12

The Trend Towards the Commercialization of Human Body Parts and of Privacy in Research with Biological Samples and Data (Big and Small)

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1. INTRODUCTION

Human subject research has to be assessed by independent multidisciplinary ethics committees in order to guarantee its quality and respect for the rights and interests of the people involved and taking part[1]. As a member of two Research Ethics Committees (REC)[2] I have witnessed the growing trend towards the commercialization of biological samples of human origin and of personal data. Human body parts (biological samples included) and personal data (and therefore privacy) are monetized in a society that has opted for scientific and technological research in order to stimulate economic and social progress. Research and scientific and technological applications are news almost every day in the media, including economics supplements, which have lately been describing the impact of digitization on business, the advantages of big data analysis and

1. See, for example, article 12, "Research Ethics Committees", of Law 14/2007, 3 July, of Biomedical Research (LIB).
2. Bioethics Committee of the University of Barcelona (member since 2011) and Research Ethics Committee of the Hospital Clínico in Barcelona (member since 2012), which functions as the same Hospital's Biobank External Ethics Committee, a possibility that the law allows. See article 6.2 b) of Royal Decree 1716/2011, 18 November, *whereby the basic authorization and functioning requirements are established of biobanks for biomedical research purposes and of the processing of biological samples of human origin, and the functioning and organization of the National Biobank Register for biomedical research are regulated*.

the successes of Iberian biotech companies[3]. I consider that practices in research associated with biological samples of human origin stored in biobanks, and the personal data flows in research with public big data, might occasionally not fulfil the established objectives, supposedly addressed to the common good and the public interest.

Bioethical reflection must help to define the problems and the opportunities of the application of scientific and technological progress, and to stimulate an informed debate in society about its impact on human beings –including future generations– and on the environment in which they live. If it does so too late and without a proper analysis and understanding of what we are facing, its contribution will be futile and it will have given rise to unwelcome practices due to the "naivety" of its principles, considered in the abstract. Bioethics will thus have encouraged an institutional discourse of safety and control of research that is far removed from reality. Bioethics will have been unable to adapt to the new scenarios in research and innovation, a facilitator of markets, because it continues to use old patterns for dealing with new and very complex problems in research and medical care.

Identifying commercial interest where there should only be research, and preventing a price from being placed on human beings (broken down into parts and data), is the challenge facing bioethical reflection in research ethics committees. For this chapter, certain practices have been chosen in the context of biobanks, as well as the situation of research into the use of big data. It is my intention to look at new situations for which bioethical analysis is not ready, and for which there is no suitable legal response either. Both these issues urgently need to be resolved. In a context of growing scientific and technological progress, a prior analysis of the ethical feasibility of any and all research and innovation is necessary, so that it really is ethical. The main objective of this chapter is to contribute to the conceptualization of the problems and to make proposals to

3. Among other news items: "La biotecnología ibérica se mete en la gran liga. Los acuerdos entre varias empresas ponen a España en el mapa mundial de la industria", *El País*, 24 April 2016, retrieved from *http://economia.elpais.com/economia/2016/04/22/actualidad/1461343830_526950.html*; "'Big data', la nueva materia prima. La privacidad gana importancia en un mundo donde los datos tiñen todas las actividades", *El País*, 4 June 2016, retrieved from *http://economia.elpais.com/economia/2016/06/03/actualidad/1464954943_672966.html*; "Seguros en la era del Gran Hermano. El big data analysis revoluciona el sector con productos a medida del cliente", *El País*, 25 April 2016, retrieved from *http://economia.elpais.com/economia/2015/04/23/actualidad/1429805089_612660.html*; "A tu banco le importa lo que haces en las redes sociales", *La Vanguardia*, 1 August 2016, retrieved from *http://www.lavanguardia.com/economia/20160731/403556388480/banco-redes-sociales-credito-algoritmo-big-data-scoring.html*. Consulted on 26 August 2016.

improve the research system, changing the ways in which biological samples and personal data flow, and patterns are established and behaviours are controlled in the field of health care.

Citizens supposedly empowered by technology –as advocated by digital business models and European research programmes[4]– will be astonished when they see that their genome and their purchasing patterns are in the hands of third parties with all sorts of interests. And that, since they have their data, if these third parties wish to venture into a new area of business, their offers will hit the target. When these citizens realize how little control there is over their data and the unwanted uses of their information and their privacy, what will happen? They might not be bothered, they might think it's fine – or not so fine, when they discover that this information is also in the hands of a private insurance company with which they wish to take out an insurance policy. When one of these citizens has Alzheimer's disease, they will no longer be able to wonder why years earlier they received in their email inbox a huge amount of advertisements for mobile phone apps about how to exercise their memory, cameras that film their habits in order to forget as little as possible and offers of homes for people with dementia. The answer must be sought in big data analysis, technology that will already have predicted their future and which, under the guise of supposed effectiveness, will already have determined the cost of their illness for the healthcare system[5]. In human subject research prices are established and there are markets for biological samples of human origin and data hiding behind the free status and the civic altruism established by law:

Donation and use of human biological samples will be free of charge, whatever their specific origin, and under no circumstances shall the compensations that are envisaged in this law be lucrative or commercial. Donation implies, furthermore, the waiving by donors of any economic or other right over the results that may be derived directly or indirectly from the investigations that are carried out with the said biological samples[6].

4. In order, for example, to grow old actively in the context of a single digital market, *https://ec.europa.eu/digital-single-market/en/research-and-innovation-ageing-well-ict*, consulted on 26 August 2016.
5. See the information available in open access on the European Union's website on Economics and Digital Society, under the slogan 'What can big data do for you?', retrieved from *https://ec.europa.eu/digital-single-market/en/what-can-big-data-do-for-you*, consulted el 26 August 2016.
6. Article 7 of Law 14/2007, of 3 July, of Biomedical Research. See also article 30 of Royal Decree 1716/2011, 18 November, *whereby the basic authorization and functioning requirements are established of biobanks for biomedical research purposes and of the processing of biological samples of human origin, and the functioning and organization of the National*

We must remember that research is the basis of our healthcare system and that the interests of science and of society must not prevail over those of the individual[7]. This chapter is not opposed to research with human biological samples or to the biobanks where they are stored and managed. Nor is it against big data analysis in research. Quite the contrary, it is a text in favour of such research, but without hidden markets, and in favour of bioethical reflection that understands the reality, that comprehends the problems from a multidisciplinary perspective, and which contributes solutions and alternatives, actually taking part in the different and very diverse processes of the creation and application of knowledge.

2. PUBLIC ASSETS AT THE SERVICE OF PRIVATE INTERESTS?

The experience I have accumulated in the assessment of projects has enabled me to see that proposals appearing to be a research project, but which in fact are not, are occasionally submitted to committees; practices designed for financial gain are disguised and presented, cloaked in the altruism that the system preaches. They are practices that may even be illicit and which cannot always be detected from the start but which, once they are identified, should not be authorized.

Some new business models are based on the financial gain obtained from human body parts[8] and from privacy by way of gathering and commercializing personal data. This may happen, for example, with certain health and wellness mobile apps (health apps), for which, in my opinion, neither the legal framework is sufficiently prepared, nor bioethical reflection has been brought up to date, in order to confront the new challenges that it now has to deal with in human subject research. Situations have

Biobank Register for biomedical research are regulated. "Cost-free status of the donation and use of biological samples of human origin. 1. The donation and use of biological samples of human origin will be free of charge, in accordance with the provisions of articles 7 and concordant ones of Law 14/2007, of 3 July. 2. The compensatory payment that may be established for the obtainment of biological samples of human origin for biomedical research purposes will only strictly be able to compensate the physical discomfort, the travel and work expenses and other problems that may arise from the taking of the sample, and it shall not represent a financial incentive. 3. Any publicity or promotional activity by the authorized centres that may encourage the donation of human cells and tissues must respect its altruistic nature, and it may under no circumstances incentivize donation through the offer of financial compensation other than the strict compensation envisaged in the previous section".

7. Article 2. Instrument of Ratification of the Agreement for the protection of human rights and the dignity of the human being with respect to the applications of Biology and Medicine (Convention on Human Rights and Biomedicine), Oviedo, 4 April 1997.

8. Article 21 of the abovementioned Convention on Human Rights and Biomedicine.

also been detected in which it has been impossible to obtain proof of information and informed consent of the patients or source subjects of the biological sample –from other countries, for example– in order to cede it to research projects. Quality, traceability and security –principles on which the law is based– are called into question[9]. Although there may be a black market for samples and data, generally speaking this is not something that is obvious.

In my opinion, colonialism in the twentieth and twenty-first centuries can also be explained through bodies[10], their parts and the associated personal data, generators of financial gain in different contexts, with an exponential ability to make money due to their potential exploitation and commercialization in different sectors and even by the company that gathers them. The digital society also feeds on these new trends in human subject research. The data-driven economy that Europe is wholeheartedly pursuing[11] stimulates health and wellness business models that are fed by personal data and behaviours, and information associated with sensitive data, such as health data, and other sociodemographic data, without their owners being aware of it and without them having any ability to control them. These situations are unwanted by the owners of the information and the biological samples; nor do they have any place in a system based on altruism and the public interest, in which the benefits of research should be for the good of the citizens.

Europe has opted for biobanks to share biological samples of human origin, so that research can be done with them and thus contribute to the increase of generalizable knowledge and to the development of therapies, treatments and operations to improve people's living conditions. Although the governance of biobanks has concerned the European Commission[12], and the requirements demanded by law to set up a biobank

9. In the context of a Biobank External Ethics Committee's activity and in accordance with the regulations covered by Law 14/2007, 3 July, of Biomedical Research, and Royal decree 1716/2011, 18 November, *whereby the basic authorization and functioning requirements are established of biobanks for biomedical research purposes and of the processing of biological samples of human origin, and the functioning and organization of the National Biobank Register for biomedical research are regulated*.

10. Along these lines, see Lysaught, M.T. (2009), "Docile Bodies: Transnational Research Ethics as Biopolitics", *Journal of Medicine and Philosophy*, 34, pp. 384-408.

11. See the Commission's communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Towards a thriving data-driven economy" (com/2014/0442 final), available on EUR-Lex database, retrieved from *http://eur-lex.europa.eu/legal-content/ES/TXT/HTML/?uri=CELEX:52014DC0442&from=EN*, consulted on 26 August 2016.

12. See the report on biobanks by the European Commission's Expert Group (2012), *Biobanks for Europe: A challenge for governance*, retrieved from *http://www.coe.int/t/dg3/*

are diverse and rigorous[13], for the moment the same cannot be said for big data research. The impact that in the context of research these practices have on people's rights calls for a change in the dynamics of who is researching, who is directing, who is assessing and controlling and who is authorizing the research. This also leads to a demand for changes in the market and to consider as a point of departure that bodies and body parts (samples included), as well as personal health data, should be kept out of commerce, and they should of course not be quoted on the stock exchange. Compliance with this condition seems impossible in the market society[14] in which we live, where even university professors are obliged to place their knowledge and innovation on the market[15].

3. PART I: BIOLOGICAL SAMPLES OF HUMAN ORIGIN AND BIOBANKS

In 2007 the Spanish Law of Biomedical Research (LIB) was passed. Among other issues related to human subject research, it establishes the legal framework for the use of biological samples in research. Samples that were previously kept in refrigerators, some of them similar to the ones we have at home, but full of human biological material: blood, DNA, tumours, brains, and so on. But what is a biological sample? "Any biological material of human origin liable to be conserved and which may contain information about the genetic make-up that characterizes a person"[16]. To become organized in order to share this material, so valuable for research purposes, from basic to clinical, that is the commitment. On this point, we have to distinguish between an anonymized or irreversibly dissociated biological sample, an unidentifiable or anonymous biological sample, and a coded or reversibly dissociated biological sample[17].

healthbioethic/Activities/10_Biobanks/biobanks_for_Europe.pdf. See also *Recommendation cm/Rec (2016)6 of the Committee of Ministers to member states on research on biological materials of human origin,* by the Council of Europe, revising the Recommendation of 2006. Retrieved from *http://www.coe.int/en/web/bioethics/biobanks*, consulted on 26 August 2016.

13. Chapter IV of Law 14/2007, 3 July, on Biomedical Research.
14. Sandel, M. (2013), *Lo que el dinero no puede comprar. Los límites morales del mercado*, Debate, Barcelona.
15. European Knowledge and Innovation Communities (KICs) are one example. See EIT Health, European Institute of Innovation and Technology, which is part of the European Union. I am a member of its Advisory Board on ethical, social and legal aspects.
16. Article 3 o) of Law 14/2007, 3 July, on Biomedical Research.
17. Law 14/2007, 3 July, on Biomedical Research, article 3 p) "Anonymized or irreversibly dissociated biological sample": a sample that cannot be associated with an identified or identifiable person, since the connection with any information that may identify

And what is a biobank? A "public or private establishment, not for profit, which houses a collection of biological samples created for the purpose of diagnosis or biomedical research, and organized as a technical unit with criteria of quality, order and destination"[18]. What is the problem in this case? That research resources and infrastructures such as public biobanks should not be associated, for example, with what are known as intermediaries of biological samples of human origin; that is, companies whose job it is, among other services, to position the samples in return for money. These companies demand, moreover, the commercial exclusive for "placing" samples for financial gain that have been donated by citizens altruistically, free of charge.

It is that simple and that serious[19]. From a mercantilist point of view, biobanks are gold mines to be exploited. If those who manage them and take part in their functioning biobank external ethics committees included – are not coordinated and prepared scientifically, technically and ethically (including human resources and materials), profit gains ground. What seems to be a research project may conceal a sale of biological samples of human origin that makes money for the biobank. Nobody said that this situation was not interesting from the strategic and financial point of view. Moreover, these practices have –formally– the backing of the relevant ethics committees, whereby the contradiction occasionally arises of bioethical reflection contributing to undesirable consequences in research activity due in part to the lack of time for proper analysis and expertise.

What appearances conceal must be detected by ethics committees, which have the obligation to be organized and to adapt to these unwelcome trends, in order to give the response needed by research – as we conceive of it, not as we put it into practice. And that objective *is* clearly regulated. Another thing entirely is that we have a model of ineffective research ethics committees that have to shoulder the entire burden. In the "bio-techno-datafied" market society, initiatives appear that are

the subject has been destroyed, or because this association requires an unreasonable effort; q) "Non-identifiable or anonymous biological sample": a sample taken without a connection to an identified or identifiable person, whose provenance is therefore unknown and it is impossible to trace the origin; and r) "Coded or irreversibly dissociated biological sample": a sample not associated with an identified or identifiable person, due to the information that identifies that person having been replaced or dissociated using a code that enables the reverse operation.

18. Article 3 d) of Law 14/2007, 3 July, on Biomedical Research.

19. "Mi tumor se vende en el extranjero", *El País*, 26 July 2016, retrieved from *http://politica.elpais.com/politica/2016/07/24/actualidad/1469369527_015224.html*, consulted on 26 August 2016.

sophisticated and tempting from the business point of view. They are complex structures that need a very keen eye to figure them out and which require a dedication that exceeds the powers permitted by the current model of research ethics committees in Spain.

I am sounding the alert here about a negative trend for the credibility of the science and technology system, a system that, in research, needs and will need the participation of the owners of the biological samples of human origin and the data, and the backing of assessors involved in ensuring that the altruism is not quantified. The source subject –"An individual, living– whatever their state of health may be –or deceased, from whom the biological sample comes" (article 3 v, LIB)– does not really know what this supposed free status conceals: exploitation and commercialization. And what is wrong with that? Some will say that, if a profit is made, part of it should be allocated to the owner of the sample and the data. But the fact is that the decision is already made, since we are obliged to waive any financial gain when we donate a biological sample for research purposes. Others will opt for a model based on compensation, and for others it will be a civic obligation, like someone paying taxes. Our altruism-based model must make solidarity prevail above any social, mercantile and even scientific interest.

We must prevent this altruism from being quantified in euros and converted into prices. Translational research gives rise to this kind of practice; the law and cultural contexts influence this type of model. Different regions have different ideas about what public and private assets are. Elsewhere the same companies acting as intermediaries for biobanks, whose operations we prohibit, are not only permitted, but they are welcomed and form part of the profitable alliances between research and markets. It is the Biobank External Ethics Committees that have the problem[20]; it is their job to

20. See Article 15. Royal decree 1716/2011, 18 November, *whereby the basic authorization and functioning requirements are established of biobanks for biomedical research purposes and of the processing of biological samples of human origin, and the functioning and organization of the National Biobank Register for biomedical research are regulated*. "Biobank External Committees. 1. External scientific and ethics committees shall be comprised of a minimum of four members with sufficient knowledge of the subjects related to the functions indicated in sections 2 and 3 of this article, who shall not take an active part in the biobank's activity. Both committees shall have their own internal operational regulations, which will establish the appropriate mechanisms to ensure independence and the absence of conflicts of interest in these committees' decision-making processes. In the event that, in relation to a specific issue, any member of the external committees shall have a direct personal or professional interest, they shall refrain from intervening. The biobank will make public the identities of the members of the external committees. The functions of the external ethics committee may be assumed by an already existing Research Ethics Committee, which will apply its own rules. […] 3. The functions of the ethics committee shall be: *a*) To

promote this altruism and, to some extent, guarantee it. The LIB gives them the power to trace the biological sample[21] and grants them some room to manoeuvre, whereby it is these committees that have to decide, in specific cases, on the cession (or not) of samples for research purposes, depending on the circumstances[22], a not inconsiderable decision-making capability.

Avoidance of the commercialization of biological samples of human origin donated to a biobank is something that depends largely on research ethics committees and Biobank External Ethics Committees, committees overloaded with work and which generally allege the lack of means and human resources to properly carry out the functions that they are assigned by law. Thus, in addition to the task of assessing projects and monitoring the ones authorized, there is that of tracing the biological samples of human origin, monitoring that has been regulated by law for many years[23], but which does not constitute a habitual practice. I believe

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ethically assess the applications for donating samples and the data associated with them. In the event that the committee issues an unfavourable ruling, this will be binding; *b*) To advise the scientific director about the adaptation of the established procedures to ensure the quality, the security and the traceability of the data and samples stored and of the procedures associated with the workings of the biobank, from the ethical point of view; *c*) To advise the scientific director about the ethical and legal aspects envisaged in the biobank's good practices document; *d*) To decide the cases in which the individualized sending of information to the source subject will be essential, in relation to the provisions for the donation of their samples and to the results of the analyses performed when they may be important for their health, and *e*) To assist the scientific director on any other issues that he/she may submit for consideration; and article 29". "Ruling of the Research Ethics Committee. In order to carry out an investigation with biological samples of human origin, the favourable ruling will be necessary, in all cases, of the Research Ethics Committees of the establishment on whose premises the samples are going to be used, or, failing that, of the committee to which the centre is assigned for which the person in charge of the investigation works".

21. Traceability, according to the Law of Biomedical Research, is the "ability to associate a specific biological material with registered information referring to each step in the process of obtaining it, and throughout the entire research process" (article 3 x).

22. See second transitory provision of the Law of Biomedical Research for samples obtained prior to its coming into effect, and article 58 for those obtained afterwards. Also De Lecuona, I. (2011), *Los comités de ética como mecanismos de protección en investigación biomédica: Análisis del régimen jurídico español*, Civitas, Cizur Menor. See also the Communication "El archivo de parafina y la interpretación del 'esfuerzo no razonable'. El caso del banco de tumores del biobanco del Hospital Clínico de Barcelona IDIBAPS" presented at the 5th National Biobanks Congress held in Lleida in November 2015 and which was awarded the prize for the best oral presentation. Authors: Ángela Martín, Itziar de Lecuona, Míriam Méndez, Marta Aymerich, María Jesús Bertrán, Neus Riba, Míriam Cuatrecasas, Anna Bosch, Raquel Bermudo.

23. The law on clinical trials has testified to this since 1978. See Royal Decree regulating clinical trials of pharmaceutical products and medicinal preparations (BOE, N.° 108, 6 May 1978, pp. 10683-10684).

that most committees would readily acknowledge that this monitoring is not done simply because "it is not possible". "It is not possible" is precisely what should not be accepted. Research is knowledge, it is power, it generates profit. Money is available, and it should be, in order to equip the system with the means for proper monitoring, not just approving projects and then switching off. In my opinion, the repeated idea that "there's no time, there's no money and there are no resources" for RECs is a fallacy that allows certain research practices to continue that ought not to have a place any more, with which a false sense of security is generated that endorses other interests, not the ones it ought to protect and promote. These other interests, sometimes far removed from the public interest or the essence of scientific research, stimulate a market where each body part and datum obtains an economic value and acquires unwelcome uses.

In my opinion, and from the legal point of view, in our context we have muddled through with an imperfect law to regulate research other than clinical trials that laid the foundations in 2007 and was developed in 2011, and which has established a system to coordinate biobanks that has given rise to double standards. Public and private biobanks advance along different paths when they should not, because the fact is that private biobanks are subject to the same regime. But, although all biobanks should be registered in the National Biobank Register[24], it is impossible to ensure that all private biobanks comply with the law currently in force. One often reads in research projects that the biological samples of human origin that are collected will belong to this or that pharmaceutical or biotech company; and/or that if results are found that determine the source subject from the genetic point of view and turn out to be in the company's interest, he or she will not be informed of this. From the assessment point of view and taking into account the current law, in our context this situation is unacceptable. The promoter is therefore told that it must comply with the requirements that are demanded or it will not be able to carry out its research[25].

The double standards are in connection with the situation of the biological samples of human origin that are sent abroad. The samples that come from other countries are regulated and must comply, as is to be expected, with the laws in force in Spain[26]. But what happens when a company

24. ePlatform for the register of biobanks and collections of samples reporting to the Instituto de Salud Carlos III, which structures the research in our context. See also the provisions applicable in Law 14/2007, 3 July, of Biomedical Research.

25. Article 59 of Law 14/2007, 3 July, of Biomedical Research.

26. Article 31 del Royal Decree 1716/2011, 18 November, *whereby the basic authorization and functioning requirements are established of biobanks for biomedical research purposes*

authorized to operate in our research, development and innovation (R+D+i) system is based abroad, and the biological samples of human origin will be taken there? There are no answers to this, apart from research ethics committees' powers to establish requirements and to demand proof of compliance with what was agreed. Is a trade in samples "made in Spain" thus fomented in other places? Are ethics committees aware of their responsibility in this respect? Research assessment infrastructure has become obsolete, overtaken by innovation in the commercial use of human samples and data. It may seem an exaggeration, but it is not. Research does not have to be a wholly not-for-profit activity, but incentives should not be given to private or spurious interests in what ought to be the public interest. Putting a price on samples is serious, although unsurprising in a society in which everything has one. So there is no longer any discussion about whether or not people should participate in research altruistically, but there *is* about the price the promoter is prepared to pay. For example, whether it is right or wrong to receive 150 euros for a lumbar puncture when others are prepared to offer up to 300 euros for this same procedure. Put simply, do they buy people's wishes? What would you do if you had to decide about these matters in research? A lumbar puncture makes it possible to extract fluid of human origin in order to investigate with it. Blood is also a biological sample. Neither the discomfort nor the risks in the extraction of these samples are the same. Nor are the prices of the same tests, depending on who requests them in order to do research and how much money they have.

I remember a project in which the reason put forward for not compensating the participants in it was summed up as follows: when there is money involved wishes are corrupted and not only can one not decide freely, but there is no motivation to take part in projects and collaborate with scientific and technological research. Do you find it appropriate or inappropriate that a patient should be "compensated" for their participation in an investigation with a credit card –which will generate for them an obligation with a bank– so that they can make purchases of up to X euros? Don't you think it's great? The person involved, if they had the

and of the processing of biological samples of human origin, and the functioning and organization of the National Biobank Register for biomedical research are regulated. "Use of biological samples of human origin coming from other countries. Biological samples of human origin from other countries may only be used for biomedical research purposes when, in their obtainment, storage or conservation and cession, besides the guarantees envisaged by the law relative to the entry and exit of samples to and from Spanish territory, the guarantees envisaged in the present Royal Decree and any other applicable laws have at least been observed, which will be assessed by the Research Ethics Committee assessing the research project and, where appropriate, by the biobank's external committees".

slightest idea of how much behaviours and data are worth now, would understand that with their participation they lose a lot and gain little. Not just in euros, but in the protection of their privacy in different facets of their life. These situations occur in research. How about 12 euros?[27]. How about 50 euros? Do you think it's a little or a lot? Meals and travel apart? It's up to you, it depends on what these people might have to go through: risks, discomfort, etc. Okay, it depends. Case by case and step by step. There are no protocols or consensus on this subject, information is not shared between committees, there are no national or local forums devoted exclusively to dealing with these matters, bearing in mind that their regulation cannot be considered recent: the LIB dates from 2007 and its regulatory development from the end of 2011.

The object of this chapter is not the "rates" of the participants in research that refer to the person as a whole; the interesting thing here is what human beings' body parts and data are worth, including from the deceased. In any case, I shall just mention that it is traditionally considered right for healthy volunteers to receive compensation for taking the trouble to participate in research. Patients taking part receive no compensation whatsoever, because it is the research itself that will compensate them, producing potential benefits for them or for the sick people they represent.

The danger to physical or mental integrity should not be associated with a mere question of financial "compensation" –in short, a price– whose amount is, moreover, hard to establish. But knowing that its quantification will depend largely on the committee's corrective judgment, it would be desirable, for the purpose of grounding the decision, for there to be pre-established procedures and registers to turn to. Regrettably, to date no work has been done in the direction of the establishment of scales of "value" of the body, parts of it, or of people's data in research.

So far I have been pointing out problems that clearly show research ethics committees' inability to react, but what about the integrity of science and of the responsible research and innovation talked about so much these days?[28]. It seems obvious that not everything should come

27. See Dal-Ré, R.; Carné, X. (2006), "¿Los pacientes deben recibir una remuneración económica por su participación en ensayos clínicos terapéuticos?" *Medicina Clínica*, vol. 127, N.° 2, June, pp. 59-65.

28. References may be multiple. See, for example, the European Code of Conduct for Research Integrity published by ALLEA (All European Academies), now being revised and which the European Union is thinking of establishing as the code of reference for its compliance by researchers in the context of research projects funded by framework programmes (i.e. Horizon 2020), retrieved from *http://www.*

down to research ethics committees' ability to evaluate and control via the monitoring of projects and donations of samples for research purposes.

The outsourcing of activities –in business language– is another risk of the commercialization of data in research related to the donation of biological samples in the context of clinical trials and other kinds of biomedical research in which people take part[29]. What do you, dear reader, think about a travel agency organizing your journeys to the hospital or centre where the research in which you have voluntarily agreed to take part will take place? You will probably say OK, no problem. You will think, in the good faith people have in research, that the different agents involved in the project will keep it confidential and that the professional secret is a guarantee, or at least that is what you read on the project's participant information sheet, and that the research is subject to compliance with Organic Law 15/1999, 13 December, of Personal Data Protection (LOPD). However, what will your opinion be about the company chosen for this task asking you if you like flying or what your favourite means of

esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf. With regard to responsible research and innovation, see for example the RRI European project to understand the areas that comprise it, and in which ethics is fundamental, and to access examples of Tools *http://www.rri-tools.eu/*, consulted on 26 August 2016. I am particularly interested in pointing out article 18 of Unesco's Universal Declaration on Bioethics and Human Rights (2005). In the context of the application of the principles it establishes: Article 18 "Decision-making and addressing bioethical issues. 1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every effort should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues. 2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis. 3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted".

29. In research in human beings, orders for data processing are made and compliance is required with the current law of personal data protection that, by the way, is almost 20 years old, Organic Law 15/1999, 13 December, of Personal Data Protection. In Europe revision has been underway of the 1995 Data Protection Directive, on which the Spanish law is based. The revision process began in 2012 and the final text came into effect in April 2016, and it leaves a great deal to be desired on the issues being dealt with here. Regulation (EU) 2016/679 of the European Parliament and of the Council, of 27 April 2016, relative to the protection of physical persons with respect to personal data processing and the free circulation of these data and due to which Directive 95/46/EC (General Data Protection Regulation) is repealed. Available at the EUR-Lex database, retrieved from *http://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=uriserv:OJ.L_.2016. 119.01.0001.01.ENG&toc=OJ:L:2016:119:TOC*, consulted on 26 August 2016.

transport is and what your favourite foods are, when it is not necessary to take a plane to travel to the research centre?

Were these questions really necessary? By the way, the company is a multinational based in, for example, the USA, and it so happens that you as a participant live close enough to the research centre or hospital to walk there. Should you fill in an online survey giving your travel and food preferences, your habits, in the context of research into, for example, Parkinson's disease? No, but if you do, which you almost certainly will, because you will not be thinking about what it says here but you will be more worried about your health (or your illness), or about other people's, you will be providing personal data in one context to be exploited in others, disproportionately and almost certainly against your will but determined by the situation. Nevertheless, in research the patient's absolute transparency ought not to be the norm; their habits should not be noted in order to make a possible prediction about what they could (or should) do next summer, or about what their favourite restaurant near where they live should be. The commercial exploitation and the monetization of data through user profiles are obvious. It is information obtained in the context of research that will be used for other purposes. Who today can guarantee that it is not?

Research initiatives have been detected that invited people to supply data about their personal health and that of relatives suffering from genetically based diseases who could be potential donors of biological samples. The aim was for sensitive personal information to be shared via Internet pages, without being able to guarantee security in processing or in access by third parties to the data obtained. They were Internet pages in which the potential participant was exposed to sharing information completely unnecessarily and not without risks. In the first place, because the accuracy and the need for the data is not guaranteed, and, secondly, because the possible discrimination that the owner of the data and their relatives might suffer if that information falls into the wrong hands could not be ruled out either. It is considered normal –and in my opinion it should not be– for candidates to take part in research projects to enter their data on Internet or the social networks. Our research and healthcare system is supposed to be designed to avoid inequality and discrimination, including the genetically based kinds[30]. They are recurring initiatives and it is true that in other contexts they are the accepted standard. But transnational collaborative research cannot just impose rules unconnected to our objectives and means. In our context, at least, it should not be like that. And not just because RECs declare that there

30. Read, among others, Law 14/2007, 3 July, of Biomedical Research.

are other alternatives less harmful and invasive for the rights of the people involved, which is true; also because neither researchers nor doctors should collaborate with databases that do not ensure confidential processing of personal data[31]. These professionals should avoid data trafficking and its unwelcome uses. It is a deontological obligation of the first order, to do with scientific integrity, and without reducing the issue to the requirement for informed consent that, in my opinion, is not always the solution to problems in research.

So far we have identified some scenarios and problems, from biological samples and biobanks to research with big data and the development of health and wellness mobile apps. We must be prepared to detect what seems to be research but is merely market niches. It is also necessary to carry out an examination that gauges the impact on the rights and interests of the people taking part or involved, and of their relatives or close friends, in research projects that are presently booming. We should be thinking about individualized genetic information or predictions of habits and behaviours to improve decision-making in research and business.

4. PART II: BIG DATA ANALYSIS APPLIED TO RESEARCH (BIG DATA) AND HEALTH APPS (*MHEALTH*)

We are witnessing a paradigm shift in the context of research, health care, and in the sphere of business. Initiatives and companies are now organized around data and not so much around processes, as we were previously used to. Data and the combination of datasets become valuable due to the information they express and their financial quantification, something that arouses great interest in public and private enterprise, on the basis of their exploitation and commercialization[32]. It can thus be understood why Facebook has acquired the WhatsApp instant messaging

31. Take as an example the Code of Ethics of the Doctors' Association of Barcelona, articles 40 and 41. Retrieved from *http://www.comb.cat/cat/colegi/docs/codi_deontologic.pdf*, consulted on 26 August 2016.

32. See the Opinion Document of the University of Barcelona's Bioethics and Law Observatory, the research centre of which I am a member, on *Bioethics and Big Data: Exploitation and Commercialisation of User Data in Public Health Care*, January 2015, available in PDF format and open access and in three languages (Catalan, Spanish and English, retrieved from *http://www.publicacions.ub.edu/refs/observatoriBioEticaDret/documents/08209.pdf*, consulted on 26 August 2016. It is an interdisciplinary study that has been included in the reference documentation to propose the reform of the Catalan big data analysis project of July 2015, and which replaces the VISC+ project (More value to health information), on big data that began life in 2013, not without criticism. For more information on this project see *http://www.bioeticayderecho.ub.edu/es/tags-noticias/big-data* and the information available at the Agency for Health Quality and

service, because of its true scope, but above all what it could potentially produce: exponential profits based on personal data, once the terms and conditions have been accepted[33]. Although there are multiple definitions of big data, focused on different aspects depending on the field of research (health, smart cities, natural catastrophes, etc.), there is agreement that volume, variety and speed define big data. Volume, due to the huge amount of data; variety, due to the mixed nature of the kinds of data available in a dataset, and speed, due to the rapidity with which data can be accessed and analysed[34].

Big data is a technology that is developing new tools to combine, analyse and exploit new datasets, establish correlations and obtain important information, making it possible to precisely predict individuals' behaviours and trends, but those of groups as well. It could be said, without wishing to be exhaustive, that big data is the result of the development of communication and information technologies, artificial intelligence, Biocomputing, and the widespread massive use of smartphones, as well as information storage services in clouds. Information and data everywhere, available in different devices at the same time, all connected or with the possibility of being connected. Computers –fixed and portable– and tablets online, the Internet of Things, biometrics[35] and wearables[36] are all examples that create a favourable atmosphere for the impending development of big data. The social networks are one of the areas in which they are present[37]. It can thus be understood why projects researching into big data have as their goal to develop apps, for example health apps[38], and healthy

Assessment of Catalonia, *http://aquas.gencat. cat/es/projectes/analitica_dades/index.html*, consulted on 26 August 2016.

33. See news item "La nueva letra pequeña de WhatsApp: cómo hará dinero con tus datos", *El Confidencial*, 26 August 2016.
34. McAfee, A. *et al*. (2012), "Big Data: The Management Revolution", *Harvard Business Review*, vol. 90, N.° 10, pp. 61-67. See also Mayer-Schönberger, V. and Cukier, K. (2013), *Big Data: A Revolution That Will Transform How We Live, Work, and Think*, Houghton Mifflin Harcourt.
35. Using fingerprints to identify someone is an example of biometrics.
36. They are electronic devices that can be worn by people as an accessory or as part of their clothing or accessories. These devices can be connected to Internet and they make data exchange possible. One example is a jacket that measures heart rate.
37. On the problems and biases in the application of big data analysis in the field of epidemiology see Pérez, G. (2016), "Peligros del uso de los *big data* en la investigación en salud pública y en epidemiología", *Gaceta Sanitaria*, vol. 30, N.°1, Jan-Feb.
38. On health apps see (2015), *The App Intelligence: Informe 50 mejores apps de salud en español*, Observatorio Zeltia, Madrid. Retrieved from *http://www.theappdate.es/static/media/uploads/2014/03/Informe-TAD-50-Mejores-Apps-de-Salud.pdf*, consulted on 26 August 2016. See also the World Bank report, Qiang C.Z., Yamamichi, M., Hausman V. and Altman, D.G. (2012), *Mobile*

lifestyles as the first step, before advancing in specific applications. The thin line between research and markets that health big data creates can also be seen; in fact, where there is big data research there is a market. The combination and exploitation of data enables us to obtain the information that we wish to find, but it also makes it possible to obtain data that, although they might not seem important, become highly sought after, for the information they express and predict, and because they enable decisions to be made that favour certain interests.

A figure becoming increasingly important in big data analysis is the data scientist, who has to solve complex problems in different areas of different disciplines, for example marketing or life sciences, who handles data from multiple sources and who seeks to extract invisible patterns in order to examine them, including all the possible variables. Along with data scientists there are other professionals such as the data miner, a computer scientist who resorts to, among others, the methods of artificial intelligence and statistics, and to database systems, also with the aim of discovering patterns. These are people with scientific backgrounds, highly specialized, who are absolutely necessary, as are hackers to certify the security or the weakness of computer systems. They are professionals who, of course, research ethics committees need as members in order to analyse what is going on in big data research, to make decisions about whether or not to authorize certain research projects and also to distinguish between what is market and what is big data research, what are commercial uses[39] and what are research practices.

The reader should think about big data analysis and also apparently harmless free mobile apps, about the link between big data and health apps: they need and reinforce one another. Data is now hard currency (in the twentieth century it was genes, now in the twenty-first it is data) and yet everything seems to be free. The person supplying data discloses an infinite amount in return for access to technology that, as I have already said, empowers users (or at least that's what they say), in a voluntary and involuntary disclosure of privacy in different formats to which different business models with a variety of interests have access. But they always have one common interest: access to datasets –including personal

Applications for the Health Sector, retrieved from *http://siteresources.worldbank.org/INFORMATIONANDCOMMUNICATIONANDTECHNOLOGIES/Resources/mHealth_report.pdf*, consulted on 26 August 2016.

39. Healthcare institutions are drafting protocols on the commercial uses of the brand with regard to developing mobile apps, to differentiate them from uses in research. Committees are being set up for this purpose to assess these situations. In my opinion, these committees should inform the institution's REC.

ones– that say absolutely everything about us and the people we are in contact with.

In my opinion, the supposedly empowered citizens to whom I referred become docile and exposed, naked and defenceless. Healthy and sick people are invited to get in touch on social media and also to "gamify" themselves (to play in order to improve their situation and their relationship with their illness, in a peer group where they are unique…). This perverse invitation presented as empowerment, and which is acceptable from a purely mercantilist point of view, is inundating the field of research, where these are not the objectives, as they are disproportionate and mercantilist. Data are needed to create ontologies through the programming of algorithms that serve to improve the decision-making of initiatives, companies, in research, etc., in the public and private spheres, or in a combination of both. Especially interesting is the use of big data analysis in research for medical purposes and the development of health apps whose goals are personalized medicine, the improvement of healthcare systems (to make them more efficient), learning about the adverse effects of medicines more quickly, predicting natural catastrophes, and their consequences in terms of the population's health. The goals are worthwhile; the means are, for now, disproportionate. As we have not spent as much time analysing the legal, social and ethical implications[40] of big data as we have developing algorithms and putting them into practice, we have failed.

The lack of privacy[41] is the price being paid for allowing unwanted access to data, the totally disproportionate gathering and possession of different kinds of data, without their owner's knowledge, by third parties unconcerned with the basic rules of human subject research: businesspeople, data miners, data scientists, people who have not been trained to respect confidentiality and process personal data. On this point, I recommend reading the reports on big data by the European Agency for Network and Information Security (Cybersecurity) (ENISA) and the European Data Protection Supervisor, especially Opinion 7/2015, on the challenges of big data (November 2015)[42]. In them the

40. Richards, N.M. and King, J.H. (2013), "Big Data Ethics", *Wake Forest Law Review*, vol. 49, pp. 393-432.

41. Cohen, J.E. (2014), "What Privacy is For", *Harvard Law Review*, N.° 126, pp. 1904-1933.

42. See ENISA's compilation of publications on big data, available at *https://www.enisa.europa.eu* (apply filter "big data menu" law), in particular, *Privacy by design in big data*, December 2015, and the European Data Protection Supervisor's webpage on big data, retrieved from *https://secure.edps.europa.eu/EDPSWEB/edps/Consultation/big_data*, consulted on 26 August 2016.

challenges, problems and the impact –positive and negative– of the use of big data analysis on people's rights in the digital society are made perfectly clear.

In this context projects are submitted to RECs for assessment, whose objective is to use mobile geolocation to identify people –suffering from certain diseases– who have pulled out of projects for reasons unknown. And what happens if someone does not wish to be located? What about the clause, so typically bioethical, about withdrawing voluntarily without any justification, thus exercising the famous withdrawal of the consent given?[43]. Not to mention the possibility of the mobile telephone being mislaid, stolen or inherited by someone other than the person who took part in the research. Big data almost certainly takes all this into account. But what about the ethics? In one of its campaigns Amnesty International pointed out that by having one's mobile switched on, "they know who we are sleeping with"[44]. Data (big and small) are valuable, in research too, of course. Remember that computerized medical records are digital platforms that allow access to personal data, and that, as we clearly see here, there is an investigative and commercial interest in cross-referencing medical records databases with other databases containing different kinds of information.

The trend in developing health apps associated with wearables and mobile devices is growing. Biometrics, biosensors, chips, smart glasses, smart watches, the Internet of Things, Internet downloads on laptops, tablets and devices connected to the smartphone that knows everything and decides for you, are all markets queuing up to gain access. From the scientific point of view, there may be some interesting research to be carried out; what needs to be ascertained is whether or not it is appropriate and necessary. And there are also some tempting market niches from the business point of view. Tempting and very profitable. Ageing well, wellbeing (autonomy and empowerment included) and healthy living are among the policies of the European Union, which funds research in information and communication technologies in these areas. Development has recently begun of a European code of conduct on privacy in the development and

43. See, for example, articles 5 and 16 of the Council of Europe's Convention on Human Rights and Biomedicine, mentioned above, on the general rule of consent in healthcare and research.

44. "The US National Security Agency gathers billions of cell phone location registrations every day, so they know where you got on the bus, where you went to work, where you slept and what other cell phones slept with you". Snowden, E., "Privacy is for the Powerless", retrieved from *https://www.amnesty.org/es/latest/campaigns/2016/03/edward-snowden-privacy-is-for-the-powerless/*, consulted on 26 August 2016.

use of health apps[45]. The bioethical problem lies in the obvious disproportion between means and ends. Gathering data for the sake of it and then exploiting them and seeing how and in what circumstances they can be made profitable – this is what must not be allowed. In practice, however, this trend is confirmed, in which data transfers (monetization included), neither wanted nor permitted, can be identified; they are moreover unacceptable, bearing in mind who will carry them out, how, for whom and when (including for how long). In my opinion these are the key questions for identifying what health research "is" and what it "appears to be, but is not", because it pursues other ends and hopes to exploit and commercialize personal data obtained in the field of health care.

In Europe, the political and economic commitment to achieving a digital society and a data-driven economy is based on the reuse of information from the public sector, where the market can also find its place[46]. It is based on the need to be competitive on a global level and at the same time to apply the principle of transparency. Data protection as a system of guarantees is one of the bases of this decision, but in the sphere of the exploitation of big data and their possible commercialization, and in the field of health apps, this protection is not completely assured. Data and personal datasets make privacy valuable. The principles of personal data protection established by European laws, such as those of necessity, proportionality or data minimization, are difficult to comply with. In this respect, the results of the Eurobarometer –a survey of 28,000 Europeans carried out in March 2015– concerning data protection in the digital society are interesting. Eighty-one per cent of Europeans considered that they did not have complete control over their online personal data. Sixty-nine per cent would like to give their explicit approval before their personal data are gathered and processed, and just 24% of Europeans said that they trust online businesses such as search engines, social network pages and Internet services[47].

45. The information is available in English only, for the moment, and the information is from 7 June 2016. It is a code to which people who develop apps and who observe the European data protection rules can voluntarily follow. "Code of Conduct on Privacy for *mHealth Apps* has been Finalised", retrieved from *https:// secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2015/15-11-19_Big_Data_EN.pdf*, consulted on 26 August 2016.

46. Directive 2003/98/EC of the European Parliament and of the Council, 17 November 2003, relative to the reuse of public sector information. Available on the EUR-Lex database, retrieved from *http://eur-lex.europa.eu/legal-content/ES/ALL/?uri=CELEX:02003L0098-20130717*, consulted on 26 August 2016.

47. See the cited European data protection law of 2016. On the results of the Eurobarometer: information available at *http://ec.europa.eu/justice/data-protection/files/*

In my opinion, the ethical or bioethical dimension of big data technologies and health apps is not being sufficiently analysed. I predict, and I would like to be proved wrong, that in the coming years keeping data confidential will be extremely difficult and what others know about us will be totally beyond our control. The rights of access, control, rectification and opposition that we currently have as a guarantee are already in doubt, nor will it be possible to speak of anonymization (only in a few cases), and the concept of the re-identification of people and data should become widespread.

The fact is that while big data and the projects and initiatives that promote it were in their infancy, we did not spend enough time producing a glossary of concepts useful for understanding what we are talking about. We use new technology and we assess it with old, useless and ineffective points of reference. As a result a false sense of security is generated about something that has not been properly assessed and which could have perverse uses. Hence my criticism that ethics committees are not adapting properly to the new times. It is necessary to include in the conceptualization of big data the fact that this technology breaks the established rules for ensuring confidential data processing. Up to now, personal data anonymization –that is, ensuring that the link between the owner and the data is irreversibly broken– was the basis for justifying data processing without infringing rights. Thus, as no one could be identified, there was no problem. Those of us who move in healthcare and research are accustomed to using concepts such as reversibly coded or irreversibly dissociated data[48], confidential processing and the obligation of confidentiality. But we are not at all used to talking about re-identifiable people or datasets. Big data makes this re-identification possible, whereby in the definition of big data it should be added that anonymization is dead and that we are entering a new scenario where the risk of re-identification exists. Moreover, it must be considered a working premise that those taking part in big data research must be given, and must understand properly,

factsheets/factsheet_data_protection_eurobarometer_240615_ en.pdf, consulted on 26 August 2016.

48. Article 3 of Law 14/2007, 3 July, of Biomedical Research. Sections: *h*) "Anonymous data": data registered without a connection to an identified or identifiable person; *i*) "Anonymized or irreversibly dissociated data": data that cannot be associated with an identified or identifiable person, as the connection with any information that identifies the subject has been destroyed, or because the said association requires an unreasonable effort, understood as the use of a disproportionate amount of time, expense and work; *k*) "Coded or reversibly dissociated data": data not associated with an identified or identifiable person, as the information that identifies that person has been replaced or dissociated using a code that permits the reverse operation.

information about its scope and significance. With their postcode, date of birth and gender it is possible to re-identify the majority of individuals "present" in a dataset[49]. This is possible if the motivation to do it is there, along with technicians who know how to do it and the necessary investment. The profits, broadly speaking, can be exponential. It would not be right to explain big data technologies without going into technical issues such as this, which pose a serious problem for researchers' ethics, for the current data protection law and for society, which at the very least ought to know what really is going on.

Now imagine, dear reader, research projects that process big data about re-identifiable profiles in the medical sphere, such as IVH positives, or those suffering from Alzheimer's, Parkinson's or schizophrenia. Start with the data stored in computerized medical records of thousands of people affected by these diseases. Think of minors, persons unable to give consent themselves because of de facto situations, imagine the sensitive data that are going to be handled and feel concerned about the vulnerability of the citizens' integrity and privacy. There are several possible combinations: accessing the downloads of their mobile devices, obtaining blood and other biological samples of human origin, geolocating them, obtaining and processing sensitive personal data through Internet surveys, combining them with their clinical data … What is the purpose of these investigations? They are legitimate objectives, but in many cases out of all proportion. The goal of amassing data and then exploiting them generally spoils the research. The means should be proportional to the ends pursued, a rule that is not usually observed in big data research. Banks, mobile telephone operators and insurance companies are obviously interested in participating in the research, development and innovation system. They may become entitled to compete in research by joining forces with well-known researchers who are prestigious in different areas of knowledge and have, among others, the best computer engineers, specialists in artificial intelligence and data scientists. RECs should ask promoters and researchers who has access, how, what for, how long for, and demand from the start an assessment of the project's impact on the human rights of the people involved and a risk minimization plan[50]. It would be a good

49. See Sweeney, L. (2000), *Simple Demographics Often Identify People Uniquely*, Carnegie Mellon University, Data Privacy Working Paper 3, Pittsburgh. Retrieved from *http://dataprivacylab.org/projects/identifiability/*.

50. In this respect, the European Union guidelines for research funding are clear (among others ethics self-assessment, available on Internet. Retrieved from *http://ec.europa.eu/research/participants/portal/doc/call/h2020/h2020-msca-itn-2015/1620147-h2020_-_guidance_ethics_self_assess_en.pdf*, consulted on 26 August 2016 (2014 version).

idea, moreover, to analyse whether public-private science and technology systems have suitable computing back-up in our context; and whether investment by the state in the development of special secure clouds ought to be a priority, thus eliminating the need to resort to outsourced commercial services who cannot guarantee that the information they store will be processed with the same confidentiality and requirements as in the medical sphere[51].

5. CONCLUSIONS AND PROPOSALS

The objective of this chapter has been to identify practices and problems in research with biological samples of human origin in the context of biobanks and in big data research, including personal data. There are market niches that go unnoticed in research projects, as well as mercantilist practices that are presented under their aegis. Research must not be stopped, though. It must be properly analysed for the purpose of clearly detecting what seems to be research but is actually the market; identifying the unwelcome illicit uses of samples and data; preventing privacy from being commercialized and supposed fairness being infringed, and avoiding discriminatory situations for the owners of the samples and the data. This is the duty of RECs. The scientific integrity of researchers is at stake in a field where people unconnected to research possess the funding and the right professional profiles to pursue commercial interests as well as purely research interests. It is necessary, in short and above all, to specify what should be off-limits to commerce in research.

Bioethics, which contributed so much to the creation of RECs in the 1960s, cannot be the only one to respond to the complexity and specialization that we are now witnessing. The paradigm on which bioethics was comfortably based in research is being torn apart by the potentiality of biobanks, big data and mobile apps, designed as business models in research and not solely and exclusively as research. It was a paradigm that eagerly pursued confidential data processing and whose safeconduct was anonymization. Society, subject to mercantilist practices in research pointing towards digitization, heavily committed to biotech and data tech, needs to reflect first on the place occupied in its list of priorities by the human biological samples and datasets that identify us with names and surnames and turn us into potential sufferers of Alzheimer's and

51. These services are resorted to due to research and hospital institutions' lack of their own clouds. This is not at all advisable as we are talking about sensitive health data, but for the moment it is a fact that no in-house systems have been developed capable of offering the same services.

potential purchasers of certain products. Datasets construct and deconstruct identities and change our future according to the use now being made of them and who is doing it. Big data and, in particular, big data research are contributing to a new concept of human nature without the providers and owners of the data even being aware of it. This exciting big data, which does not cease to propose effectiveness and efficiency, more precise knowledge more quickly, has neither gathered nor cross-referenced sufficient data about what the ethical guidelines that ought to frame its work should be like.

It is the duty of RECs to avoid commerce in research and to monitor the approved projects, but for that they must be equipped with human and material resources with the support of the management teams of the research centres where they operate. They cannot apply obsolete patterns and rules to new problems in order to generate a false sense of security in which unwelcome practices prosper, including unwanted uses of biological samples of human origin and personal data. What we have is a model of ineffectiveness of RECs that must be reviewed and changed. Along these lines new organizational and working formulas are needed that include the greater involvement and professionalization of their members and a possible remuneration in keeping with the duties assigned to them. There is an urgent need for the activation of registers, established by law for many years, and this ought to be a priority for development and innovation plans in science and technology. In these registers the identities of who is accessing biological samples and data, how, when, with what funding and for what reason, could be consulted – samples and data that can be neither destroyed nor transferred outside the secure perimeters of public healthcare infrastructures, and a basic cornerstone of which are computerized medical records stored in databases.

As the law currently states, public biobanks must not pursue private interests, nor can they commercially exploit biological samples donated altruistically, in the face of the mercantilist trends described in this chapter that hope to exploit and commercialize samples donated by people. RECs –in their capacity as Biobank External Ethics Committees– must therefore not regard the traceability of biological samples of human origin as a merely residual task.

It is necessary to create operational networks between the different RECs concerning the practices that refer to biological samples in biobanks. At the same time, collaboration and permanent communication between the director of the biobank, the institution's legal services and the committees must be strengthened, in order to be on the lookout for possible business dealings in connection with samples.

Education, training and skills building, in both ethics and in technical issues related to translational practices in research with biological samples of human origin and personal data in the context of big data and health apps, are necessities of the first order.

Interdisciplinary analysis in the areas analysed is crucial. To be effective and to make the research assessment and monitoring system credible it is necessary for specialists in big data analysis to join RECs, as well as those in cloud computing and computer and network security systems, who will identify the strengths and weaknesses of the techniques for exploiting and combining data with the available computer systems. Only this way will it be possible to develop and apply creative solutions for proper personal data processing and the protection of privacy.

Public awareness must be raised about the concept of re-identification, which destroys the foundations of personal data protection, something that RECs have not internalized.

And, of course, research projects in big data and in health apps must incorporate an analysis of the impact of these initiatives on human rights, and outline plans to mitigate and minimize the risks along the lines established by the European Union.