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Back to Main Page

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Consent Requirements

What Are the Terms and Conditions of Informed Consent?

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Abstract

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The special GDPR rules for informed consent are a cornerstone in the context of research activities, even though the discipline of informed consent is not exclusive to the protection of the personal data framework and other legal sources contain requirements for the expression of a person's will. To make biomedical activities consistent with the law and with fundamental ethical principles (e.g. dignity and self-determination), information has to be provided that meets the requirements of the various legal sources. Therefore, not only the requirements of a specific legal discipline (i.e. the GDPR), but also the entire legal and ethical framework forming the basis of informed consent, should be taken into account.

1. Introduction

As observed in other chapters of this Handbook, Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (hereinafter referred to as 'GDPR')[1] sets special rules for consent and rights in the context of research activities.

However, the discipline of informed consent is not exclusive to the protection of a personal data framework and other legal sources provide for requirements to express will.

The legal obligation to require the consent of a person who is involved in an activity that may affect his or her interests is relatively recent.

From a legal perspective, it is only since the second post-war period that legal sources have begun to consider this issue, usually referring to informed consent in the case of health care treatment (see, for example, Aarticle 32 of the Italian Constitution of 1948; Aarticle 7 of the Constitution of Finland; paragraph 2, subparagraph 2 of the German Constitution).

Symbolically, the first document on research ethics was adopted by the medical scientific community in Nuremberg, the site of the trial of the Nazi criminals who also included scientists and doctors.

The so-called 'Nuremberg Code' on medical experimentation makes the voluntary consent of the individual an absolutely essential requirement of medical research.

However, the question of informed consent has been absorbed into that of medical practice, and over the following years, the legal sources did not give any relevance to the expression of will in scientific activity in hypotheses other than medical treatment.

Recent constitutional charters, or those recently modified, deal with consent in the specific field of scientific research. Thus, the Swiss Constitution in article 118b, which came into force on 7 March 2010, tackles informed consent in the case of research on human beings. The 1991 Constitution of Bulgaria (Aarticle 29), of Slovenia (Aarticle 18), of Hungary (Aarticle III, paragraph 2) and of Croatia (Aarticle 23) also prohibit medical or scientific experimentation without the consent of the person concerned.

At the national level, laws or other pieces of legislation regulate consent in the scientific field (see, in particular, Book I, Title I, Chapters 2, 3 and 4 of the French Civil Code, amended by the laws on bioethics).

European Union law and the system of the European Convention on Human Rights (the ECHR) deal with consent across Europe. In particular, 'bio-legal' issues have already been framed in the Charter of Fundamental Rights of the European Union. Article 3,

paragraph 2 of the Charter establishes the general rule that 'In the fields of medicine and biology, the following must be respected in particular: (a) the free and informed consent of the person concerned, according to the procedures laid down by law'.

The issue of informed consent is not directly addressed by the European Convention of Human Rights (the 'ECHR'), but the European Court of Human Rights (the 'ECtHR') has found its rationale in health matters in Article 8 ECHR (Right to respect for private and family life).

The Council of Europe promoted the adoption of a specific regional convention on the subject of biomedicine, namely the 'Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine', the so-called Convention on Human Rights and Biomedicine – Oviedo, 4 April 1997, and its Additional Protocols.

The Oviedo Convention considers as a 'general rule' that 'An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it' (Article 5). The need for consent is required in all matters regulated by the Convention on Biomedicine, such as scientific research (Article 15) and the donation of human organs or tissues (Article 19).

In the discipline of personal data protection, the consent of the person concerned represents the fundamental condition for the legitimate processing of such data, as laid down by Aarticle 8, paragraph 2 of the Charter of Fundamental Rights and by secondary EU law, such as the GDPR. In addition, other important EU legal sources, such as the Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, require informed consent to research in the biomedical field. The same occurs in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (see, in particular, Article 13 of the Directive 2004/23/EC).

2. The Adequacy of the Information

According to the above-mentioned legal framework at the national and European levels, consent to research activities must be obtained under certain conditions.

Consent should be informed, that is, based on information allowing 'an appreciation and understanding of the facts and implications of an action'. The data subject is entitled to receive in a clear and understandable manner accurate and full information on all relevant issues.[2]

To this end, the information must be provided in an 'adequate' manner (Article 13, paragraph 1, Convention of Oviedo Additional Protocol on Biomedical Research), both subjectively and objectively.

From the subjective point of view, the information is adequate if it is provided by professionals qualified to carry out the medical treatment, research or other professional activities.

For example, the Declaration of Helsinki (paragraph 26) states that information about the intervention should be communicated by a 'physician or another appropriately qualified individual'.[3]

Article 29, paragraph 2(c) of Regulation (EU) no. 536/2014 specifies that the information will be provided 'in a prior interview with a member of the investigating team who is appropriately qualified according to the law of the Member State concerned'.

The information is subjectively appropriate if it is expressed in an understandable form (Article 13(1), Additional Protocol on Biomedical Research) considering the personal situation and context (especially social, cultural and economic) (European Group on Ethics in Science and New Technologies 2003, point 1.29).

According to the ECtHR, in *Csoma v. Romania*,[4] informed consent must be requested from the person concerned even if he or she is an experienced professional.

In general, it is necessary to avoid both 'information overload' and generic and superficial communication. The researcher is tasked with communicating the necessary information to make the decision to consent or reject the activity under consideration (European Commission 2010, p. 37; Comitato Nazionale per la bioetica 1992).

Moreover, it is not only necessary to guarantee accessibility to information but also to ensure that it is clearly understandable (if, for example, when information is given in writing, it is necessary to use characters of appropriate type and size).[5]

Information is supposed to be adequate from an objective point of view, when 'all the necessary information is given at the moment the consent is requested, and that this should address the substantive aspects of the processing that the consent is intended to legitimise'.[6] Even though information to be provided is that set out by Aarticle 13 GDPR and by other legal sources, it depends 'on when, and the circumstances in which, consent is requested'.

3. Information to Be Provided

Adequacy of the information is also an objective requirement and information must address certain details, namely: a) relationships with the research group and research establishment; b) legal base, purpose and context of the research activity; c) risks and other consequences; d) information concerning storage, security and confidentially; e) categories of recipients and international transfer

of data and materials; f) rights of the person involved in the research activities; g) additional information. These features deserve a thorough scrutiny.

3.1. Relationships with the Research Group and Research Establishment

The legal sources refer to the necessity of providing the persons involved in the research activities with information about the following:

- The legal entity (e.g., university, centre of research, health research establishment) which is carrying out the research activities (see GDPR, Aarticle 13 ff., which refers to the identification of the 'controller'); in particular, the information sheet must provide 'the identity and the contact details of the controller and, where applicable, of the controller's representative' as well as, if applicable, the contact details of the data protection officer (DPO; see Article 13, paragraph 1, let. [a] and [b]).
- The contact details of the contact person of the research group (see, for example, paragraph 1.1.2.b, Annex IV, Directive 2006/17/EC). The contact details should refer to easy means for the persons involved in the research to use, such as email and phone numbers, to directly contact the research group.

3.2. Legal Base, Purpose and Context of the Research Activity

The individual is entitled to receive information on the purpose of the processing as well as the legal basis for the processing (see GDPR, aArticle 13, paragraph 1.c).

In the case of research activities, it is necessary to provide information concerning the project or the field of research.

According to the legal sources in the biomedical fields, which are also useful for all scientific disciplines, the information should explain the objectives and nature of the activity (see article 29, paragraph 2.a.i of Regulation 536/2014; article 5 Oviedo Convention); 'the nature, extent and duration of the procedures involved, in particular, details of any burden imposed by the research project' (see Article 13, paragraph 2.i, Additional Protocol to the Oviedo Convention on Biomedical Research); and 'the source of funding of the research project' (see Article 13, paragraph 2.viii, Additional Protocol on biomedical research).

3.3. Risks and Other Consequences

The information should refer to the possible risks, discomforts or other consequences arising from participation in the research activities.

The necessity to provide this information is emphasised by the legal sources concerning biomedical activities, including the research (see Article 29, paragraph 2.1.i Regulation [EU] no. 536/2014; Article 5 Oviedo Convention).

In addition, Article 13 of the Additional Protocol refers to specific biomedical research that needs to identify '(iii) measures to address adverse events that may affect the persons involved' and '(vi) measures for adequate compensation in case of damage'.

3.4. Information Concerning Storage, Security and Confidentially

According to Aarticle 13, paragraph 2.a GDPR, the data subject will receive information concerning 'the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period'.

This kind of information may also concern the storage of the biological material together with personal data.

It is advisable to provide the person with information concerning the measures put in place to ensure the security and confidentiality of the personal data and the biological material. This is in application of the dispositions concerning the duties of security charged on the controllers (see GDPR, Aart-icle 35) and in storing human cells and tissues (see Directive 2004/23/EC, Aarticle 14).

Both the GDPR and other legislation consider anonymisation or pseudonymisation as the main measures to be implemented in order to ensure security and confidentiality. However, this does not prevent the adoption of all other necessary technical and organisational measures (see GDPR, recital no. 28).

3.5. Categories of Recipients and International Transfer of Data and Materials

The GDPR establishes that the data subject be informed about the category(ies) of recipients of the personal data 'if any' (see Aarticle 13, paragraph 1, let. d), if this is known at the moment of data collection.

For example, this implies that the research group will inform the person if his/her data will be transferred to other partners of a research project. The transfer is subject to the measures to ensure the security and confidentiality, such as anonymisation and pseudonymisation. The data subject should be informed of such measures.

The provisions mentioned seem to refer only to a case in which the transfer is put in place within the European Union. In the case of transfer towards a third country, the data subject must be specifically informed (see Aarticle 13, paragraph 1, let. e), and the existence of an adequacy decision by the Commission or the application of other safeguards provided by Articles 46 and ff must be taken into account.

3.6. Rights of the Person Involved in the Research Activities

According to Article 16, point iv), of the Oviedo Convention ‘the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection’.

Among the rights established by the GDPR (see GDPR, Aarticle. 13, paragraph. 2, let. b), is ‘the existence of the right to request from the controller access to and rectification or erasure of personal data or restriction of processing concerning the data subject or to object to processing as well as the right to data portability’ (see GDPR, Aarticless. From 15 to 21).

The person must be informed about the right to withdraw from the research at any time as provided by Article 16, v, Oviedo Convention. The GDPR tasks the controller with the obligation to inform the data subject of the right to withdraw from the processing of personal data at any time ‘without affecting the lawfulness of processing based on consent before its withdrawal’ (see GDPR, Aarticle. 7, paragraph 3; Aarticle. 13, paragraph 2, let. c,).

Recital no. 33 of the GDPR should be taken into consideration with regard to the research activities, as it lays down that ‘It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose’.

Therefore, the persons involved in the research activity must be informed of the possibility to restrict the processing of his/her personal data (or biological material) to specific projects or research or to exclude the use of such data and material for specific fields of research.

Otherwise, the data/material may be used in further research activities.

For the specific case of clinical trials, Regulation no. 536/2014 puts the attention on the use of the data for ‘future scientific research (e.g., medical, natural or social sciences research purposes), and in this case, ‘it is necessary that the subject gives consent to use his or her data outside the protocol of the clinical trial and has the right to withdraw that consent at any time’ (see Regulation 536/2014, recital no. 29).

Freedom of consent also includes the right to know and not to know (paragraph 6.C.18.3 Right to know - right not to know, from the Council of Europe’s Guide for Members of Research Ethics Committees) (Rodotà 1995; Santosuosso 2002, p. 27). Not wanting to know the outcome of treatment or research is an expression of freedom accorded to the individual and, therefore, does not conflict with the right to consent (Andorno 2004). This right is affirmed, for example, by Aarticle. 5(c) of the UNESCO Declaration on the Genome and by Aarticle. 10(2) of the Oviedo Convention.

3.7. Additional Information

The information sheet should provide any other insight necessary to allow the individual to have a complete view of the activity in which he/she is involved, the context of that activity, the consequences, the follow-up, etc.

For example, the information sheets should make the persons aware of the approach to so-called ‘incidental findings’, that is, information which may arise from research activities which refers to a serious risk (physical, psychological, social) to the persons or fundamental interests but that is unrelated to the purpose and beyond the aims of the study (e.g., discovery of a serious illness during a study on the styles of life using wearable devices).

Another case may be information concerning the strategy of communication of the results of the research activities. It would be best practise to actively involve the person in the dissemination of the output of the research in which he/she was engaged. The persons may decide to be in touch with the staff to know the future developments of the project or research or to participate in dissemination events, to follow the social network concerning the research, to become a partner of the association that supports the research and so on.

4. Withdrawal and Freedom of Consent

As stated in the previous sections, consent must be freely given. This means that the subject must effectively choose whether or not to be involved in the activities for which he or she receives the information.[7]

Free consent is ensured when there is no intimidation, coercion or threat of negative consequences in the event the person does not give consent.[8] In addition, ‘any pressure that would lead individuals to accept a higher level of risk than would otherwise be acceptable to them’ is considered illegitimate coercion.

Coercion and intimidation can be conveyed by acting on social, economic and financial factors.[9]

Manipulation should also be avoided; this more precisely implies, ‘to alter people’s behaviour by influencing them in ways that somehow bypass rational agency; rather than influencing them through reason and argument, we (typically through some ‘sleight of hand’) seek to change their mind by appealing (consciously or otherwise) to non-autonomous and/or non-rational parts of the person’ (European Commission 2010, p. 38).

Furthermore, threats of sanctions or refusal of health treatment or other benefits are prohibited.

Inappropriate influence may imply, for example, attempts to influence close relatives or veiled threats to deny access to services to which individuals would otherwise be entitled.[10]

The inappropriate influence may also be of an economic nature. In this view, all financial inducements or other kinds of incentives aimed at improving the economic or personal situation of the individual are not permitted (see Aarticle 31, paragraph 1, lett. d Regulation 536/2014) (Nuffield Council on Bioethics 2002).

In principle, giving compensation or other forms of economic benefit to the participant is acceptable in so far as the amount or entity is not so high as to exercise an undue pressure on him/her. This occurs when people are induced to accept a higher level of risk in comparison with what they would have accepted without any form of benefit or compensation.

Let's consider an employee's consent: in this case, it could be difficult to consider consent as effectively free. Thus, special attention needs to be paid to consent acquired in the context of an employment relationship. In particular, consent should not be linked to gaining or losing work or career opportunities.[11]

The freedom to accept participation in research even implies the right to refuse to give consent or to subsequently revoke it.

Giving consent for the aforementioned purposes differs from the manifestation of the will to conclude contracts or other agreements of a patrimonial nature as regulated by the civil codes.

In fact, in the case of authorising interventions that may affect personal interests, consent may be freely revoked by the individual at any time (see article 5, Oviedo Convention; see also Aarticle 13, paragraph 3, Additional Protocol on Biomedical Research; Aarticle 9, paragraph 2, Additional Protocol to the Oviedo Convention on Genetic Testing for Health Purposes, 2008).[12]

The refusal or withdrawal of consent may not lead to any form of discrimination against the person, in particular regarding medical care (Aarticle 14, paragraph 2, Additional Protocol on Biomedical Research; see also Aarticle 28, paragraph 4, Regulation [EU] n. 536/2014).[13]

However, to protect the scientific research, it should be taken into account that 'The withdrawal of consent shall not affect the lawfulness of processing based on consent before its withdrawal' (Aarticle 7, paragraph 3, GDPR). An analogous provision is laid down by Aarticle 28, paragraph 4, Regulation (EU) 536/2014 specifically for clinical studies.

The person should be informed about this limitation concerning the effect of any withdrawal (see paragraph 3 of the Aarticle 7 of the GDPR).

5. Form of the Information and of Consent

The GDPR and the other sources also provide formal requirements concerning informed consent.

According to Aarticle 12, paragraph 1 GDPR, 'the information shall be provided in writing, or by other means, including, where appropriate, by electronic means'. The obligation of providing information in a written form also concerns the clinical study (see Regulation [EU] no. 536/2014, Aarticle 29, paragraph 3).

If requested by the data subject, the information may be provided orally. This may be useful to give further information or to clarify some points on the information sheet.

Consent must also be an 'unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her' (GDPR, Aarticle 4, no. 11).

The statement may be expressed in several ways (see GDPR, recital no. 32), such as 'ticking a box when visiting an internet website, choosing technical settings for information society services or another statement or conduct which clearly indicates in this context the data subject's acceptance of the proposed processing of his or her personal data'. Meanwhile 'silence, pre-ticked boxes or inactivity should not therefore constitute consent'.

A simple omission of an action cannot be considered a valid expression of consent[14] (e.g., the failure to reply to an e-mail[15]).

Furthermore, the data controller must be sure that the person giving consent is indeed the data subject. This is especially the case when consent is requested through telematic instruments.

In general, consent can be given in any form, including orally, provided that the other conditions are respected (the subject is free to express consent and has all the necessary information).[16]

In some cases, EU documents require unambiguous consent expressed through an explicit form,[17] that is, a written form. This occurs when the collection of data or material carries a risk of deeply affecting the interests of the person involved in the research activities.[18] In fact, the explicit form is used when collecting special categories of data (those revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, and the processing of data concerning health or sexuality; see GDPR, Aarticle 9, paragraph 2.a). The explicit form, or the written form, is also requested in biomedical research (see Aarticle 16(v) of the Oviedo Convention and Recital 30 of Regulation no. 536/2014) and in specific cases, such as the removal of human biological material.[19]

When the person is unable to write, the consent must be recorded 'through appropriate alternative means, for instance through audio or video recorders' (see Regulation [EU] no. 536/2014, recital no. 30 ~~of~~).

If the consent to the processing of personal data must be expressed in a written form, (GDPR, A~~a~~rticle~~.~~ 7, paragraph 2) and if the declaration has to be given in a context which refers also to other matters (usually this is the case with informed consent in biomedical fields), 'the request for consent shall be presented in a manner which is clearly distinguishable from' the other issues (such as those concerning the medical intervention or the collection of biological samples).

To conclude, it is advisable to use written forms to express consent, especially in research activities and even if the written form is not mandatory.

This is also in view of the obligation of the controller to give evidence that the data subject has consented to the processing of his or her personal data (see GDPR, A~~a~~rticle~~.~~ 7, paragraph 1).

6. Conclusion

Informed consent is an important instrument to implement several types of mandatory international, EU and national legislation (e.g., those concerning the protection of personal data, the use of biological material and clinical trials) and, above all, to make biomedical activities consistent with fundamental ethical principles, such as dignity and self-determination.

To comply with those principles and law, information has to be provided in a manner to meet the requirements of the various legal sources in a text which addresses the different topics. Therefore, not only should the requirements of a specific legal discipline be taken into consideration, such as Regulation (EU) 2016/679, but also the entire legal and ethical framework at the bases of the informed consent.

That result should be achieved without sacrificing the necessary clarity and comprehensibility of the text by adopting adequate drafting strategies.

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1 – Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), O.J. 4.5.2016 L 119/1.

2 – Article 29 Working Party, *Working Document on the processing of personal data relating to health in electronic health records*, on 15 February 2007, paragraph 4, cc.

3 – World Medical Association, *Declaration of Helsinki*, *Ethical Principles for Medical Research Involving Human Subjects*. www.wma.net.

4 – Judgement of 15 January of 2013, case no. 8759/05.

5 – See paragraph III.A.1 of the Opinion 15/2011 *on the definition of consent*, issues by Article 29 Working Party on 13 July 2011.

6 – Ibid.

7 – See Article 29 Working Party, *Opinion 15/2011 on the definition of consent*, ref.

8 – Ibid.

9 – See Article 29 Working Party, *Working Document on the processing of personal data relating to health in electronic health records*, ref.

10 – Council of Europe Steering Committee on Bioethics, Guide for Research Ethics Committee Members, January 2012.

11 — See Article 29 Working Party, Opinion n. 8/2001, on the processing of personal data in the employment context, of 13 September 2001 and Article 29 Working Party, Working document of the on a common interpretation of Article 26(1) of Directive 95/46/EC of 24 October 1995.

12 — An application of revocability can be found in the case of *Evans v. United Kingdom* of 10 April 2007, decided by the ECtHR.

13 — According to the Recommendation of the Committee of Ministers of the Council of Europe Rec(2006)4 of 15 March 2006 (which concerns research on biological material of human origin), the person who withdraws or modifies his or her consent, apart from the fact that he or she must not be discriminated against, for example, in terms of health treatment, has the right to have the biological material destroyed or rendered anonymous (Article 15, paragraph 2).

14 — See the paragraph III.A.3 of the *Opinion 15/2011 on the definition of cons*ent, ref.

15 — Article 29 Working Party, *Opinion* 5/2004 *on unsolicited communications for marketing purposes under Article 13 of Directive 2002/58/EC,* of 27 February 2004.

16 — See paragraph III.A.1, *Opinion 15/2011 on the definition of consent*, ref.

17 — The two concepts should be considered to be different. See also Article 29 Working Party, *Working Document on the processing of personal data relating to health in electronic health records (EHR)*, of 15 February 2007.

18 — See paragraph III.A.3 de la *Opinion 15/2011 on the definition of consent*, ref.

19 — See Article 3, Appendix to the Resolution no. (78) 29 *on harmonisation of legislations of member states relating to removal, grafting and transplantation of human substances, adoptato* by the Committee of Ministers of the Council of Europe of 11 May 1978.