European Humanist Federation

KEEP DOGMA OUT OF EUROPEAN RESEARCH

POSITION PAPER

On the Framework Programme for Research and Innovation:
"Horizon 2020" (2014-2020)[1]

The EHF advocates that :

- the ethical framework for "Horizon 2020" and more generally for research in Europe should rest on shared values and not on dogma. It is therefore necessary to encourage all scientific options on the basis of research objectives and relevant medical considerations and not to rule them out in advance on the basis of religion.

- the EU should adopt a less restrictive and more ambitious approach to funding for human embryonic stem cells (hESC) research.

Therefore, the EHF urges that :

- the EU allows funding for projects which include the creation of new hESC lines from 'spare' embryos created for *in vitro* fertilisation when permitted by national legislation. This means abandoning the 2006 compromise under which the EU Commission "*will not submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells";*

- when appropriate and where permitted, the EU allows European funding for the creation of human embryos for research purposes or for the procurement of stem cells (including by means of somatic cell nuclear transfer). This requires amending Article 16 of the Commission proposal;

- the EU simplifies administrative burdens for hESC researchers and makes European ethical review more transparent. When composing the ethical review panel, the European Commission should clarify its guidelines, focus on the expert's scientific background and ensure a pluralist representation of existing ethical views.

- the EU promotes wide public discussion on stem cell issues, providing accurate information as a basis for debate fitting our pluralist societies. This implies modifying Article 22 of the Commission proposal.

[1] Brussels, 30.11.2011 COM(2011) 809 final.

The European Humanist Federation (EHF) unites over 50 member organisations in over 20 countries and speaks in the interest of people who have no religion (between a third and a half of Europeans[2]) but who share the same values: human rights, equality and non-discrimination, freedom of conscience, impartiality of public institutions. The EHF is recognised as a dialogue partner by the European institutions under Article 17 TFEU.

1- Towards non-instrumentalised and dogma-free research

As a humanist and secularist organisation, the EHF attaches great importance to freedom of research. Research activities should be conceived and conducted as an open search for truth, with a determination to follow the evidence. The EHF therefore condemns the recent proposals from the Roman Catholic Church representatives (COMECE) to make research projects funding conditional on pre-set political agendas, e.g. delivering empirical proofs of their own contested view of the social efficiency of « traditional » families by comparison with other « intrinsically unstable » family structures. No one with any notion of how scientific research is conducted could possibly make such a self-serving proposal. This blatant illustration of instrumentalisation of research is completely contrary to the principles – freedom of research and scientific autonomy – stated in the European Charter for Fundamental Rights (Article 13) and endorsed by respondents to the consultation on the European Research Area framework.

Freedom of research does not mean that any research with any objective can be conducted. As a humanist and secularist organisation, the EHF is the last to deny that ethical considerations must play a part in directing both the objectives and the methods of scientific research. But the ethical framework for such decisions must rest on shared principles and values and not on ideological dogma. This must also apply to EU funding for human embryonic stem cells (hESC) research. The EHF is very concerned to see that, in the past, the EU has clearly retreated in the face of religious pressure, which has resulted in a confusing and hypocritical situation for European researchers.

2- Towards a coherent and ambitious approach on European funding for human embryonic stem cells research

The incoherent current practice

Like any other scientific research, hESC research must be responsible and must respect EU fundamental rights. The European Humanist Federation fully agrees with the exclusion from EU funding of research aiming at human cloning for reproductive purposes or modify human beings in ways that could be genetically inheritable. However, the current practice on European funding for hESC research (under the Seventh Framework Programme – FP7) is **too restrictive** and ethically **incoherent**.

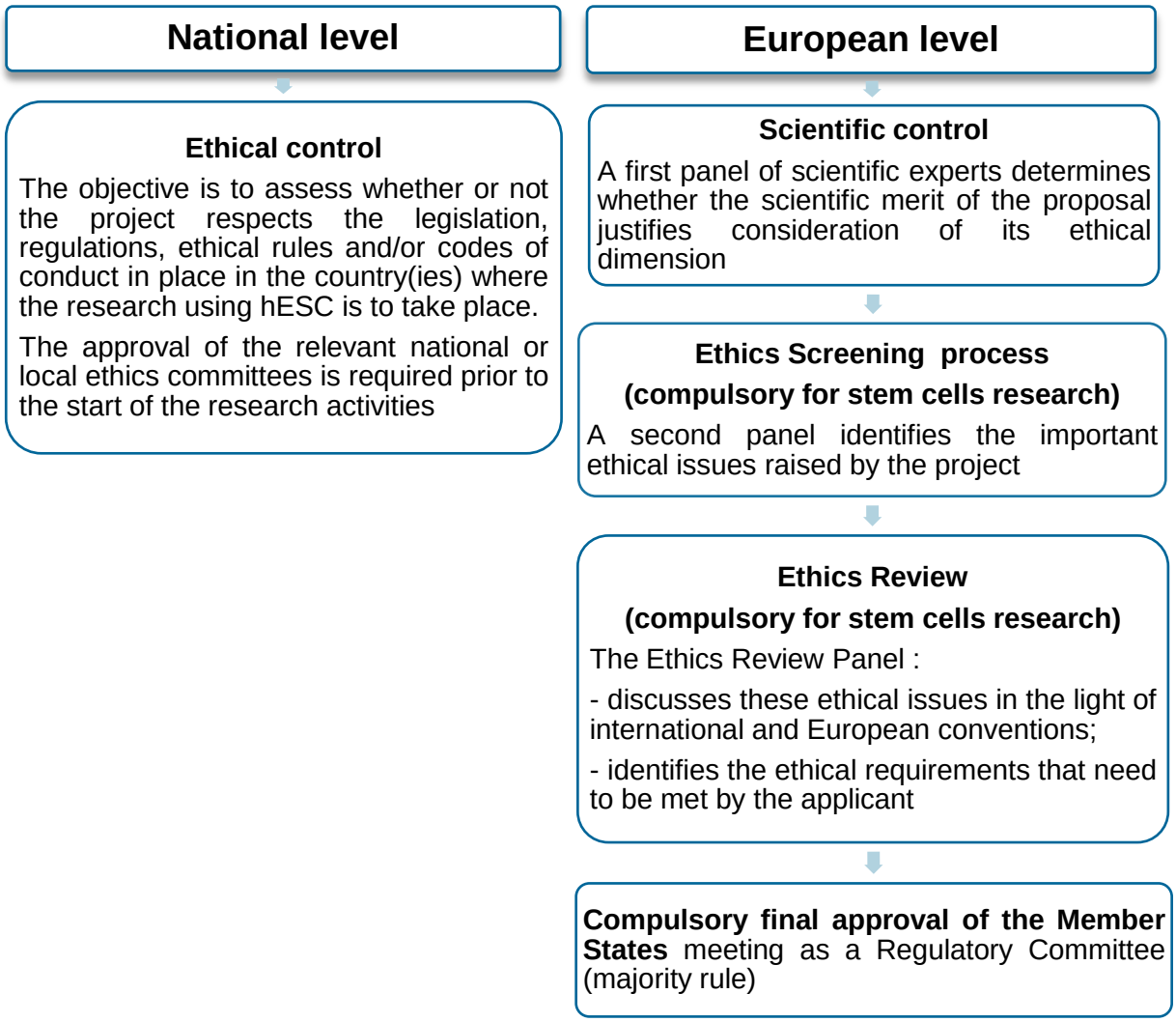
First, the EU excludes from funding the creation of new human embryonic stem cell lines from supernumerary embryos on the ground that the process involves the destruction of these embryos. However, the EU allows funding for subsequent steps of research using existing human embryonic stem cells![3] To be plain, as long as the creation of new stem cell lines (and thus the destruction of embryos) is paid by private funds, the EU is willing to support the use of these lines and to be associated with potential scientific breakthroughs. This hypocritical compromise is the consequence of direct religious pressure from the

[2] Eurobarometer 2005, Eurobarometer 2006 ;Eurobarometer 2010
[3] "Statements by the Commission. Re Article 6", Official Journal of the European Union, 30.12.2006, (12), p. 2.

Vatican and several Member-States during negotiations of the previous Framework Programme in 2006.

Second, in its article 6, "FP7" forbids funding of "*research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cells procurement, including by means of somatic cell nuclear transfer*." In "Horizon 2020", the European Commission excludes again this scope of research. This means that the EU will continue to fund research based on supernumerary embryos only ("extra" embryos created for *in vitro* fertilisation and so destined for destruction). What about research which cannot achieve its scientific or therapeutic purpose with supernumerary embryos? Should Member-States allowing these activities in their own countries (United Kingdom, Belgium, and Sweden) be automatically excluded from EU funding?

Third, under "FP7", the decision procedure on granting EU funding for hESC research is complex and opaque. Here below is a summary of ethical review procedures that hESC projects need to go through before being granted EU money:



One of the main problems is the way the European Commission appoints the European Ethics review panel. In October 2011, a parliamentary question was addressed to the Commission on this particular point but received an evasive answer: *"Ethics review panels are composed of external, independent experts specialised in ethical issues from different background with a reasonable geographical and gender balance*". Effective pluralism is very

important to guarantee a balanced ethical review. In the current situation, it is hard to understand what criteria drive the Commission's choice[4].

Furthermore, the need for final approval by Member-States complicates and delays the procedure even further since countries have different regulations on hESC research and different ethical values. We hope that the new "Horizon 2020" framework will be the opportunity to streamline and simplify these administrative burdens for participants.

Why is it necessary to encourage European public funding for embryonic stem cell research?

- **First, because hESC research is scientifically promising**. One of the three priorities of "Horizon 2020" is to tackle societal challenges. Among them, health and demographic ageing have been identified as issues to address urgently. The EHF does not support hESC research at all costs and recognizes that alternatives exist. However, in order to reach new therapeutic breakthroughs, European researchers should not be prevented by considerations of funding from using any promising scientific procedure allowed by their national legislation. Even if not all researchers are equally enthusiastic about its medical usefulness, hESC research must not be excluded given that it has been proved that these cells have valuable biological properties. The fact that they can multiply endlessly and can morph into any type of cell found in the body may help us to treat several degenerative diseases, to better understand genetic anomalies, to discover new drugs and eventually even to replace organ transplants. Moreover, even if adult stem cells have raised hopes, many researchers are still cautious about their real therapeutic potential. For example, there are reports saying that induced pluripotent stem cells have been rejected by recipients' immune systems. Therapies based on embryonic stem cells would offer perfect immune compatibility. It is thus necessary to encourage all scientific options on the basis of scientific results, not rule them out in advance on the basis of religious doctrine.

- **Second, because it would help increase EU competitiveness in fundamental and therapeutic research.** "Horizon 2020" aims at contributing to reaching "Europe 2020" objectives and implementing the European Research Area by attracting new talent and investment to the EU. The results of the consultation on "Horizon 2020" show that alongside market-directed research, fundamental research is also seen as a means to improve Europe's scientific base through "unconventional" projects. The current situation is clearly an obstacle to these objectives: how can the EU attract new researchers if it discourages research with complex legal procedures and political feebleness? These considerations have been all the more vital since 2009 when the USA finally allowed federal funding for responsible hESC research in order to invest in promising medical avenues. Already since 2009, three clinical trials have been authorized by the USA for paralysis and eye' diseases.

- **Third, because it would ensure responsible and controlled hESC research**. The EHF fully agrees with the necessity to control these activities and believes that responsible research would be achieved better with public than with private funding. Decreasing public funds would only lead to a greater involvement of private firms and so create new ethical risks.

[4] For more information about the Ethics Panels, see the European Commission's website : http://ec.europa.eu/research/science-society/index.cfm?fuseaction=public.topic&id=1290

- **Fourth, because it would respect EU principles of subsidiarity and complementarity**. The EHF agrees that no funding should be granted for research activities that are prohibited in all the Member States and that no activity should be funded in a Member State where such activity is forbidden. Therefore, our request is in line with the principles of subsidiarity (article 5 TEU), complementarity and coherence between EU and Member States' research policies (Articles 180 and 181 TFEU). Allowing EU funding – where it is permitted under national law - for research involving hESC, including activities that create and destroy human pre-embryos, would never oblige Member States that forbid one or both procedures to allow them in their countries.

- **Finally, because it would be compatible with European values**. The EU is a secular institution and has embraced human rights, equality and non-discrimination as fundamental to its notion of European citizenship (article 2 TEU). A move towards a less restrictive European funding regime for hESC research would clearly protect science from ideological interference. Several political signs confirm the existence of strong religious pressure on hESC research, such as the recent European Court of Justice decision in *Greenpeace v. Brüstle* which defines the human embryo very widely and grants it human dignity from the conception onwards. Philosophically speaking, the EHF thinks that something which has *only the potential to become* a person *cannot* at this very early development stage (less than 14 days)[5], be granted human rights[6]. According to the majority of scientists, embryos at this stage do not have the physical – let alone the emotional - properties which are usually associated with personhood and should rather be called "pre-embryos". None of this means that arguments from respect for life and for human dignity are illegitimate: far from it, but they need to be pursued in ways that start from the facts and are comprehensible and contestable by everyone, not on the basis of unquestionable religious dogma. The EU's primary ethical concern should be with the human dignity of suffering people: on this there is ethical consensus.

Our recommendations for "Horizon 2020"

The EHF urges that the Council abandons the compromise adopted in 2006 by Member States and thus stops excluding from EU funding research which includes the procurement of new embryonic stem cells so long as it is allowed under the legislation of the relevant Member State(s)[7].

⇨ **Why?** Because supernumerary embryos are destined for destruction in all cases. It is therefore absurd to refuse funding the derivation of new stem cells from human embryos that will never be implanted into a woman's uterus. It is all the more absurd since the EU already grants some funding for other research activities using human embryonic stem cells. The current compromise is clearly symbolic and in no way follows scientific and reason-based arguments.

[5] Stem cells are derived from the embryo at the blastocyst stage, around the 6th or 7th day.
[6] Different religions take different views on this specific issue: Judaism and Islam argue that the embryo does not attain full human status before 40 days, so both these religions permit some research on embryos in view of the importance of helping others.
[7] Text of the compromise available on http://eur-lex.europa.eu

Article 16 of the Commission's proposal – "Ethical principles" should be modified as follows :

1. "All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

   Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

2. Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.

3. The following fields of research shall not be financed :
   (a) research activity aiming at human cloning for reproductive purposes;
   (b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable;

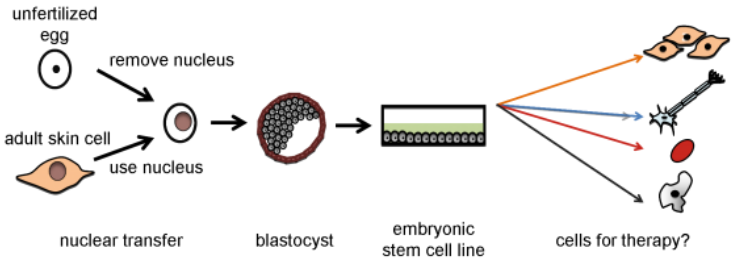
   ~~*(c) research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.*~~

4. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden*. For supernumerary embryos, the European Commission will stop with the current practice and will submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos. 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 may be financed where permitted by the relevant Member States, if the objects of the research cannot be achieved by use of supernumerary embryos.*

5. The fields of research set out in paragraph 3 may be reviewed within the context of the interim evaluation set out in Article 26 (1) in the light of scientific advances."

⇨ **Why?** First, some people argue that it is morally worse to create an embryo with the intention of destroying it in research, than it is to create spare embryos as a byproduct of fertility treatment because the latter are created for the purpose of producing child. However, since it is widely accepted that spare embryos created for IVF will be destroyed, it should also be ethically acceptable to create and destroy embryos (aged up to 7 days) for research purposes.
Second, research cannot always achieve its purpose by using supernumerary embryos. Embryologists argue that the quality of spare embryos from IVF is not always optimal and that the freezing process can distort the results of the whole research. But above all, the creation of new embryos by means of somatic cell nuclear transfer will be indispensable in the future for the therapeutic application of hESC research.

Somatic cell nuclear transfer:



Source : http://www.eurostemcell.org

As this diagram shows, this process often miscalled "therapeutic cloning" produces stem cells ensuring perfect compatibility between the patient and the new healing cells. For now, researchers work mostly with supernumerary embryos. But this process will be indispensable in the future if they want to apply their scientific discoveries to patients and treat degenerative diseases (e.g. Parkinsonism, Huntington's and Alzheimer's diseases, diabetes and heart failure).

Ethical screening and review panels: since this ethical review is mandatory for projects involving human embryonic stem cells and the composition of those panels is a prerogative of the European Commission, the EC should clarify its guidelines, focus on the expert's scientific background and ensure a pluralist representation of existing ethical views when composing those panels.

Article 22 of the Commission's proposal – "Information, communication and dissemination" should be modified as follows:

The European Commission shall implement information and communication actions concerning Horizon 2020, including communication measures concerning supported projects and results. Budget allocated to communication under Horizon 2020 shall also contribute to covering the corporate communication of the Union's political priorities as far as they are related to the general objective of this Regulation.

Activities to disseminate information and carry out communication activities shall be an integral task under all of the actions supported by Horizon 2020.

In addition, the following specific actions shall be supported:
(e) initiatives to foster dialogue and debate on scientific, technological and innovation related issues with the public, and to take advantage of social media and other innovative technologies and methodologies; *Particular attention shall be paid to initiatives on sensitive ethical issues such as hESC research. On such issues, the European Commission shall take special steps to support wide dialogue and debate involving all points of view.*

⇨ **Why?** First, because public debates about hESC research very often set religious authorities and confessional organisations in opposition to scientists. There is an urgent need to involve citizens and civil society organisations in this scientific and ethical debate. Second, because ethics is too often seen as the monopoly of churches and confessional organisations. There is an honourable tradition of religious ethics, but also an equally honourable and even older tradition of ethics based on non-religious human values which needs to be brought to bear in this sort of policy debate.