

ETHICAL ACCEPTABILITY OF USING GENERIC CONSENT FOR SECONDARY USE OF DATA AND BIOLOGICAL SAMPLES IN MEDICAL RESEARCH

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Abstract: The research idea starts from the previous identification of certain elements of generic consent for research activities found in informed consent (IC) forms used in therapeutic activities in hospitals that have the right to conduct medical research on human subjects in Northeast Romania. The paper questions the ethical acceptability of secondary use of data and biological samples in medical research, in the context of obtaining generic therapeutic consent from patients. The objective of the research is to analyze the Romanian context of using the IC obtained in therapeutic purposes as a starting point for the research activity. We wish to argue that the practice of obtaining a generic consent - for using the data obtained and the biological samples collected in the therapeutic process for secondary analysis - raises serious ethical issues regarding the validity and effectiveness of the IC.

Key words: generic consent, ethical acceptability, secondary use of data, biological samples, medical research

Aceptabilidad ética de usar consentimiento genérico para uso secundario de datos y de muestras biológicas en investigación médica

Resumen: La idea de este estudio proviene de la identificación previa de ciertos elementos de consentimiento genérico para actividades de investigación, que se encuentran en formularios de consentimiento informado usados en actividades terapéuticas en hospitales que tienen la potestad de realizar investigación médica con sujetos humanos en el Noreste de Rumania. Este estudio cuestiona la aceptabilidad ética del uso secundario de datos y muestras biológicas en el contexto de obtener consentimiento genérico de pacientes en terapia. El objetivo de esta investigación consiste en analizar el contexto en Rumania al usar consentimiento informado en terapia como punto inicial de actividad de investigación. Argumentamos que la práctica de obtener consentimiento genérico —para usar los datos obtenidos y las muestras biológicas recolectadas en el proceso terapéutico en análisis secundario— preocupa éticamente respecto de la validez y efectividad del consentimiento informado.

Palabras clave: consentimiento genérico, aceptabilidad ética, uso secundario de datos y muestras biológicas, investigación médica

Aceitabilidade ética do uso de consentimento genérico para uso secundário de dados e amostras biológicas em pesquisa médica

Resumo: A ideia de pesquisa tem sua origem a partir da identificação anterior de certos elementos do consentimento genérico para atividades de pesquisa encontrados em formulários de consentimento informado (CI) usados em atividades terapêuticas em hospitais que têm o direito de realizar pesquisa médica em seres humanos no nordeste da Romênia. O artigo questiona a aceitabilidade ética de uso secundário de dados e amostras biológicas na pesquisa médica, no âmbito da obtenção do consentimento genérico terapêutico de pacientes. O objetivo da pesquisa é analisar o contexto romeno do uso do CI obtido por fins terapêuticos como ponto de partida para a atividade de investigação. Nós gostaríamos de argumentar que a prática de obter um consentimento genérico - para utilizar os dados obtidos e as amostras biológicas coletadas no processo terapêutico para análise secundária - levanta sérias questões éticas a respeito da validade e da eficácia do IC.

Palavras-chave: consentimento genérico; aceitabilidade ética; uso secundário de dados; amostras biológicas; pesquisa médica

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Introduction

The paper starts from the identification of certain elements of generic consent for research activities, found in the Informed Consent (IC) forms used in therapeutic activities, in hospitals that have the right to conduct medical research on human subjects in North-East Romania.

In a brief analysis of hospitalization forms from a public clinical recovery hospital, we noticed that the hospitalization forms included a number of informative paragraphs with role of IC for potential future medical researches on human subjects.

The objective of the research is to analyse the ethical acceptability using the IC obtained in therapeutic purposes as a starting point for the research activity.

In the scientific literature, there are controversies in using the data collected in the therapeutic process in further research activities in at least 3 situations: 1) without the need for IC (for research); 2) Broad Consent; 3) the need for research IC, separate from the therapeutic IC.

We are interested in whether or not a broad formulation of IC could be ethically used for allowing the conducting of research and for further publication of the resulting data.

We argue that, in the Romanian context, the practice of obtaining a mixed IC for using the data obtained and the biological samples collected in the therapeutic process for secondary analysis raises serious ethical issues regarding the validity and effectiveness of the IC.

Meanings of consent in literature

The essence of the therapeutic IC is such that the patient gives the medical staff permission to perform an intervention relevant to his/her health condition(1). Proper respect for the patient's autonomy requires an ethical approach to the process of gaining the IC, sensitive to the way in which the patient understands the situation and expresses his/her consent in accordance to what he has understood.

IC for research represents the process in which the

participant of the research agrees to participate, after being informed about the procedures, risks, and benefits(2).

The practice of gaining IC can be interpreted in a formalist manner by referring to strict rules of gaining IC and their formalization, turning the IC into an instrument of fulfilling the legal obligations of respecting the patients' rights. IC can be approached in a paternalist manner, the rules being transparent, offering to therapist the possibility to manipulate the patient's decision by presenting the risks, benefits, and procedures(2).

Starting from the scientific literature, we have identified 3 theoretical situations of ethical using of the data and the biological samples collected in the diagnosis and treatment process: without the need for express IC, BC, or specific IC.

No need for consent for secondary use in future researches of the data research and samples collected in therapeutic process.

The data and biological samples are already available for the medical units; therefore, none of the patient's rights are being harmed (co-ownership of data), and the patient cannot be exposed to a state altered from the current condition.

The lack of need of such IC can be justified when the risks associated with the research are minimal or equal to those given by the therapeutic context with no additional difficulty for the patient.

The manner of obtaining data makes the patient and the medical unit co-owners of such data, giving both parts the usage right. In the absence of an expressed mention of non-acceptance of data processing for research purposes, the agreement can be considered implicit, the hospital being one of the owners with disposal rights on the data and samples(3).

There is another opinion which supports that an IC for secondary use of data is not necessary. According to this opinion, the IC for secondary use of data and biological samples can be included in the IC for therapeutic procedures(4,5). We consider that this opinion could have been shared by the issuers of the IC forms we used for analysis

in our research, as long as the analysed IC forms request the patients to agree both with therapeutically intervention and.

Broad Consent

The current literature offers multiple definitions on Broad Consent (BC). BC involves offering the individual the option of consenting to future research that has a specific context and content, rather than for a specific, individual research projects(6). Grady defines BC as being consent for an unspecified area of subjects of possible future research, whose content and process are at least known to the participant(7).

BC is mostly debated in the context of biobanks(8,10,6). In order to be accepted as “informed”, there should be a new consent requested anytime the research frameworks are being modified. BC is not informed consent in the true sense, in the absence of the specific information referring to research(11-13).

Ploug & Holm (2015) use the idea of meta-consent as being the interplay between the BC and Dynamic Consent(6). Dynamic Consent is an alternative model of consent in which the patient has the possibility to inform on the use of data and biological samples through the means of an online platform that is updated daily. The individual is offered the possibility of withdrawing his data from use in research he/she does not agree with.

Considering that the term BC is used in association with biobanks, we prefer to consider the specific of wide formulating of consent for future use of data through the term reminded by Onara O’Neil(14) – generic consent.

The need for research IC that is separate from the therapeutic IC

Obtaining consent implies a process; Beauchamp & Childress(15) set out a series of 7 components of the process of gaining informed consent.

The elements of disclosure (preconditions): (1) competence in understanding and making decisions; (2) voluntary decision;

The elements of information: (3) the disclosure

(the material information); (4) the recommendation (of a plan); (5) understanding (in disclosure and recommendation);

Elements of consent: (6) the decision (in favour of the plan); (7) the authorization (of the chosen plan).

Grady shows that the process of gaining IC involves a series of multiple elements, including disclosure, understanding, voluntary choice, and authorization.

An argument in favour of the need for separating the research IC from the therapy IC is to avoid the Therapeutic Misconception(16), since obtaining the consent from the participation to the research differs from the IC for therapy(17). The patient will be influenced to consider that the research is directly oriented towards his/her own good and not the common good for knowledge development in medicine. Research may not involve specialized care: giving placebo medication to a patient whom is withdrawn the basic treatment might endanger the health condition maintained by the classic medication.

Consent references within Romanian Legal Framework

IC is regulated by Law no. 46, from January 21, 2003, on the patient’s rights, updated on May 20th, 2015, in Chapter 3, Patient’s consent on medical intervention. This chapter refers to the procedure of gaining IC both for medical intervention, and in the context of involving the patients in didactic activity and medical research(18). The legislation does not expressly require a standard form of IC, but the practice makes all medical units apply their own IC form introduced to the patients in the admission forms, even before diagnosis. Patients are rarely presented IC forms during hospitalization, especially when there are complicated medical interventions. The IC form is standardized in some situations, being available for download on the medical institution’s website with blanks for filling in the patient’s identification and/or diagnosis/therapeutic procedures that are recommended or are to be refused.

The forms automatically include data on the

patient's consent, so that the information and samples collected in the process of diagnosis and therapy can be used in further research activities.

Methodology

First, we performed content analysis on a series of IC forms, following the identification of situations in which the patients are asked to sign IC forms for therapy and automatically involve themselves in future potential medical research of which the purpose, specifics, benefits, or risks are not made known to them.

For the current paper, we analysed 11 forms and we selected the most relevant content to be brought into discussion.

We gave up on similar expressions identified in different forms, making sure not to eliminate information that is different, regardless of whether they support the paper's thesis or not. The forms selected in order to be considered in the analysis, upon reading all collected, are given by abbreviations, as follows:

IC1 –patient's consent for chemotherapy

IC2 –patient's consent for surgical intervention

IC3 – IC fragments introduced in the content of the hospitalization forms – ENT department.

IC10 – patient's consent on the methods of diagnosis, therapy, anaesthetics and surgery

IC11 – patient's consent on the investigations, therapeutic procedures, for participation in the medical educational process and respecting the internal rules for the hospitalized patients

After analysis of the IC forms, we continued the research by conducting in-depth interviews with doctors, medical assistants, and decision makers in the medical system, namely members of the EC.

The interviews' purpose was to identify how the Informed Consent (IC) is understood by professionals in the medical field, particularly in the medical care institutions in Iasi (North-eastern city in Romania). We were interested in identifying whether the medical staff that applies IC as

an ethical tool have knowledge – and are willing to apply it in their daily practice – of the bioethical principles which should underlie the adoption and implementation of such a tool.

A series of questions expressly targeted the attitude of the respondents on using the data obtained in the process of diagnosis and treatment in further research and considering the generic consent as a legitimate form of consent in research.

Participants & Data Collection

The participants were 10 medical representatives (doctors, managers, chairs of ECs, nurses) of Romanian medical institutions (Iasi city) who are allowed to conduct medical research on human subjects. The sampling was carried out by the snowball method while respecting the affiliation of the respondents to institutions selected as subjects for our research. The respondents were aged between 28 and 60 years; five respondents were male and five were female. As specific criteria of inclusion we considered whether the potential respondents had published scientific research results for medical research conducted within the selected institution in the last five years. We identified medical staff other than physicians—for example, nurses, psychologists, etc.—and we included them in the sample. We included at least two hospital directors in the sample.

The data were collected between March and June 2016; The interviews followed a previous content analysis of a series of IC forms collected from medical institutions from Iasi;

Limits of the Research

The results and conclusions could be extended to other contexts in which BC is used to justify the use of data obtained in the therapeutic process for further research activities.

The research is tributary to a social-constructionist paradigm, which allows a certain degree of subjectivity in the analysis of the qualitative data. This might bring criticism regarding the contamination of the analysis of data with the investigators' subjective opinions. In order to diminish the possible influences, methodological triangulation was

used by analysing both the IC forms and the data obtained by interview, both in the coding process, and in the analysis one.

Informed consent forms analysis

The content of the IC forms is mostly oriented towards the therapeutic intervention; references to the research part are sporadic, failing to ensure the real quality of consent for medical research. From the perspective of voluntary participation in the research activity connected to the therapeutic one, interferences between the IC for intervention or treatment, and IC for medical research were identified. With regard to these interferences, we consider it necessary to bring into discussion certain possible ethical risks.

Generic Consent & the Quality of Medical Care

Into the analysed forms, the possibility of refusal to participate in the research is not specified and neither are any references to the patient being informed regarding the nature and future objectives of the research. The only reference to the doctor's obligations, from the perspective of the research, is of non-maleficence. The principle of beneficence is excluded and that of autonomy is partially violated. The formulation of the majority of the IC forms we analysed violates the categorical imperative. Although the therapy is oriented towards the patient, the elements of IC in the research digress from it, wrongly considering that the simple non-maleficence justifies the ethical nature of any future research.

The real nature of the IC document does not arise, which does not refer to the patient's requested contribution to the scientific research and medical education, nor the fact that it was made clear for the patient.

What is more, introducing non-specific consent might influence the patient to believe in the absence of his/her participation in the research activity required, or will determine the absence of therapy.

The criteria of exclusion of certain therapeutic procedures do not expressly formulate the possibility of refusal to participate in research activity.

From an ethical perspective, it can be interpreted as an abuse of the dominant position of the doctor in front of the patient.

The same situation of uncertain consent can be found in the authorization of filming or photographing different parts in medical or scientific interest. Even though it is referred to the obligation of blurring the elements of physiognomy, this is in order to alleviate the patient's stress and increase his/her trust in the physician, the expressed incapacity of refusal being able to create confusion with respect to his/her dignity.

(IC1) (...) *I authorize* / (IC2) *I consent* (TO) the photographing or filming the body or different parts of it for medical or scientific purpose, but the doctor is obliged to mask the essential elements of the physiognomy that could lead to my identification (...)

The same situation of uncertain consent can be also found in the authorization for filming or photographing different parts of the body with medical or scientific purpose. The expressed impossibility of refusal to be photographed or filmed may create confusion regarding the respect for dignity.

Consent for Harvesting, Storage, and Use of All Biological Products

The assent of the subject regarding the use of "all biological products taken" is given in order to "establish the diagnosis or treatment", and not for its use in order to conduct scientific research.

The implicit assent is not in favour of using the biological samples in research activity, for which the patient does give his/her assent for participation.

(IC2), (IC7) *"I consent and explicitly express my agreement to the harvesting, storage, and use of all biological products taken from my body, in order to establish the diagnosis or treatment."* (IC10, paragraph 7)

Although reproduced in the form in reverse order, in the previous paragraph, (IC10, paragraph 6) *"tissues or parts of organs surgically removed can be examined in medical, scientific and educational purposes"*, we can interpret that as any biological

sample can be used in further research, in any possible form.

Mandatory Consent & Possible Experiments on Human Subjects

(IC10, paragraph 9) "During hospitalization, there are situations in which passive participation in clinical medical education and scientific research can be involved, the only final purpose is the benefit and interest of the patients".

This formulation could be interpreted as implicitly authorizing some experiments on human subjects without specific consent, as long as it happens during the patient's hospitalization. The declared purpose of the participation in the research it might be considered into the interest and benefit of the patients, but without it being explained.

Currently, the medical research is performed for the benefit of future patients – in the spirit of responsibility for the patients that are not present, including those belonging to future generations – and not necessarily for the immediate benefit of current, direct patients. The lack of delimitation of benefits and beneficiaries of the research might lead to misunderstanding and error in consent (therapeutic misconception).

Generic Consent & DNA Analysis

The formulation in (IC10) makes no reference to whether a possible clinical trial is being considered: for example, a study of phase III of testing certain innovating medicines, or whether it only refers to the observation of the patient's stages of evolution.

"The biological material harvested (blood, tissues, organs) in diagnosis purposes can also be examined in scientific research purposes (including DNA analysis), training, it can be photographed and published without my express consent, keeping the confidentiality." (IC10), (IC3)

We consider that in order to consent to a procedure of scientific research which implies, for example, DNA analysis, the subject should at least understand what benefits this analysis could bring him/her. Some subjects may concur with the idea according to which the human genome should be

in the immaterial, intangible heritage of humanity, and that no experiments should be conducted on our own genome and will, therefore, refuse the generating of data about their own DNA.

The patient may legitimately consider that beyond the simple medical data analysis, its biological evidence, including the DNA sample, can be subject to advanced research, for example, that referring to the generating of stem cells, from organic tissues or DNA manipulation. A suspicious subject may extrapolate this information and raise questions regarding the preservation of tissues in the medical institution, which receives the authorization or different transfers for research purposes to other medical institutions, which have the capacity for research in the genetic field.

Another ethical risk of using wide IC for research (generic consent) is:

(IC11) "The harvested biological material (blood, tissue or organs) for the purpose of diagnosis, can also be expressed in other areas of scientific research, and can be photographed and published without any other explicit authorization from me, preserving the confidentiality".

This can create a false impression of harvesting for the purpose of diagnosis, the harvesting that might have research as a sole purpose and that, eventually, would endanger the patient's life.

"(...) I authorize the photographing or filming of my body or different parts of it in medical or scientific purposes, but the doctor is obliged to mask the essential elements of my physiognomy that might lead to my identification (...)." (IC1), (IC10)

"I also agree to be photographed and I agree that the photos can be published in scientific medical journals." (IC3)

Findings from interviews

IC for research versus IC for therapy

The most respondents are aware of the need for a different IC for the research activity.

"In research, things are more detailed, but it is a different activity. The research activity is with volunteer

subjects that accept to come, the terms are totally different and are made in the spirit of the companies that sell a particular product, (...) The IC, when I started working, had 2 pages, and now it has 20.” (I04)

“In the clinical studies there is a rather long document.” (I06)

We can observe in I04’s discourse that the IC is still seen as a form that “had 2 pages” and it has subsequently increased to 20; the respondent relates to the simple IC form, neglecting the process of gaining the IC. What is more, the respondent draws the attention that the forms “are made in the spirit of the companies that are selling a product”, not of a team that implements research, but the company that finances it. The correct procedure would be that the research team to propose the protocol, which implicitly contains the IC, to the IRB for evaluation and approval. The financing company should not be involved in the protocol since it represents an interested third party, whose implication is able to generate a conflict of interest.

In the data analysis, we have identified references to possible abuse of the dominant position of the doctor and the medical institution (teaching hospital):

“It is presumed that the patient knows the functions and the specifics of the hospital (teaching hospital) and his/her arrival to such hospital anticipates the presumption that he knows what is going on, accepting to participate to the specific actions of the hospital (therapeutic, didactic, research)” (I03)

It is assumed that signing the IC is just a formality, the agreement being already implicit. This leads to the vulnerabilization of the patient, who is put in difficulty to refuse the participation to research. This aspect becomes even of greater importance since the IC forms are usually signed in the admission process, before any other procedure, including diagnosis, to be done.

“(In research) there are stipulated all aspects, risks, benefits, procedures, how many visits will there be, how many times, how long will the interview take, if they have the right to eat, if the doctor will be paid,

that you can report them, there are introduced cases of malpractice of the sponsor and the investigator. It means it is more comprehensive.” (I04)

The respondents show that a research IC is more detailed, with more comprehensive information regarding the risks, benefits, procedures etc. On the other hand, the IC for therapy:

“(...) is an informed consent with providing data, of maximum 3 pages (in medical practice)” (I04)

We again observe the strict administration relating to the IC, identified in number of pages, the information technicality, but without reference to the real ethical reflection.

Blurred Consent – Can IC Generate Misunderstanding and Misconception?

The doctors interviewed make the distinction between the IC for research through invasive procedures and the need for voluntariness and non-invasive procedures (I01). There are respondents that consider there is no difference between the IC for research and that for medical practice.

“No, I don’t see any difference. The consent is a consent, be it therapeutic or for research. But the research in the area of clinical studies is also treatment. We are in the common denominator.” (I02)

The common denominator between the medical practice and the medical research becomes the IC. The respondent considers medical research an advanced form of individual therapy in the benefit of the patient. The confusion seen in doctors can be transferred to the patient, especially when BC is requested the by the very IC form for therapeutic intervention.

Later, as the interview performs, the respondent tints his statements:

“At first, I was telling you that obtaining IC in medical practice is no different than in research on human subjects, but methodologically, there is a difference. Practically, in clinical studies they work more, since the degree of suspicion on clinical studies is much higher.” (I02)

This might suggest the lack of a preliminary re-

reflection on the ethical role of IC, and the interview itself offers an opportunity for reflection. The ethical reflection can be considered peripheral, the lack of it being justified by the overload of the doctor with administrative situations, of actual practice, medical emergencies, the pressure of the lack of human resources, and of time.

In some cases, the difference between the IC for therapy and that for research is nuanced, from the perspective of the clarity of information offered through the IC form. The lack of clarity in the IC for therapy is attributed to the abundance of therapeutic procedures, of possible effects, etc., which cannot all be contained in one form.

“Absolutely (I see a difference between the IC for medical practice and that in clinical trials)! They cannot be compared. This one, from the medical practice, is very brief. It only has some references to what is about to happen: the procedure, treatment, information on possible side effects, but it is not a very clear one (...)” (106)

The criteria for differentiating the two types of IC, identified by the respondents, are either the dimension of the forms, or the clarity of information, without taking into consideration the existence of an overlap between therapy and research in the IC form.

Discussions and recommendations

We argue that, in the Romanian context (North-Eastern region), the practice of gaining a wide IC for using data and biological samples collected in the therapeutic process for secondary analysis, raises serious ethical issues regarding the validity and effectiveness of the IC. The model of the mix of consent was analysed by using generic consent for research included in the IC for therapy.

We consider necessary that the persons performing medical research to be able to make the distinction between the situations in which the IC is required and then be able to acknowledge, describe for IRB, and apply the process of obtaining the IC.

In an international context, such a separation is regulated through institutional ethics policies that can delimitate the specifics of the researchers that

expressly require IC. We do not deny the fact that there can be research that would use a retrospective reconsideration of certain data collected in the therapeutic process, for example in documenting new diseases, and the reclassification of certain cases previously diagnosed as belonging to a particular disease, are situations in which we find it necessary to use data previously collected, based on a potential generic consent.

We cannot agree with the use of collected samples and data without the request of a specific consent, even in the situation in which it is argued that such actions do not infringe upon any subjective right of the patient and cannot harm him/her.

We find it necessary to have consent for secondary use of data, but we don't see it connected to therapeutic consent, since it leads to misconception, abuse of power etc.

Introducing alternatives for obtaining the consent, such as generic consent, dynamic consent, meta-consent (previously described in the article), by the regulation of the research institutions would facilitate their use in practice, only in the context in which there would be a real institutional or individual interest, for the ethics of research. In the countries, wherein the ethics of research is being pioneered, such as Romania, the use of wide consent can be a legal cover that would not consider the ethical implications of practice and the possible risks for the subjects.

In order to simultaneously satisfy, the need for consent in research of collected data and biological samples and respect the right to be informed, to autonomously express the will on the use of data, reducing the risk of misunderstanding or compulsory consent can be fulfilled through the use of a wide consent, such as meta-consent. Meta-consent aims to approve the secondary use of data and biological samples, and is signed after the procedures, diagnosis, and treatment, upon release or after since it is a separate form and expressly destined to a research activity.

In the case of patients in the terminal phase, the use of data and biological samples collected and preserved can only be done after obtaining the consent of the caregivers. No research activity

should be possible by involving the hospitalized patients based on wide consent, but only based on IC for research. The research should be conducted as much as possible after the therapeutic activity, or when they are enrolled in the studies, with fully informing them with regard to the nature of the research, risks, benefits etc.

We recommend that the Romanian legislation, but also that of other states in which the ethics of research is at an early stage, to establish an ethics policy of separating the wide research consent from any form of consent for therapy. The obtaining of the research consent should not be done by the team that performed the therapy, and not before the end of the period of therapy.

We also recommend conducting extensive ethical training programs addressed to the medical personnel conducting research activities, but also to those involved in the development of ethical policies.

The analysis of the IC forms and data collected through interviews lead to a few appreciations referring to the wide use of IC as an instrument of legal justification of the medical activity and of research, and less as an instrument of ethical reflection.

We can characterize the procedure of gaining consent as being “blurred consent”, since, according to the examples of IC we analysed, the patient cannot clearly understand what he is consenting to and the limitations of the consent, regarding the use of data and collected samples. From the analysed forms emerges no concern of those implicated in the ethics policy of the institutions, regarding the promotion of patients’ autonomy, reducing the role of the consent to its administrative function. What is more, not even the interviewed doctors, belonging to institutions with the right of medical research, have no obvious ethical reflection, referring to the limitations of involving patients in the research or the promotion of their autonomy.

We consider that using a mixed IC form that comprises both the agreement for therapeutic practice and that for research (present and future) is, at least, questionable from the perspective of the

abuse of a dominant position in the medical institution. The use of BC elements is connected to the quality of the medical act, extending the legitimate limits of consent for intervention and transforming the IC into generic consent, including the collection, storage and use of data and biological samples. Applying the IC form, even before the diagnosis and therapy procedures, transforms the IC into mandatory consent, since the vulnerable patient can have difficulty in establishing the limitations of the consent, or if the absence of the acceptance to use the data for research can jeopardize the quality of the therapeutic act.

Conclusions

The forms analysed contain references to the implicit consent of the patient to participate in activities with a research nature that were not specified. There were cases in which this generic consent approach has generated situations of risk to the patient by correlating the “blurred” generic consent with particular situations that lead to malpractice.

The elements of generic consent are, in our opinion, introduced illegitimately in the IC forms in order to allow for a secondary use of the given data obtained during the diagnosis and the patient’s therapy, especially after tissue sampling. The right to use the data obtained for research purposes during diagnosis or therapeutic intervention may transform the clinical, therapeutic act into illegitimate study on human subjects.

The use of images obtained during diagnosis or treatment may lead to the patient’s vulnerability; if they knew those were being used for other purposes they may not have expressed their agreement. Both the agreement to participation in research, and to activities in medical education, should be requested separately, making them subject to a different informed consent. In offering these types of IC, it should be clearly explained to the patient that the refusal to participate in the research or medical education would not endanger his/her access to adequate treatment for his/her health condition.

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