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HAL Authorization

Eurostemcells- Legal update

Regulation of stem cell research in France By Aurélie Mahalatchimy* and Emmanuelle Rial-Sebbag**

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I- Research on human stem cells

A) Current legal position

In the French legal system, two pieces of legislation must be respected when a research is performed on human stem cells.

First, the rules regarding research on human participants must be fulfilled (a written protocol must be submitted including the information document and the consent form).

Second, specific rules apply to collection of human material (including the biobanking activity).

According to article L1121-1 of the French Public Health Code¹, three categories of research are considered to involve the human person:

- Interventional study (clinical trial)
- Interventional study (clinical trial) with minimal risk study
- Non-interventional study (clinical trial)

In case Human Stem Cells are considered to be to be part of a research involving the human person, and if the cells are used by an institution for its scientific purposes (case 1) or when an institution wants to preserve and prepare human tissues and cells, organs, blood and blood components or derivatives products in order to give them up to another institution for research purposes (case 2), the only opinion of a local Research Ethics Committee ("Comité de Protection des

¹ https://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=62D39AE001EEB74CFB7C5D5A2A517ECA.tpdila19v_2?idArticle=LEGIARTI000032722870&cidTexte=LEGITEXT000006072665&categorieLien=id&dateTexte=

Personnes”, CPP) must be seek. It will assess the quality of the information to research participants and if provided the informed consent for biobanking, the obtaining of informed consent and its modalities, the scientific and ethical relevance of the project. The French National Agency for the Safety of Medicines and Health Products (ANSM) should be informed of these research activities if they are conducted on the same site as therapeutic activities. In the latter case, The French National Agency for the Safety of Medicines and Health Products (ANSM) can request the suspension or the prohibition of the research activities for health safety reasons (Article L1243-3 of the French Public Health Code²)

In case Human Stem Cells are not considered to be to be part of a research involving the human person (for the biobanking activities, re-used of human cells), French law distinguishes activities for which a preceding declaration is required and activities that need to be authorised by the French Ministry of Research, and by the Health Regional Agency if the research institution is also a health establishment (providing care, therapeutic activities).

For more information, please see: https://appliweb.dgri.education.fr/appli_web/codecoh/IdentCodec.jsp (French)

In both case, an authorisation from the French National Agency for the Safety of Medicines and Health Products (ANSM) has to be obtained for interventional studies. Moreover, the French National Agency for the Safety of Medicines and Health Products (ANSM) has to be informed in case of other studies (interventional study with minimal risk and non-interventional study) (Article L1121-4 of the French Public Health Code³).

For more information, please see: [http://ansm.sante.fr/Activites/Essais-cliniques/Recherches-impliquant-la-personne-humaine-RIPH/\(offset\)/](http://ansm.sante.fr/Activites/Essais-cliniques/Recherches-impliquant-la-personne-humaine-RIPH/(offset)/) (French)

B) Ethical and regulatory oversight

Local Ethics Committee (“Comité de Protection des Personnes”) for ethical approval of the research project.

French National Agency for the Safety of Medicines and Health Products (ANSM)⁴ for authorization of interventional studies and to be informed in case of other studies (interventional study with minimal risk and non-interventional study)

French Ministry of Research⁵ and Health Regional Agency (“Agence Régionale de Santé”)⁶:

²https://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=97E7418CD65AE9B9B0BDBA09B73D57EC.tpdila19v_2?idArticle=LEGIARTI000025449694&cidTexte=LEGITEXT000006072665&categorieLien=id&dateTexte=

³<https://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006685833&dateTexte=&categorieLien=cid>

⁴ <http://ansm.sante.fr/>

⁵ <http://www.enseignementsup-recherche.gouv.fr/>

⁶ <https://www.ars.sante.fr/>

- To be jointly sent the preceding declaration of research if the research institution is also a health establishment (providing care, therapeutic activities).
- Can be opposed to the activities
- Can suspend or prohibit these activities at any time
- To jointly deliver the required authorization if the research institution is also a health establishment (providing care, therapeutic activities).

II- Research on human embryonic stem cells

A) Current legal position

After almost 20 years of prohibition and prohibition with exceptions, the 2011 law on bioethics as amended in 2013 authorises research on human embryos and embryonic stem cells under specific conditions:

- The scientific relevance of the research is established
- The research, whatever fundamental or applied, has a medical purpose
- In accordance with the current scientific knowledge, the research cannot be conducted without these human embryos or embryonic stem cells
- The research project complies with ethical principles for research on embryos and embryonic stem cells

Embryos used for research must come from the assisted reproduction process (IVF), and should no more be part of a parental project. Previous written informed consent must be obtained from the donors' couple, and should be renewed after three months. It is revocable at any time without reasons.

Research projects that meet these criteria can be authorised by the French Biomedicine Agency ("Agence de la Biomédecine").

B) Ethical and regulatory oversight

The French Biomedicine Agency ("Agence de la Biomédecine")⁷ delivers authorisation of research on human embryos and embryonic stem cells.

III- Selected bibliography

A) Laws, regulations, guidelines

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Law strengthening health safety for medicines and health products, LOI n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du

⁷ <https://www.agence-biomedecine.fr/>

médicament et des produits de santé
<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025053440&categorieLien=id>

Law on research involving the human person, LOI n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine
<https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025441587&categorieLien=id>

Law authorising research on human embryos and embryonic stem cells, LOI n° 2013-715 du 6 août 2013 tendant à modifier la loi n° 2011-814 du 7 juillet 2011 relative à la bioéthique en autorisant sous certaines conditions la recherche sur l'embryon et les cellules souches embryonnaires
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