Commissioner Carlos Moedas

Commissioner Moedas meets S.E. Mgr Alain Paul Lebeaupin, Apostolic Nuncio to the European Community

Friday, 13/03/2015

10:30 [Commissioner's Office]

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Contributors: B1, B7, C1, E1, E5
RTD colleague(s) at meeting:

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Key messages

- **Religious tolerance, preventive and repressive policies against violent radicalisation and the peaceful coexistence of religions** in Europe are of utmost importance. The Commission fully supports these aims and will continue to fund research in these areas.
- Whilst subject to strict oversight, **human embryonic stem cell research** is legal in the vast majority of Member States. After discussion in Council and Parliament, it was decided that Horizon 2020 could support research involving the use of human embryonic stem cells with strict conditions.
- The new Commission will continue to support **social innovation** in order to create new jobs and encourage growth, social inclusion and greater citizens' engagement in a Union of democratic change. Religious authorities can play a useful role in supporting social innovation.
- **Science diplomacy** can be a useful tool for furthering peace in international relations.

1. STEERING BRIEF

1.1 Scene setter

This briefing relates to the following areas within DG Research and Innovation: Social Innovation (B1), Religion and radicalization in Social Sciences and Humanities Research (B6), Research Ethics and Research Integrity (B7), Peace (Science Diplomacy) (C1), and Stem Cell Research (E1 and E5).

DG RTD has also consulted DG JUST which is in charge of the dialogue with churches, religious associations or communities and philosophical and non-confessional organisations that started in the early 1990s. This dialogue was given legal force by the Lisbon Treaty (Art.17 TFEU).

The European Commission will adopt in the months to come a European Agenda on Security for 2015-2020 which will address several aspects such as identifying policy tools to prevent and address radicalisation; stepping up the fight against terrorism financing; strengthening cooperation between Europol and other European agencies and reinforcing the fight against arms trafficking.

1.2 Objectives

- To ensure the Apolostolic Nuncio of the Commission's commitment to support the message of peace made by all religious authorities in Europe and to carry out research on the benefits of peaceful religious coexistence in Europe and the causes of violent radicalisation.
- To show that concerns related to stem cell research are taken into account and that the necessary measures have been put in place concerning the research projects involving the use of human embryonic stem cells.
- To point out that research ethics is the basis of the research funded under the EU Framework Programmes.
- To inform about the research and innovations actions carried out in the area of social innovation in Europe, an area where religious authorities could also play a useful role.
- To stress that science can play a useful peace role in diplomatic relations and therefore that science diplomacy should be encouraged.

1.3 Line to take

- Stress that there is a place for everyone in Europe independently of their religion, as indicated in the Orientation debate in the College on 21 January 2015.
- Refer to the Informal meeting of the Heads of State or Government of 12 February 2015 who in order to prevent radicalisation and safeguard values call for:
    - communication strategies to promote tolerance, non-discrimination, fundamental freedoms and solidarity throughout the EU, including through stepping up inter-faith and other community dialogue, and narratives to counter terrorist ideologies, including by giving a voice to victims;
    - initiatives regarding education, vocational training, job opportunities, social integration and rehabilitation in the judicial context to address factors contributing to radicalisation, including in prisons.
- Highlight the need for a peaceful coexistence of religions in Europe while acknowledging the tensions at play in societies. Consequently, the Commission is willing to support research in the area of religion and radicalisation.
- Highlight the importance of stem cell research, both "adult" cells and human embryonic stem cells. Stress the consensual approach taken by the EU institutions in this area.
- Highlight that social innovation contributes to achieving the goals of the new Commission around jobs, growth, fairness and democratic change, and that Commissioner Moedas will ensure that research innovation, including social innovation, will play an important role. Fully recognise the important role that the Church plays in this area.
- Highlight the importance of science diplomacy as a key element of international cooperation contributing to peace and prosperity.

2. SPEAKING POINTS

I fully share the ambitions of the dialogue between churches, religious associations or communities as well as philosophical and non-confessional organisations as stated by Art.17 of the TFEU and I am willing to offer the support of research to this dialogue. In particular, more research under Social Sciences and Humanities should be envisaged. The Commission will continue to apply strict ethical rules regarding research on stem cells.

2.1. Religion and radicalization in research in Social Sciences and Humanities (SSH)

- Religion or some aspects of religion have been the subject of research in Social Sciences and Humanities under FP7. In total, more than € 10 million have been invested in this field in FP7, mostly from the Humanities (History, Philosophy, Theology) and the Social Sciences (Political Sciences, and Sociology).
- In Horizon 2020, Societal Challenge 6, the Commission will invest around € 10 million in these fields. Thus, Horizon 2020 will support several topics which will reflect upon religious diversity in Europe as well as cultural and political history and current state of religious tolerance and co-existence, but which will also open the floor for investigating the roots and developments of political, societal and religious radicalisation.
- The following topics (that will have to be confirmed by the Programme Committee in the next months) are proposed for the 2016 and 2017 Horizon 2020 programme under the Societal Challenge 6 – "Europe in a changing world: inclusive, innovative and reflective societies":

1) **"Contemporary radicalisation trends in Europe"** researchers will investigate the scope, origins, dynamics and drivers of radicalisation, violence and hate crime with particular focus on young generation and the role of inequalities and discrimination for its radicalisation. This research is aiming at enhancing the knowledge base on the scope, origins, causes and dynamics of radicalisation, on provision of indicators for evaluating policies with regard to their effects on radicalisation and on giving recommendations on how to address religious fundamentalism in particular.

2) "**Situating Europe into the global context: the virtues of intercultural understanding"** will touch upon global trends of secularization and religious radicalisation from the comparative world-wide perspective. In this case, researchers will compare and analyse various types and experiences of the functioning of secular and religion-based states

and clarify reasons for and pathways of transformation between the two perceptions of the role of religion in state governance.

3) "Religious diversity in Europe – past, present and future" should consider the widest possible historical and geographical comparative perspective and touch upon the long history of the role which religious beliefs and affiliation to religious groups and communities played for the functioning of societal relations in Europe. It should also identify the political, social and economic tools for overcoming religious intolerance and ensuring the preservation of democratic European values of peaceful coexistence among the diverse religious communities existing in today's Europe.

4) "Shifting global geopolitics and Europe's preparedness for managing risks and fostering peace" will identify and investigate global and regional external risks facing the EU by considering the rise of radical Islamic groups, movements, conflicts and risks in Syria, Iraq, South Asia, Sub-Saharan Africa as well as in other countries and regions.

2.2 Human embryonic stem cell research

- Whilst subject to strict oversight, human embryonic stem cell research is legal in the vast majority of Member States[1]. After discussion in Council and Parliament, it was decided that Horizon 2020 could support research involving the use of human embryonic stem cells on the condition that (1) national legislation is respected (EU projects must follow the laws of the country in which the research is carried out), (2) projects are scientifically validated by peer review and undergo rigorous ethical review, and (3) EU funds may not be used for derivation of new stem cell lines or for research that destroys blastocysts including for the procurement of stem cells.

2.3. Social Innovation

- Social innovation can play a significant role in addressing societal challenges and responding to social needs. Social innovation is about improving peoples' lifes and peoples' capabilities –using the economy, through application of new technological and business solutions.
- In the last five years as part of the Innovation Union, DG Research and innovation, has been strongly supporting research, innovation, capability building and piloting and scaling

[1] It is unlawful in Slovakia, Lithuania and Poland, see annex 1

up of new schemes. We have invested more than 23 million in research in social innovation, and additionally supported big projects in health, environment, and agriculture and food.

- Horizon 2020 continues to support social innovation, by going beyond research towards piloting/ experimenting so as to have a higher impact at European level.
- The Juncker Commission has placed a big emphasis in ensuring that we bring together all stakeholders and resources of society and build synergies in favour of our common objectives for social cohesion and inclusion, for less poverty and better skills in Europe.

2.4 Science Diplomacy

- Not only is the EU the world's largest trading partner and aid donor, a key contributor to international organisations, and a significant provider of security in its own right and in cooperation with key strategic partners.
- The EU is also a leading global actor in research and innovation. This is especially important in a world of increasing fragmentation and geopolitical tensions where science can be a means of building bridges between people of different cultures and societies and help making informed political decisions to identify and jointly address shared challenges.
- Science diplomacy is an emerging term in the EU context and a recent one at the broader international level. It covers a broad range of initiatives and instruments that link international scientific cooperation with the external relations domain: from EU diplomatic relations with strategic international partners, to challenges in the European Neighbourhood, to those related to development policy, humanitarian assistance, trade and international negotiations on global challenges such as climate change.
- Science diplomacy has three main dimensions:
    1. First, 'science diplomacy' can help to support peace.
    2. 'science in diplomacy' provides evidence and advice to inform and support external action objectives, for instance towards a more effective sustainable development policy, or towards an equitable solution in the Middle East.
    3. Second, 'diplomacy for science' can facilitate international scientific cooperation, for example by brokering agreements on international multilateral initiatives, on joint research infrastructures, programmes and projects, or through bilateral and bi-regional policy dialogues.
- One example of 'science diplomacy for peace' is taking place in the Middle East. The synchrotron particle accelerator, SESAME, in Jordan, has the joint support from

countries often at odds, ranging from Israel to Iran, Pakistan, Egypt, and Palestine. It brings together researchers from countries that would normally never meet. SESAME now allows researchers to collaborate across the Middle East.

- SESAME has undoubtedly a great potential to contribute to broader science diplomacy in the region by fostering scientific collaboration between Europe, the Middle East and the EU's extended neighbourhood. The EU support not only provides additional funds for this project, it also sends a strong message of political endorsement to assure contributions from local partners.

3. DEFENSIVE POINTS

3.1. Research Ethics and Research Integrity

Q1. What are the main elements of the ethics approach in Horizon 2020?

Research ethics including research integrity is the basis of the trust society has in the scientific endeavour. It is a key in guaranteeing the quality of the research outcome. Horizon 2020 is unambiguous about its priorities and considers research ethics as a prerequisite condition for achieving excellence. There is no excellence when there is no ethics.

Horizon 2020 activities related to ethics have two main pillars. The first focuses on minimising the breaches of ethics principles and related legislation in the activities funded. The second aims at promoting the highest ethical standards in the research and innovation system, in the EU and internationally.

Q2. How is ethics compliance ensured in activities funded under Horizon 2020?

Horizon 2020 has a robust ethics legal framework. All funded activities will need to comply with the ethical principles and the relevant National, Union and international legislation including the Charter of Fundamental Rights.

This is ensured by the Ethics Appraisal Scheme. It starts at the project proposal stage with the Ethics Review process. For each project raising ethical issues, prior to the signature of a contract, an analysis is conducted by independent ethics experts. The concerned projects are then monitored by the EC project officers and when required, by the help of experts. The type of issues is very diverse: human involvement and intervention (human subjects in research), data protection, dual use, malevolent use of research results, animal welfare, fair benefit sharing, environment protection, etc.

In the case some research activities are carried out outside the Union, Horizon 2020 requires that the same research would have been allowed in an EU Member State. The objective of this measure is to reduce the risk of "ethics dumping"; the exportation of unethical practices outside the EU.

Q3. How does Horizon 2020 promote high ethical standards?

At policy level, beyond the ethics appraisal scheme, Horizon 2020 regulation stresses "the need to promote the highest ethical standards".

Concretely, this will for example be achieved via activities to:

- Better understand the socio-economic costs associated with research misconduct, its deep roots and the way to effectively promote research integrity.

• Support the design of effective responses to the risks of ethics dumping in public and private research via practical methodologies to improve the adherence to high ethical standards in areas of the world where it is most needed

As regards research integrity, the commission services are developing a Research integrity strategy and a research integrity code of conduct for Horizon 2020 activities. In addition my services have started close cooperation with the Research Integrity responsible authorities in the Member States in order to facilitate the exchange of good practice and a possible alignment of activities to foster the responsible conduct of research.

Q4. What type of ethics related research is funded under Horizon 2020?

Horizon 2020 builds on the previous research programmes (FP7 and FP6) which have financed several projects in the area of research ethics along the following main axis:

• Networking or capacity building, through for example the support for the European network of National Research Ethics Committees and the European Forum of National Bioethics Committees

• Research on privacy issues related to new technologies and applications, from biometrics for security through to the Internet of Things.

• Research into ethical implications of new applications or emerging technologies, such as synthetic biology and human enhancement.

All these activities not only improve the knowledge base or facilitate the work of the actors but also have an impact on the legislative process at the EU level and have provided substantial input to the design and implementation of EU legislation (i.e. clinical trials, data protection, dual use, animal protection).

3.2. Stem cells

Q1. Why is stem cell research important and included in Horizon 2020?

Stem cells are the body's supplier of new cells. Stem cells fix our injured or diseased tissues and replace cells when they routinely die. They keep us healthy and prevent us from ageing prematurely. The best example of the use of stem cells in therapy is bone marrow transplantation for overcoming cancer of the blood. These are tissue-specific or "adult" cells and can only be used for regenerating blood. But for many tissues the only way to obtain the cells needed is by cultivating embryonic stem cells, which can potentially form any of the hundreds of cell types found in the body and which can multiply indefinitely. The first isolation and culturing of human embryonic stem cells in 1998 stirred great interest, particularly in view of the potential of these cells for the treatment of incurable diseases, such as Parkinson's or blindness, and opened-up the field of regenerative medicine.

Research on stem cells is also carried out in order to better understand basic biological processes, such as development and differentiation, to make models of disease in order to test new drugs ("disease in the dish"), to develop toxicity testing systems that replace the use of

animals in research, to provide new treatment options for cancer and to develop advanced therapies to treat rare, common and incurable diseases.

Because of its high potential stem cell therapy is seen as a possible next revolution in medical treatment providing enormous possibilities for growth and diverse applications. Europe has a very strong science base in the area and numerous efforts are being undertaken by Member States and the EU to stimulate innovation in the field, develop the associated industry and translate results into treatments for patients.

Q2. What is the European Commission's position on human embryonic stem cells and how is human embryonic stem cell research handled in Horizon 2020?

For the Commission, human embryonic stem cells are an important field of study; however, they are controversial because they are obtained from *in vitro* fertilisation programmes when spare blastocysts[2] are donated for research and are not implanted.

Whilst subject to strict oversight, human embryonic stem cell research is legal in the vast majority of Member States[3]. After discussion in Council and Parliament, it was decided that Horizon 2020 could support research involving the use of human embryonic stem cells on the condition that:

- National legislation is respected – EU projects must follow the laws of the country in which the research is carried out;
- Projects be scientifically validated by peer review and undergo rigorous ethical review;
- EU funds may not be used for derivation of new stem cell lines or for research that destroys blastocysts including for the procurement of stem cells.

The full position is set out in a Commission Statement published in the Official Journal at the same time as the Horizon 2020 decision[4] and the internal business process for projects involving use of human embryonic stem cells is attached in annex 2.

In order to encourage innovation, the Commission does not favour any one type of stem cell over others in research; subject to the conditions mentioned above, it is science that should determine the best cell type for a particular use and that to this end all avenues should be kept open for research as needed. In the Seventh Framework Programme, of the 87 projects involving stem cells supported by the Health programme, 27 involve human embryonic stem cells.

Q3. Are there alternatives to human embryonic stem cells?

Owing to their unique characteristics of being able to form any of the cells in the body and to multiply indefinitely, no alternative can fulfil all their functions. The nearest alternative is the

[2] A blastocyst is the structure consisting of about a hundred cells formed at about five or six days after fertilisation and not yet implanted in the uterus.
[3] It is unlawful in Slovakia, Lithuania and Poland, see annex 1
[4] Official Journal of the European Union, C373/12 of 20.12.2013.

induced pluripotent stem cell which is created from adult tissue without destruction of the blastocyst. These cells are now being used extensively in drug testing but their clinical use is limited because of the genetic modifications they carry. In addition, the natural embryonic cell will always be needed for studying development and for comparative purposes.

It should be noted that at the moment the number of human embryonic stem cell lines banked[5] means there is not a great pressure to produce new lines. By collating information on the characteristics of the different lines that have been developed the European registry helps avoid duplication and unnecessary blastocyst destruction.

Q4. What is the status of clinical research based on human embryonic stem cells?

World-wide there are now 12 registered clinical trials of therapies based on human embryonic stem cells[6]. Of these, three are taking place in Europe; one for heart repair in Paris and 2 for blindness in London. It is probable that more products of human embryonic stem cell research will reach the clinical trial phase in the near future. The EU funds clinical research on innovative therapies, including for children and vulnerable populations, and there is currently a drive in the field of rare diseases. All EU-funded clinical trials are subject to strict ethical review and management during the life of the project. As health care issues, clinical trial regulation and ethical rules are a Member State competence.

Q5. What happened to the European Citizens Initiative "One of us"?

This Citizens Initiative, which proposed a ban on human embryonic stem cell research, was answered by the Commission on 28 May 2014[7]. Commissioner Máire Geoghegan-Quinn said at the time:

> *"We have engaged with this Citizens' Initiative and given its request all due attention. However, Member States and the European Parliament agreed to continue funding research in this area for a reason. Embryonic stem cells are unique and offer the potential for life-saving treatments, with clinical trials already underway. The Commission will continue to apply the strict ethical rules and restrictions in place for EU-funded research, including that we will not fund the destruction of embryos."*[8]

Q6. What is the Commission's position on mitochondrial donation (3-parent in vitro fertilisation)?

Mitochondrial donation is a new technique to help parents with genetic disorders of the mitochondria. It involves the mother's egg nucleus being transplanted into a donor egg from which the nucleus has been removed. It has been in the news recently because on 24 Feb 2015, following approval in the Commons, the UK Upper House voted to pass regulations permitting mitochondrial donation, making the UK the first country in the world to legislate for the use of mitochondrial donation techniques in treatment.

The EU has supported biomedical research underlying mitochondrial disease; however, assisted reproduction is not a priority in Horizon 2020.

[5] Around 600 in European human stem cell registry www hescreg.eu
[6] See list in annex 3
[7] COM(2014) 355 final
[8] European Commission press release IP/14/608, 28 May 2014

4. BACKGROUND INFORMATION

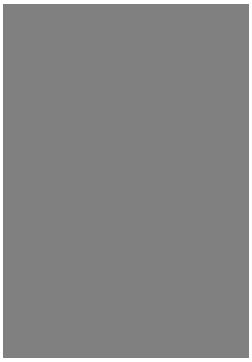
4.1 Curriculum vitae of S.E. Mgr Alain Paul Lebeaupin

CURRICULUM VITAE

de

S.E. Mgr Alain Paul LEBEAUPIN

Nonce Apostolique auprès de l'Union Européenne



4.2. Dialogue with churches, religious associations or communities and philosophical and non-confessional organisations - under the responsibility of DG JUST

Since the early 1990s, the Commission has developed a dialogue that is probably unique in the world: European political institutions seek the opinion of religions and communities of convictions in order to factor their views into the policy making process. Dialogue with "churches, religious associations or communities, philosophical and non-confessional organisations" was given legal force by the Lisbon Treaty (Article 17 TFEU). This is governed by guidelines established in 2013.

Objective A two-way discussion on policy. The Commission stands ready to discuss policy issues where the EU has a competence and take their views into account in the policy making process. It also proactively consults religious and non-confessional organisations on relevant issues (eg. freedom of religion or belief, migration, social policies).

Dialogue partners The guidelines specify: "dialogue partners can be churches, religious associations or communities as well as philosophical and non-confessional organisations that are recognized or registered as such at national level and adhere to European values. There is no official recognition or registration of interlocutors at the European level." All dialogue partners are encouraged to register under the EU Transparency Register, but so far this is voluntary.[9] There are in total about 50 registered organisations of which the vast majority are religious organisations. Their numbers are growing.

Issues Recent included Kosher/Halal slaughtering versus animal welfare (SANCO); climate change and migration (CLIMA/HOME); Guidelines on freedom of religion and belief (EEAS); Antidiscrimination; Anti-Semitism/Racism, Charter of Fundamental Rights (Freedom of conscience, freedom of speech, freedom of religion and beliefs), Europe of the citizen (JUST); Labour market/European Social model (EMPL); TTIP (DG TRADE), the European elections and the future of the EU in general (the subject in June 2014). The place of religion in the public space has become a focal point for legal conflict in many European countries in recent years, which is reflected by the rising number of cases before national courts and the European Court of Human Right – notably the place of religious symbols in the public space and "life-stance" issues such as embryo stem cell research, abortion and euthanasia.

Meetings The customary pattern has been an annual high-level meeting with the Presidents of EP, Council and Commission with about 20 religious leaders or non-confessional representatives respectively. These 4-hour high-level meetings are the flagship events of the dialogue and include a press conference. The June 2014 meeting included the innovation of a joint declaration by the religious leaders and the Presidents of the three institutions (on the case of [redacted], the [redacted] condemned to death for

[9] The register includes a special category for "representative offices of churches and religions". The non-confessional organisations register under "civil society" or any other category they regard as appropriate.

apostasy[10]). The meetings are supplemented 5-6 dialogue seminars per year on working level with individual organisations and stakeholders.

Consultations "Ad-hoc consultations" are a recent instrument which focuses on specific and timely input on certain policy documents. A first ad-hoc consultation was organised in 2012 in the context of drafting "EU guidelines on religion and belief", adopted by the Council in June 2013. In the process we pro-actively consulted the main Christian churches, a Jewish and a Muslim organisation as well as a Humanist and a Free-tinker organisation. The outcome was tangible and rewarding for all sides as a concrete result was attained in relatively short time.

4.3. Religion in Research in Social Sciences and Humanities(SSH)

Religion or some aspects of religion have been the subject of research in Social Sciences and Humanities under FP7. Thus, the following projects have been funded in this area:

- **ACCEPT PLURALISM (Tolerance, pluralism and social cohesion: responding to the challenges of the 21st century in Europe)** - Duration: 2010–2013; EU contribution: 2,601,430 €
  The project addressed the need to explore and understand tolerance of ethnic, cultural and religious diversity in European societies and sought to identify key messages for policymakers. In particular the project analysed the kinds of tolerance existing in practice in 14 EU Member States and one candidate country.
- **RELIGARE (Religious diversity and secular models in Europe: innovative approaches to law and policy)** - Duration: 2010–2013; EU contribution: 2,699,943 €
  RELIGARE focused on religions, belonging, beliefs and secularism. The project investigated the diversity of convictions in contemporary Europe with a focus on law and on questions relating to management of pluralism under State Law.
- **REMC (Religious education in a multicultural society: school and home in comparative context)** – Duration: 2008-2009: EU Contribution: 828.842 €
  This project explored how religious/secular beliefs are formed in the arenas of the education system and the family across different EU country contexts.
- **FACIT (Faith based organization and exclusion in European cities)** – Duration: 2008-2010; EU contribution: 1,495,980 €
  The project examined the current role of faith based organisations in matters of poverty and other forms of social exclusion (such as homelessness or undocumented persons) in cities. A faith based organisation is any organisation that refers directly or indirectly to religion or religious values, and functions as a welfare provider or as a political actor.
- **IME (Identities and modernities in Europe: European and national identity construction programmes, politics, culture, history and religion)** – Duration: 2009 – 2012; EU contribution: 1,447,773 €
  The project addressed three major issues regarding European identities: what they are, in what ways they have been formed and what trajectories they may take in the future.

[10] This was referenced by Secretary of State Kerry and widely covered in the [redacted] media

- **RESPECT (Towards a topography of tolerance and equal respect: a comparative study of policies for the distribution of public spaces in culturally diverse societies)** – Duration: 2010 – 2011; EU contribution: 1,341,533 €
  The RESPECT project aimed to address the issue of tolerance in the distribution of public spaces from both a theoretical and applied perspective, employing the tools of comparative analysis across a highly representative set of European and non-European countries.
- **EURISLAM (Finding a place for Islam in Europe: cultural interactions between Muslim immigrants and receiving societies)** – Duration: 2009-2012; EU contribution: 1,448,283 €
  The project explored how different traditions of national identity, citizenship and church-state relations have influenced European immigration countries' incorporation of Islam and the consequences of these approaches for patterns of cultural distance and interaction between Muslim immigrants and their descendants and the receiving society.

Moreover, under the ERANET **HERA JRP CE (Humanities in the European Research Area – Cultural Encounters)** - Duration: 2012 – 2016; EU contribution: 6,000,000 €, four out of the 18 projects co-funded through this ERANET are on religion:

- **Currents of Faith, Places of History: Connections, Moral Circumscriptions and World-** Places of History brings together a multidisciplinary team of scholars who share a concern for religion, mobility, place and heritage in the Atlantic space. Our goal is to rethink creatively theories of Atlantic history by focusing on 'religious Diasporas' via three main concepts: ideas of 'connections', 'moral circumscriptions' and 'world-making'.
- **Defining and Identifying Middle Eastern Christian Communities in Europe (DIMECCE)**The objectives of this interdisciplinary project are to explore the migrant experiences of Middle Eastern Christian communities in Europe in order to identify the cultural encounters taking place and to examine their impact on defining and shaping identities. The European context is central to understanding the similarities and differences of these experiences and can add to current understandings of the categorization of migrants and its implications on integration and the construction of identity within migrant groups.
- **Encounters with the Orient in Early Modern European Scholarship (EOS)**The project will explore how the Orient changed from being a source for Christian truths to being an object of cultural studies. The three main objectives will be 1) to describe the scholarly and religious incentives for this encounter between Europe and the Orient; 2) to document the exchange of knowledge, ideas, values and material objects this encounter stimulated in the early modern period, and 3) to explore the institution- al, conceptual and religious transformations which the encounter initiated in theology and Biblical studies, in the teaching and learning of Arabic and other Oriental languages, in literature and poetry, and in historical and anthropological thinking in general.
- **Iconic Religion. How Imaginaries of Religious Encounter Structure Urban Space (IcoRel)** The interdisciplinary research group focuses on religious icons and icons of religious encounter in the metropolises of Amsterdam, Berlin and London. In order to consider the complex nature of icons and to analyze how the religious dimension may become dominant over other dimensions of meaning, *Iconic Religion* combines spatial, material-aesthetic, visual analysis, and communicative-semiotic approaches with dis- course analysis and reception studies. The project expects to achieve

research results on the mechanisms of how religious images in the urban space construct either stereotypes or concepts of successful cultural encounter.

5. ANNEX(ES)

5.1 Human stem cell regulations and legislation in Europe (May 2010)

Annex 1: Human stem cell regulations and legislation in Europe (May 2010)

Country	Reproductive cloning prevented by national law	Research authorised by national law on				Prohibition of human embryonic stem cell (hESC) research	No specific legislation regarding hESC research	Ministry or official body in charge
		Stem cells*	Human embryos		Aborted foetuses			
			Procurement of stem cells from super-numerary embryos	Creation of human embryos for research purposes**				
Austria[1,2]	●	●						Federal Chancellery
Belgium	●		●	●				Public Health & Research (W) Justice & Health (F)
Bulgaria[3,4]	●						●	Health
Croatia[3,4]							●	N/A
Cyprus[3,4]	●						●	Independent Body
Czech Republic[3,4]	●		●					Health
Denmark[3]	●		●					Science Technology and Innovation
Estonia[3,4]	●		●					Social Affairs
Finland	●		●		●			Social Affairs and Health
France	●		●		●			Health
Germany	●	●						Federal Ministry of Health
Greece[3,4]	●		●					Development and Health
Hungary[3,4]	●		●		●			Health
Iceland[3,4]	●		●					Health and Social Security
Ireland		●						Department of Health and Children
Italy	●	●			●			Health
Lithuania[1,3,4]						●		Health
Luxembourg[6]							●	Health
The Netherlands	●		●		●			Health, Welfare and Sports
Norway[3]	●		●		●			Health and Care Services
Poland[1]						●		Health and Social Affairs & National Education and Science
Portugal[3,4]	●		●					Health
Romania[3,4]	●						●	Health
Slovakia[1,3,4]	●				●	●		Health
Slovenia[3,4,7]	●		●		●			Health
Spain[3,4]	●		●		●			Health & Science and Innovation
Sweden[8]	●		●	●	●			Health and Social Affairs & Education
Switzerland[3,4]	●		●					Federal Office of Public Health
Turkey[3,9]	●						●	Health
United Kingdom	●		●	●	●			Department of Health

* Prohibiting the procurement of stem cells from supernumerary embryos but allowing the import and use of stem cell lines.
** SCNT is not considered in this table: Belgium, Sweden, UK, Spain and Portugal allow SCNT by law, while Finland and the Czech Republic neither prohibit nor allow it by law.
1. Countries that voted against the Council Decision on hESC research during FP7 (www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/intm/90654.pdf)
2. AT: The Austrian Bioethics Commission published an opinion on 16 March 2009 which recommends allowing hESC derivation from supernumerary IVF embryos.
3. Countries who have signed and ratified the 1997 Convention of the Council of Europe on Human Rights and Biomedicine CETS 164 (http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=4/16/2009&CL=ENG)
4. Countries who have ratified the 1998 Protocol on the Prohibition of Cloning in Human Beings CETS 168 (http://conventions.coe.int/Treaty/en/Treaties/Html/168.htm)

Specific national committee(s)	Competences of the committee members	Committee website(s)
Bioethics Commission	Medical experts (reproductive medicine, gynaecology, psychiatry, oncology, pathology), legal experts, sociologists and experts in philosophy, theology and microbiology.	www.bka.gv.at/DesktopDefault.aspx?TabID=3575&Alias=english
Advisory Committee on Bioethics[5]	Biologists, ethicists, lawyers, philosophers, physicians and theologians.	https://portal.health.fgov.be/portal/page?_pageid=56,512676&_dad=portal&_schema=PORTAL
Central Ethical Committee[5]	Medical doctors, pharmacist, pharmacologist and laywer.	Not available
N/A	N/A	N/A
National Bioethics Committee	Biologist, geneticist, medical doctor, psychologist and sociologist.	www.bioethics.gov.cy
(a) Bioethical Commission of the R & D Council and (b) Ethical Committee of the Ministry of Health[5]	Bioethicist, biologist, biotechnologist, ethicists, geneticist, immunologist, medical scientist, molecular biologists, philosophers, physiologist, sociologist and theologian.	www.vyzkum.cz/FrontClanek.aspx?idsekce=15908
Council of Ethics[5]	Bishop, former politician, journalist, lawyer, lay persons, scientists, teacher, theologian and vicar.	www.etiskraad.dk/sw293.asp
Council on Bioethics	Ethicists, lawyers, medical doctors and ministry representatives.	http://eetika.ut.struktuur.ee/260565
Sub-committee on Medical Research Ethics of the National Advisory Board on Health Care Ethics[5]	Ethicists, medical doctors, lawyers and lay persons.	www.etene.org/e/index.shtml
Biomedicine Agency[5]	Lay persons, philosophers, theologians, scientists and medical doctors.	www.agence-biomedecine.fr
(a) German National Ethics Council (Deutscher Ethikrat) and (b) Central Ethics Commission for Stem Cell Research[5]	(a) Scientists, politicians, lawyers, lay persons, philosophers, medical experts, bishop and theologians and (b) biologists, ethicists, medical experts and theologians.	www.nationalerethikrat.de www.rki.de/cln_049/nn_216782/EN/Content/Institute/DepartmentsUnits/StemCell/StemCell__node.html?__nnn=true
National Bioethics Commission	Lawyers, philosophers, scientists and theologians.	www.bioethics.gr/index.php?category_id=3
Health and Scientific Council/National Scientific and Ethical Committees[5]	Bioethicist, biologist, geneticist, lawyer, lay person, medical doctors, nurse and priest.	www.ett.hu (in Hungarian only)
National Bioethics Committee	Lawyers, medical doctors, philosophers, scientists and theologians.	www.visindasidanefnd.is
Irish Council for Bioethics[5]	Ethicists, lawyers, scientists, philosophers and physicians.	www.bioethics.ie/
National Bioethics Committee[5]	Ethicists, lawyers, medical doctors, scientists, pharmacologists and patient representative.	www.palazzochigi.it/bioetica/eng
Bioethics Committee	Ethicist, geneticist, lawyer, medical doctors, philosophers, psychologists, psychiatrist and priest.	http://bioetika.sam.lt/index.php?-1876243809
(a) National Consultative Bioethics Commission for Health and Life Sciences and (b) Committee for Research Ethics (Ministry of Health)	Government representative (Social Security), lawyers, medical doctors, social workers, teachers and theologians.	www.cne.public.lu/
Central Committee on Research Involving Human Subjects[5]	Ethicists, medical doctors, nurses, scientists and pharmacologists.	www.ccmo-online.nl
National Committee for Medical and Health Research Ethics[5]	Ethicists, lawyer, lay persons, pharmacist, philosopher and psychologist.	www.etikkom.no/In-English/
N/A	N/A	N/A
(a) National Committee for Reproductive Medicine and (b) National Council of Ethics for the Life Sciences[5]	(a) Biologists and medical doctors and (b) geneticists, legal experts, medical doctors, philosophers and theologians.	www.cnecv.gov.pt/cnecv/en/
Bioethics Commission of Health and Family	N/A	N/A
National Ethics Committee	Geneticist, medical doctor, ministry representative (Health), priest, sociologist and theologian.	www.health.gov.sk
(a) National Committee for Medically Assisted Reproduction and (b) National Medical Ethics Committee	(a) Ethicist, lawyer, medical doctor, ombudsman representative and psychologist and (b) ethicist, lay person, lawyer, physicians, psychologist, sociologist and theologian.	Not available
(a) National Commission on Human Reproduction and (b) Observatory of Law and Ethics	Scientists, lawyers, psychologists and government representatives (Health).	Not available
National Council on Medical Ethics	Ethicists, lawyer, medical doctors, politicians and ministry representative (Health and Social Affairs).	www.smer.se
National Advisory Commission on Biomedical Ethics[5]	Ethicists, lawyers, lay persons, medical doctors and scientists.	www.swissethics.ch www.bag.admin.ch/nek-cne/
Ethics Council[5]	Medical doctors, a pharmacist, and ministry representatives (Health).	Not available
(a) Human Fertilisation and Embryology Authority and (b) Human Genetics Commission[5]	Ethicists, journalist, lawyers, lay person, medical doctors and scientists.	www.hfea.gov.uk www.hgc.gov.uk

5. Apart from national committee(s), whether existing or not, there are local and/or regional ethical committees.
6. LU: A new law is under preparation. Opinion against human reproductive cloning has been given in 2004. Opinion for the authorisation of research on stem cells obtained from supernumerary embryos and of creation of embryos for therapeutic purposes has been given in 2003.
7. SI: Research on supernumerary embryos from IVF procedures (and thus the procurement of hESC) is allowed with zygotes or embryos until 14 days of development.
8. SE: Tissue from aborted fetuses may be used for medical purposes only.
9. TK: hESC research has been suspended at all levels by the Turkish Ministry of Health and legislation regarding hESC research is under preparation.

5.2 Business process for projects involving use of human embryonic stem cells (hEST) in Horizon 2020

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

Directorate E - Health

Brussels, 23 May 2014

BUSINESS PROCESS FOR PROJECTS INVOLVING USE OF HUMAN EMBRYONIC STEM CELLS (hESC) IN HORIZON 2020[1]

This process is mandatory in all parts of Horizon 2020 for all projects which involve use of human embryonic stem cells. It applies to full proposals only and is not needed for Stage 1 proposals in the 2-Stage submission process.

1. Scientific evaluation and ethics assessment

a. Proposals follow the standard grant proposal submission and evaluation as described in the Vademecum[2].
b. During the evaluation process, panel moderators need to ensure that proposals involving use of human embryonic stem cells are identified.
c. Consensus reports and Evaluation Summary Reports of proposals involving use of human embryonic stem cells and passing thresholds need to include the sentence: ***"Use of human embryonic stem cells is necessary to achieve the scientific objectives set out in the proposal".***
d. Proposals involving use of human embryonic stem cells and passing thresholds are submitted to ethics assessment as described in the Vademecum. No project will be funded without ethics clearance.
e. Proposals submitted to ethics assessment are examined by at least five assigned experts *(for the appointment of the experts, see section IV of the H2020 Vademecum).*
f. The experts assess each proposal on the basis of:
   a) Compliance with national and European legislations and procedures (as described in the Statement by the Commission) and the requirements in 2 a.c) below;
   b) The panel prepares an ethics assessment report, offers its opinion and prepares ethics requirements. The ethics requirements become contractual obligations;
   c) The panel indicates the time period within which the requirements have to be fulfilled. In addition, the panel indicates if the project should undergo ethics check and audit and indicates the appropriate timetable after the signature of the Grant Agreement.
g. On the basis of the ethics opinion, a proposal may be refused ethics clearance.

[1] Based on Statement by the Commission (OJ C 373, 20.12.2013, p.12)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:373:0012:0015:EN:PDF
[2] https://webgate.ec.europa.eu/fpfis/wikis/display/iknowplus/H2020+Documentation

2. Grant Agreement Preparation

a. The following items need to be included in the Description of Work

a) Any ethical requirements indicated in the Ethics Assessment Report.
b) A table indicating which project partners are going to use which hESC lines, their origin and date of derivation according to the following format:

Country	Beneficiary	hES cell line	Origin of cell line	Date of derivation

c) A statement that the human embryonic stem cell lines used in the project are registered in the European hESC registry (www.hescreg.eu) or, for lines not so registered, a statement confirming that:

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

b. Article 34.3 of the model grant agreement has to be complied with as indicated in the Annotated Model Grant Agreement. Note that this stipulates that approvals for all hESC work from institutional/local/national ethical committee(s) or other regulatory agencies should be provided and kept on file.

c. Grant Agreement Preparation Report indicates that all above requirements have been complied with and is signed by project officer.

3. Comitology

Before grant signature, Member State approval by vote needs to be obtained.A document containing the following is submitted to the committee acting in accordance with the examination procedure:

a. Project title and abstract;

b. List of participants;

c. The table of human embryonic stem cell lines and their place of use indicated in section 2b above.

4. Reporting, monitoring and audit

The issues included in the Grant Agreement and annex 1 must be strictly followed-up and implemented. Projects may be subjected to an ethics audit at any time during the life of the project, and 2 years after the end of the project. 30% of all types of research activities (e.g. SC1 collaborative research projects, ERC grants, Marie Skłodowska-Curie Actions, SME Instrument) involving the use of human embryonic stem cells will be audited.

a. Project officer checks all work on human embryonic stem cells mentioned in reports for compliance with the technical annex and authorisations and reports in the SYGMA IT tool for project assessment. Approval of reports by the PO is obligatory before any payment to the project can be made.

b. Any external review should include a report on compliance with ethical issues;

c. If requested by evaluation experts, ethical review or PO during negotiation, projects should include independent ethical advice (advisory board or individual expert) and particular attention should be paid by PO or ethical review to any report made by them.

d. On request by a PO or external review report, or if flagged during the Ethics Assessment, an ethics follow-up and audit may be carried out by the Ethics Sector, Directorate B, with external expertise and including a site visit if needed.

e. Projects are asked to provide relevant information on the hESC that they are using to the European hESC registry (www.hescreg.eu).

5. Introducing new hESC lines not listed in the technical annex

No research on hESC lines not mentioned in the technical annex may be undertaken. If a coordinator wishes during the course of a project to include work on new hESC lines not listed in the technical annex, Member State authorisation for the new lines needs to be obtained using the same procedure mentioned in section 3 above and a contract amendment is required.

6. Project Completion

a. The final report includes a questionnaire on ethics which requests details on how the requirements of the ethics review made at the beginning of the project have been complied with.

b. Project officer checks all work on human embryonic stem cells mentioned in reports for compliance with the technical annex and authorisations, reports as in intermediate reports and completes project assessment report which has to be approved before final payment can be made.

c. As an additional safeguard in the event of any possible irregularity the Commission may initiate a technical audit or review relating to the proper execution of the project up to 2 years after the end of the project.

5.3 Registered clinical trials involving human embryonic stem cells and human induced pluripotent stem cells (December 2014)

Human embryonic stem cells (in clinicaltrials.gov database):

These treatments all involve culturing human embryonic stem cells in the laboratory and then applying growth factors and other stimulants to direct their differentiation to the cells of interest. Most of the trials listed are safety studies of the treatments so efficacy is not expected to be evident at this stage; however, signs of efficacy have been noted in some of the blindness trials.

Spinal cord injury repair

For patients who have had accidents, such as falling from a ladder or a car crash. The treatment consists of transplanting nerve cells grown in the laboratory into the injury site in an attempt to rejoin the severed parts. The first trial, which has been completed, demonstrated safety of the treatment. The second trial will test increasing doses of cells to determine the optimum number for efficacy.

1. Safety Study of GRNOPC1 in Spinal Cord Injury
   Geron, USA
   Identifier: NCT01217008

2. Dose Escalation Study of AST-OPC1 in Spinal Cord Injury
   Asterias Biotherapeutics, INC, USA
   Identifier: NCT02302157

Heart repair

After heart attack, heart muscle cells die. This trial applies muscle progenitor cells in a gel patch to hearts of heart attack patients in order to regain heart beating function.

3. Transplantation of Human Embryonic Stem Cell-derived Progenitors in Severe Heart Failure (ESCORT)
   Assistance Publique - Hôpitaux de Paris (Menasché)
   Identifier: NCT02057900

Type 1 diabetes treatment

Type 1 or juvenile diabetes results from the autoimmune destruction of the insulin-producing beta cells in the pancreas. The subsequent lack of insulin leads to increased blood and urine glucose. Regular insulin injections are essential for survival. This treatment consists of growing insulin-secreting cells in the laboratory, placing them in a semi-permeable capsule that permits the diffusion of insulin and glucose but prevents antibody ingress, and placing it under the patient's skin.

4. A Safety, Tolerability, and Efficacy Study of VC-01™ Combination Product in Subjects With Type I Diabetes Mellitus
   Viacyte, USA
   Identifier: NCT02239354

Treatments for blindness

The eye is a favoured site for stem cell treatment because the immune system is weaker there than in other organs, meaning that transplanted cells are less prone to attack by the body's defences and require less suppression of the immune system by drugs. Moreover, the eye is relatively self-contained and could be removed easily in case of problems with the treatment. All the treatments in this section involve applying new retina cells derived in the laboratory from human embryonic stem cells in order to revive light sensitivity. One of the main differences between the trials concerns the method of application of the cells and whether or not they are applied in a biomaterial bandage to hold them in place.

The different forms of blindness studied include macular degeneration, which occurs in "dry" and "wet" forms, and usually affects older adults and results in a loss of vision in the center of the visual field; and Stargardt's macular degeneration, an inherited condition that usually starts between the ages of 6 and 12 years old and causes progressive vision loss usually to the point of legal blindness.

5. A Study Of Implantation Of Human Embryonic Stem Cell Derived Retinal Pigment Epithelium In Subjects With Acute Wet Age Related Macular Degeneration And Recent Rapid Vision Decline
   Pfizer-Univ Coll London (Coffey)
   Identifier: NCT01691261

6. Safety and Efficacy Study of OpRegen for Treatment of Advanced Dry-Form Age-Related Macular Degeneration
   Cell Cure Neurosciences Ltd, Israel
   Identifier: NCT02286089

7. Safety and Tolerability of Sub-retinal Transplantation of hESC Derived RPE (MA09-hRPE) Cells in Patients With Advanced Dry Age Related Macular Degeneration (Dry AMD)
   Advanced Cell Technology, USA
   Identifier: NCT01344993

8. A Phase I/IIa, Open-Label, Single-Center, Prospective Study to Determine the Safety and Tolerability of Sub-retinal Transplantation of Human Embryonic Stem Cell Derived Retinal Pigmented Epithelial(MA09-hRPE) Cells in Patients With Advanced Dry Age-related Macular Degeneration(AMD)
   CHA Bio & Diostech, Korea
   Identifier: NCT01674829

9. Safety and Tolerability of Sub-retinal Transplantation of Human Embryonic Stem Cell Derived Retinal Pigmented Epithelial (hESC-RPE) Cells in Patients With Stargardt's Macular Dystrophy (SMD)
   Advanced Cell Technology, UK (Bainbridge and Dhillon)
   Identifier: NCT01469832

10. Sub-retinal Transplantation of hESC Derived RPE(MA09-hRPE)Cells in Patients With Stargardt's Macular Dystrophy
    Advanced Cell Technology, USA

Identifier: NCT01345006

11. Safety and Tolerability of MA09-hRPE Cells in Patients With Stargardt's Macular Dystrophy (SMD)
    CHA Bio & Diostech, Korea
    Identifier: NCT01625559

12. Research With Retinal Cells Derived From Stem Cells for Myopic Macular Degeneration
    University of California, Los Angeles Advanced Cell Technology, USA
    Identifier: NCT02122159

Human induced pluripotent stem cells

One study has been initiated using human induced pluripotent stem cells as starting material for the treatment of eye disease in a similar way to the trials described above.

1. A Study of transplantation of autologous induced pluripotent stem cell (iPSC) derived retinal pigment epithelium (RPE) cell sheet in subjects with exudative age related macular degeneration

   RIKEN Laboratory for Retinal Regeneration, Japan
   WHO International Clinical Trials Registry Platform
   Identifier: JPRN-UMIN000011929