**Translating stemness: the governance of stem cell innovation in the US and in Europe**

(project proposal by XXX)

**Background.** The governance of biomedical innovation is among the thorniest policy issues for contemporary liberal democracies. Today, the clinical translation of stem cell research into clinical applications for patients (regenerative medicine) represents yet a novel regulatory challenge that will have a remarkable impact on innovation strategies both in the US and in Europe. In Europe the governance of regenerative medicine is harmonized through dedicated legislation composed of both directives and regulations; in the US, judicial controversies over stem cell treatments offered to patients before clinical validation (*USA v. Regenerative Sciences LLC*) have recently marked the emergence of a centralized governance regime, assigning the Food and Drug Administration a major oversight role in the field.

**Objectives.** The emergence and applicability of those models of governance deserve a deep comparative appraisal – one that has not been attempted yet. This is needed to both clarify what is happening and to improve policy-making options that, while fostering innovation, should also promote a critical consideration of the wider societal and ethical issues at stake.

*Specific objectives*:

1. Gain insight into the regulatory mechanisms concerning the development of stem cell-based therapies in the US, in comparison with European counterparts.
2. Identify common regulatory issues in the US and in Europe and produce recommendations to improve science policy in this field of translational medicine.

**Methodology**

*Connect*: get in contact with élite figures in US regulatory agencies, scientific societies, companies and patients’ associations and interview them for the project (contacts will start before departure).

*Analyze*: perform in-depth controversy research about the activity of stem cell clinics in the US to be compared with European cases.

*Map*: systematically map the regulatory differences between the US and Europe (deliberative policy analysis).

*Interpret*: adopting a co-productionist framework, uncover how policy-making about stem cell translation relies on the stipulation of scientific categories (e.g. cells-as-drugs) and how, in turn, science embeds specific ideas about acceptable and unacceptable forms of biomedical innovation.

*Disseminate*: write at least one academic paper, or a policy article in a scientific journal; illustrate the results of the project at the host institution and back in Europe through dedicated seminars or participation to academic conferences.

**Collaboration with the US partner**

Prof. XXX, director of the “XXX” Program at XXX University agreed to host this project. She has unique expertise in cutting-edge science policy research and collaborates with other top-class figures in both the humanities and the life sciences. The present proposal fits excellently with on-going research in stem cell governance at the XXX Program: Prof. XXX is thus the optimal host for this project. Furthermore, the applicant has gained considerable acquaintance with the topic of the project throughout his doctoral studies and his research activities both in Italy and France.

For these reasons, the collaboration between the applicant and the host institution promises to be fruitful and conducive to tangible academic achievements.