

INFORMATION FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES  
AND AGENCIES

EUROPEAN COMMISSION

**Declarations of the Commission (Framework Programme)**

(2013/C 373/02)

**STATEMENT BY THE COMMISSION**

For the Horizon 2020 Framework Programme, the European Commission proposes to continue with the same ethical framework for deciding on the EU funding of human embryonic stem cell research as in the 7th Framework Programme.

The European Commission proposes the continuation of this ethics framework because it has developed, based on experience, a responsible approach for an area of science which holds much promise and that has proven to work satisfactorily in the context of a research programme in which researchers participate from many countries with very diverse regulatory situations.

1. The decision on the Horizon 2020 Framework Programme explicitly excludes three fields of research from Community funding:
  - research activities aiming at human cloning for reproductive purposes;
  - research activities intended to modify the genetic heritage of human beings which could make such changes heritable;
  - 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.
2. No activity will be funded that is forbidden in all Member States. No activity will be funded in a Member State where such activity is forbidden.
3. The decision on Horizon 2020 and the provisions for the ethics framework governing the Community funding of human embryonic stem cell research entail in no way a value judgment on the regulatory or ethics framework governing such research in Member States.
4. In calling for proposals, the European Commission does not explicitly solicit the use of human embryonic stem cells. The use of human stem cells, be they adult or embryonic, if any, depends on the judgment of the scientists in view of the objectives they want to achieve. In practice, by far the largest part of Community funds for stem cell research is devoted to the use of adult stem cells. There is no reason why this would substantially change in Horizon 2020.
5. Each project proposing to use human embryonic stem cells must successfully pass a scientific evaluation during which the necessity of using such stem cells to achieve the scientific objectives is assessed by independent scientific experts.
6. Proposals which successfully pass the scientific evaluation are then subject to a stringent ethics review organised by the European Commission. In this ethics review, account is taken of principles reflected in the EU Charter of Fundamental Rights and relevant international conventions such as the Convention

of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997 and its additional protocols and the Universal Declaration on the Human Genome and the Human Rights adopted by UNESCO. The ethics review also serves to check that the proposals respect the rules of the countries where the research will be carried out.

7. In particular cases, an ethics check may be carried out during the lifetime of the project.
8. Each project proposing to use human embryonic stem cells must seek the approval of the relevant national or local ethics committee prior to the start of the project. All national rules and procedures must be respected, including on such issues as parental consent, absence of financial inducement, etc. Checks will be made on whether the project includes references to licensing and control measures to be taken by the competent authorities of the Member State where the research will be carried out.
9. A proposal that successfully passes the scientific evaluation, the national or local ethics reviews and the European ethics review will be presented for approval, on a case by case basis, to the Member States, meeting as a committee acting in accordance with the examination procedure. No project involving the use of human embryonic stem cells will be funded that does not obtain approval from the Member States.
10. The European Commission will continue to work to make the results from Community funded stem cell research widely accessible to all researchers, for the ultimate benefit of patients in all countries.
11. The European Commission will support actions and initiatives that contribute to a coordination and rationalisation of HESC research within a responsible ethical approach. In particular, the Commission will continue to support a European registry of human embryonic stem cell lines. Support for such a registry will allow a monitoring of existing human embryonic stem cells in Europe, will contribute to maximise their use by scientists and may help to avoid unnecessary derivations of new stem cell lines.
12. The European Commission will continue with the current practice and will not submit to the committee acting in accordance with the examination procedure proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells. The exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells.

### **Declaration on Energy**

'The Commission acknowledges the essential future role of end-user energy efficiency and renewable energy, the importance of better grids and storage in maximising their potential, and the need for market uptake measures to build capacity, improve governance and overcome market barriers so that energy efficiency and renewable energy solutions can be rolled out.

The Commission will endeavor to ensure that at least 85 % of the energy challenge budget of Horizon 2020 is spent in non-fossil fuels areas, within which at least 15 % of the overall energy challenge budget is spent on market up-take activities of existing renewable and energy efficiency technologies in the Intelligent Energy Europe III Programme. This Programme will be implemented by a dedicated management structure and will also include support for sustainable energy policy implementation, capacity building and mobilisation of financing for investment, as been undertaken until today.

The remaining part will be devoted to fossil based technologies and development options, which are considered essential for reaching the 2050 vision and supporting the transformation to a sustainable energy system.

Progress towards these targets will be monitored and the Commission shall regularly report on the progress achieved.'

### **Declaration on the Article 6.5.**

'Without prejudice to the annual budgetary procedure, it is the Commission's intention to present in the context of the structured dialogue with the European Parliament an annual report on the implementation of the budget breakdown set out in Annex II of Horizon 2020 by priorities and specific objectives within these priorities, including any application of Article 6(5).'

### **Declaration on Article 12**

'Upon request, the Commission will present the adopted work programmes to the responsible Committee in the European Parliament.'

### **Declaration on Seal of Excellence**

'Union level intervention enables EU-wide competition to select the best proposals, thereby raising levels of excellence and providing visibility for leading research and innovation.'

The Commission considers that positively evaluated European Research Council, Marie Skłodowska-Curie, teaming actions, phase-2 SME instrument or collaborative project proposals that could not be funded for budgetary reasons, have still met the Horizon 2020 criterion of excellence.

Upon approval of the participants, this information can be shared with the responsible authorities.

The Commission therefore welcomes any initiatives to fund such projects by national, regional or private sources. In this context, cohesion policy also has a key role to play through building capacity.'

### **Declaration on Spreading excellence and widening participation**

'The Commission is committed to set up and implement the measures to close the research and innovation divide in Europe under the new heading "Spreading Excellence and widening participation". The level of funding foreseen for these measures will not be lower than the amount spent in the Seventh Framework Programme on the actions addressing "widening participation".'

The new activities of COST undertaken in the context of "widening participation" should be supported by the budget allocated to "Spreading excellence and widening participation". The activities of COST which do not fall thereunder, and which should be of a equal order of magnitude in terms of budget, should be supported from the budget allocated to "6. Europe in a changing World — Inclusive, innovative and reflective societies".'

The major part of the activities related to the Policy Support Facility and to the transnational networks of National Contact points should also be supported by the budget allocated to "6. Europe in a changing World — Inclusive, innovative and reflective societies".'

### **Declaration on the SME instrument**

'SME support in Horizon 2020 is of major importance and represents a prominent part to achieve its objective to foster innovation, economic growth and job creation. Therefore, the Commission will ensure high visibility of SME support in Horizon 2020, in particular through the SME instrument in the work programmes, guidelines and communication activities. All efforts will be undertaken that it is easy and straightforward for SMEs to identify and use the opportunities provided for them in the Societal Challenges and LEITs.'

The SME instrument will be implemented through a single centralised management structure responsible for the evaluation and management of the projects, including the use of common IT systems and business processes.'

The SME-instrument shall attract the most ambitious innovation projects of SMEs. It will be implemented primarily in a bottom up manner via a continuously open call tailored to the needs of SMEs as set in the specific objective "innovation in SMEs" while taking into account priorities and objectives of LEITs and societal challenges and allowing for cross-challenge/LEITs proposals, underpinning the bottom-up approach. This call may be reviewed/renewed every two years, to take into account the biannual strategic programmes. Where appropriate, calls on specific topics of strategic interest can be organised in addition to the call described above. These calls will use the concept and procedures of the SME instrument as well as its single entry point for applicants and the accompanying mentoring and coaching services.'

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