

# **Gene Editing in Brazil**

***-Brief remarks on the current scenario of ethics in research-***

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# Disclaimer

I hereby declare that, despite the fact that I am a full member of CONEP- National Commission for Ethics in Research (Brazil), and the Dean of the Life Sciences School at the Pontifical Catholic University of Paraná (Brazil), I am not officially representing none of these institutions and the remarks done in this presentation expresses only my personal opinion and experience.

# Legal and regulatory issues in Brazil concerning genetic manipulation

## LEGAL AND REGULATORY BODIES:

- **CNTBio-National Biosafety Technical Commission** is a multidisciplinary consulting and deliberating collegiate which provides technical support to the Government, which formulate, update and implement the National Biosafety Policy and establishes safety technical norms regarding the authorization of research- related activities and evaluation of their zoo-phytosanitary, human health and environmental risk.
- **ANVISA-Brazilian National Health Surveillance Agency**, is responsible for the approval, inspection and regulation of any products which involves the possibility of risk to health obtained as the result of genetic engineering.
  - **Just one article (6<sup>th</sup>) in the National Law of Biosecurity (Law 11.105 – March 24<sup>th</sup>, 2005): “...It is banned genetic engineering in human germinal cells, human zygotes and human embryo.”**
- **Note that this law has 41 articles and primarily was directed to legislate on genetically modified crops.**
  - **Due the lack of specific legislation on human research and assisted reproduction, the guidelines in these issues are the resolutions (not laws) enacted by CONEP or CFM.**

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## *LEGAL AND REGULATORY BODIES:*

- **CONEP/CNS-Brazil's National Committee for Ethics in Research**, whose members are appointed by the Health Ministry's National Health Council (CNS). CONEP is a multidisciplinary collegiate and is legally responsible for establishing ethical guidelines for health research as well as evaluating and ethical approving of research protocols which enrolls humans as participants.

**CNS Resolution #466/2012 (main guideline for ethics in research in Brazil) has no reference to the issue of human embryo research, but merely determine that all researches in the country, must be evaluated by an ethics committee in research. This resolution also mentions the Universal Declaration on the Human Genome and Human Rights (UNESCO, 1997).**

**CNS Resolution #340/2004 is an specific guideline to genetic researches and allows DNA editing only in somatic cells.**

**There`s no an ethic algorithm. The commission evaluate case by case.**

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## *LEGAL AND REGULATORY BODIES:*

- **CFM-Federal Council of Medicine**, is responsible for professional regulation in the area of medicine.

**CFM Resolution #2121 (September 24, 2015), allows researches with discarded human embryos from assisted reproduction processes and with a diagnosis of genetic disease-causing, but there`s no specific mention on DNA editing.**

# Gene editing in Brazil

- There are some research centers in Brazil working with gene editing and applying CRISPR/Cas9 technology.
- Research centers which are able to apply this technology are centralized in the South and in the Southeast Region of Brazil (mainly at São Paulo and Rio de Janeiro), which are the richest regions of the country and the most populated as well.
- As researches involving human genome manipulation of embryonic stem cells are forbidden in Brazil, these researches are focused on *in vitro* or *ex-vivo* gene editing in somatic cells.

# Gene editing in Brazil

- At this point, there`s no relevant public discussion about this issue in Brazil.
- It`s not exaggerated to say that the typical Brazilian citizen is not informed about the repercussions and the potential of CRISPR-Cas9 technology.
- The discussions, at this time, are restrict to some scientific associations and universities and this issue is virtually ignored of the current discussions at the political and governmental environment.
- Neither, social movements and religious instances, are not yet expressing opinions or guidelines specifically on this subject, at least in a public outreach manner, in contrast to what happened with their opinion about other issues that are already notorious and generic, like transgenic seeds and the use of human embryos in researches.
- In my opinion, Brazilian scientists are a little cautious about the potential risks of this technology. Colleagues with who I talked to, think that in the future this technology, like similar ones, would be “domesticated” and that the scientific community will be able to self regulate the applications of this molecular tool, and so help legislators to create specific laws.

# Final remarks

- Gene editing is possible since the seventies (TALENs).
- Gene editing by CRISPR-Cas9 tends to scare all of us. Not so much by the novelty, but by its accessibility.
- So far, I have not noticed any relevant initiative to improve the Brazilian legislation or regulatory procedures, in order to adapt it to the new possibilities of gene editing and its potential consequences.
- We should be more concerned on regulate application, instead of regulate researches with CRISPR-Cas9.
- Regulatory bodies in Brazil have become more flexible regarding the application of genetic engineering. An example is the recent CNTBio approval of the use of genetically mosquitoes to fight dengue epidemics.

**Thank you!**