



## **Ethics Assessment in Different Countries**

### **France**

*Delphine Stoffel, Ingrid Callies, Katrine Rojkova, and Sudeep Rangi*

*UNESCO*

June 2015

### **Annex 4.d**

#### **Ethical Assessment of Research and Innovation: A Comparative Analysis of Practices and Institutions in the EU and selected other countries**

#### ***Deliverable 1.1***

This deliverable and the work described in it is part of the project *Stakeholders Acting Together on the Ethical Impact Assessment of Research and Innovation - SATORI* - which received funding from the European Commission's Seventh Framework Programme (FP7/2007-2013) under grant agreement n° 612231



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## 1 Introduction

The aim of this report is to analyse the existing structures and agents for the ethical assessment of research and innovation (R&I) in France, both for the public and private sectors. It will analyse how the national and regional government have developed organisational structures, laws, policies and procedures for ethical assessment; how both publicly funded and private research and innovation systems address ethical issues in research and innovation; and how ethical assessment plays a role in the activities of professional groups and associations for research and innovation and of civil society organisations (CSOs).

On the 1<sup>st</sup> of January 2015 France had a population of 66.3 million inhabitants, with the capital, Paris, having 2.2 million inhabitants on the 1<sup>st</sup> of January 2014.<sup>1</sup> French is the national language throughout the French Republic, which is considered a unitary semi-presidential constitutional republic.

The nominal GDP<sup>2</sup> for France was \$2.817 trillion and the GDP per capita was \$44,099 per inhabitant in 2013.<sup>3</sup> In France, the major economic sectors are the following: industry, energy,<sup>4</sup> agriculture and tourism. The most important industrial sector is the chemical industry (including pharmaceutical).<sup>5</sup> Other sectors include telecommunication, aerospace, defence, shipbuilding, construction and civil engineering, textiles and the automobile industry sectors. Moreover, the two notable sectors are tourism and the weapon industry, with France being the fourth largest weapons exporter in the world.

In the R&D<sup>6</sup> sector the Gross Domestic Expenditure (GERD) in 2011 was \$53,428.41 million, this reflects the R&D intensity in France. The same year, the GERD as a percentage of GDP was 2.19%.<sup>7</sup> The spending in the field of R&D in France, compared to other OECD members, positions France as the fourth highest spender.

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<sup>1</sup>L'Institut national de la statistique et des études économiques.  
<http://www.insee.fr/fr/themes/theme.asp?theme=2>

<sup>2</sup> Gross Domestic Product

<sup>3</sup>The Statistics Portal. <http://www.statista.com/statistics/263593/gross-domestic-product-gdp-per-capita-in-france/>

<sup>4</sup> In the energy sector, France is the world-leading country in nuclear energy. In this domain, the EDP (Electricity of France) is France's largest provider that is part private part public, the government owing 70% of the capital.

<sup>5</sup> Sanofi, the biggest French pharmaceutical company, spent 4.8 billion Euros in R&D in 2013.

<sup>6</sup> Research and Development.

<sup>7</sup> OECD MSTI database, 2011 figures. [http://stats.oecd.org/Index.aspx?DataSetCode=MSTI\\_PUB](http://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB)

Percentage of GERD funded by	Government	Other national sources	Abroad
2011	35.15%	2.06%	7.75%

**Table 1<sup>8</sup>: The percentage of R&D expenditure financed by government, industry, other domestic sources, and sources abroad**

Percentage of GERD performed by	Business Enterprise sector	Higher Education sector	Government	Private non-profit sector
2011	63.95%	20.95%	13.85%	1.5%

**Table 2<sup>9</sup>: The percentage of R&D expenditure financed by government, industry, other domestic sources, and sources abroad**

Ethics assessment is carried out by both public and private ethics assessment boards. However, for research on human subjects as well as for research on animals, ethics clearance by competent state bodies is mandatory.<sup>10</sup> Therefore, research institutions do not necessarily house their own specific institutional mechanism for ethics clearance. When it comes to R&I in the field of biomedical research and life sciences, there are for instance the Committees of Protection of Persons (CPPs), the French National Agency for Safety of Medicine and Health Products (*ANSM*), the National Commission on Informatics and Liberty (*CNIL*). For ethics assessment of research on animals, there are the Ethical Committees for Animal Experimentation<sup>11</sup> and the National Commission on Animal Experimentation.<sup>12</sup> However, some establishments such as Institut Pasteur<sup>13</sup> or Agence Nationale de Recherches sur le Sida et les hépatites virales (*ANRS*) play a role in the ethics assessment of R&I. Most of them do not have their own internal ethics evaluation bodies and rely on independent experts.

Furthermore, some of the major R&D entities in the Higher education sector, such as for example the National Centre for Scientific Research (CNRS) and the National Institute for Health and Medical Research (INSERM), under the authority of the Ministry of Education and research, have established their own ethics committees. Several ethical evaluation committees of the major R&D implementing entities may be approached with a view of obtaining their opinions prior to launching research protocols. These committees are only institutional committees, not accredited under French law but sometimes registered with the Office for Human Research Protections (OHRP) in the United-States. In the higher education

<sup>8</sup> OECD MSTI database, 2011 figures. [http://stats.oecd.org/Index.aspx?DataSetCode=MSTI\\_PUB](http://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB)

<sup>9</sup> OECD MSTI database, 2011 figures. [http://stats.oecd.org/Index.aspx?DataSetCode=MSTI\\_PUB](http://stats.oecd.org/Index.aspx?DataSetCode=MSTI_PUB)

<sup>10</sup> Competent means here that it's in the state bodies' scope of application. Such as CPP, and C.E.E.A as well as CCTIRS and CNIL for the personal data.

<sup>11</sup> Les Comités d'éthique en expérimentation animale (C.E.E.A.).

<sup>12</sup> Commission nationale de l'expérimentation animale.

<sup>13</sup> Institute Pasteur plays an important role in ethics assessment as it has its own code of ethics that must be applied. This code guarantees that this private foundation that is a research foundation conducts its research in a rigorous ethical framework, respecting ethics in regard of research on the living, in regard to human dignity and human rights, according to ethical principles accepted by the international community.

sector, some researchers in the field of social and human sciences, especially those whose research protocols involve human persons, have started to create ethics committees in their laboratories.<sup>14</sup>

Historically, ethics assessment structures appeared in the 1970s. In France, in the 1970s and in the 1980s hospitals started creating their own local and independent ethic committees; at that time, there weren't any public ethics boards yet. Since French doctors were researchers as well, they had to abide to the international obligation of having their research protocols reviewed by an ethics board if they wanted to publish their research. Therefore, one can say that this change was due to demands on an international basis coming from the Anglo-Saxons approach to research. It was only in 1988 when the Huriet-Sérusclat Law was passed that the "Comités Consultatifs pour la protection des personnes dans la recherche biomédicale" (CCPPRBs) were established.<sup>15</sup> This is how the independent ethics committees in hospitals got fewer as a governmental institution was put in place.<sup>16</sup> The governmental institution that was established by the Huriet-Sérusclat Law aimed at protecting the human in biomedical research; therefore ethics assessment in France takes mainly place in this context.

When it comes to the development in ethics assessment in regard to evaluation of sanitary risks, this is related to the health crises in the 1990s, when there were various health scandals such as the contaminated blood scandal (1991), hormone of growth scandal (1992), the mad cow disease scandal or the asbestos scandal. These various crises lead for instance to the adoption in 1993 of the first agency of security<sup>17</sup> forming the French health surveillance system.<sup>18</sup>

## 2 National and regional government institutions and policies

This chapter will provide a discussion of the national government institutions and policies relating to research and innovation. In its sections, the following will be examined: the general institutional structure of the French government and government-controlled institutions; governmental institutions with a role in ethics assessment; and national laws and policies for ethics assessment.

### 2.1 Institutional structure of government

In this section, the general institutional structure of the French government and government-controlled institutions, as it relates to research and innovation, will be laid out. The following topics will be included in the discussion: the form of government; the nature of and relations

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<sup>14</sup>For example, CERNI – *Comité d'éthique pour les recherches non interventionnelles, le pôle Grenoble cognition* (Ethics committee for non-interventional research, Cluster Grenoble Cognition (Official web site : <http://www.grenoblecognition.fr/index.php/ethique/ethique-soumettre-un-dossier>).

<sup>15</sup> CCPPRB, today, they are called the Comité de protection des personnes (CPP).

<sup>16</sup> Jean-Christophe, Mino, et al., 'Le projet éthique de l'Institut Curie: une aide à la réflexion des professionnels', Laennex, 2005/3 Tome 53, pp.30-42

<sup>17</sup> Loi n° 93-5 du 4 janvier 1993 relative à la sécurité en matière de transfusion sanguine et de médicament.

<sup>18</sup> These scandals gave rise to the so-called « sécurité sanitaire » in France, a concept that defines various laws that have been adopted to safeguard patients and their rights, such as the law n° 93-5 du 4 janvier 1993 on safety in blood transfusion and medication.

between the executive, legislative and judicial branches; the major ministries and government organisations; and the role of government in research and innovation in the private sector.

## 2.2 General structure of government

France is a unitary semi-presidential Republic. Its current constitution is of the 5<sup>th</sup> Republic that was approved in 1958 by referendum (and amended since). The constitution has strengthened the authority of the executive power. The executive branch is made up of the President of the Republic<sup>19</sup> and the government, led by the Prime Minister, who is appointed by the President himself.<sup>20</sup> The government shapes to a great extent the agenda of the Parliament. The Parliament is the legislative body, bicameral, composed of the National Assembly and a Senate. The National Assembly deputies represent local constituencies, whereas the Senate represents territorial collectives. Both the National Assembly and Senate represent French citizens living abroad.<sup>21</sup> Both chambers conduct legislative sessions at separate locations and following different procedures. In case of disagreement between the two chambers, the National Assembly has the final authority.

## 2.3 Government organisations relevant to research and innovation

In regards to major ministries and government organisation relevant for R&I, on the national level, two main government ministries share the responsibility for R&I policy: the Ministry of Education, Higher Education and Research<sup>22</sup> (MENESR) and the Ministry for the Economy, Industry and Digital Affairs.<sup>23</sup> In addition, under direct authority of the Prime Minister, the highly endowed Commissariat-General for Investment<sup>24</sup> plays a complementary structuring role, being entrusted with the implementation of the “Investments for the Future Programme” launched in 2010.

Furthermore, the Ministry of social affairs, health and rights of women, has an office for clinical innovation and research. The Ministry of Health has recently for example launched a campaign in 2015 that calls for research projects on care and health care delivery.

Moreover, the public research institutions will be discussed in Section 3a, and the agencies that fund the research project carried out mostly by public research institutions, such as the National Research Agency (ANR),<sup>25</sup> Bpifrance<sup>26</sup> and the Agency for Environment and Energy Management (ADEME) will be discussed in Section 3c.

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<sup>19</sup> Currently Francois Hollande.

<sup>20</sup> Currently Manuel Valls.

<sup>21</sup> Assemblée nationale en France; <http://www2.assemblee-nationale.fr/decouvrir-l-assemblee/role-et-pouvoirs-de-l-assemblee-nationale/les-institutions-francaises-generalites/l-assemblee-nationale-et-le-senat-caracteres-generaux-du-parlement>

<sup>22</sup> Official web site of MENESR. <http://www.enseignementsup-recherche.gouv.fr/>

<sup>23</sup> Official web site of the French Ministry for the Economy, Industry and Digital Affairs.

<http://www.economie.gouv.fr/les-ministeres/missions-ministere-economie-redressement-productif-numerique>.

<sup>24</sup> Official web site of the Commissariat Général à l'Investissement. <http://www.gouvernement.fr/le-commissariat-general-a-l-investissement>

<sup>25</sup> Official website of ANR. <http://www.agence-nationale-recherche.fr/>

<sup>26</sup> Official web site of Bpifrance. <http://www.bpifrance.fr/>

## 2.4 Governmental institutions for ethics assessment

To start with, there is no specific committee dedicated to the ethics of research within the Ministry of Health. However, the law No. 2012-300 of 5 March 2012 on research involving the human person, called the “Jardé” Law (Loi n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine or loi dite Jardé) that has not yet entered into force, creates a national commission for research involving human beings, responsible for the coordination, harmonisation and assessment of Committees for the Protection of Persons, established under the supervision of the Minister for Health. The National Consultative Ethics Committee for Health and Life Sciences (CCNE)<sup>27</sup> was created by a presidential decree in 1983.<sup>28</sup> France was the first country to put in place an independent multi-disciplinary committee.<sup>29</sup> Since, the members of the committee are appointed by the President of the Republic, one can consider that the government plays an important role. The mission of the CCNE is to study scientific progress and its ethical issues. This committee produces opinions that are not binding but that can enlighten the government. In practice, the government often follows the opinions of the CCNE.

The Committees of Protection of Persons (CPP)<sup>30</sup> were created by law.<sup>31</sup> These committees must approve, monitor and review biomedical research protocols involving human beings. The CPPs are designated to assess research protocols they receive. The CPPs focus on the protection of persons in a given research project. Article L1123-1<sup>32</sup> of the Public health code states that the Minister of Health approves the CPPs and determines their geographical competence. Moreover, financial resources are granted by the State as well.

The French National Agency for Safety of Medicine and Health Products<sup>33</sup> was established by law.<sup>34</sup> The ANSM is a governmental agency placed under the supervision of the Ministry in charge of health, as well as funded by the government. The ANSM mission is to evaluate the safety of drugs and health products.<sup>35</sup> The ANSM conducts expert assessment of healthcare products and acts as a decision-making body in the field of sanitary regulation. Its General Manager takes decisions on behalf of the State. However, the ANSM is not directly involved in the ethical dimension. The aim of the ANSM is to fulfill its missions by adjudicating ethical clearance to research projects. However, safety can be conceived as an ethical issue. In

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<sup>27</sup> Comité consultatif national d'éthique pour les sciences de la vie et de la santé (CCNE).

<sup>28</sup> Decree No. 83-132 of 23 February 1983 establishing a National Consultative Ethics Committee for Life Sciences and Health (OJ of 25 February 1983).

<sup>29</sup> Pierre Le Coz, « Comité consultatif national d'éthique », Encyclopaedia Universalis

<sup>30</sup> Comités de Protection des Personnes (CPP).

<sup>31</sup> The CCPPRBs (Comités Consultatifs de Protection des Personnes dans la Recherche Biomédicale) were created in 1988 by the law called « Huriet-Sécrusclat », the CCPPRB were replaced by the law of the 9 of August 2004 concerning biomedical research on humans. (LOI n° 2004-806 du 9 août 2004 relative à la politique de santé publique)

<sup>32</sup> Article L1123-1, Modifié par LOI n°2011-1977 du 28 décembre 2011 - art. 59.

[http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=D427065F329F0B8671B4DA288DD9F8FB.tpdil a24v\\_3?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006685866&dateTexte=&categorieLien=cid](http://www.legifrance.gouv.fr/affichCodeArticle.do;jsessionid=D427065F329F0B8671B4DA288DD9F8FB.tpdil a24v_3?cidTexte=LEGITEXT000006072665&idArticle=LEGIARTI000006685866&dateTexte=&categorieLien=cid)

<sup>33</sup> Agence nationale de sécurité du médicament et des produits de santé (ANSM) .

<sup>34</sup> LOI n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits de santé

<sup>35</sup> Peigné Jérôme, « La publicité des produits de santé », Les tribunes de la santé, 2014/4 n°45, p.69-78

biomedical research, the ANSM guarantees patient safety.<sup>36</sup> The French Biomedicine Agency<sup>37</sup> is a governmental agency that deals with the collection and transplantation of human organs, tissues and cells, reproduction and embryology and human genetics. The ABM is a public institution under the authority of the Ministry of Health. The ABM has an orientation council (Conseil d'orientation) that guides the ABM when it comes to respecting the patients and donors on the basis of ethical principles.<sup>38</sup>

The French Health Authority<sup>39</sup> role is to assess scientifically certain medical practices with the aim of enhancing the quality of health care.<sup>40</sup> The High Council on Biotechnology<sup>41</sup> is an independent public body in charge of shedding light on the public decision makings in the areas of biotechnology, including GMOs.<sup>42</sup> The HCB is under the supervision of the Ministries in charge of the environment, agriculture, research, health and consumer affairs. The HCB is made up of two committees, a scientific committee<sup>43</sup> as well as an economic, ethical and social committee.<sup>44</sup> These committees are in charge of giving opinions and recommendations. The CS evaluates the impact of biotechnologies on the environment and on public health. The CEES's reflection is larger, as it takes in account economical, sociological and ethics impact of biotechnologies.

The French national Research Agency (ANR)<sup>45</sup> is a public organisation under the supervision of the Ministry of research.<sup>46</sup> It is a public administrative establishment that funds scientific research. The importance ANR assigns to the consideration of ethical issues is demonstrated by the adoption of a Code of ethics in 2009.<sup>47, 48</sup>

The Common advisory committee for ethics in agricultural research<sup>49</sup> was created by CIRAD<sup>50</sup> and by INRA.<sup>51</sup>

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<sup>36</sup> Interview of Dr Dominique Martin, General Manager of The French National Agency for Medicines and Health Products Safety (Agence nationale de sécurité du médicament et des produits de santé or ANSM), Mrs Carole Le Saulnier (Director of Legal and Regulatory Affairs at ANSM) and Dr Cécile Delval (Director of Assessment at ANSM).

<sup>37</sup> Agence de la biomédecine (ABM).

<sup>38</sup> Agence de la biomédecine. <http://www.agence-biomedecine.fr/Conseil-d-orientation>

<sup>39</sup> Haute Autorité de Santé (HAS).

<sup>40</sup> Byk Christian, Chapitre 5 : *Les agences sanitaires et la biomédecine : nouvelle légitimité technocratique et stratégie de partage du pouvoir*, Journal international de Bioéthique, 2014/1 vol 25 p.99-110

<sup>41</sup> Haut Conseil des biotechnologies.

<sup>42</sup> Genetically modified organisms.

<sup>43</sup> Comité scientifique(CS).

<sup>44</sup> Comité économique, éthique et social (CEES).

<sup>45</sup> Agence nationale de la recherche. <http://www.agence-nationale-recherche.fr/en/about-anr/about-the-french-national-research-agency/>

<sup>46</sup> Sénat français. <http://www.senat.fr/rap/a13-160-5/a13-160-58.html>

<sup>47</sup> Code of ethics, ANR – French National Research Agency, Réf.: DIR-REG-050809-L-01-01, 05/08/09: [http://www.agence-nationale-recherche.fr/fileadmin/user\\_upload/documents/uploaded/2009/code-of-ethics.pdf](http://www.agence-nationale-recherche.fr/fileadmin/user_upload/documents/uploaded/2009/code-of-ethics.pdf).

<sup>48</sup> More details in point 3.c on research funding organisations.

<sup>49</sup> CIRAD. <http://www.cirad.fr/qui-sommes-nous/organigramme/instances-et-comites/comite-consultatif-commun-d-ethique> and <http://www.cirad.fr/qui-sommes-nous/le-cirad-en-bref>

<sup>50</sup> Center for International Cooperation in Agricultural Research for Development.

<sup>51</sup> National Institute of Agronomic Research.



The Parliamentary Office for Evaluation of Scientific and Technological Choices<sup>52</sup> was created in 1983 by the National Assembly and the Senate to assess projects in highly technical fields. The two chambers of the French Parliament therefore decided to establish an inter-parliamentary Office, responsible for informing Parliament's action in science and technology. OPECST gathers information, implements study programs and makes scientific and technological assessments.<sup>53</sup>

The National Centre for Scientific Research (CNRS) is a public organisation under the responsibility of the French Ministry of Education and Research. The CNRS Ethics Committee,<sup>54</sup> COMETS, an independent advisory body, advises the Board of Directors of CNRS. Comets represents all disciplines in both type and parity of representation. The Comets is not directly involved in scientific controversies and does not address individual cases. However, in contact with the CNRS's Mediator, the Committee may examine concrete cases raising ethical concerns, contributing to its reflection. The committee issues opinions on general aspects of scientific research.<sup>55</sup>

The Ethics Committee of INSERM<sup>56</sup> was established by the INSERM,<sup>57</sup> in order to develop reflection on ethical issues raised by medical, scientific and clinical research in conformity with a vocation of being a full-fledged stakeholder in the dialogue between the medical and scientific communities and society as a whole. There is also a Scientific Integrity Office of the INSERM (*Délégation à l'intégrité scientifique* or DIS)<sup>58</sup>, which deals with individual situations where there are problems related to scientific integrity. Their mission is related to professional ethics.<sup>59</sup> In addition to the Ethics Committee, INSERM has established its Institutional Review Board,<sup>60</sup> CEEI/IRB, with the mission to provide advice on research projects involving humans, in order to protect the rights and welfare of the people involved in research.<sup>61</sup>

An agreement was reached between CNRS and INSERM that the CEEI/IRB delivers opinions regarding the compliance of research projects with ethical legal provisional and practices, while the Regulatory Bioethics Unit of the Institute of Biological Sciences (INSB) of CNRS is

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<sup>52</sup>L'Office parlementaire d'évaluation des choix scientifiques et technologiques (OPECST).  
<http://www.senat.fr/opepst/presentation.html#c581572>

<sup>53</sup> The OPECST focuses for instance on energy and energy policies, the environment new technologies, life science, biotechnology and research and innovation policies.

<sup>54</sup> Official web site of the CNRS. <http://www.cnrs.fr/comets/spip.php?article31>

<sup>55</sup> For more details see point 3.d on research performing organisations.

<sup>56</sup> Official website of the Comité d'éthique de l'INSERM. <http://www.ethique.inserm.fr/qu-est-ce-que-l-inserm/organigramme/comites/comite-d-ethique-de-l-inserm>.

<sup>57</sup> French National Institute of Health and Medical Research, a public scientific and technological institute, which operates under the joint authority of the French Ministry of Health and French Ministry of Research.

<sup>58</sup> INSERM. <http://english.inserm.fr/what-s-inserm/organisation-chart/committees/dis>

<sup>59</sup> Indeed, Inserm contributed to the development of a National Deontology Charter for research professions (Charte nationale de déontologie des métiers de la recherche) which is the actual Code of Conduct for Inserm researchers.

<sup>60</sup> Comité d'évaluation éthique de l'Inserm (CEEI/IRB).

<sup>61</sup> See point 3.d on research performing organisations.

deemed competent to deal with the issues related to the modification to be introduced into the legislation and regulation on bioethics.<sup>62</sup>

The Advisory Committee on the Treatment of Research Information in the Health Field<sup>63</sup> is under the authority of the Ministry of Research. This committee reviews information processed in the field of health research before referring to the National Commission for Information and Liberty (CNIL). Its role is to give its opinion on the research methodology, the need to use personal data and the relevance of this data in regards to the objective of the research aim. The CNIL is the national data protection agency that ensures the protection of the human identity, human rights, privacy and individual and public liberties. The CNIL is an independent administrative authority; however the government finances it.

The National Commission on Animal Experimentation<sup>64</sup> (CNEA) is under the supervision of the Ministry in charge of research as well as the one in charge of agriculture. The CNEA gives its opinion on proposed amendment of laws of regulations on animal experiments. The CNEA can be asked to give advice to the ministries for instance on subjects related to the methods to be put in place to avoid the use of living animals in experiments or recommendation in regards to the breeding of animals for laboratory use.

The National Committee for Ethics in Animal Research (CNREEA)<sup>65</sup> is placed with the CNEA. The CNREEA is in charge of producing opinions on ethical question related to animal experimentations.

The Ethical Committees for Animal Experimentation<sup>66</sup> are found throughout the country and are under the authority of the Ministry of research. These committees render an ethical evaluation of research projects using animals. However, the authorisation to conduct the research is formally given by the Ministry itself.

Furthermore, there are other institutional ethics committees, such as the ethics committees of the Institut Pasteur.

## 2.5 National laws and policies for ethics assessment

France has national legislation concerning human subject research in biomedical research, which is mostly regulated by the Public Health Code (articles L. 1121-1 et seq.).<sup>67</sup> Obligatory

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<sup>62</sup> See point 3.d research performing organisations.

<sup>63</sup> Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé (CCTIRS). <http://www.hcsp.fr/docspdf/adsp/adsp-39/ad397070.pdf>

<sup>64</sup> Commission nationale de l'expérimentation animale (CNEA). <http://ethique.ipbs.fr/commissionNationale.html>

<sup>65</sup> Comité national de réflexion éthique sur l'expérimentation animale (CNREEA). <http://www.legifrance.gouv.fr/affichCodeArticle.do?cidTexte=LEGITEXT000006071367&idArticle=LEGIARTI000027040122&dateTexte=&categorieLien=cid>

<sup>66</sup> Comités d'éthique en expérimentation animale (CEEA). <http://pstanimaleries.univ-tours.fr/comites-d-ethique/les-comites-d-ethique-en-experimentation-animale-334495.kjsp>

<sup>67</sup> Recently, a law deeply restructured this framework: the Law No. 2012-300 of 5 March 2012 on research involving the human person, called the "Jardé" Law (Loi n° 2012-300 du 5 mars 2012 relative aux recherches impliquant la personne humaine or loi dite Jardé). However, to date, this law is still not applicable. Indeed, the publication of the European "Regulation on Clinical Trials on Medicinal Products for Human Use" (2014/546/EU) by the European Commission suspended the implementation process of the "Jardé" Law. The new Regulation will apply no earlier than 28 May 2016.

ethics review is limited to “interventional research” and to the collection of human biological samples for scientific purposes.<sup>68</sup>

When using animals in research, since 2013,<sup>69</sup> in transposition of European Directive 2010/63/EU revising Directive 86/609/EEC on the protection of animals used for scientific purposes adopted on 22 September 2010, French legislation<sup>70</sup> requires ethical clearance by way of a favourable evaluation opinion issued by the Ethical Committees for Animal Experimentation<sup>71</sup> before experimentation on animals.

Furthermore, when it comes to legislation on impact assessment related to the environment, Article 5<sup>72</sup> of the French Charter of the Environment<sup>73</sup> spells out the requirement of a State to put in place risk assessment procedures in respect of activities that are likely to significantly affect the environment. The right to the environment in France is currently the subject of the Environment Code.<sup>74</sup> The provisions related to the environmental impact assessment are codified in Book I, Part II, Chapter II entitled “Environmental Evaluation” which is composed of two sections: Section 1: Impact assessment studies of works and development programmes and projects<sup>75</sup>; and Section 2: Evaluation of certain plans and documents with significant impact on the environment<sup>76</sup>. The contents of the impact assessment study are codified in Articles from L.122-1 to L.122-3 and in Article R.122-5 of the Code of the Environment. The content of the impact assessment is proportionate to the environmental sensitivity of the area affected by the project, the importance and nature of the works to be undertaken and their expected impact on the environment and human health.<sup>77</sup>

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<sup>68</sup> Clinical trials of medicinal products and medical devices, application of new medical methods, applied medical research, research in everyday care.

<sup>69</sup> Arrêté du 1er février 2013 relatif à l'évaluation éthique et à l'autorisation des projets impliquant l'utilisation d'animaux dans des procédures expérimentales. <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027038013&dateTexte=&categorieLien=id>

<sup>70</sup> French Rural and Maritime Fishing Code Articles from R214-117 to R214-126.

<sup>71</sup> Comités d'éthique en expérimentation animale (C.E.E.A.).

<sup>72</sup> When the occurrence of any damage, albeit unpredictable in the current state of scientific knowledge, may seriously and irreversibly harm the environment, public authorities shall, by applying the precautionary principle and in the areas within their jurisdiction, ensure the implementation of risk assessment procedures and the adoption of provisional and proportionate measures to preclude the occurrence of the damage” (Art. 5. - Lorsque la réalisation d'un dommage, bien qu'incertaine en l'état des connaissances scientifiques, pourrait affecter de manière grave et irréversible l'environnement, les autorités publiques veillent, par application du principe de précaution et dans leurs domaines d'attributions, à la mise en oeuvre de procédures d'évaluation des risques et à l'adoption de mesures provisoires et proportionnées afin de parer à la réalisation du dommage).

<sup>73</sup> The French Charter of the Environment of 2004, which is part of the constitutional legislative block by decision of the French Parliament and thus is part of the highest French law, proclaims in its Article 1 that, “Everyone has the right to live in a balanced environment which shows due respect to health” (“Chacun a le droit de vivre dans un environnement équilibré et respectueux de la santé”).

<sup>74</sup> Code de l'environnement, Version consolidée au 1 juin 2015. <http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006074220>

<sup>75</sup> Articles from L122-1 to L122-3-3 of the French Public Health Code.

<sup>76</sup> Articles from L122-4 to L122-12 of the French Public Health Code.

<sup>77</sup> France applies in the legislation the provisions of the Directive 85/337/CEE of the European Council of 27 June 1985, modified, on the assessment of the effects of certain public and private projects on the environment.

Moreover, there is the law n°96-1236 of the 30<sup>th</sup> December 1996 on air and the rational use of energy<sup>78</sup> which amends section 2 of the Act of 10 July 1976 and provides the supplements to the impact assessment studies of development projects. This impact assessment is done in regard to assessing the possible damages to the environment and human health under Article 19.

Different laws and regulations exist in regard to the creation of different institutions that have a role in ethics assessment, such as:

- Decree No. 83-132 (Decree No. 83-132 of 23 February 1983 establishing a National Consultative Ethics Committee for Life Sciences and Health (OJ of 25 February 1983)<sup>79</sup>
- Law ‘Huriet-Sécrusclat’ of 1988 that created the CCPPRBs, replaced by the CPPs created by the law of the 9 of August 2004 on public health policy<sup>80</sup>
- Law n°2011-2012 of the 29 December 2011 creating the French National Agency Safety of Medicine and Health Products
- Law n°98-535 of 1 July 1998 on strengthening health monitoring and control of product safety for humans creating the Sanitary Surveillance Institute
- The bioethics law of 2004 creating the French Biomedicine Agency
- The law of 13 August 2004 on health insurance creating the French Health Authority<sup>81</sup>
- Article 3 of Law N°2008-595 of 25 June 2008 on genetically modified organisms (GMOs) creating the High Council of Biotechnology<sup>82</sup>
- The French national Research Agency has the status of public administrative institution since the decree n°2006-963 of 1<sup>st</sup> August 2006 on the organisation and operation of the National Research Agency<sup>83</sup>

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<sup>78</sup> Loi n° 96-1236 du 30 décembre 1996 sur l'air et l'utilisation rationnelle de l'énergie.

<http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000381337>

<sup>79</sup> Décret n° 83-132 du 23 février 1983 portant création d'un Comité consultatif national d'éthique pour les sciences de la vie et de la santé (JO du 25 février

1983).<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000687778&dateTexte=20130207>

<sup>80</sup> Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique.

<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000787078&dateTexte=&categorieLien=id>

<sup>81</sup> Loi n° 2004-810 du 13 août 2004 relative à l'assurance

maladie.<http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000625158&dateTexte=&categorieLien=id>

<sup>82</sup> Loi n°2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés (OGM).

<http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000019066077&categorieLien=id>

<sup>83</sup> Décret n° 2006-963 du 1er août 2006 portant organisation et fonctionnement de l'Agence nationale de la recherche.

- Decree n°2015-210 of 24 February 2015 establishing the National Council of acquired immunodeficiency syndrome (AIDS) and chronic viral hepatitis, created the French National AIDS & Viral Hepatitis Council<sup>84</sup>
- The Parliamentary Office for Evaluation of Scientific and Technological Choices was created by a law n° n° 83-609 du 8 July 1983<sup>85</sup>
- The Advisory Committee on the Treatment of Research Information in the Health Field was created by a law n°94-548 1 July 1994<sup>86</sup>
- The National Commission on Animal Experimentation was established by the decree No. 87-848 of 19 October 1987 on the experiments carried out on animals<sup>87</sup>
- The National Committee for Ethics in Animal Research was established by the decree n°2013-118 of 1 February 2013 on the protection of animals used for scientific purposes<sup>88</sup>

Most of these have been codified.<sup>89</sup>

### 3 Public research and innovation systems

#### 3.1 General structure and the role of government

France has a longstanding tradition of scientific research in which the State plays a significant role. French public administrations and private companies funded, in 2011, €46.4 billion of R&D activities, which were carried out both in France and abroad. The major part (59%) of the national external expenditure on R&D (GERD) was provided by the private sector, while public administrations financed 41%.

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<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000817685&fastPos=1&fastReqId=118063614&categorieLien=id&oldAction=rechTexte>

<sup>84</sup> Décret n° 2015-210 du 24 février 2015 portant création du Conseil national du syndrome immunodéficientaire acquis (sida) et des hépatites virales chroniques.

[http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=5915050CAE144A86134AFA5E4456FDE8.tpdila07v\\_1?cidTexte=JORFTEXT000030285480&categorieLien=id](http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=5915050CAE144A86134AFA5E4456FDE8.tpdila07v_1?cidTexte=JORFTEXT000030285480&categorieLien=id)

<sup>85</sup> Loi n°83-609 du 8 juillet 1983 portant création d'une délégation parlementaire dénommée Office parlementaire d'évaluation des choix scientifiques et

technologiques.<http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000692488>

<sup>86</sup> Loi n° 94-548 du 1 juillet 1994 relative au traitement de données nominatives ayant pour fin la recherche dans le domaine de la santé et modifiant la loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés.<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000547135&dateTexte=>

<sup>87</sup> Décret n°87-848 du 19 octobre 1987 relatif aux expériences pratiquées sur les animaux vertébrés.<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000522762&dateTexte=20030806>

<sup>88</sup> Décret n° 2013-118 du 1er février 2013 relatif à la protection des animaux utilisés à des fins scientifiques.<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000027037840&dateTexte=&categorieLien=id>

<sup>89</sup> "Codified" derived from the process of "codification", as meaning a type of legislation that covers a law system or particular area of law, as opposed to the Anglo-Saxon original approach of law being created through precedents, through case law.

At operational level, the French public research and innovation system is structured around a small number of agencies that fund the research projects carried out mostly by public research institutions. These agencies include the National Research Agency (ANR);<sup>90</sup> Bpifrance;<sup>91</sup> the Agency for Environment and Energy Management (ADEME) as well as the French National Agency for Research on Aids and viral hepatitis (ANRS).

At the research performers' level, R&D in France is carried out in different institutional sectors, public and private, the state, higher education, non-profit institutions, business sector, as well as from abroad.<sup>92</sup>

The public research institutions may be: Public administrative establishments (EPAs); Public industrial and commercial institutions (EPICs) that are state-controlled entities of industrial or commercial nature; furthermore, there are Technical Research Establishments (EPSTs); and Public Industrial and Commercial Establishments (EPICs).

EPIC entities: the Commission for Atomic Energy and Alternative Energies (CEA), the National Centre for Space Studies (CNES), the National Aerospace Research Centre (ONERS), the French Research Institute for Exploitation of the Sea (IFREMER), the Agricultural Research Centre for International Development (CIRAD), the French Institute for Radiological Protection and Nuclear Safety (IRSN), the French Geological Survey (BRGM), the French National Agency for Radioactive Waste Management (ANDRA), the French Building Research Institute (CSTB), the Institut polaire français Paul Émile Victor (IPEV), the National Laboratory for Meteorology and Testing (LNE), the National Institute for Industrial Environment and Risks (INERIS) and the French Agency for Environment and Energy Management (ADEME).

EPST entities: the National Centre for Scientific Research (CNRS), the National Institute for Agronomic Research (INRA), the National Institute for Health and Medical Research (INSERM), Research Institute for Development (INRIA), the Institut de recherche pour le développement (IRD), the National Centre for Agricultural Machinery, Rural Engineering, Water and Forest Management (CEMAGREF), the National Institute for Transport and Safety Research (INRETS), the Central Laboratory for Roads and Bridges (LCPC) and the National Institute for Demographic Studies (INED).

Moreover, several alliances bring together public and private sectors stakeholders of research: Aviesan,<sup>93</sup> the National Alliance for Life Sciences and Health; Ancre,<sup>94</sup> the National Coordinating Alliance for Energy Research; Allistene,<sup>95</sup> the Alliance for Digital Science and

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<sup>90</sup> Official website of ANR. <http://www.agence-nationale-recherche.fr/>.

<sup>91</sup> Official web site of Bpifrance. <http://www.bpifrance.fr/>.

<sup>92</sup> Official website of the Ministry of National Education, Higher Education and Research. <http://www.enseignementsup-recherche.gouv.fr/cid75958/conseil-strategique-de-la-recherche.html>.

<sup>93</sup> Official web site of Aviesan. <http://www.aviesan.fr/fr/aviesan/accueil/menu-header/instituts-thematiques-multi-organismes/sante-publique>

<sup>94</sup> Official web site Ancre. <http://www.allianceenergie.fr/>

<sup>95</sup> Official web site Allistene. <https://www.allistene.fr/>

Technology; AllEnvi,<sup>96</sup> the Alliance in the field of environmental research; Athena,<sup>97</sup> the National Alliance of humanities, social sciences and humanities.

Finally, the evaluation of R&D institutions is carried out by the High Council of Evaluation of Research and Higher Education.<sup>98</sup>

### 3.2 National research associations and standard-setting bodies

To start with, there is the French Academy of Medicine (l'Académie de Médecine), a research association with legal standing, under public law, with special status placed under the protection of the President of the Republic. Its mission is to respond, on a non-profit basis, to the requests of the Government on any matter relating to public health and take care of all study and research subjects that can contribute to advances in the art of healing.

The National Academy of Medicine is independent from the government. Its decisions take effect without prior authorisation. It enjoys financial autonomy under the sole control of the Court of Auditors (Cour des Comptes). Independence and relevance of its reports and communications ensure its unique place and attribute to it an important role in the issues related to health. It may receive a request for an opinion from the public authorities but it may also decide to elaborate an opinion on its own initiative in the fields of health, in particular on the issues of public health and medical ethics.

The French Academy of Medicine has several permanent commissions and several working groups. Among these permanent commissions, the Academy has the Commission “Ethique et Droit” (Ethics and Law Commission) which is composed of about 20 permanent members, several corresponding members and a couple of invited members. It carries out the reflection on the issues of ethics, law and health practices and research. The French National Academy of Medicine is directly involved in research and innovation, including in the areas of their ethical, social and environmental consequences.

At present, the Academy issues its opinions either at the request of the public authorities or on its own initiative on the urgent issues in the medical practice and science, including on ethical issues. The issues which are in the centre of public debates and public policies related with research in life sciences, such as genetics, end of life, personal autonomy, ethical issues related to medically-assisted reproductive technologies, emotional and sexual life of people with disabilities, etc., constitute the areas of work of the Academy. The reports and the opinions of the French National Academy of Medicine are submitted to the President of the Republic, the French Government, as well as are made available for the public.<sup>99</sup>

There are other Academies, represented by the Institute of France, such as the French Academy, the Academy of Inscriptions and Letters, the Academy of Sciences, the Academy of Fine Arts and the Academy of Moral and Political Sciences.<sup>100</sup>

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<sup>96</sup> Official web site AllEnvi. <http://www.allenvi.fr/>

<sup>97</sup> Official web site Athena. <http://www.allianceathena.fr/>

<sup>98</sup> Haut conseil de l'évaluation de la recherche et de l'enseignement supérieur (HCERES)

<sup>99</sup> Anonymised interview of a member of the Academy of Medicine conducted by UNESCO.

<sup>100</sup> Institut de France. <http://www.institut-de-france.fr/fr/une-institution>

The evaluation of R&D institutions is carried out by the High Council of Evaluation of Research and Higher Education (*Haut conseil de l'évaluation de la recherche et de l'enseignement supérieur*<sup>101</sup> (HCERES)), which was established by the Law on Higher Education and Research of 22 July 2013 and the implementation decree of 14 November 2014.<sup>102</sup> HCERES replaces the Agency of Evaluation of Research and Higher Education (*Agence d'évaluation de la recherche et de l'enseignement supérieur*<sup>103</sup> – AERES).

The HCERES assesses higher education institutions, research units at the request of the institutions to which they belong, assesses the training and qualifications of higher education institutions, as well as assesses investment programmes and structures that receive public funds for research or higher education. The criteria on which the assessment is based are for instance the principles of objectivity, transparency and equal treatment between structures.<sup>104</sup>  
<sup>105</sup> This can be considered to be a form of ethics assessment in regards to these principles.

Furthermore, within the HCERES, there is the *Observatoire des Sciences et Techniques (OST)*, an Observatory of Science and Technology that conducts research and policy analysis. The OST is interested in the data regarding funding and human resources, on higher education and research, on companies, on scientific publications, European projects or data concerning patents. The OST, however, does not assess research and policy as its interest is in data; its role is therefore to observe, rather than actually assess.

The French Health Authority (Haute Autorité de Santé - HAS), is a scientific independent public authority, created by a law on 13 August 2004 on health insurance.<sup>106</sup> It was created to enhance the quality and sustainability of the health system. It works to improve the quality of the health system to ensure all sustainable and equitable access to care as effective, safe and efficient as possible.

Moreover, the HAS helps in regard to public decision making as to funding reimbursable medical goods and services, with the aim to preserve solidarity and equitable funding of the health system. The HAS supports health professionals to improve their clinical practices, as to be able to provide more effective, and safer healthcare. The HAS therefore promotes good practices in regard to the health care. The safety concern of the HAS can be considered as a form of ethical assessment. The HAS also guides professionals concerning good clinical practice, by producing recommendations and tools for health professionals.

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<sup>101</sup> The French Research Code, Article: Article L114-3-1.

[http://www.legifrance.gouv.fr/affichCode.do?sessionId=2DB489B72FD49169E64B464C28697B86.tpdjo12v\\_3?idSectionTA=LEGISCTA000027748427&cidTexte=LEGITEXT000006071190](http://www.legifrance.gouv.fr/affichCode.do?sessionId=2DB489B72FD49169E64B464C28697B86.tpdjo12v_3?idSectionTA=LEGISCTA000027748427&cidTexte=LEGITEXT000006071190).

<sup>102</sup> For more information see the Report on the Evaluation of Research and Higher Education was prepared by former Rector Denise Pumain, Professor of University Paris 1 Panthéon – Sorbonne, and Frédéric Dardel, Rector of Paris - Descartes University, and submitted to the French Minister of Higher Education and Research in January 2014 to inform the creation of such a Council. [http://cache.media.enseignementsup-recherche.gouv.fr/file/Actus/98/8/Rapport\\_Pumain\\_Dardel\\_295988.pdf](http://cache.media.enseignementsup-recherche.gouv.fr/file/Actus/98/8/Rapport_Pumain_Dardel_295988.pdf)

<sup>103</sup> Official web site of AERES. <http://www.aeres-evaluation.fr/>.

<sup>104</sup> Official web site of HCERES. <http://www.hceres.fr/PRESENTATION/Missions>

<sup>105</sup> Rapport, L'évaluation de la Recherche et de l'Enseignement supérieur. [http://cache.media.enseignementsup-recherche.gouv.fr/file/Actus/98/8/Rapport\\_Pumain\\_Dardel\\_295988.pdf](http://cache.media.enseignementsup-recherche.gouv.fr/file/Actus/98/8/Rapport_Pumain_Dardel_295988.pdf)

<sup>106</sup> Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie.

<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000625158>



### 3.3 Research funding organisations

The French public R&I system is structured around a small number of agencies that fund the research projects carried out mostly by public research institutions. In any case, all research projects on human beings or on animals should obtain ethical clearance by the State boards.

The French national Research Agency (ANR) is a public organisation depending on the Ministry of Higher Education and Research. Furthermore the ANR is an EPA.

The ANR is responsible for implementing the funding of research projects in France. This public entity encourages the respect of its own framework established in 2014 in regards to ethics policy and scientific integrity and of its Code of ethics from 2009 that enforces the principles of objectivity, selflessness, respect of information confidentiality during the evaluation process, as well as prevention of conflict of interest by making it obligatory for all concerned parties to sign a document attesting to the fact that they have made themselves familiar with the code. This framework must apply to researchers and agencies' depositors, as well as to all people involved in the activities of the ANR. Furthermore, the ANR has other relevant tools in regards to ethics assessment related to their funding activity, such as the process of peer review and the appeals board.<sup>107</sup>

In addition, the Agence Nationale de Recherches sur le Sida et les hépatites virales (ANRS),<sup>108</sup> finances research and allocates grants in all areas of research that relates to AIDS and viral hepatitis. The projects and grant applications submitted are evaluated by seven Commissions taking into account ethical principles.<sup>109</sup> When it comes to financing research being carried out in developing countries, the principles respected must be those set forward in their ethical charter on research in developing countries, as well as internationally accepted ethical principles.<sup>110</sup>

The Agency for Environment and Energy Management (ADEME), reports to the Ministries of Ecology and Sustainable Development, Research and Industry, advises and provides financial support to research projects. The ADEME helps financing research projects in the areas of waste management, soil conservation, energy efficiency and renewable energy, as well as the quality of the air and the fight against noise. To the authors knowledge, an ethics charter does not currently exist. The Bank of Investments (Bpifrance) is a French organisation financing business developments and plays a role in financing R&I. However, to our knowledge there are no specific ethical principles to be respected beforehand. Bpifrance adheres to their *Charte de responsabilité sociétale*, Social Responsibility Charter that underlines that they should take into account non-financial criteria, such as environmental, social and governance criteria within their investment strategy, development and assistance to businesses, this however concerns more generally the management of Bpifrance and not the criteria on which funds are being attributed.

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<sup>107</sup> ANR. <http://www.agence-nationale-recherche.fr/missions-et-organisation/qualitedeontologie/>

<sup>108</sup> ANRS. <http://www.anrs.fr/Qui-sommes-nous/Presentation-de-l-ANRS/L-ANRS-et-ses-missions>

<sup>109</sup>For further information on the ANRS. <http://www.anrs.fr/Qui-sommes-nous/Organisation/Fonctionnement-et-structures>

<sup>110</sup>For further information on the ANRS. <http://www.anrs.fr/Rubriques-transversales/Outils-pour-la-recherche/Pays-en-developpement/Textes-de-reference/Principes-ethiques>

The Institut Pasteur is a private funding establishment that plays an important role in ethics assessment as it has its own code of ethics that must be applied. This code of ethics guarantees that this private foundation will conduct its own research in a rigorous ethical framework, respecting ethics in regard to research on the living, in regard to human dignity and human rights, according to ethical principles approved by the international community.

There are various associations, such as the association “Sidaction”<sup>111</sup> which allocates funding in the field of AIDS research. The decision on which research to fund is based on the recommendations of expert committees.

Sidaction has, for example, the associative committee and the quality of life and health care committee. The experts in these committees study the funding applications and make proposals to the board of directors. To the authors’ knowledge, there are no specific ethical codes that need to be taken into consideration before allocating funds. In 2006, Sidaction has launched a program on ethics of research on AIDS in Africa.

Furthermore, there is the “AFM/telethon”<sup>112</sup>, an association of patients, parents and activists in the fight against rare genetic diseases as well as neuromuscular diseases, which finances research in these fields too. However, to our knowledge there is no specific ethics assessment in determining how to spend their funding, but there’s a committee dealing with the financial management of the association.

The “Fondation de France”<sup>113</sup> is a foundation that financially supports for instance environmental research, medical research on eye diseases, cardiovascular diseases, Parkinson’s diseases and various other illnesses. To our knowledge, this foundation engages in respecting financial transparency but doesn’t include ethics assessment before attributing funds.

Also, the Fondation de la recherche médicale (FRM) finances research in all medical fields. However, there is no specific ethics assessment before funding a certain research. The FRM has a scientific council that implements the foundation’s scientific commitments, but there’s no reference to our knowledge to ethical commitments.

Furthermore, these research-funding organisations do not specifically interact with research performing organisations; however the ANRS sponsors clinical trials as well. Moreover, the ANRS is an independent agency of the INSERM and therefore interacts with this research-performing organisation.

To the authors’ knowledge, there is no specific mention of particular attention to ethical issues as a condition for basic funding for universities and other public research institutions; the ethics assessment addressed above concerns funding in general. The funding of research is detached from the ethical compliance, set down in the legislative framework of 1988 (Huriet-Sérusclat), then codified in the Public Health Code, a framework that had put in place the

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<sup>111</sup> Official website of SIDACTION. <https://www.sidaction.org/notre-organisation>

<sup>112</sup> AFM Telethon. <http://www.afm-telethon.fr/association/nos-missions-633>

<sup>113</sup> Fondation de France. <http://www.fondationdefrance.org/Nos-Aides/Vous-etes-un-organisme#3134>

CPPs. All research projects on human beings or on animals should obtain ethical clearance by the State boards.

### 3.4 Research performing organisations

Within the National Centre for Scientific Research (CNRS) (see 2.b) there is the CNRS Ethics Committee (Comets). It addresses the ethical implications of the major issues involving research. CNRS has given Comets responsibility for coordinating the new steps taken to address the operational ethics. For questions related to ethics regulations, Comets can appeal to internal or external CNRS expertise. Since its creation, Comets has produced approximately thirty opinions and published a practical guide based on the analysis of the difficult situations that research stakeholders (researchers, teacher-researchers, accompanying research) may face with recommendations on, *inter alia*, good practices to be adopted in terms of publications, data processing, opening the results to the scientific community, communication, measures to avoid conflicts of interest.

Furthermore, within the French National Institute of Health and Medical Research - INSERM (see 2.b), there is the Ethics Committee of INSERM (*Comité d'éthique de l'INSERM*). The INSERM established its Ethics Committee which is requested to develop reflection on ethical issues raised by medical, scientific and clinical, research in conformity with a vocation of being a full-fledged stakeholder in the dialogue between the medical and scientific communities and society as a whole. Furthermore, there is a Scientific Integrity Office of the Inserm (*Délégation à l'intégrité scientifique* or DIS)<sup>114</sup> too. This delegation “deals with individual situations where there are problems related to scientific integrity”.<sup>115</sup> Their mission is related to deontology.<sup>116</sup> In addition to the Ethics Committee, INSERM has established its Institutional Review Board (Comité d'évaluation éthique de l'Inserm whose abbreviation is CEEI/IRB). CEEI/IRB's mission is to provide advice on research projects involving humans, in order to "protect the rights and welfare of the people involved in research." This Institutional Review Board (i.e. officially recognised by the Office of Human Research Protection (OHRP) of the United States of the America) reviews individual research projects, which need an ethical clearance according to most medical and scientific journals but are outside the scope of the Committees for the Protection of Persons (Comités de Protection des Personnes or CPP)'s statutory tasks.<sup>117</sup>

The Atomic Energy Commission (CEA)<sup>118</sup> is a major actor in the field of research such as, low-carbon energies (nuclear and renewable) or the information and health technologies. The CEA has an office of biomedical studies on animal (Bureau des études biomédicales chez l'animal (BEBA)). Its ethical assessment is inspired by the European directive n°2010/63. The ethical value behind this European directive is to reduce the animal's suffering.

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<sup>114</sup> INSERM. <http://english.inserm.fr/what-s-inserm/organisation-chart/committees/dis>

<sup>115</sup> Anonymised interview of a member of the Comité d'éthique de l'Inserm conducted by UNESCO.

<sup>116</sup> Indeed, Inserm contributed to the development of a National Deontology Charter for research professions (Charte nationale de déontologie des métiers de la recherche) which is the actual Code of Conduct for Inserm researchers.

<sup>117</sup> Outside de scope of the CPPs means that the research does not involve human beings as defined by the law of 1988 (Huriet-Sérusclat) as subsequently revised and codified in the Public Health Code.

<sup>118</sup> CEA. <http://www.cea.fr/le-cea/presentation-generale>

Moreover, the Institute of research and development (IRD) is a French research body. Their main research objective is to contribute to the social, economic and cultural development of the South. This Institute has an Advisory Committee on deontology and ethics (CCDE).<sup>119</sup> The CCDE reviews research protocols from an ethical point of view. This committee has established a “Good Practice Guide” for research. Also, the IRD plays a role in ethics training.

The CIRAD<sup>120</sup> (Centre de coopération internationale en recherche agronomique pour le développement) is a public institution. It has a joint Consultative Ethics Committee for Agricultural Research with the National institution of agricultural research (INRA), which examines ethical issues in the areas of agriculture, food, environment and sustainable development. Moreover, this committee plays a role in ethics training.

One must also mention the CHUs (Centres Hospitaliers Universitaires), public university hospitals performing clinical research. They adopt their own ethical codes, engage in ethics training and establish their own ethics committees too.

Some universities have recently established ethics committees within their structure that may deal with ethical issues related to research on human beings and questions related to intellectual property.<sup>121</sup> Moreover, some universities have ethics committees that reflect on ethical issues raised by research in the social sciences including psychology or other disciplines.<sup>122</sup>

## **4 Private research and innovation systems**

### **4.1 General structure and the role of government**

In this section, the focus will be on the French government policies and initiatives in regard to CSR (Corporate Social Responsibility).

The French industry is mainly made up of the food industry, the automobile industry, the industry of electronic devices, the chemical, pharmaceutical and cosmetic industry as well as the construction of aircraft and spacecraft, rail, ship industry and the arms industry.

The Chambers of Commerce and Industry (CCI) represent the interest of commercial companies and industries. Some of the CCIs in various French cities adopt ethical charters related to professional ethics but do not mention CSR directly.

In addition, there are public organisations that are supposed to give an impulse to the CSR, such as the National Council for sustainable development.<sup>123</sup> In 2003, a National Sustainable Development Strategy (NSDS) was adopted by an interdepartmental Committee on

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<sup>119</sup> IRD. <http://www.ird.fr/ird.fr/l-ird/organigramme/instances-et-comites/le-comite-consultatif-de-deontologie-et-d-ethique>

<sup>120</sup> CIRAD. <http://www.cirad.fr/qui-sommes-nous/organigramme/instances-et-comites/comite-consultatif-commun-d-ethique>

<sup>121</sup> Example: <http://www.univ-paris8.fr/Le-comite-d-ethique>

<sup>122</sup> Université de Lille, comité d'éthique d'établissement. <https://www.univ-lille3.fr/recherche/presentation-et-missions/comite-ethique/>

<sup>123</sup> Conseil National du Développement Durable.

Sustainable Development and by Senior Officials Committee responsible for monitoring sustainable development.

In the pharmaceutical industry, Leem is the association representing drug companies in France. It has established a committee of ethics and vigilance (Codeem).<sup>124</sup> Leem also has a specific group in charge of CSR issues.

In the food industry, there's the ANIA, National Association of Food Industries<sup>125</sup> that brings together national federations and regional associations representing food companies.

France is active in promoting investments that respect the CSR principles, on a legislative level. To start with, the article 116 of the Code of Commerce is a consequence of the new law on economic regulations (NRE)<sup>126</sup> of 2001. It indicates that listed companies should give information on social and environmental consequences of their activities in their annual report. Furthermore, CSR was a topic of the discussion at the “round table Grenelle” in 2008. The “Grenelle de l'environnement” is an open debate in France that brings together representatives of national and local government and organisations, such as members from the industry as well as professional associations. The “Grenelle Environment Round Table”, instigated by Nicolas Sarkozy (former president), aimed at defining the public policy on sustainable development issues. The discussion in 2008 led to the action program to be included in article 53 of the law of the 3 August 2009 implementing the “Grenelle Environment” discussion.<sup>127</sup>

Later, there was the law of 12 July 2010<sup>128</sup> on the national commitment to the environment, the decree of 30 January 2012 relating to information by portfolio management firms social, environmental and governance as reflected in their investment policy, the decree of 24 April 2012 on the transparency obligations of companies on social and environmental matters and the decree of 13 May 2013 giving detailed rules in which independent third party leads its mission.<sup>129, 130</sup>

The Medef is the movement of the enterprises of France, the biggest employer federation in France. The Medef plays an informative role when it comes to CSR. The Medef recently

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<sup>124</sup> Comité de déontovigilance des entreprises du médicament.

<sup>125</sup> Association nationale des industries alimentaires.

<sup>126</sup> Legifrance. <http://legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000223114>

<sup>127</sup> The Law n°2009-967 of 3 August 2009 relating to the environmental Grenelle, the so called “Grenelle I” law, is a law that formalises commitments made the de “Grenelle environment” debate of 2008. <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000020949548&dateTexte=&categorieLien=id>

<sup>128</sup> The “Grenelle I” law was completed in 2010 by a law of the 12th July 2010 on national commitment to the environment. This framework met den need for action in the field of ecological emergency. <http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022470434>

<sup>129</sup> To be more precise, the law of 12 July 2010 (“Grenelle 2”) created an obligation of verification of the environmental and social information given in the reports provided by the competent authorities as defined by this law, prior to debating the budget of these authorities. This information must be checked by a third independent party. This decree, gives details about the mission of verification as well as the criteria of delivering a certificate of compliance to the article R.255-105-1 of the Commercial Code. [http://www.developpement-durable.gouv.fr/IMG/pdf/joe\\_20130614\\_0007.pdf](http://www.developpement-durable.gouv.fr/IMG/pdf/joe_20130614_0007.pdf)

<sup>130</sup> <http://www.developpement-durable.gouv.fr/Quelles-sont-les-demarches-qui.html>

published a guide called “Heading towards CSR, social responsibility of business as a performance driver”.<sup>131</sup> The guide puts forward good practices when it comes to CSR.

Finally, there are several alliances, which bring together the industry and public-private partnerships in the R&I field. For instance, Aviesan is in direct contact with the health industry. Aviesan has established an Alliance for Research and Innovation in health industries (Ariis)<sup>132</sup>. Ariis created synergy between industry and public-private partnerships with the aim to improve patient care.<sup>133</sup>

#### 4.2 Industry associations, accreditation, certification & standard setting organisations

The Observatory for CSR (*Observatoire sur la responsabilité sociale des entreprises, ORSE*) was created in 2000 to collect and analyse information on CSR, which it disseminates on socially responsible investments in France and abroad.<sup>134</sup> The ORSE promotes the exchange of information among its members and organises training sessions.

In 2002, the agency VIGEO<sup>135</sup> was created to assess companies on social and environmental parameters, as well as offer CSR evaluation on the request of a company.

The French Association for Standardisation AFNOR<sup>136</sup> organises and participates in the development of standards (French, European or international standards) and administrates the French standardisation system. In regard to CSR, they promote the respect of the ISO 26000 standard. Moreover, AFNOR produced a methodological guide for the inclusion of sustainable development issues in the strategy and management of companies.

The IMS<sup>137</sup> is a network of businesses engaged in society that was created in 1986 by business leaders. They implement various tools to promote CSR and best practices.

On the governmental level there is a platform that has been put into place by the prime minister to promote CSR in 2013 and to get the actors to work together.<sup>138</sup> This platform is installed with the General Office of the strategy and foresight (CSPF).

The “RSE France” has been accredited as an “undertaking independent third party” (ITO) since 15 March 2014. RSE France is empowered by the Grenelle III law to examine the social, societal and environmental information that is published by companies.

Furthermore, the French Association for foreign trade (Association du commerce extérieur) promotes the Business Social Compliance Initiative (BSCI), which intends to improve the

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<sup>131</sup> “Cap vers la RSE, faire de la responsabilité sociétale de l’entreprise un levier de performance”.

<sup>132</sup> Alliance pour la recherche et l’innovation des industries de santé.

<http://www.aviesan.fr/fr/aviesan/accueil/menu-header/partenariats-industriels>

<sup>133</sup> Official website of the ARIIS. <http://www.ariis.fr/nous-decouvrir/nos-missions/>

<sup>134</sup> Investissement socialement responsable (ISR).

<sup>135</sup> Official website of VIGEO. <http://www.vigeo.com/csr-rating-agency/fr/1-2-2-historique>

<sup>136</sup> Official website of AFNOR. <http://www.afnor.org/>

<sup>137</sup> Official website of IMS. <http://www.imsentreprendre.com/>

<sup>138</sup> Official website of the „Ministère de l’écologie, du développement durable et de l’énergie”.

<http://www.developpement-durable.gouv.fr/La-plateforme-pour-la-promotion-de.html>

European level of CSR in the supply chain. Members of this association encourage obtaining a “Social Accountability Standard certificate”.<sup>139</sup>

### 4.3 Industry

In the food industry, the ANIA (National Association of Food Industries)<sup>140</sup> brings together national federations and regional associations representing food companies. The ANIA and the ACTIA,<sup>141</sup> a national coordination structure that federates the activities of technical institutes in the food industry, researchers, engineers, technicians and others, have put together a “Kit RSE ANIA-ACTIA, an assessment tool to approach CSR in the field of the food industry.”<sup>142</sup>

Within the pharmaceutical industry, Leem (the French professional organisation representing the pharmaceutical industry) is strongly involved in research and innovation, through fundamental research, clinical research but also work on access for patient’s drugs. Leem has established the Codeem (*Comité de déontovigilance des Entreprises du Médicament*). Its main objective is to promote and make applicable the ethics rules of the profession. The Codeem also helps to resolve difficulties on professional ethics issues between two companies.

The Codeem is composed of two sections: the “Commission de déontologie” (Section of ethics) and the “Section des litiges et des sanctions” (Section in charge of litigation and sanctions). Stakeholders such as patients’ associations might go to the Section in charge of litigation and sanctions with a complaint.

Moreover, the Leem also coordinates the CSR strategies of its members, by having established a “CSR Commission”.<sup>143</sup> The CSR is addressed in Leem’s annual reports, mentioning social impact. Companies also take individual measures.

To give an idea of the collective action of the Leem, the pharmaceutical companies in France address together the subject of counterfeit drugs by signing a declaration of principles, for instance with the customs. Furthermore, Leem has adopted "Professional ethics rules" for member companies of Leem.<sup>144</sup>

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<sup>139</sup>M. Michel Doucin, Ambassadeur chargé de la bioéthique et de la responsabilité sociale des entreprises, La responsabilité sociale des entreprises: L’engagement de la France.

[http://www.diplomatie.gouv.fr/fr/IMG/pdf/La\\_RSE\\_\\_l\\_engagement\\_de\\_la\\_France.pdf](http://www.diplomatie.gouv.fr/fr/IMG/pdf/La_RSE__l_engagement_de_la_France.pdf)

<sup>140</sup>Association nationale des industries alimentaires.

<sup>141</sup>Official website of ANIA. [http://www.ania.net/sites/default/files/kit\\_rse\\_plaquette\\_0.pdf](http://www.ania.net/sites/default/files/kit_rse_plaquette_0.pdf)

<sup>142</sup>Kit RSE ANIA-ACTIA un outil d’évaluation pour une démarche de responsabilité sociétale adaptée à l’agro-alimentaire. Le kit RSE ANIA -ACTIA a été réalisé sur la base de la norme ISO 26 000, norme de référence en matière de RSE. Il s’inscrit dans la continuité du guide d’utilisation de cette norme pour le secteur agro-alimentaire, rédigé par l’Ania et Coop de France et publié par l’Afnor en août 2012 (Accord AC X30-030).

<sup>143</sup>Responsabilité Sociétale des Entreprises du Médicament. <http://www.leem.org/article/responsabilite-societale-des-entreprises-du-medicament>

<sup>144</sup> Interview of Grégoire Moutel, President of the Codeem conducted by UNESCO.

## 5 Professional groups and associations in the R&I field

### 5.1 National associations for R&D professions

The National Association of Research and Technology<sup>145</sup> (ANRT) brings together public and private actors in research and innovation. Its three main actions are CIFRE Conventions, FutuRIS prospective platform, and the improvement of partnerships in research.<sup>146</sup> To our knowledge, the ANRT does not play a particular role in ethics assessment, but its aim is to help improve the efficiency of the French system of research and innovation, particularly of public-private relationships.

However, there are professional associations that have created their own professional ethics code, such as the « Société Nationale des Ingénieurs Professionnels de France » (SNIPF) or association of professionals in the field of psychology.

The SNIPF has developed its own professional code of ethics (Charte d'éthique de l'ingénieur).<sup>147</sup>

In the field of psychology, there is the “Fédération Française des Psychologues et de la Psychologie” (FFPP)<sup>148</sup> as well as the “Association professionnelle des psychotechniciens diplômés (APPD). “THE APPD was the first professional association to establish a fascicle which is the basis of ethical principles for the professionals in the field of psychology. In 1961 the “Société française de psychologie” adopted the first professional ethics code for psychologists.

These professional ethics codes are not enforced in the legislative framework. However, this is the case for the code of professional ethics (Code de déontologie) of medical doctors established by decree in 2004.<sup>149</sup> The respect of this professional code is assured by the “Conseil de l'ordre des Médecins” the licensing board in charge of the defending the framework for the medical profession and although of making sure that medical doctors apply the rules of the profession.

The ethics guidance these professional organisations involve in is that of ethical guidance related to a specific profession.

### 5.2 National organisations for (ethics) assessors

There are two major national organisations for ethics assessors in France. The National Conference for the Committees for the Protection of Persons<sup>150</sup> (Conférence Nationale des

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<sup>145</sup> L'Association nationale de la recherche et de la technologie.

<sup>146</sup> Official website of ANRT. <http://www.anrt.asso.fr/>

<sup>147</sup> Charte d'éthique des Ingénieurs. <http://www.etudes-ingenieur.fr/charte-ethique-ingenieur.php>

<sup>148</sup> FFPP. <http://www.lepsychologue.org/psychologie/federation-francaise-des-psychologues.php>

<sup>149</sup> Décret n° 2004-802 du 29 juillet 2004 relatif aux parties IV et V (dispositions réglementaires) du code de la santé publique et modifiant certaines dispositions de ce code Les dispositions réglementaires des parties IV et V du code de la santé publique font l'objet d'une publication spéciale annexée au Journal officiel de ce jour (voir à la fin du sommaire).

[http://www.legifrance.gouv.fr/affichCodeArticle.do?jsessionid=BAFB05F8850577B0342E1553E65EC46F.tpdila22v\\_3?idArticle=LEGIARTI000025843568&cidTexte=LEGITEXT000006072665&dateTexte=20150511](http://www.legifrance.gouv.fr/affichCodeArticle.do?jsessionid=BAFB05F8850577B0342E1553E65EC46F.tpdila22v_3?idArticle=LEGIARTI000025843568&cidTexte=LEGITEXT000006072665&dateTexte=20150511)

<sup>150</sup> UNCPC. <http://www.cncpp.fr/>



Comités de Protection des Personnes, CNCP) is an association formed by members of most of the various CPPs. This association aims to establish and operate a network of CPPs; however, it does not self-assess the work done by the CPPs.

The CNCP helps individual CPPs to interact with each other through workshops and symposiums. The CNCP promotes the reflection on the legislative changes and different working methods of the CPPs. Throughout these workshops the CNCP develops assessment templates. However, these are mere recommendations and are not binding for the CPPs. All in all the CNCP is a national organisation for ethics assessors from the CPPs.

Furthermore, the Inter-professional Group of Research Reflection and Communication (*le Groupe Interprofessionnel de Réflexion et de Communication sur la Recherche* or *GIRCOR*<sup>151</sup>) is an association representing major organisations using animal testing.

In 1991, the GIRCOR created the Interprofessional Working Group on Ethics Committees for Laboratory Animals (*le Groupe de réflexion interprofessionnel sur les comités d'éthique appliquée à l'expérimentation animale* or *GRICE*<sup>152</sup>) which drove the harmonisation of the functioning of ethics committees related to animal testing prior to the recent regulations. In 2009, the GRICE has written and published an ethical assessment guide for research projects using animals for scientific purposes. This guide describes in detail the principles and methods of ethics review. The National Committee for Consideration of Ethics in Animal Experimentation (*Comité National de Réflexion Ethique sur l'Expérimentation Animale* or *CNREEA*<sup>153</sup>) has made this guide a reference for the ethics assessment.<sup>154</sup>

## 6 CSOs

### 6.1 The CSO landscape

The “*Waldeck-Rousseau law*” (1884) established the freedom of association in France. This law allows the creation of an association by citizens without prior authorisation. However, the object of the association must be lawful.<sup>155</sup>

The Associations of Patients (*Les associations de patients et d'usagers du système de santé*) are highly active.<sup>156</sup> These associations give their moral support and advice to patients as well as their financial and legal support. The associations of patients are often funded by the health industry, therefore article L.1114-1 of the Public Health Code requires for companies

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<sup>151</sup> Recherche animale. <http://www.recherche-animale.org/qui-sommes-nous>

<sup>152</sup> Recherche animale. <http://www.recherche-animale.org/centre-ressources/lethique-de-la-recherche/les-comites-dethique/le-grice-0>

<sup>153</sup> Articles R214-134 to 136 of the Rural and Maritime Fisheries Code (*Code rural et de la pêche maritime*). [http://www.legifrance.gouv.fr/affichCode.do?sessionId=205362DB07BD62C8B4AB7DFC4AE6ED91.tpdjo03v\\_1?idSectionTA=LEGISCTA000027039880&cidTexte=LEGITEXT000006071367&dateTexte=20150120](http://www.legifrance.gouv.fr/affichCode.do?sessionId=205362DB07BD62C8B4AB7DFC4AE6ED91.tpdjo03v_1?idSectionTA=LEGISCTA000027039880&cidTexte=LEGITEXT000006071367&dateTexte=20150120)

<sup>154</sup> Anonymised interview of a member of the GRICE conducted by UNESCO.

<sup>155</sup> Loi du 1er juillet 1901 relative au contrat d'association, 17-04-2010.

<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000006069570&dateTexte=20100317>

<sup>156</sup> ARS. <http://www.ars.iledefrance.sante.fr/Les-associations-de-patients-e.125459.0.html>

producing and commercialising health products that they declare to the HAS (Haute Autorité de Santé) the amount of money they give to these associations on a yearly basis.<sup>157</sup>

Since the law of 4<sup>th</sup> March 2002,<sup>158</sup> the associations that declare themselves as having a 'health sector activity, can play a role in the representation of the health users in various forums. Furthermore, not only do they have to declare themselves but they also need an approval to be able to represent users of the health system. This requirement is found in the articles L114-1 and R 1114-2 of the Code of Public Health (CSP).

Furthermore, since the “Médiateur” scandal in 2010, the legislative framework for compensation for medical accidents has changed. This legislation now enables approved associations that have been founded to defend the interest of patients or victims of a side effect of a health product, to participate at the orientation council of the National Office for compensation of medical accidents (Office national d’Indemnisation des Accidents Médicaux, ONIAM).<sup>159</sup>

There are other accredited associations<sup>160</sup> in the field of improving conditions of patients. Their work can be acknowledged by the institution in which they are active<sup>161</sup> and with whom they have passed an agreement of their intervention as a voluntary association. The members of these associations can represent the users of the health system at forums and can be asked to give advice.

In addition to churches as civil society actors,<sup>162</sup> there are specific religious foundations. Such as, the foundation *Jérôme-Lejeune* which supports research on trisomy 21. This is a foundation of Christian inspiration and is engaged against abortion and euthanasia. This foundation is financed by donations.

The foundation “*Oeuvre de la Croix Saint-Simon*” takes care of the social and medical needs of vulnerable people from the beginning to the end of their life. Furthermore, within this foundation there is the “CNDR Soins Palliatif.”<sup>163</sup> This foundation is engaged against social inequalities and discrimination of vulnerable people.<sup>164</sup>

Also, there are consumer protection associations, such as the “*UFC-Que Choisir*”. Their aim is to inform, to council and to defend consumers. One could consider their aim to ensure the

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<sup>157</sup> HAS. [http://www.has-sante.fr/portail/upload/docs/application/pdf/2010-05/guide\\_financement\\_assos\\_2010.pdf](http://www.has-sante.fr/portail/upload/docs/application/pdf/2010-05/guide_financement_assos_2010.pdf)

<sup>158</sup> Loi n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé

<sup>159</sup> ARS. <http://www.ars.iledefrance.sante.fr/Les-associations-de-patients-e.125459.0.html>

<sup>160</sup> Associations de malades et d’usagers du système de santé. <http://www.sante.gouv.fr/l-agrement-des-associations-de-malades-et-d-usagers-du-systeme-de-sante.html>

<sup>161</sup> CIRCULAIRE N°DHOS/SDE/E1/2004/471 du 4 octobre 2004 relative à la convention définissant les conditions d’intervention des associations de bénévoles dans les établissements de santé et comportant une convention type. [http://circulaire.legifrance.gouv.fr/pdf/2009/04/cir\\_5828.pdf](http://circulaire.legifrance.gouv.fr/pdf/2009/04/cir_5828.pdf)

<sup>162</sup> Dinechin Olivier. L’Église et la bioéthique en France. In: *Revue des Sciences Religieuses*, tome 74, fascicule 1, 2000. Bioéthique et christianisme. pp. 27-38.

[http://www.persee.fr/web/revues/home/prescript/article/rscir\\_0035-2217\\_2000\\_num\\_74\\_1\\_3518](http://www.persee.fr/web/revues/home/prescript/article/rscir_0035-2217_2000_num_74_1_3518)

<sup>163</sup> Fondation Oeuvre de la Croix Saint Simon. <http://www.soin-palliatif.org/cndr/presentation/fondation-oeuvre-croix-saint-simon>

<sup>164</sup> Croix Saint Simon. <http://www.croix-saint-simon.org/qui-sommes-nous>

safety of products to be an ethical issue. Furthermore, there are other associations such as the association *Léo Lagrange pour la Défense des Consommateurs*, a national association that provides citizens with information, advice and legal aid. Its partners are the following: “Conseil regional Ile-de-France”, “Secrétariat d’Etat à l’industrie et à la consommation” and “Ministère de l’Ecologie, du Développement et de l’Aménagement Durables”.<sup>165</sup>

Moreover, there are various associations that protect animals, such as the National Council for animal protection (CNPA),<sup>166</sup> which is under the supervision of the Ministry of Agriculture and funded by this Ministry too. The members of the CNPA sit in on various consultative committees of the Ministry, where their influence helps change legislations in favor of the protection of animals.<sup>167</sup>

There are foundations that protect the environment, such as France nature environment (FNE),<sup>168</sup> the association Humanity and biodiversity,<sup>169</sup> the federation of the Friends of the earth or the National federation of fishing and the protection of the aquatic environment.<sup>170</sup> In general, to the authors’ knowledge, these foundations are funded by donations.

Among the associations that engage in the protection of human rights and liberties, there are “Ligue des Droits de l’Homme”, Amnesty international France, the Action of Christians against torture<sup>171</sup>, the association Together against death penalty<sup>172</sup> as well as the “Fédération internationale des ligues des droits de l’Homme”. The actors of civil society are funded by donations and specific subsidies.

Furthermore, the different labour unions play an important role in the CSO landscape. These unions defend individual and collective interests of employees at a national level across various sectors.

Moreover, there is the Confédération française démocratique du travail (CFDT), the French Democratic Confederation of Labour. In 2014, for example, the CFDT expressed its concern about the conditions of the privatisation of the plasma market imposed by an EU directive.<sup>173</sup>

The union, known as the French Blood Establishment (Etablissement français du sang) plays an important role in creating awareness to ethical issues too.

The “Syndicat de la Médecine Générale (SMG)”<sup>174</sup> has recently established a Charter for health solidarity (Charte pour une santé soldiaire), which for instance underlines the necessity

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<sup>165</sup> Leo Lagrange pour la Défense des Consommateurs. [http://www.leolagrange-conso.org/00\\_partenaires.php?idrub=PA](http://www.leolagrange-conso.org/00_partenaires.php?idrub=PA)

<sup>166</sup> Conseil National de la Protection Animale (CNPA). [http://www.cnpa.be/index\\_fr.html](http://www.cnpa.be/index_fr.html)

<sup>167</sup> OABA. [http://www.oaba.fr/CNPA/pdf/CNPA\\_brochure.pdf](http://www.oaba.fr/CNPA/pdf/CNPA_brochure.pdf)

<sup>168</sup> FNE. <http://www.fne.asso.fr/>

<sup>169</sup> Association d’humanité et de biodiversité. <http://www.humanite-biodiversite.fr/>

<sup>170</sup> Fédération nationale de la pêche et de la protection du milieu aquatique (FNPF).

<sup>171</sup> Action des chrétiens pour l’abolition de la torture (ACAT).

<sup>172</sup> Ensemble contre la peine de mort (ECPM).

<sup>173</sup> L’avenir du don du sang éthique inquiet syndicats et associations. <http://www.lanouvelrepublique.fr/Deux-Sevres/Actualite/Sante/n/Contenus/Articles/2014/11/14/L-avenir-du-don-du-sang-ethique-inquiete-syndicats-et-associations-2116749>

<sup>174</sup> SMG. <http://www.smg-pratiques.info/-Le-SMG,4-.html>

of protecting personal rights.<sup>175</sup> A famous example of the role that the SMG has come to play in ethics assessment, is the “Affaire Médiateur”. The SMG fielded a complaint against the French Agency for Safety of Health Products for failure to inform consumers.<sup>176</sup>

A recent example of the influence of these unions is the influence of the Ugict-CGT<sup>177</sup> (Union Générale des Ingénieurs, Cadres et Techniciens) on the bill dealing with the directives concerning secrecy (projet de loi Macron). An article of the bill has been withdrawn due to the rapid reaction of this union and other activists.<sup>178</sup>

Furthermore, there are other unions too, such as the « Confédération française de l'encadrement - Confédération générale des cadres » (CFE-CGC)<sup>179</sup>, the union “FO-force ouvrière”<sup>180</sup>, the « Union fédérale de l'action sociale » (UFAS)<sup>181</sup>, the “CGT” union (Confédération générale du travail)<sup>182</sup>, the “Syndicat national des professionnels infirmiers” (SNPI)<sup>183</sup>, the “Union fédérale des médecins, ingénieurs, cadres et techniciens (UFMICT)<sup>184</sup>, the « Union fédérale de la santé privée (UFSP)<sup>185</sup> or the “Union Syndicale de la Psychiatrie”(USP).<sup>186</sup>

At first glance, these unions do not seem to play a direct role in ethics assessment but they can establish ethics charters or intervene in societal debate, which also includes ethical topics.

Additionally, little public data exists regarding labour union funding in France, making the question difficult to answer

## 6.2 The role of CSOs in ethics assessment

Inside the institutional organisation of ethics assessment in France, some of the members of the National Ethics Committee (CCNE) are members of CSO organisations. Alain Grimfeld, former president of the CCNE, is the president of the ethics committee of the association “ADEF-Résidences”, which is an association that has created and manages nursing homes and handicap facilities. This is the case for other ethics committees too, such as the CPPs or ethics committee of the INSERM. Within the CPPs, members from the scientific community and members from the civil society are in equal counts.

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<sup>175</sup> SMG. [http://www.smg-pratiques.info/IMG/pdf/charte\\_pour\\_une\\_sante\\_solidaire\\_27\\_03\\_2015.pdf](http://www.smg-pratiques.info/IMG/pdf/charte_pour_une_sante_solidaire_27_03_2015.pdf)

<sup>176</sup> <http://lci.tfl.fr/science/sante/mediator-un-syndicat-de-medecin-va-porter-plainte-contre-l-afssaps-6471628.html>

<sup>177</sup> UGICT. <http://www.ugict.cgt.fr/>

<sup>178</sup> UGICT. <http://www.ugict.cgt.fr/ugict/presse/retrait-de-lamendement-secret-des-affaires>

<sup>179</sup> CFE-CGC. <http://www.cfecgc.org/>

<sup>180</sup> Force ouvrière. <http://www.force-ouvriere.fr/>

<sup>181</sup> UFAS. <http://www.sante.cgt.fr/Union-federale-Action-sociale-UFAS>

<sup>182</sup> CGT. <http://www.cgt.fr/>

<sup>183</sup> SNPI. <http://www.syndicat-infirmier.com/>

<sup>184</sup> UFMICT. <http://www.sante.cgt.fr/Union-federale-Medecins-ingenieurs>

<sup>185</sup> UFSP. <http://www.sante.cgt.fr/Union-federale-Sante-privee-UFSP>

<sup>186</sup> USP. <http://www.uspsy.fr/>

## 7 Discussion <sup>187</sup>

In France ethics assessment primarily takes place in ethics assessment boards within governmental institutions, boards that are under the supervision or funded by the government. Therefore, research institutions mainly depend on the competent state bodies for ethics assessment and don't necessarily have their own specific institutional set up for ethics clearance. Exceptions include the ethics boards of the National Centre of scientific research (CNRS), the National Institute of Health and Medical Research (INSERM), or even the Institut Pasteur.

Historically, ethics assessment structures appeared in the 1970s, hospitals started creating their own local and independent ethics committees. However, these slowly disappeared as the government started putting into place ethics assessment boards, such as the Committees of Protection of Persons (CPPs) in 1988 with the law "Huriet-Sérusclat" (they were previously called *Comités consultatifs de protection des personnes dans la recherche biomédicale* or CCPPRB).

Furthermore, one can say that the approach to ethics assessment is closely linked to the historical background of international frameworks created after World War II, such as the Nuremberg Code or the Helsinki Declaration. This is most likely because the CPPs deal with ethical concerns in the field of biomedical research and life sciences, such as respect of individual autonomy through informed consent. This requirement of consent is consistent with that issued, for example, through the Nuremberg Code.

While a very rigorous legal framework exists for ethics assessment practices within France, there have nonetheless been criticisms voiced. Within the system, "ethics" assessment can be confused with the requirement to check for compliance with the legislative framework, conflating legal and ethical obligations.

The CPPs must give an opinion and the National Agency for Safety of Medicine and Health Products (ANSM) (which is under the supervision of the Minister in charge of health) must give an authorisation before a research involving human beings can take place. Both the CPPs and the ANSM assessments are based on the compliance to the laws in force.

This is also the case with the Institutional Review Board, CEEI/IRB of the INSERM, which deals with the delivery of opinions regarding the compliance of research projects with ethical legal provisions.

Moreover, the CPPs and the ANSM are funded by the government. The members of the CPPs are for instance appointed by the regional prefect and the ANSM takes decision on behalf of the government, therefore the role government plays is to be considered.

Diversity may also be found in the ethics assessment landscape in France. Indeed, there are other governmental institutions, such as the French Biomedicine Agency (ABM) that has its own council (*Conseil d'orientation*), the High Council on Biotechnology, which has two committees and then the Parliamentary Office for Evaluation of Scientific and Technological

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<sup>187</sup> Some of the elements for the conclusion were taken from an anonymised interview conducted by UNESCO.

Choices (OPECST) which gathers information, implements study programs and makes scientific and technological assessments. This illustrates the diversity of the ethics assessment landscape in France. There are also the National Commission for Information and Liberty (CNIL) and an Advisory Committee on the Treatment of Research Information in the Health Field. With regard to animals, there are the National Commission on Animal Experimentation (CNEA) and the National Committee for Ethics in Animal Research (CNREEA) placed within the CNEA that deals with ethics assessment when it comes to research using animals. The fact that ethics assessment is scattered can be considered to be an advantage of the French ethical clearance set up. However, some may say that this underlines the absence of a harmonised approach to ethics assessment on a national level.

More specifically, the CPPs have been openly criticised for the reasons mentioned below by the public and academics. This has had its consequence on a legislative basis; the law “Huriet-Sérusclat” has been revised by other laws, and more recently by the law “Jardé” that has not yet entered into force because it requires the elaboration of an implementation order that’s been suspended due to a recent European directive.

Secondly, the fact that CPPs are local is an advantage as the investigators and sponsors can directly interact with the CPPs’ members. However, researchers have the choice of the CPP they’ll be submitting their protocol to, which can lead to them choosing the more lenient committees.

Also, the CPPs can be criticised for having no monitoring procedures after giving a favourable opinion. There is an association formed by members of most of the various CPPs: the National Conference for the Committees for the Protection of Persons (Conférence Nationale des Comités de Protection des Personnes, CNCP). However, this association only aims to establish and operate a network of CPPs and is not a monitoring body.

Other recent considerations include the fact that CCP members are volunteers who are not paid for the most part and not properly trained for their mission. Consequently, there are disparities in the effective implementation of ethics assessment reviews when dealing with the review of protocols. This has never really been studied due to confidentiality issues.<sup>188, 189, 190</sup>

Because of these weaknesses, the “Jardé” Law seeks to simplify the procedure by putting in place a regulatory requirement for the submission of all research projects carried-out on human beings to CPPs. However, this would not enlarge the ethics assessment approach, if the principles were to remain the same and the ethics assessment would be purely based on regulatory compliance. This new law is also putting into place the random designation of the

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<sup>188</sup> Fauriel, I., G. Moutel, N. Duchange, I. Callies, I. François, C. Huriet, C. Hervé, “Improving protection for research subjects in France: analysis of regional ethics committees” *Regul Toxicol Pharmacol*, 2004, 40(3), pp. 312-8. <http://www.ncbi.nlm.nih.gov/pubmed/15546685>

<sup>189</sup> Fauriel, Isabelle, Grégoire Moutel, Irène François, Luc Montuclard, Christian Hervé, “The protection of persons and biomedical research in France. A multicentre study of 10 committee”, *LEM - Laboratoire d'éthique médicale et médecine légale*, 2006. <http://www.hal.inserm.fr/inserm-00090254/document>

<sup>190</sup> Fauriel, Isabelle, Grégoire Moutel, Nathalie Duchange, Irène François et Christian Hervé, “Evaluation of Decision-Making by CCPRBs Laboratoire d'Éthique Médicale, de Droit de la Santé et de Santé Publique, Faculté de Médecine Necker, Paris, France, 2004. [http://www.journal-therapie.org/index.php?option=com\\_article&access=dkey&dkey=10.2515/therapie:2004069&lang=fr](http://www.journal-therapie.org/index.php?option=com_article&access=dkey&dkey=10.2515/therapie:2004069&lang=fr)

committee in charge to evaluate the research project in question. Furthermore, the “Jardé” Law wants to create a National Commission for research involving human beings that would coordinate and harmonise the assessment of CPPs. This Commission would be under the supervision of the Ministry of Health; the government influence would be maintained. The French law being in transition phase brings along strong criticism of the legislative framework in place at the present moment.

While there is a seemingly strong governmental influence on ethics assessment in France, any influence is counterbalanced by civil society and professional association participation, such as with patient associations previously cited in this report. Furthermore, though members of the CPPs are government designated, mitigating factors might limit the government influence on their selection. For example, protocol review is strictly confidential, members cannot lose their position, and membership does not bear on career prospects. In this way, the state driven ethics assessment framework may be able to maintain independence from government influence.