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CONSENT TO RESEARCH: EXCEPTIONAL SITUATIONS

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Obtaining informed consent of participants constitutes an established and recognized requirement in research ethics. However, for various reasons and under varied circumstances, the ethical and legal norms may allow an exception to the requirement of individual consent. On the other hand, it is difficult to identify general criteria for applying this exception. In this edition, the search for balance between the principles and values involved are first discussed. Then, the elements for justification of the exception frequently encountered in the norms are reviewed. Finally, the authorization mechanisms usually associated with the exception are described. This article raises the difficulty of identifying the specific criteria and conditions under which the exception to consent will receive a wide acceptance given that there is no consensus in the norms or in people who interpret them. Thus, it appears that more coherence and consistency is needed among the many studied standards in order to reach a general rule.

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INTRODUCTION

Obtaining informed consent from the participant is probably one of the research prerequisites that are best known to researchers and to the general public. This is the most eloquent realization of several fundamental principles in research ethics, such as human dignity, from which arises the respect of autonomy, privacy and integrity. Individuals are sometimes surprised that there is a part of the research that is being done without going through the classical process of obtaining individual informed consent. For various reasons and under different circumstances, the ethical and legal norms may sometimes open the door to such research exception. Two traditional examples are the research conducted in emergency situations⁴ and the ones where the temporary retention of certain information to participants is necessary to ensure the scientific validity of the study.⁵ In these exceptional cases, the standard procedure for obtaining consent is somehow overruled by other authorization mechanisms. We may think of an authorization granted by a research ethics board or by the law.

However, little is said and little is written about this type of research taking place without individual consent. This is probably explained by the difficulty of addressing a way to do research that appears, at first sight, to oppose a basic principle. Sometimes, the topic also raises some opposing views.⁶ As for the ethical norms that address the topic, they do so in an incidental way and without addressing the issue in its entirety. It is therefore difficult to identify general criteria in applying the exception. However, this research exception often targets important objectives to improve health which could not otherwise be achieved. The issue is particularly relevant today given the development of large banks of biological materials (biobanks) and the existence of databases at the population-level in the absence of a large initial consent. It is often impossible to obtain a new individual consent from all participants several years after collection, particularly due to difficulties contacting them.⁷ Some agree that the biobanks' situation, containing biological material already collected, is sufficiently different to justify a distinct practice to allow an exception to the

standards of consent.⁸ In other situations, obtaining individual consent may create a selection bias that considerably diminishes the value of scientific research.⁹ In our post-genomic era, access to biological material and to its related information is considered essential to the development of new pharmaceutical products, medical devices, diagnostics and therapies.¹⁰

In this context, it is important to expand our knowledge about the exception to individual consent to better understand it. In this edition, we propose (1) to discuss the search for balance in the principles and values involved, (2) to review the justification for the exception and (3) to summarize the authorization mechanisms that accompany it. We believe that a better understanding of this exception will help conceive its relevance and identify situations where it may be applicable.

1. SEARCHING FOR A BALANCE

OBTAINING INDIVIDUAL CONSENT: A CLASSIC REQUIREMENT

The *Nuremberg Code* of 1947 is the first text on fundamental ethics of international scope that declares the importance of informed consent as a condition to participate in any "experiment" involving humans.¹¹ Then in 1964, the first *Declaration of Helsinki* states that participation is a voluntary act that requires consent.¹² In 1966, the United Nations' *International Covenant on Civil and Political Rights* applies this requirement for any "medical or scientific experimentation".¹³ A series of other important norms of international or transnational scope then followed endorsing the principle which included *Proposed International Guidelines for Biomedical Research Involving Human Subjects* in 1982,¹⁴ the *Convention on Human Rights and Biomedicine* in 1997¹⁵ and the *Universal Declaration on Bioethics and Human Rights* in 2005.¹⁶ Today, obtaining informed consent of participants clearly constitutes an established and recognized requirement in research ethics.

PRINCIPLES AND VALUES INVOLVED

In their broadest sense, one can say that the ethical norms for research are dedicated to preserving the **dignity** inherent in every human being.¹⁷ The respect of dignity "is a major ethical imperative".¹⁸ Other outlined principles and values are all derived from the desire to protect human dignity.

Consent is an act that embodies, or materializes, a significant value conveyed by research ethics which is the **autonomy** of the person¹⁹: "Informed consent in medical ethics is commonly viewed as the key to respecting patient *autonomy*".²⁰ Autonomy refers to a person's ability to take his/her own decisions and to act accordingly.²¹ Consent is also the principle of personal **integrity** when it comes to situations where the research includes biological samples or interventions in the sphere of the psychology or morality of individuals. The impact of research on the "physical, mental and social integrity" should be minimized.²²

Finally, consent is also based on the principle of respect for **privacy** when the research aims to use information concerning individuals. Access to personal information, as well as the control and dissemination of such information is of considerable importance in research ethics as they relate to autonomy and human dignity.²³ The collection, use and storage of human genetic data are considered to present risks for the respect of human rights and human dignity.²⁴

On the other hand, conducting research in a society is also based on principles and values privileged by this society. The value given to the **advancement of scientific knowledge** is the basic element in the motivation of societies to encourage and support research. The preamble of the *Universal Declaration on Bioethics and Human Rights* states that scientific and technological progresses are the source of "great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life."²⁵ The advancement of knowledge allows the improvement of people's health and well-being. Research is premised on a "fundamental moral commitment to advancing human welfare, knowledge and understanding."²⁶ In this sense, research contributes to

public well-being; it "draws its good social value from the achieved realizations among human beings."²⁷ One of the most compelling proofs that research is based on the values supported by society is the importance given to the preservation of trust between researchers and the public.²⁸ The normative documents frequently reiterate the importance of maintaining the public's trust and support in favor of research.²⁹ This confidence is even described as essential.³⁰

A certain **freedom of research** is also recognized in its pursuit. The *Universal Declaration on Bioethics and Human Rights* recognizes "freedom of science and research"³¹ and the *International Declaration on Human Genetic Data* states that freedom of research is part of fundamental freedoms.³² *The Convention on Human Rights and Biomedicine* states that "scientific research [...] shall be carried out freely."³³

THE EXCEPTIONS TO CLASSICAL CONSENT: FINDING A BALANCE

As previously noted, the prior consent of the individual is a fundamental norm in research ethics. Research carried out without obtaining consent from the participant is an exception, or variation to this standard. In reading the texts governing the ethical conduct of research, we find that "the requirement for informed consent may be waived in some circumstances".³⁴ However, the exception to a norm that receives unanimous acceptance cannot be achieved without a substantial justification and ensure recognition of human dignity. The rationale for this exception must find its source in the balance between, on one hand, principles and values protected by the consent requirement (**dignity, autonomy, integrity, privacy**, etc.) and, on the other hand, the principles and values conveyed by the research (**advancement of knowledge, freedom of research**, etc.).³⁵ To find situations where the exception is justified, it becomes necessary to resolve "the potential conflict between research interests, the safety, personal integrity (including privacy) and autonomy of research subjects, and the preservation of public trust in biomedical research."³⁶

To summarize, the undermining of the principles and values underlying the consent

requirement must be offset by the benefits expected from applying the principles and values associated with the research activity. For example, if an epidemiological search was permitted from governmental health data without the prior consent of individual citizens concerned, we could see a risk of harm to autonomy or privacy of such individuals; but in return we should expect significant benefits for improving population health. In addition, protective measures would be likely to maintain the present balance, such as legal authorizations and ethical approvals.

2. JUSTIFICATION ELEMENTS

When the balance of "Protection of participants-Advancement of research" is reached, there may be circumstances justifying an exception to the classical individual consent. To identify those situations where there is a balance, we conducted a review of different norms regarding the ethics of research from the HumGen database (www.HumGen.org).

The identified norms recognize a multitude of situations in which balance is reached and that could justify an exception. We have identified and selected those that contained the main points of convergence. They represent the contributing elements for the justification. We kept six elements of justification: a) the importance of research, b) epidemiological research, c) impossibility, d) pre-existing data and biological material, e) minimal risk and f) protection of rights. These elements are important in achieving the balance mentioned above. They are sometimes found as a single justification, but are often associated with one or more other justification elements. Although some standards may have a limited application context (e.g.: nutrigenomics research, medical records research, etc.), the latter will not be systematically detailed enough to identify general principles. Therefore, we have outlined each of these justification elements.

A) THE IMPORTANCE OF RESEARCH

The importance of research, i.e. importance of benefits that could help society, is an element of justification for the exception to classical consent that is usually found in

normative documents.³⁷ This element refers to a situation where "the research is expected to produce important public health benefits."³⁸ One should then ask: "how important is the research?"³⁹ and assess whether "the benefits of the knowledge to be gained are judged to clearly outweigh the risk."⁴⁰ The criteria of significance can also be formulated differently by having the proposed research correspond "to an important public interest reason."⁴¹ Biobanks, consisting of biological materials already collected, could open the door to research without classical consent when they offer "important and otherwise unobtainable data".⁴²

B) EPIDEMIOLOGICAL RESEARCH

Some peculiarities of epidemiological studies explain that the exception for research without individual consent frequently applies. The objective of this research is to "elucidate the characteristics in a population of the prevalence and incidence of a disease".⁴³ When wishing to use epidemiological research data or biological material already collected, and when usability was not initially known, it is noted that "the consent issue here is a delicate one".⁴⁴ It is then suggested that rules be adopted "to waive the individual consent requirement".⁴⁵ The exception to consent for epidemiological research is sometimes also permitted when the importance of this type of research for medical and scientific ends is justified.⁴⁶ Sometimes, the types of epidemiological studies that could be conducted without individual consent are limited: "observational research"⁴⁷, "non-interventional study"⁴⁸ or "large-scale genetic epidemiology studies".⁴⁹ Some justifications for the exception of individual consent correspond to the particularities of epidemiological research, even if it is not named. For example, the exception applies when "there is a risk of introducing bias into the research because of the loss of data from segments of the population that cannot be contacted to seek their consent".⁵⁰

C) IMPOSSIBILITY

The impossibility of conducting research by obtaining a formal individual consent from each individual participant is one of the justi-

fications most frequently mentioned in the norms. This impossibility refers to the concept of necessity; in these situations, we conclude that it is necessary to use the exception in order to achieve the research objectives.

Some norms refer to the concept of impossibility without providing details on what may be the impossibility. Thus, the exception applies when the "requirement of individual informed consent would make the conduct of the research impracticable"⁵¹ or when "prior, free, informed and expressed consent cannot be obtained".⁵² For example, since the irreversible dissociation between a person and data (often called anonymization) makes consent impossible, it could justify an exception.⁵³ Other absolute impossibilities could justify the absence of individual consent, particularly when the law prohibits contact with individuals⁵⁴ or when seeking consent from deceased individuals in regards to the use of biological material already collected.⁵⁵

Other norms provide more details on the concept of impossibility: the impossibility here often takes the form of a practical difficulty.⁵⁶ The practical difficulty is different from the absolute impossibility as it relates to the importance of challenges to overcome in order to obtain consent. Thus, the exception would find a place when "it is impracticable to gain consent"⁵⁷ or when "the research could not practicably be carried out" without recourse to an exception to individual consent.⁵⁸

The practical difficulties which give rise to research without individual consent are sometimes illustrated by specific examples. Obviously, the first recognized difficulties are those related to the necessary steps to contact the individuals. This could include research on body parts already taken because "sometimes, it will not be possible, or very difficult, to find the persons concerned again in order to ask for their consent".⁵⁹ The cost and the burden associated with the process to find individuals are also elements that can cause an inability to justify the exception,⁶⁰ as when the sums required are disproportionate because the consent may be unreasonable.⁶¹ Therefore, one should assess if all "the additional financial, mate-

rial, human, organizational and other resources needed to obtain consent could impose a hardship or burden on the researchers or organization so burdensome that the research could not be done".⁶²

Then there are the difficulties caused by the overwhelming number of people to contact. Obtaining the consent of each could make the research impossible.⁶³ At last, if individuals cannot be reached "through reasonable efforts", researchers may be facing a case of impossibility that justifies the exception.⁶⁴ In this regard, the proportion of probable relocated participants and the lack of updated information should be considered since it could make the individual consent impracticable.⁶⁵

D) PRE-EXISTING DATA AND BIOLOGICAL MATERIAL

A large proportion of norms which contain an exception for research without individual consent consider that using data or biological material already collected is a contributory factor to justify the absence of consent. The collection prior to research may have occurred, for example, in clinical care, or at another research project. It could also include data previously collected by health authorities in government records. Since the purpose of the initial use is different from the purpose of the proposed research, we often speak in these cases of "secondary use".⁶⁶

Obviously, we are concerned only with situations where the intended use of data and biological material is not "consistent with the original informed consent".⁶⁷ It is therefore not a case where a general consent authorizing the type of intended research, would have been previously obtained.⁶⁸ The exception focuses on the biological material obtained "without an explicit consent"⁶⁹ or "without any future use provisions".⁷⁰

Thus, we find a very large number of norms that justify the exception to individual consent, taking into account pre-existing data and biological materials to be used. These standards are grouped around the general idea that "the information and consent arrangements may vary according to the circumstances, thus allowing for flexibility since the express consent of an individual to the

use of parts of his body is not systematically needed".⁷¹ Different terminologies are used to describe the data and biological material already collected and covered by the exception, among them: "Existing collections",⁷² biobanks "established from existing collections",⁷³ "stored biological material",⁷⁴ collected biological samples⁷⁵ and "previously collected tissues".⁷⁶

Sometimes, the norms make a distinction to apply an exception when data is concerned: a separate rule may apply to the "secondary use of data"⁷⁷ to "human genetic data"⁷⁸ or to researches that involve "only excerpting data from subjects' records".⁷⁹ There are also norms that limit their scope to data and biological materials that are derived from the provision of clinical care.⁸⁰ Finally, the number of elapsed years since the collection may allow the consideration that old collections "should be regarded as abandoned", and thus be used for new purposes.⁸¹

E) MINIMAL RISK

The degree of risk to participants is a crucial element when balancing the protection of the participant with the advancement of knowledge. It is naturally an element of justification for the exception to individual consent. A number of norms specifically refer to the degree of risk posed by the research at the time of allowing this exception. Those standards require that research "poses minimal risk"⁸² or "involves no more than minimal risks to the subjects".⁸³ In other words, an exception to individual consent may be permitted when demonstrating that research involves "no more than low risk".⁸⁴ There are also norms where risk minimization⁸⁵ and lack of harm to participants⁸⁶ are prerequisite for the exception. Then, in cases where research is done solely from the data, the risk assessment could only refer to privacy and confidentiality.⁸⁷

A risk can be described as minimal when the prejudice and the discomfort it engenders are not higher than those incurred "in routine daily life activities of general population."⁸⁸ In the context of biomedical research, one could say that the risk is minimal if the proposed intervention "will result, at the most, in a very slight and temporary negative impact on the health of the person concerned"⁸⁹ As

for the notion of "low risk", it refers to situations where the only risk considered is caused by discomfort.⁹⁰

F) PROTECTION OF RIGHTS

Protecting the rights of the participant is the fundamental element of ethical norms. The presence of this element above all those that justify an exception to individual consent is indispensable. However, how to handle this element of justification differs greatly from one norm to another.

We first find norms which anticipate that the exception to individual consent must ensure that "the rights and welfare of the participant are not adversely affected."⁹¹ It should therefore be ensured, when dealing with the exceptions, that the rights or interest of participants are not compromised.⁹²

In addition, a good number of norms focus on the protection of two specific rights: confidentiality and privacy. Classical consent could benefit from an exception in that "there is an adequate plan to protect the confidentiality of data."⁹³ Establishing a means for restricting access to information, that could identify individuals, is one way to ensure that the rights of participants are protected. If the data or biological material are coded⁹⁴ or does not allow identification of the subject⁹⁵ it might be possible to justify the exception to individual consent. For even stronger reasons, the same conclusion is found in the use of data or biological materials which are anonymous.⁹⁶

3. AUTHORIZATION MECHANISMS

A form of authorization is often required before a research with an exception to consent may be undertaken. Indeed, we note that a prior authorization mechanism is almost always expected according to the norms. The exception to individual consent would require providing "review processes, in accordance with applicable law, including research ethics committees or comparable oversight mechanisms."⁹⁷ These control mechanisms somewhat substitute for individual consent to ensure that the rights and interests of individuals will be protected. This explains why, given the analogy, we can

sometimes read that the role of research ethics board is to give "its consent"⁹⁸ to research.

Although the role of the authorization mechanism remains substantially the same, it is represented in different forms. We have retained the most frequently stated protective mechanisms, which are: a) approval by an independent organization, b) compliance with the law and c) information and the lack of opposition. Each can be requested separately, or concomitantly with one or more of the others.

A) APPROVAL BY AN INDEPENDENT ORGANIZATION

The most popular authorization mechanism is undoubtedly the approval of the consent exception by an organization that is independent of researchers.

The research ethics board is the independent body which is usually appointed to perform this function.⁹⁹ For many standards, "the research [with exception to consent] may be done only after consideration and approval of a research ethics committee."¹⁰⁰ In other words, the research ethics committee is responsible for lifting the requirement of informed consent.¹⁰¹

Different organizations, other than research ethics boards, sometimes authorize research that is making an exception to individual consent. This authorization can replace or be added to that of the research ethics board. These organizations are diverse. They are usually generically referred to as "relevant oversight bodies"¹⁰², "appropriate authority"¹⁰³ and "authorized entity".¹⁰⁴ It is rather the local legislation that determines precisely which organizations have this mandate, e.g. the Data Protection Authority of Iceland,¹⁰⁵ the Commission d'Accès à l'Information du Québec¹⁰⁶ and the Swiss Federal Commission of Experts of Professional Secrecy in Medical Research.¹⁰⁷

B) CONFORMITY WITH THE LAW

The second mechanism involved in allowing the research exception to consent depends on the local legislative measures. The role of

the law in this regard acts on two axes, firstly by a general framework to be respected, and secondly by specific provisions outlining exceptions.

Compliance with the general legal framework is one way to ensure the protection of individuals, despite the absence of individually expressed consent. The norms that contain this mechanism require that the exceptional consent is permitted only after ensuring that the proposed use "agrees with locally applicable legal requirements"¹⁰⁸ or is in "accordance with ethical and legal standards adopted by States".¹⁰⁹

As for specific exceptions, they are normally found in local law. These provisions provide for situations in which the exception to consent is allowed. We identified some standards that indicate that in the absence of consent, the research could take place "in accordance with domestic law"¹¹⁰ or "in accordance with applicable law".¹¹¹ According to this approach the "limitations on this principle of consent should only be prescribed for compelling reasons by domestic law."¹¹²

C) INFORMATION AND ABSENCE OF OPPOSITION

The third mechanism for authorization is distinct from others in that it is not a permission but a group of process: the information and the observation of absence of opposition. This form of authorization, less conventional, has the same objectives through other means.

The simplest mechanism is to provide information to individuals involved in research. This may include individuals from whom the biological material or data that have been collected¹¹³ or if they are deceased, relatives of these people.¹¹⁴ In a broader sense, the researcher may be asked to inform the general public about the research.¹¹⁵

The transmission of information can also be accompanied by a requirement to consult the concerned individuals, such as "representatives of those who contributed data"¹¹⁶ or "family groups, aboriginal peoples, community representatives, consumer associations [...]".¹¹⁷

In many cases, the objective of such a notification is to provide opportunities for those concerned to express their opposition by withdrawing from the research. The individual has been duly informed, and has the option to request that the data or biological material that concerns him/her be removed from the research (this procedure is called "opt out").¹¹⁸

It should be mentioned that a certain number of norms use the criteria of absence of opposition without mentioning the obligation concomitant information. It is then required to demonstrate that no objection to the proposed use is known.¹¹⁹ This lack of opposition could also result from an evaluation of the individual's presumed wishes. In this regard, it would be appropriate to take into account the similarity between the proposed project and a project prior to which the individual has already consented,¹²⁰ "the expectations of a reasonable person in the circumstances"¹²¹ and whether "individuals have previously objected to the secondary use of their data".¹²²

CONCLUSION

Following the analysis of the norms, it is not easy to extract a general rule on the exception to consent. Even if we do not question the need to balance between the participants' protection and the advancement of knowledge, ways to achieve this balance is not generally agreed on in the norms or by the individuals interpreting it.¹²³

Our analysis identified six elements for justification that are frequently encountered in the norms: the importance of research, epidemiological research, impossibility, pre-existing data and biological material, minimal risk and protection of rights. Each of these elements appears to be involved in the justification for the waiver of the requirement of consent, but no consensus exists as to whether these elements are sufficient when separated or whether they should be associated with one or more elements. Among the studied norms, a large variety of approaches exist on this issue. In addition, several standards studied limit their application to a specific context that has not been detailed here (for example, the

residual biological material from clinical care, or even historical coded data). This adds to the complexity.¹²⁴

Furthermore, the implementation of authorization mechanisms seems to be an element almost always required in the absence of consent. We have highlighted: the approval by an independent agency, compliance with the law and, finally, information and the absence of opposition. These mechanisms would alleviate the difficulty for individuals involved in research to protect their own rights and assert their will. Except for approval by a research ethics boards,¹²⁵ it seems even more difficult to draw a clear conclusion as to the situations where these mechanisms are necessary and to their implementation methods.

Accordingly, it is difficult to identify the criteria and conditions under which the consent exception will receive broad acceptance. It therefore remains complex for researchers, ethics committees and the public to identify situations where the exception could be used. Since ethical standards often address the issue from a limited perspective, it makes it difficult to generalize these rules. For each given situation, it becomes necessary to combine all norms. Thus, it appears that more coherence and consistency are necessary among the many studied standards to help identify a general rule. This reflection could be an opportunity to discuss this issue among the organizations and, ultimately, lead to the development of more uniform criteria.

⁴ International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, *Guideline for Good Clinical Practice*, adopted by the Steering Committee (10th June 1996), s. 4.8.15; Council for International Organization of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: 2002), commentary on Guideline 6. See also: J. Thompson, « Ethical challenges of informed consent in prehospital research », (2003) 5:2 CJEM 108, at 110.

⁵ *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, *supra* note 4, commentary on Guideline 6; Council for International Organization of Medical Sciences (CIOMS), *International Ethical Guidelines for Epidemiological Studies*, Genève, 2008, commentary on guideline 6.

⁶ See: B.M. Hofmann, « Bypassing consent for research on biological material », (2008) 26:9 Nat. Biotechnol. 979; L. Lwoff, « Ethics of research on human biological materials »,

(2008) 26:1 Nat. Biotechnol. 29; B. V. Veen, « Human tissue bank regulations » (2006) 24 Nat. Biotechnol. 496.

⁷ D. B. Resnik, « Re-consenting human subjects: ethical, legal and practical issues » (2009) 35 J. Med. Ethics 656, at 656.

⁸ G. Helgesson, J. Dillner, J. Carlson, C.R. Bartram & M.G. Hansson, « Ethical framework for previously collected biobank samples », (2007) 25:9 Nat. Biotechnol. 973, at 975. See also: J. S. Forsberg, M. G. Hansson & S. Eriksson, « Changing perspectives in biobank research: from individual rights to concerns about public health regarding the return of results », (2009) 17 EJHG 1544.

⁹ *Idem.*, at 974.

¹⁰ Organisation for Economic Cooperation and Development (OECD), *Best Practice Guidelines for Biological Resource Centres*, (Paris: 2007), at 94.

¹¹ *Nuremberg Code*, from *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, vol. 2, U.S. G.P.O, Washington, D.C., 1949, at 181-182.

¹² World Health Organisation (WHO), *Declaration of Helsinki, Recommendations Guiding Doctors in Clinical Research*, Tokyo, 1964, s. 3a.

¹³ United Nations General Assembly, *International Covenant on Civil and Political Rights*, (Genève : 1966), s. 7.

¹⁴ Council for International Organization of Medical Sciences (CIOMS), *Proposed International Guidelines for Biomedical Research Involving Human Subjects*, Genève, 1982, s. 6.

¹⁵ Council of Europe, ETS, *Convention for the Protection of Human Rights and Dignity of the Human Being With Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, no. 164 (Oviedo: 1997), s. 16. See also: C Council of Europe, *Additional Protocol to the Convention on*

Human Rights and Biomedicine, concerning Biomedical Research (Strasbourg: 2005), s. 14.

¹⁶ United Nations Educational Scientific and Cultural Organization (UNESCO) *Universal Declaration on Bioethics and Human Rights* (2005), s. 6. See also: United Nations Educational Scientific and Cultural Organization (UNESCO), *Universal Declaration on the Human Genome and Human Rights* (Paris: 1997), s. 5 ; United Nations Educational Scientific and Cultural Organization (UNESCO), *International Declaration on Human Genetic Data* (2003), s. 8.

¹⁷ World Medical Association (WMA), *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, Seoul, 2008, s. 11 ; *Universal Declaration on the Human Genome and Human Rights*, *supra* note 16, s. 2.

¹⁸ International Bioethics Committee of UNESCO, *Report on Confidentiality and Genetic Data* (Morocco : 2000), at 1.

¹⁹ O. O'Neil, « Some limits of informed consent », (2003) 29 J. Med. Ethics 4, at 5.

²⁰ International Bioethics Committee of UNESCO, *Report of the International Bioethics Committee of UNESCO (IBC) on Consent* (Paris: 2007), at 25.

²¹ National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, Washington, 1979 ; *Universal Declaration on the Human Genome and Human Rights*, *supra* note 16, s. 5.

²² *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, *supra* note 17, s. 23.

²³ Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada,

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (1998, with 2000, 2002 and 2005 amendments), at 3.1.

²⁴ *International Declaration on Human Genetic Data*, *supra* note 16, preamble.

²⁵ *Universal Declaration on Bioethics and Human Rights*, *supra* note 16, preamble.

²⁶ *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, *supra* note 23, at i.4.

²⁷ Groupe-conseil du Fonds de la recherche en santé du Québec, *Rapport final du groupe-conseil sur l'encadrement des banques de données et des banques de matériel biologique à des fins de recherche en santé* (Québec : 2007), at 29.

²⁸ National Council on Ethics in Human Research (NCHER), *Final Report of the Task Force to Study Models of Accreditation for Human Research Protection Programs in Canada* (Ottawa: 2002), at 4.

²⁹ Canadian Biotechnology advisory Committee (CBAC), *A Report from the Canadian Biotechnology Advisory Committee on Biotechnology and Health Innovation: Opportunities, Challenges and Public Policy*, (Ottawa: 2004), at 32. See also: National Health and Medical Research Council, Australian Research Council, Australian Vice-Chancellors' Committee, *National Statement on Ethical Conduct in Human Research* (Australia: 2007), s. 2.3.8.

³⁰ Interagency Advisory Panel on Research Ethics, *Draft 2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: 2008), at 1.

³¹ *Universal Declaration on Bioethics and Human Rights*, *supra* note 16, preamble.

³² *International Declaration on Human Genetic Data*, *supra* note 16, preamble.

³³ *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, *supra* note 15, s. 15.

³⁴ Organisation for Economic Cooperation and Development (OECD), *OECD Guidelines on Human Biobanks and Genetic Research Databases* (Paris: 2009), par. 27.

³⁵ K. J. Maschkep, « Navigating an ethical patchwork—human gene banks », (2005) 23:5 Nature Biotechnol. 539, at 542.

³⁶ G. Helgesson, J. Dillner, J. Carlson, C.R. Bartram & M.G. Hansson, *supra* note 8, at 973.

³⁷ See, for instance : European Nutrigenomics Organisation (NuGO), *Bioethics Guidelines on Human Studies* (Colney : 2006), guideline 5 ; *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, *supra* note 4, commentary on guideline 4 ; German National ethics Council, *Biobanks for Research* (Berlin: 2004), at 58.

³⁸ World Health Organisation, *Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells and Fluids in Research* (Genève: 2000), at 6.

³⁹ *International Ethical Guidelines for Epidemiological Studies*, *supra* note 5, commentary on guideline 4.

⁴⁰ Swedish Medical Research Council, *Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research* (Switzerland: 1999), at 4.

⁴¹ *International Declaration on Human Genetic Data*, *supra* note 16, s. 16 (see also s. 17).

⁴² *International Ethical Guidelines for Epidemiological Studies*, *supra* note 5, commentary on guideline 24.

⁴³ *Report of the International Bioethics Committee of UNESCO (IBC) on Consent*, *supra* note 20, at 23.

⁴⁴ *Idem.*, at 24 (see also at 9).

⁴⁵ *Idem.*, at 9, 24.

⁴⁶ *International Declaration on Human Genetic Data*, supra note 16, s. 17.

⁴⁷ *International Ethical Guidelines for Epidemiological Studies*, supra note 5, commentary on guideline 4.

⁴⁸ *Idem*.

⁴⁹ *OECD Guidelines on Human Biobanks and Genetic Research Databases*, supra note 34, s. 3.1.

⁵⁰ Canadian Institutes for Health Research (CIHR), *Best Practices for Protecting Privacy in Health Research*, (Ottawa : 2005), at 7.

⁵¹ *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, supra note 4, commentary on guideline 4.

⁵² *International Declaration on Human Genetic Data*, supra note 16, s. 16 b.

⁵³ *Idem*.

⁵⁴ *Best Practices for Protecting Privacy in Health Research*, supra note 50, s. 3.3.2.

⁵⁵ *Bioethics Guidelines on Human Studies*, supra note 37, guideline 18. See also: *Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research*, supra note 40, at 4.

⁵⁶ American Society of American Genetics, “*Statement on Informed Consent for Genetic Research*”, (1996) 59 *Am. J. Hum. Genet.* 471, at 473; *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, supra note 23, rule 2.1 c) ; *Guideline for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research*, supra note 38, at 6 ; *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, supra note 17, s. 25 ; *International Ethical Guidelines for Epidemiological Studies*, supra note 5, guideline 24 ; *Report of the International Bioethics Committee of UNESCO (IBC) on Consent*, supra note 20, at 9.

⁵⁷ European Society of Human Genetics, *Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues*, (Birmingham : 2001), s. 12.

⁵⁸ 45 C.F.R. 46.116d (United-States).

⁵⁹ Council of Europe, *Explanatory Report on the Convention on Human Rights and Biomedicine* (Strasbourg : 1997), par. 137.

⁶⁰ *International Ethical Guidelines for Epidemiological Studies*, supra note 5, commentary on guideline 4.

⁶¹ *Bioethics Guidelines on Human Studies*, supra note 37, guideline 18.

⁶² *Best Practices for Protecting Privacy in Health Research*, supra note 50, element 3. See also : *Biobanks for Research*, supra note 37, at 58.

⁶³ *Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research*, supra note 40, at 4 ; *Best Practises for Protecting Privacy in Health Research*, supra note 50, element 3.

⁶⁴ Council of Europe, *Recommendation Rec(2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin*, (Strasbourg : 2006), s. 22.

⁶⁵ *Best Practices for Protecting Privacy in Health Research*, supra note 50, element 3.

⁶⁶ See for example: *Bioethics Guidelines on Human Studies*, supra note 37, guideline 18.

⁶⁷ *OECD Guidelines on Human Biobanks and Genetic Research Databases*, supra note 34, at 33. See also : *Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research*, supra note 40, at 4 ; *Recommendation Rec(2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin*, supra note 64, s. 22.

⁶⁸ Sometimes referred to as « broad consent » (*OECD Guidelines on Human Biobanks and Genetic Research Databases*, supra note 34, par. 28) or « consent [...] for unspecified future research » (International Society for Biological and Environmental Repositories, *2008 Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research* (Bethesda : 2008), s. K2.200).

⁶⁹ *International Ethical Guidelines for Epidemiological Studies*, supra note 5, commentary on guideline 24.

⁷⁰ *Guideline for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research*, supra note 38, at 6.

⁷¹ *Explanatory Report on the Convention on Human Rights and Biomedicine*, supra note 59, par. 137.

⁷² *Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues*, supra note 57, s. 12.

⁷³ *OECD Guidelines on Human Biobanks and Genetic Research Databases*, supra note 34, at 32.

⁷⁴ *Bioethics Guidelines on Human Studies*, supra note 37, guideline 18.

⁷⁵ *International Declaration on Human Genetic Data*, supra note 16, art. 16.

⁷⁶ *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, supra note 23, rule 10.3. Also: 45 C.F.R. 46.101b.

⁷⁷ *Idem.*, supra note 23, rule 3.3.

⁷⁸ *International Declaration on Human Genetic Data*, supra note 16, s. 16 b).

⁷⁹ *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, supra, note 4, commentary on guideline 4.

⁸⁰ *Idem*. See also: World Medical Association, *Declaration on Ethical Consideration Regarding Health Databases*, (Washington : 2002), s. 21.

⁸¹ *Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues*, supra note 57, s. 14.

⁸² *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, supra note 4, commentary on guideline 4.

⁸³ *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, supra note 23, rule 2.1. See also : *Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues*, supra note 57, s. 12 ; 45 C.F.R. 46.116d ; *International Ethical Guidelines for Epidemiological Studies*, supra note 5, commentary on guideline 4 ; *OECD Guidelines on Human Biobanks and Genetic Research Databases*, supra note 34, at 30 ; Nepal Health Research Council, *National Ethical Guidelines For Health Research in Nepal*, (Népal : 2001), s. 5.3 ; *Statement on Informed Consent for Genetic Research*, supra note 56, at 473.

⁸⁴ *National Statement on Ethical Conduct in Human Research*, supra note 29, s. 2.3.6.

⁸⁵ *International Ethical Guidelines for Epidemiological Studies*, supra note 5, commentary on guideline 4.

⁸⁶ *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, supra note 23, rule 3.1.

⁸⁷ Bioethics Advisory Committee (Singapore), *Personal Information in Biomedical Research*, (Singapore : 2007), s. 18.

⁸⁸ Indian Council of Medical Research, *Ethical Guidelines for Biomedical Research on Human Subjects* (New Delhi : 2007), at 11. Also « risk that is no more likely and not greater than that attached to routine medical or psychological examination » : *National Ethical Guidelines For Health Research in Nepal*, supra note 83, s. 5.3.

⁸⁹ *Additional Protocol to the Convention on Human Rights*

and Biomedecine, concerning Biomedical Research, *supra* note 15, s. 17.

⁹⁰ National Statement on Ethical Conduct in Human Research, *supra* note 29, s. 2.1.6.

⁹¹ OECD Guidelines on Human Biobanks and Genetic Research Databases, *supra* note 34, at 27.

⁹² International Ethical Guidelines for Epidemiological Studies, *supra* note 5, guideline 24; International Ethical Guidelines for Biomedical Research Involving Human Subjects, *supra* note 4, commentaire sur la ligne directrice 4; American Society of American Genetics, "Statement on Informed Consent for Genetic Research", (1996) 59 *Am. J. Hum. Genet.* 471, p. 473; Énoncé de politique de trois Conseils, *Éthique de la recherche avec des êtres humains*, *supra* note 23, règle 2.1.

⁹³ National Statement on Ethical Conduct in Human Research, *supra* note 29, art. 2.3.6; International Ethical Guidelines for Biomedical Research Involving Human Subjects, *supra* note 4, commentary on guideline 4.

⁹⁴ Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research, *supra* note 40, at 4. Also: 45 C.F.R. 46.101b.

⁹⁵ Fonds de la recherche en santé du Québec (FRSQ), *Standards du FRSQ sur l'éthique de la recherche en santé humaine et l'intégrité scientifique*, (Montréal : 2008), at 43.

⁹⁶ International Declaration on Human Genetic Data, *supra* note 16, s. 16; Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, *supra* note 23, rule 10.3; International Ethical Guidelines for Epidemiological Studies, *supra* note 5, commentary on guideline 24; Recommendation Rec(2006)4 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin, *supra* note 64, s. 23; Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues, *supra* note 57, s. 9.

⁹⁷ OECD Guidelines on Human Biobanks and Genetic Research Databases, *supra* note 34, s. 3.6. Also: Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research, *supra* note 68, s. K2.200.

⁹⁸ Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues, *supra* note 57, s. 12.

⁹⁹ See: Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Materials for Research, *supra* note 68, at 48; International Ethical Guidelines for Biomedical Research Involving Human Subjects, *supra* note 4, guidelines 4; Standards du FRSQ sur l'éthique de la recherche en santé humaine et l'intégrité scientifique, *supra* note 95, at 43; International Ethical Guidelines for Epidemiological Studies, *supra* note 5, guideline 24; International Declaration on Human Genetic Data, *supra* note 16, s. 16 b); Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research, *supra* note 40, at 4; OECD Guidelines on Human Biobanks and Genetic Research Databases, *supra* note 34, at 31; Guideline for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research, *supra* note 38, at 6; Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues, *supra* note 57, s. 22; Bioethics Guidelines on Human Studies, *supra* note 37, guideline 18; Declaration on Ethical Consideration Regarding Health Databases, *supra* note 80, art. 21.

¹⁰⁰ Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, *supra* note 17, s. 25.

¹⁰¹ Guidelines on Human Biobanks and Genetic Research Databases, *supra* note 34, at 30 and s. 4.B.

¹⁰² Best Practices for Protecting Privacy in Health Research, *supra* note 50, s. 3.3.6.

¹⁰³ OECD Guidelines on Human Biobanks and Genetic Research Databases, *supra* note 34, s. 4B.

¹⁰⁴ *Idem.*, at 27.

¹⁰⁵ Biobanks Act, no. 110/2000 (Islande), s. 9.

¹⁰⁶ An Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, R.S.Q., c. A-2.1 (Québec), s. 125; An Act Respecting the Protection of Information in the Private Sector, R.S.Q., c. P-39.1 (Québec), s. 21.

¹⁰⁷ Conseil fédéral suisse, Ordonnance du 14 juin 1993 concernant les autorisations de lever le secret professionnel en matière de recherche médicale, (Switzerland : 1993), ss. 1-3; Académie suisse des sciences médicales, *Biobanques: Prélèvements, conservation et utilisation de matériel biologique humain; Directives médico-éthiques et recommandations*, (Bâle : 2006), at 9.

¹⁰⁸ International Ethical Guidelines for Epidemiological Studies, *supra* note 5, commentaire sur la ligne directrice 4.

¹⁰⁹ Universal Declaration on Bioethics and Human Rights, *supra* note 16, s. 6. See also Good Clinical Practice, *supra* note 4, s. 4.8.15; Biobanks for Research, *supra* note 37, at 56; Declaration on Ethical Consideration Regarding Health Databases, *supra* note 80, s. 21.

¹¹⁰ International Declaration on Human Genetic Data, *supra* note 16, art. 16 b) et 17 a).

¹¹¹ OECD Guidelines on Human Biobanks and Genetic Research Databases, *supra* note 34, art. 4B. Voir aussi: International Ethical Guidelines for Epidemiological Studies, *supra* note 5, ligne directrice 4.

¹¹² International Declaration on Human Genetic Data, *supra* note 16, s. 8 a).

¹¹³ Guideline for obtaining informed consent for the procurement and use of human tissues, cells and fluids in research, *supra* note 38, at 6; Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, *supra* note 23, règle 3.4; Act on Biobank, *supra* note 105, art 7.

¹¹⁴ Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research, *supra* note 40, p. 4.

¹¹⁵ Best Practices for Protecting Privacy in Health Research, *supra* note 50, art. 3.3.7.

¹¹⁶ Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, *supra* note 23, rule 3.4. Also: International Ethical Guidelines for Epidemiological Studies, *supra* note 5, commentary on guideline 4.

¹¹⁷ Best Practices for Protecting Privacy in Health Research, *supra* note 50, s. 3.3.5.

¹¹⁸ Explanatory Report on the Convention on Human Rights and Biomedicine, *supra* note 40, par. 137; Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research, *supra* note 59, at 4; Comité consultatif de bioéthique de Belgique, *Avis No 25 du 17 novembre 2003 relatif à la durée de conservation des fiches de sang et la confidentialité des données concernant le dépistage des anomalies congénitales métaboliques*, (Brussels : 2003), at 10; Biobanks for Research, *supra* note 37, at 56.

¹¹⁹ International Ethical Guidelines for Epidemiological Studies, *supra* note 5, commentary on guideline 4; Bioethics Guidelines on Human Studies, *supra* note 37, guideline 5; National Statement on Ethical Conduct in Human Research, *supra* note 29, s. 2.3.6; Biobanks for Research, *supra* note 37, at 57.

¹²⁰ Research Ethics Guidelines for Using Biobanks, Especially Projects Involving Genome Research, *supra* note 40, at 4.

¹²¹ *Best Practises for Protecting Privacy in Health Research*,
supra note 50, s. 3.3.4.

¹²² *Idem*.

¹²³ See: K. J. Maschkep, *supra* note 35 ; D. B. Resnik, *supra*
note 7; M.G. Hansson, J. Dillner, C.R. Bartram, J. Carlsson
& G. Helgesson, « Should donors be allowed to give broad
consent to future biobank research? », (2006) 7 *Lancet*
Oncol. 266 ; G. Helgesson, J. Dillner, J. Carlson, C.R.
Bartram & M.G. Hansson, *supra* note 8; B. V. Veen, *supra*
note 6.

¹²⁴ B.V. Veen, *supra* note 6.

¹²⁵ Even a research ethics board's approval is not subject to
consensus regarding data or biological samples that cannot be
traced back to the participant (see for example : 45 C.F.R.
46.101b).