4) How is all of the processed data relevant and limited to the purposes of the project? 5) Details of the anonymisation techniques 6) Justification of why research data will not be anonymised or pseudonymised 7) Details of the data transfers (type of data transferred and country to which it is transferred)	
If **YES**:	Does It involve the processing of special categories of personal data (e.g. genetic, health,				1) Justification for the processing of special	

	sexual, lifestyle, ethnicity)?				categories of personal data 2) Why can the research objectives not be reached by processing anonymised data (if applicable?	
	Does it involve processing of genetic, biometric or health data?					1) Declaration confirming compliance with the laws of the country where the data was collected
Does your research involve further processing of previously collected personal data (including use of pre-existing data sets or sources, merging existing data sets)?					1) Details of the database used or of the source of the data 2) Details of the data processing operations 3) How will the rights of the research participants be safeguarded? 4) How is all of the processed data relevant and limited to the purposes of the project? 5) Justification of why the research data will not be anonymised (if relevant)	1) Declaration confirming lawful basis for the data processing 2) Permission by the owner/manager of the data sets (if applicable) 3) Informed consent forms, information sheets and other consent document (if applicable)
Does your research involve publicly available data?					1) Confirm that the data used in the project is publicly available and can be freely used for the project	1) Permission by the owner/manager of the data sets (if applicable)

It is planned to export personal data from non-EU countries into the EU?				Details of the type of personal data to be exported. How will the rights of the research participants be safeguarded?	1) Declaration of confirming compliance with GDPR (chapter V)
It is planned to import personal data from non-EU countries into the EU?				1) Details of the types of personal data to be imported	1) Declaration confirming compliance with the laws of the country in which the data was collected

5. Animals

Regarding research involving animals, the research project must comply with applicable international, EU and national law. In particular, the project must comply with the EU directive 2010/63/EU that is designed to limit the use of animal testing for scientific purposes but be aware that some European countries may have stricter rules. This implies that 3R (replacement, reduction and refinement) strategy should be implemented where possible:

- Replacement: replacing animal use by an alternative method or testing strategy (without use of live animals).
- Reduction: reducing the number of animals used.
- Refinement: improving the breeding, accommodation and care of animals and the methods used to minimise pain, suffering, distress or lasting harm to animals.

Remember that you must obtain all the authorisations for the supply of animals and the animal experiments before you can start to use animals.

Section 5: Animals	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Do your research involve animals?				1) Details of the species and rationale for their use, numbers of animals to be used, nature of the experiments, procedures and techniques to be used 2) Justification of animal use (including the kind of animals to be used) and why alternatives cannot be used	

If **YES**:	Are they vertebrates?					
	Are they genetically modified?				1) Details of the phenotype and any inherent suffering expected 2) What scientific justification is there for producing such animals? 3) What measure will you take to minimise suffering in breeding, maintaining the colony and using the GM animals?	1) Copies of GMO authorisations

6. Third countries

This section concerns research involving countries not designated in the Annex A.

Section 6: Third countries	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
In case countries not designated in the Annex A are involved, do the research related activities undertaken in these countries raise potential ethics issues? *Specify the countries involved:*				1) Risk-benefit analysis 2) What activities are carried out in countries non designated in the Annex A?	1) Copies of ethics approvals and other authorisation (if required) 2) Confirmation that the activity could have been legally carried out in a EU country (for instance an opinion from an appropriate ethics structure in an EU country)

7. Health and safety

The health and safety of all human participants in research must be a priority. By so, it must comply with international, EU and national law, in particular the legislation on public-health control and safety at work

Section 7: Health and safety	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Does your research involve the use of elements (chemicals, radioactive material) that may cause				1) Details of the health and safety procedures.	1) Safety classification of laboratory

harm to humans, including research staff? **For research involving human participants, see section 2.**					

8. Misuse of research results

Research results could be misused for unethical purposes despite being carried out with no intentions.

Section 8: Misuse of research results	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Do your research have a potential for misuse of research results?				1) Risk-assessment 2) Details of the applicable legal requirements 3) Details of the measures to prevent misuse	1) Copies of authorisations (if required) 2) Copies of security clearances (if applicable) 3) Copies of ethics approvals (if applicable)

9. Other ethics issues

Section 9: Other ethics issues	YES	NO	Page	Information to be provided	Documents to be provided/kept on file
Are they any other ethics issues that should be taken into consideration? *Please specify:*				1) Any relevant information	1) Any relevant document