

Aitziber Emaldi Ciri3n, has addressed the following congresses in this last months: "Terapia g3nica y regenerativa: el riesgo de la eugenesia", organised by the association Fe, salud y dignidad humana, February 22, 2008; "Utilizaci3n de muestras biol3gicas: informaci3n y consentimiento", III Jornada de Investigaci3n Cl3nica: Muestras Biol3gicas y Biobancos. Organised by the Fundaci3n para la Investigaci3n Biom3dica del Hospital Universitario Ram3n y Cajal, Madrid, April 10, 2008; "La investigaci3n biom3dica: aspectos 3tico-jur3dicos", II Jornada de Comit3s de 3tica asistencial de la regi3n de Murcia, organised by the Hospital General Universitario Reina Sof3a, Murcia, 29 April, 2008; "El nuevo marco de la ley de investigaci3n biom3dica", International Congress on the "Los avances del Derecho ante los avances de la Medicina", organised by the University Pontificia de Comillas, Madrid, June 16-18, 2008; "An3lisis de la ley org3nica 10/2007, de 8 de octubre, reguladora de la base de datos policial sobre identificadores obtenidos a partir de ADN", organised by the Spanish Agency for the Protection of Data, May 21, 2008.

Likewise, she has written an article entitled "Human biological samples in research: juridical perspective", *Bioethis Global & Social aspects*, Ed. European Association of Global Bioethics, 2008, pp. 137-147.

In February, she was named Manager of the Alumni Association of the University of Deusto.

Pilar Nicol3s has addressed the following congresses: "Condiciones de legalidad de la exportaci3n de datos personales desde Europa a terceros pa3ses" and "Tratamiento de datos en el sector de la salud en Europa", in the *International Seminar on the regulation of the processing of personal data. Cuestiones disputadas*, Centro de Estudios en Derecho inform3tico, University of Chile; "La nueva era de la investigaci3n biom3dica" in the Congress *La Ley de investigaci3n biom3dica y los biobancos*, Hospital Cl3nico of Barcelona;

"Aspectos jur3dicos aplicables en la obtenci3n y uso de c3lulas obtenidas por reprogramaci3n inducida" in the *II Jornadas de Medicina Regenerativa*, Hospital Gregorio Mara33n; "Implicaciones legales de la ley de Investigaci3n Biom3dica en c3ncer hereditario" in the training Course on *Genetic Counsel and Hereditary Cancer*, organised by SEOM; "Ethical and legal issues of genetic testing", at the *3rd Familial Cancer Conference*, CNIO; and "Obtenci3n y utilizaci3n de datos gen3ticos en la contrataci3n de seguros. La dif3cil concreci3n de la prohibici3n de discriminaci3n", *International Congress on the advances of law when facing the advances in medicine*. She has published: "La protecci3n de los datos gen3ticos de car3cter personal en Derecho penal espa3ol: un caso pr3ctico", *Temas de Derecho Penal. Book honoring Guillermo Cornejo Cuadrado*, Editorial Adrus, Arequipa, 2008. She participates in the Nominal Group for the study of the "Non-financing of health technologies in Hospitals" of the Office for Health Planning and Regulation of the Health Department of the Basque Government.

Sergio Romeo Malanda has joined the University of Las Palmas de Gran Canaria as a professor of Criminal Law in March, 2008. He has published the following works: "*El aborto criminol3gico derivado de una reproducci3n asistida no consentida*", in *Temas de Derecho Penal*, Editorial Adrus, Arequipa, 2008; "*Pharmacogenetic testing: Legal considerations for consent, privacy and disclosure*" (jointly with Dianne Nicol), *Personalized Medicine*, 5 (2); *La utilizaci3n de materiales biol3gicos humanos con fines diagn3sticos y terap3uticos*, *Estudios de Deusto*, n3 1 (2008); *Minoria de edad y aborto: algunas consideraciones sobre consentimiento y confidencialidad*; *Revista Humanitas*, n3 28, (online access: www.fundacionmhm.org). Additionally, he has given the following conferences: "La menor de edad ante la interrupci3n del embarazo: consentimiento y confidencialidad", at the International Congress *Los avances del Derecho antes los avances de la biomedicina*

held in Madrid (Spain) June 16-18, 2008; "El Derecho penal y la protecci3n de los intereses de los consumidores", in the Course "*Los derechos de los consumidores y la jurisdicci3n civil, penal y mercantil*", organised by the Consejer3a de Empleo, Industria y Comercio (Gobierno de Canarias) and the Instituto Nacional de Consumo (Ministry of Health and Consumption) in Las Palmas de Gran Canaria, June 11, 2008.

Leire Escajedo San Epifanio has published the following works: «*Biotechnologie, Sant3 et Environnement dans L'union Europ3enne: Aspects Politiques et Juridiques*», *Revue du March3 commun et de l'Union europ3enne*, n3517, avril 2008, pp255 a 266 ; "Productos transg3nicos y alimentaci3n en el Tercer Mundo: el Derecho como instrumento de equilibrio", in *Biotechnologia, Desarrollo y Justicia*, Inter-University Chair in Law and the Human Genome, Bilbao, 2008, pp317 a 369. Regarding Congresses and Scientific Events, she has participated in: Seminario Internacional Complutense de Derecho Constitucional Europeo "La (des)constitucionalizaci3n en la Uni3n Europea", held in Madrid, April 17 and 18, 2008, speaking on "Sobre la Constitucionalizaci3n de la Biomedicina en la Uni3n Europea: clonaci3n humana y eugenesia en la Carta de Derechos Fundamentales"; Congreso Internacional Los Avances del Derecho ante los Avances de la Medicina, Universidad pontificia de Comillas (Madrid), in collaboration with the University of Deusto and Ram3n Ll3l, 16-18 of June, 2008. Speech entitled "La libertad fundamental de investigaci3n y los nuevos controles 3ticos a la actividad biom3dica"; speaker at the *Jornada de Presentaci3n del Comit3 de 3tica de Intervenci3n Social de Guip3zcoa*, 23 May, 2008, organised by the Provincial Government of Guip3zcoa at the campus of the University of Deusto in San Sebasti3n. Topic: "*¿A qu3 llamamos Comit3s de (Bio)3tica? Cu3ntos y cu3les son; por qu3 y desde cu3ndo existen; qu3 hacen, c3mo y d3nde*".

Inter-University Chair in Law and Human Genome

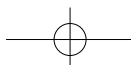
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Perspectivas

en Derecho y Genoma Humano

Number 11, June 2008

Inter-University Chair BBVA Foundation-Provincial Government of Biscay in Law and the Human Genome. University of Deusto, University of the Basque Country

Director: Prof. Dr. iur. Dr. med. Dr. h.c. mult. Carlos María Romeo Casabona

This issue is also published in Basque and Spanish

News

Carlos María Romeo Casabona has been named member of the European Research Area Board (ERAB)

The European Commission has named Carlos María Romeo Casabona, Director of the Inter-University Chair in Law and the Human Genome, as a new member of the European Research Area Board (ERAB).

The twenty two members of this entity, in which Romeo Casabona is the only Spaniard and the only lawyer, shall provide counsel to the European Executive in matters of Research. These experts, whose backgrounds are from the academic, scientific and business sectors, shall provide independent counsel to the European Commission in matters of scientific research and policy and shall promote the European Research Area.

The debate on the future of science in Europe has highlighted the urgent need to increase efforts by Member States, by the scientific community and the business sector in order to improve European research, achieve a more efficient transfer of its results to society, by promoting, among other measures, a patent and the review of its legal regime and by assuring the EU's world leadership in this field. The new European Research Area Board is called upon to carry on a key role in the development, promotion and evaluation of the political initiatives and activities aimed at reaching the objectives that Europe has set out in the field of research.

The establishment of this Committee shows the importance of having the counsel of the most distinguished experts in an area that shall each time more have a more relevant position in the political agenda of the European Commission. One of the key tasks for the ERAB shall be to draft an annual report for the European Community Executive on the state of research in Europe.

The members of ERAB were proposed to the European Commission by an independent Committee made up by Claudie Haigneré, former French Minister of Research and New Technologies; Vaira Vike-Freiberga, former President of Letonia; and Andrew Dearing, Secretary General of the European Industrial Research Management Association.

Besides Romeo Casabona, the members of the European Research Area Board are Reinhold Achatz, Vice-President of Siemens Corporate Research and Technologies (Germany); Robert Aymar, General Manager of Cern (Switzerland); Lajos Balint, Director of International Relations at the National Information Infrastructure Development Office in Hungary; Jean Botti, technical delegate of EADS (Germany); Adelheid Ehmke, President of the European Platform of Women Scientists (Belgium); Frank Gannon, Director General of Science Foundation Ireland; Barbara Haering; Executive Director of ECONCEPT (Switzerland); David King, Director of the Smith School for Enterprise and the Environment (United Kingdom); Leif Kjaergaard, Technical Delegate of Danisco A/S (Denmark); Marja Makarow, Executive Director of the European Science Foundation; Karol Musiol, Dean of the Jagiellonian University (Krakovia, Poland); Zaneta Ozolina, Professor at the University of Letonia; Maria Cristina Pedicchio, Professor at the School of Sciences at the University of Trieste (Italy); Alain Pompidou, Researcher at the National Centre for Science Research (France); Unni Steinsmo, President of SINTEF (Norway); Lena T. Torell, President of the Royal Swedish Academy of the Engineering Sciences (Sweden); Jan Van de Biesen, Vice-President of Phillips Research (Netherlands); Georg Winckler, President of the Association of European Universities (Belgium); John Wood, Dean of the School of Engineering of the Imperial College (London, United Kingdom; elected as President of the Committee) Ingrid Wünnig Tschool, Responsible for Science and Research at Robert Bosch Stiftung (Germany); and Nüket Yetis, President of TÜBITAK (Turkey).

Opinion

SIMONE PENASA (Italy) Challenges in the research and commercialisation of new medicines. Reflections from a Seminar (Bilbao, October 29, 2007)

Due to a Congress organised by the Inter-University Chair in Law and the Human Genome, held the 29 of October, 2007 at the University of Deusto, it seems opportune to reach some conclusions on what has been a very fruitful cross-disciplinary debate. Furthermore, in a legal sector - the research and

commercialisation of medicines- that as highlighted by Prof Romeo Casabona in his *Presentation*, is subject to a constant and radical progress in both techniques as well as in lines of research. All this, within a global context that, if on the one hand allows a virtuous circulation of competences, knowledge and results, while on the other hand amplifies those issues of legal, economic and social nature.

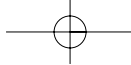
Regarding the research and commercialisation of new medicines, there seems to be three different levels, characterised by a growing legal relevance.

At a first level, which we can define as *descriptive*, we would place the scientific evolution that characterises this ambit in relation with society and therefore also with the law and its actors. Different interests clash, constitutionally recognised, whose protection must be reciprocally harmonised and balanced due to the regulatory intervention of Law. The essential core of this clash is set, on the one hand, in relation with the interests of enterprises, and that of society. The issue of determining a reasonable equilibrium between them is framed within the relation that links general interests (health, privacy, integrity, but also to scientific knowledge and progress for diagnostic or therapeutic ends) and private interests (to financial investment and to the economic exploitation of scientific discoveries): in terms of legal measures of regulation, the relation is placed between a system of patents and the tutelage of the autonomy, the free development and the integrity of the persons involved (which guarantees individual rights previously mentioned). This is an equilibrium which is hard to reach and which needs of legal instruments in its regulatory intent and that are effective in its aim of guaranteeing rights and liberties, which tend to safeguard the public health without excessively burdening the scientific activity of enterprises, insofar as a factor of promoting the scientific and technical research aimed at the common welfare, in accordance with constitutional principles.

How can we achieve this? In this manner we reach the second level of legal relevance- defined as *normative*, which is characterised by a critical analysis of the legal instruments that characterise the reality of the research and commercialisation of medicines. In fact, the issue of the legal regulation of scientific research and the commercialisation of its results



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highlights and reveals the inability and insufficiency of the mere legislative instrument in order to guarantee an efficient and certain discipline. The legislative instrument oftentimes reveals -when facing a new and constantly evolving reality- as too detailed, complex, changing and technical to develop its traditional regulatory function.

The *administrative "path"* (in this sense, the interventions of Mr. Fernández Brañas, *the European Patent Office and the biotechnological patent*, and of Prof. Bellver Capella), can be traced in a system of authorisations, under unequivocal conditions and limits, whose finality is to guarantee and promote public health to the essential standard that must be the filter of any authorisation. Special relevance seems to express the level of International Law (Prof. Esplugues Mota, *International Commerce of Medicines*, in which it would be possible to establish some common compulsory standards for the majority of international subjects; for example, *ex ante*, through the insertion in the necessary legal body of law in order to enter in supranational institutions *and ex post* through an international system of arbitration).

The judicial *"path"* (Prof. De Angel Yagüez, *Medicines, public health and legal responsibility*, contemplates the intervention of magistrates as a re-balancing between rights and interests that have already clashed in spite of specific measures of control, authorisation and monitoring.

Finally, there is the *"path of self-regulation"* (Dr. Martín Uranga, *Biomedical research with innovative medicines*, with which there is a recognition of the directly disciplinary role of subjects who are directly involved in research, both from the perspective of the enterprises and research teams as well as from the persons involved in the activities, among which is necessary to reach a shared assumption of the risk through the participation in the mechanisms of regulation. In this ambit, the technical committees develop an essential function, both in the sense of the previous authorisation and establishment of criteria and conditions- according to a perspective based in the *"case by case approach"* - as well as by the successive and constant activity of monitoring and control of the authorised projects.

Once we recognise this plurality of the potential legal instruments, which elements could represent relevant criteria in order to choose among them? In order to answer this question, we have to enter in the third level of legal relevance, which we could define as *methodological*. If the common objective to the different normative instruments must be a balanced pondering of the relevant interests and rights, the parameter of evaluation of the legal usefulness of each one must be the level of effectiveness reached in the regulation, monitoring and control of the research activity and in the guarantee of the rights of the persons involved. This effectiveness should be evaluated through a set of qualitative and quantitative criteria, among which we should highlight - from a perspective of the research enterprises and teams- both the transparency and independence of the authorisation and information process offered to the entities of control such as the evaluation of therapeutic, safety and quality efficacy of the medicine; on the other hand - from a patient's perspective- we should highlight the recognised function, reach and the nature itself of the *consent* in research and therapy, which being a simple procedure of administrative authorisation must become an effective medical, conscious, informed and responsible act: not so much an automatic and instantaneous event, but rather a constant assumption of the responsibility in a process of participation throughout the research. In this plural composition of interests, the responsibility of the public powers is decisive, by for example, developing a necessary function of

equilibrium among private and public investment that could guarantee a greater level of control and fairness in the lines of research; all this, in accordance with the enunciated tasks by the Constitution, harmonising the fostering of technical and scientific research and the duty of the protection of health, guaranteeing an active and permanent safety of the medicines.

In conclusion, analysing these three levels of legal relevance in a systematic manner, the intertwining thread in its harmonising function must be the guiding criterion of whichever activity of regulation in this ambit: there is evidence of a better effective control throughout the research or experimentation activity, through procedural mechanisms of authorisation, consent and monitoring, rather than a control guaranteed only in an eventual manner by a system of legal prohibitions, obligations and sanctions, rigid and certain *"in the books"* but fragile and uncertain *"in action"* as it is lacking operative instruments that can make it effective.

News on the Inter-University Chair in Law and the Human Genome

POSEIDON PROJECT Meeting in Bilbao of the European

Last February 1, 2008, the University of the Basque Country held a meeting of the European project POSEIDON, which is coordinated by French scientist Anne Cambon-Thomsen and which has among its principal objectives the improvement of the safety of the transplant of allogeneic haematopoietic stem cells and to make its access more equal to this type of therapy throughout the European Union. The meeting was held with all the members of the Work Project 4 (WP4), under the coordination of Prof. Dr. Carlos María Romeo Casabona. WP4 deals with the legal aspects raised by the donation of haematopoietic stem cells and the application of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

LATINBANKS PROJECT, Study on the legal and social implications of the creation of banks with biological material in Latin America.

During the 22 and 23 of February, the University of Deusto held the first meeting of the researchers in the Project LATINBANKS which represents the beginning of the cooperation among twelve European and Latin American universities within the framework of the ALFA Program of the European Commission through the establishment of the network MEDNET. The meeting, divided into three sessions, was inaugurated by Professor Carlos María Romeo Casabona and Jürgen Simon, who are Project coordinators, and was moderated by Professor Helena Montiz (University of Coimbra-Portugal) and Myriam Blumberg-Mokri (Paris), as well as by Professor Manuel Lobato García-Miján (Spain). The following intervened: Professor Salvador Dario Bergel (University of Buenos Aires - Argentina), Ingrid Brena Sesma (Nacional Autónoma University of Mexico), Lorena Donoso Abarca (University of Chile), María de Fátima Freire de Sá (Pontificia Universidad Católica de Minas Gerais - Belo Horizonte, Brazil), Carolina Figueredo Carrillo (Universidad Externado de Colombia, Bogotá) and Carlos Valerio (Association of Medical Law of Costa Rica, San José); and with the participation of Professor Bruno Torquato de Oliveira Naves (Pontificia Universidad Católica de Minas Gerais - Portugal) and Heike Bockmann (University of Lüneburg - Germany).

In agreement with the objectives of the Project, there was a thorough compilation of information related with the different banks of biological material in existence throughout Latin America and several problems and obstacles were detected in relation with their functioning and regulation. In this sense, and during the debate, an agreement was reached that throughout the following months, the twelve researchers should focus their attention towards the analysis of the legal and organisational structures of the aforementioned banks of biological material in order to draft proposals for their optimal use.

XENOME PROJECT

Within the activities of the European Project XENOME, which is coordinated by Dr. Emanuele Cozzi, a seminar entitled *Scientific Legal and Ethical Aspects of Xenotransplantation* was held in Zubiria Etxea (University of the Basque Country). The presentation of this event was made by Prof. Romeo Casabona, coordinator of the Congress, and had the following interventions: "State of the art on preclinical studies" (Emanuele Cozzi, Italy), "State of the art on biosafety issues" (Yasu Takeuchi, Japan), "Legal issues related to xenotransplantation: an overview on the current concerns" (Asier Urruela, Spain); "Legal and ethical principles in scientific research: general framework" (Sadek Beloucif, France), "Comparative analysis between EU member States Law" (João Paulo Remedio Marques, Portugal), "The Italian regulatory context in the recent years with regard to cloning and transgenesis" (Cesare Galli, Italy), "An experience inside the Council of Europe working party on Xenotransplantation" (Marialuisa Lavitrano, Italy), "The introduction of New and Emerging Health Technologies in Public Health Systems" (José Asua Batarrita, Spain), "The roles of publics in Xenotransplantation" (Mariachiara Tallachini, Italy).

BIOTETHED PROJECT

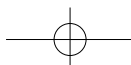
Last March, between the 4th and 8th, a meeting was held among the members of the research project entitled "Biotheted" financed by the European Commission. In this meeting, the design for the next edition of the Advanced Course on Bioethics and Biotechnology was held. Representing the Inter-University Chair in Law and the Human Genome, Dr. Iñigo de Miguel Beriain was in attendance. The aforementioned course was held in Bucharest (Romania) and the following attended as members of the Chair Dr. María Jorqui and Attorney Emilio José Armaza Armaza.

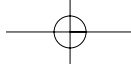
Collaboration with the Agency for Quality, of the Ministry of Health and Consumption

During a period of two years, members and collaborators of the Chair (C.M. Romeo Casabona, A. Urruela Mora and A. Libano Beristain, with the counsel of Chair in Procedural Law of the University Autónoma of Barcelona M. Cachón) have issued a report for the Quality Agency of the Ministry of Health and Consumption entitled "Establecimiento de un sistema nacional de notificación y registro de incidentes y eventos adversos: aspectos legales". It is made up of three documents of over three hundred pages, with conclusions and final proposals.

International Committee of Experts on congresses and seminars of the Chair

The International Counselling Committee for the celebration of Conferences and Seminars of the Chair has been created. Its function is the collaboration in the drafting of programmes for the Conferences and Seminars, both in the choosing of its topics as well as speakers; as well as in the diffusion of its results. In this manner, the aim is to integrate outside specialists to the activities of the Chair in order to provide their knowledge and experience in order to continue improving in the established working guidelines. The members who are already part of this Committee are from European countries





(Spain, Germany, Belgium, France, Italy, Netherlands, United Kingdom), Latin America (Argentina, Brazil, Chile, Colombia, Costa Rica, Mexico, Uruguay), North America (Canada), Australia as well as members from international entities (European Union).

Enciclopedia de Biolaw and Bioethics

The Chair in Law and the Human Genome has begun the preparation of an Encyclopaedia on Biolaw and Bioethics. This compilation will ease the quick and simple access, but thorough, of all matters of the life sciences that involve ethical or legal issues, in which the scientific rigour and the clear exposition shall be combined. There are over two hundred experts as invited authors in each of the topics that are going to be developed in the Spanish as well as Latin American ambit.

XV Conference on Law and the Human Genome

The Inter-University Chair in Law and the Human Genome held during the 21 and 22 of April its traditional Conference on Law and the Human Genome, which this year is in its 15th Edition. The coordination was the responsibility of Dr. Aitziber Emaldi Cirión.

The inaugural speech, which was entitled "Del Genoma Humano a la medicina individualizada" was addressed by Mr. Jaime del Barrio, General Manager of the Roche Institute, Madrid, which led to the first session, which focused on "genetic analyses", which was moderated by Dr. María Jorqui Azofra, member of the Inter-University Chair in Law and the Human Genome. This session had the participation of Prof. Dr. Luis González Morán, Member of the Counselling Board of the Chair in Bioethics of the University Pontificia de Comillas, who spoke on "the consent of the patient"; Prof. Dr. Fernando Abellán, Professor of the Health Law Masters of the European University of Madrid, whose topic was "the Protection of Genetic Data"; and Prof. Dr. María del Rosario Sánchez Morales, Professor of Sociology of the UNED, who spoke on the "Social Impact and the public perception of genetic analysis".

The second session dealt with the issue of "The identification of DNA Profiles in a criminal process". Dr. Óscar García, President of the Spanish and Portuguese Group of the International Forensic Genetic Society was responsible for moderating this part, who had the collaboration of Prof. Dr. Ángel Carracedo, Chair in Health Law and Director of the Health Law Institution of the University of Santiago, who spoke on "Presupuestos científicos de la investigación por perfiles de ADN en el proceso penal"; and Prof. Dr. Eduardo Osuna Sánchez de Albornoz, Chair in Health Law at the University of Murcia, who spoke on "La bioinformática como herramienta fundamental en la investigación genética"; and his Excellency Mr. Vicente Gimeno Sendra, Chair in Procedural Law at the UNED and Emeritus Justice of the Constitutional Court, who spoke on "La Ley Orgánica 10/2007, reguladora de la base de datos policial sobre identificadores obtenidos a partir del ADN".

The third session was entitled "Biomedical Research: some ethical and legal issues", moderated by Professor Ana Adoración Castro Jover, Chair in Ecclesiastic Law of the State of the University of the Basque Country. The following participated, Mr. Luis Fernando Niño, National Justice of Oral Criminal Courts of Buenos Aires, Argentina, with the speech entitled "Principios jurídicos implicados en la investigación biomédica"; Dr Stella Maris Martínez, Official Defence Attorney for the Supreme Court of the Nation, Argentina, who spoke on "Los delitos sobre manipulaciones genéticas"; and Prof. Dr. Ana Fernández-Coronado González, Chair in Ecclesiastic Law of the State of the Complutense University of Madrid, who spoke on "Libertad de Conciencia y Bioética".

Declaration of the *Hinxton Group* on the scientific, ethical and political challenges raised by gametes derived from pluripotent stem cells.

For many centuries, scientists have researched the development of ova and sperm in mammals. The greater part of this work has been developed in animals, particularly on the mouse. The capacity to culture pluripotent stem cells in vitro shall ease the research on the development of human ova and sperm. As a consequence, we can already foresee that it will be possible to obtain ova and sperm from pluripotent stem cells in a laboratory. This line of research raises ethical and social issues that can be seen in different manners in different cultures. The aim of this document is to provide information for the public discussion on the state of science and its possible social implications and to draft recommendations on policy and putting into practice. The *Hinxton Group* (International Consortium on Stem Cells, Ethics and Law) was created in 2004, upon the initiative of the Bioethics Institute John Hopkins Berman, for the purpose of gathering personalities from different nationalities and different areas of knowledge in order to explore the ethical, legal and political challenges of transnational scientific collaboration that is derived from the existing legal variations at the international level in relation with research with stem embryos and cells.

This Declaration is the second which is presented by this group, put forth the 11th of April, 2008 and with the participation of the Director of the Chair, Carlos Romeo who is a member of the *Hinxton Group* since its creation.

The complete text of the declaration can be seen in the web page of the Chair

Publications of the Inter-University Chair

Revista de Derecho y Genoma Humano/Law and the Human Genome Review.

Has published Issue No. 28, January-June 2008, with the following content: *Del genoma humano a la medicina individualizada* (Jaime del Barrio); La clonación humana y el resguardo de los intereses de las mujeres (Marcela Ahumada Canbes); El estatuto jurídico del embrión en España: de la ley de reproducción de 1988 a la clonación terapéutica de nuestros días (Fernando Abellán-García Sánchez); Preimplantation genetic diagnosis: an ambiguous legal status for an ambiguous medical and social practice (Christian Byk); Reserva judicial y otras cuestiones relacionadas con el empleo del adn en la investigación penal (Parte II) (José Francisco Etxeberria Guridi); *Ethical, legal and social issues related to cell therapy* (Carlos María Romeo Casabona); The previous risk treatment of the transgenic crops in the Brazilian biosafety regulatory system (Bruno Taus Job e Meira); *Investigaciones con células troncales embrionarias en Brasil y la (in)constitucionalidad del Artículo 5º De La Ley De Bioseguridad (Parte I)* (María De Fátima Freire De Sá / Bruno Torquato De Oliveira); El estatus biológico del embrión humano. Nuevas repercusiones bioéticas y biojurídicas (Jorge Alberto Álvarez-Díaz)

Biotecnología, Desarrollo y Justicia

This monograph is a reflection of the incidence of globalisation in the development of Biotechnology and on the guidelines that should be observed in this process in order to follow the principle of justice, from a cross-disciplinary and transcultural perspective, which is evidenced in the participation of such by authors from different European, Latin American and Asian countries.

The challenge of our time is that the ethical globalisation is undertaken within a framework of transculturality that encompasses the universal acceptance of certain shared values and rights capable

of providing answers that the challenges of a globalised world and, at the same time, assuring the respect, in case be, and the cultural and social traditions of peoples and collective groups.

Activities of the members of the Inter-University Chair

Carlos Romeo Casabona has published several works, among which the following should be highlighted: "Política legislativa penal y extrapenal en relación con la biotecnología humana", in *El derecho ante la biotecnología. Estudios sobre la nueva legislación española en biomedicina*, University of Lleida, Departament de Dret Public, Héctor C. Silveira Gorski (Ed.), Icaria Editorial, Barcelona, 2008; "Decisiones ante la proximidad de la muerte del paciente: interrupción o no iniciación del tratamiento", in *Aspectos médicos y jurídicos del dolor, la enfermedad terminal y la eutanasia*, Fundación Lilly and Unión Editorial, Manuel Gómez Tomillo (Director); "Globalization and the Dynamic Role of Human Rights in Relation to a Common Perspective for Life Science", in Marcus Düwell/Christoph Rehmann-Sutter/Dietmar Mieth (Eds.), *The Contingent Nature of Life*, Springer, The Netherlands, 2008; "La Ley de Investigación Biomédica: un nuevo y completo mapa para la investigación científica", in *Redes de Investigación en medicamentos*, Farmaindustria, nº 10, 2008. Additionally, he has been a speaker in several national and international forums: "El debate jurídico actual sobre la investigación y terapia con células madre: la nueva regulación en España y en otros países europeos", Simposio Internacional *Da sociedade globalizada aos desafios da biomedicina*, organised by PUCPR-Curitiba, Brazil, March 4-8; "Human Biotechnology, Globalisation and Symbolic Criminal Law", International Symposium "Ethik und Recht im Bereich der Gesundheit", organised by Yeditepe Üniversitesi and Instituto Roche, Istanbul, April 17-19; "The legal approach to medical liability", European Conference *The ever-growing challenge of Medical Liability: National and European Responses*, organised by the Council of Europe, Strassburg, June 2-3; "Muestras biológicas e investigación con células madre", Jornada sobre *la Ley 14/2007: un nuevo escenario para la Investigación Biomédica*, organised by Fundación Salud 2000, Madrid, January 23, 2008; "La ley de investigación biomédica y su incidencia en la práctica asistencial", Clinical Hospital Session organised by Hospital Universitario de Canarias, Tenerife, March 26, 2008. Furthermore, he has directed the Conference entitled "Derecho Penal y Globalización", organised by the International University Menéndez Pelayo in collaboration with the Generalitat Valenciana and the Fundación de la Universidad Internacional Valenciana (Universidad Internacional Menéndez Pelayo, April 28-30, 2008).

Iñigo de Miguel has published the article entitled "¿Existe un derecho a la identidad genética?", in the review *Arbor*, nº 730, March-April 2008, pages 261-276 and the chapter entitled "La Clonación. ¿Sueño o quimera? Un análisis ético jurídico de la transferencia de núcleos celulares" and "La Clonación. ¿Sueño o quimera? Un análisis ético jurídico de la transferencia de núcleos celulares", in the text *Bioética y Bioderecho*, coordinated by Rafael Junquera De Estéfani. Furthermore, he addressed the lecture entitled "El Concepto de Embrión en la Ley 14/2007, de 3 de Julio de 2007, de Investigación Biomédica", in the Congress entitled "Los avances del Derecho ante los avances de la Medicina" organised by the Jesuit Universities and held in Madrid, 16-18 June, 2008. He has also attended the meeting of the European research project entitled "Privileged" held in Sheffield (United Kingdom) 8-11 January and the European research project "biotethed", held in Bucharest (Romania), 4-6 March.

