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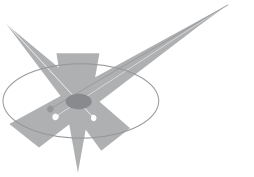

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The influence of the European and Polish acts of law, regulations and standards on the forms and the contents of the informed consent for oncological treatments

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Summary

Aim The aim of this work was to analyze the influence of the European and the Polish acts of law, the principals of The Polish, Physician's Code of Ethics, and the standards of The Accreditation Program for Hospitals on the forms and contents of the informed consent for oncological treatments given by the patients in The Great Poland Cancer Centre.

Materials/Methods The Polish acts of law, The European Convention on Bioethics, the guidelines of The Polish, Physician's Code of Ethics and the standards of The Accreditation Program for Hospitals were compared in terms of their similarities and compatibility referring to the informed consent. Subsequently based on the related contents of the above documents, the informed consent forms for the oncological treatments were designed.

Results As a result the following examples of informed consent forms for oncological diagnostics and treatments were designed: a) informed consent form for diagnostics examination with contrast medium, b) informed consent form for radiotherapy, c) informed consent form for surgery.

Discussion It is undeniable that the consent of the patient is a prerequisite to any medical treatments. The individual must be informed and understand the treatment that he or she will undergo. The patient has to know the advantages (benefits) and disadvantages (risks, potential complications) of the proposed medical intervention. When obtaining the consent the patient should be informed of details of diagnosis and prognosis with or without the proposed medical intervention and the uncertainties and questions should be explained and answered. Therefore the informed consent forms used in The Great Poland Cancer Centre are not only documents proving that the patient agreed to perform the treatment but also tools that allow the patient to comprehend the purpose, benefits and risks of the proposed medical intervention and to participate in the decision making process.

Key words **informed consent • oncological treatment • patient information**

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Background

Informing patients about their health conditions, the treatment plan, shearing the process of decision making by the physician and the patient as well as the informed consent for the proposed treatment is the key to the realization of patients' rights and fundamental freedoms [1,2].

Free and informed consent for any medical intervention is the principal of good clinical practice, and it is dictated not only by the international, European and national law, but also by The Physician's Code of Ethics and Quality Assurance Programs such as The Accreditation Program for Hospitals designed by The American JCAHO (*Joint Commission on Accreditation in Hospital Organizations*) and adopted in Poland by The Quality Monitoring Centre (*pol. CMJ – Centrum Monitorowania Jakości*) from Cracow [3].

Although a free informed consent in written or oral forms has been required in Poland since 90's, it has started to be given only recently. The main reasons for this are as follows:

a) increasing awareness of patients in terms of law and their health care,
b) some patients are becoming less afraid of asking physicians for information, and also have more courage to express their expectations and discuss with their physicians about their health conditions,
c) increasing influence of media, informing patients of their rights [1],
d) the necessity to safeguard physicians and hospitals from lawsuits,
e) the entrance of Poland into the European Union and the standardization of Polish law with the European law,
f) popularity of Quality Assurance Programs in hospitals, for example The Accreditation Program for Hospitals, designed by JCAHO, implemented in Poland in 1998, [3], where a free, informed consent for medical interventions (for example: surgery, invasive procedures, diagnostic procedures, biopsy, radiotherapy, chemotherapy, dialysis, medical examination for teaching purposes, medical researches, palliative care) is acknowledged as the standard of good clinical practice,
g) and simply, democracy and westernization of the Polish culture.

Aim

The aim of this work was to design the informed consent for oncological treatments given by the patients in The Great Poland Cancer Centre, based on the European Convention on Bioethics, and the Polish acts of law, the principals of The Polish, Physician's Code of Ethics and the standards of The Quality Programs for Hospitals.

Materials and Methods

The European Convention on Bioethics (*Convention for Protection of Human Rights and Dignity of Human Being regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, established in Oviedo on April 4th, 1997*) [4] is the basic European act of law determining principals of the protection of human rights, dignity and autonomy of the individual in relation to medical interventions. It also regulates:

- equal access to health care,
- directives referring to the removal of organs and tissues for transplantation purposes,
- directives on conducting scientific researches [4].

The European Convention on Bioethics is not a declaration, a set of recommendations or postulates but an act of law. Its ratification creates for a country certain responsibilities and duties. It is also an ideal tool for the standardization of ethical principals not only within Europe but also in other countries, because The Convention on Bioethics is one of the few European acts of law opened to the ratification by non-European countries. (The representatives from The United States of America and Canada were active participants in creating this Convention.) [5].

However The Convention establishes only the required minimum of the protection of human rights. None of the provisions of the Convention is limiting the internal regulations of the country. The Country may implement a wider measure of the protection with regard to the application of biology and medicine stipulated in The Convention. (*article 27 of the European Convention on Bioethics*) [4].

One of the main regulations of The Convention is the protection of human interests and the autonomy of the individual, including the respect of the patient's rights and the right to give a free and informed consent for any medical interventions. (*article 5 of the European Convention on Bioethics*) [4].

Taking into account the Polish acts of law (including *Act on the Profession of Physician, established by The Minister of Health on December 5th, 1996, with further changes - articles 31 to 36; Act on Health Care Institutions, established by The Minister of Health on August 30th, 1991, with further changes – article 19; Act on Removal and Transplantation of Cells, Tissues and Organs, established by The Minister of Health on October 26th, 1995, with further changes – article 9; and The Code of Physician's Ethics – article 12 to 19)* [6–9] there is no doubt, that the Polish law also defines the basic regulations referring to the protection of patient's rights (Table 1).

Based on the documents given above it seems undeniable that the consent of patients is a prerequisite to any medical interventions either in an expressed (oral, written) or an implied form (non written consent when patients cooperates with a particular action e.g. physical examination) [10]. Every individual is entitled to decide what is performed on or with its body, therefore any procedure done without an explicit consent of a patient, or with a deceitfully obtained consent may be considered illegal [11]. Most patients do not like to be kept ignorant as to the nature of the proposed treatment or any other medical interventions and its effects on their health. It is therefore unacceptable for a patient to receive only partial and hasty explanations [1,12,13]. The informed consent is therefore only valid when the patient receives detailed explanations and information regarding the proposed treatment before the consent is given. The physician is obliged to inform and discuss with the patient, the diagnosis of the disease, the proposed medical care, procedures involved in the medical intervention, alternative therapies to the proposed treatment, the treatment process, its benefits, side effects, (especially, irreversible side effects), risks, discomforts and complications. It means that

Table 1. The comparison of The European Convention on Bioethics, Act on the Profession of Physician, Act on Health Care Institutions, The Polish, Physician's Code of Ethics, The Accreditation Program for Hospitals in terms of regulations, guidelines and standards for the informed consent.

The European Convention on Bioethics	The Act on the Profession of Physician	The Act on Health Care Institutions	The Polish, Physician's Code of Ethics	The Accreditation Program for Hospitals
INFORMED CONSENT – GENERAL REGULATIONS				
Article 5 – An **intervention in the health** field may only be carried out after the person concerned has **given free and informed consent to it.** The person concerned may freely withdraw consent at any time.	*Article 32* – (1) The Physician may conduct **the examination or any other medical procedure** (with exceptions given in this Act) **after receiving an informed consent from the patient.** (7) **If the Act does not constitute otherwise, the informed consent may be given orally or in an implied form** (the patient cooperates with a proposed action of the physician). *Article 33* – **The examination of the patient or any other medical procedure without the informed consent of the patient is unacceptable.** *Article 34* – (1) Only after receiving a **written informed consent** from the patient the physician may **conduct surgical procedures or use treatment or diagnostic methods which cause an increased risk to the patient.**	*Article 19* – Patient has the right to: (3) **give an informed consent for specific medical intervention** or to withdraw the consent, after receiving the appropriate information.	*Article 15* – (1) **Diagnostics, treatment and prophylactics procedures, require informed consent** from the patient. *Article 15* –(3) If the patient does not give the informed consent for the proposed treatment, the physician should still give the best possible medical care to the patient.	*Standard PP 4* – **The hospital has a list of procedures requiring the informed consent from the patient.** Some procedures being conducted in the hospital require the informed consent of the patient. *Standard PP 4.1.* Patient gives a free and informed consent **for surgery.** *Standard PP5* – Patient gives the informed consent **for any medical experiment.**

The European Convention on Bioethics	Act on the Profession of Physician	Act on Health Care Institutions	The Polish, Physician's Code of Ethics	The Accreditation Program for Hospitals
RIGHT TO INFORMATION				
Article 5 – The patient shall beforehand be given appropriate information as to the purpose and **nature** of the intervention as well as on its **consequences** and **risks.** *Article 10* – (1) Everyone has the right to respect for private life in relation to **information about his or her health.** (2) Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.	*Article 31* – (1) the Physician is obliged to give the patient or his/her representative an **comprehensible information about his/her state of health, diagnosis, proposed and possible methods of diagnostics and treatment, predictable consequences of their application and consequences which will occur if the procedures are not performed and also about the results of the treatment and the prognosis.**	*Article 19* – Patient has the right to: (2) the information about his/her state of health.	*Article 13* – (2) Information given to the patient should be understandable for him or her. (3) Patient has the right to be informed about the **possible risks of the diagnostic examinations and treatments, expected benefits of the conducted procedures, and possibilities to use other (alternative) medical procedures.**	*Standard PP 2* – The hospital provides the patient, information about his/her state of health according to the acts of law being in force.

The European Convention on Bioethics	Act on the Profession of Physician	Act on Health Care Institutions	The Polish, Physician's Code of Ethics	The Accreditation Program for Hospitals
		RIGHT TO INFORMATION		
(3) in exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interest of the patient.	(3) On the patient's demand the doctor does not have to give the information referred to in Article 31(1) above. (4) In exceptional cases, if according to the doctor the information about the prognosis will influence the best interest of the patient, the physician may limit the information about his/her health condition and prognosis. Under such circumstances the physician may give the information to the patient's representative or an authority. However, the physician is obliged to give the patient the requested information on his or her demand. *Article 34* – (2) **Before receiving an informed consent from the patient, the physician is obliged to give the patient information referred to in Article 31 above.** (7) The patient under the age of 16 is given information in the form that will allow him or her to understand the diagnostics or treatment process. The opinion of the minor is heard.	*Article 19* – Patient has the right to: (2) the information about his/her state of health.	*Article 16* – (1) according to patient's wishes the physician does not have to inform the patient about his or her state of health or treatment. Patient may also appoint the persons which will contact the physician on behalf of the patient. Giving information to the patient's family should be agreed with the patient. *Article 17* – In case of an adverse prognosis, the physician should inform the patient about it in a very gentle and graceful way. The information about the diagnosis and an adverse prognosis may not be given to the patient only when the physician is deeply convinced, that this information may cause a serious harm and suffering to the patient. However if the patient demands it, the physician should give him or her the complete information.	*Standard PP 3* – the treatment plan is explained to the patient. The individual treatment plan allows the patient to make decision either to give or withdraw the informed consent to the proposed treatment. It also decreases the anxiety of the patient. **The Physician should also explain the patient the complications and consequences of the proposed treatment.**

The European Convention on Bioethics	Act on the Profession of Physician	The Polish, Physician's Code of Ethics
	PROTECTION OF PERSONS NOT ABLE TO CONSENT	
Article 6 – (1) an intervention may be only carried out on a person who does not have the capacity to consent, for his or her direct benefit. (2) where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law. The opinion of the minor should be taken under consideration as an increasingly determining factor in proportion to his or her age and degree of maturity. (3) Where, according to law, an adult does not have the capacity to consent to an intervention because of mental disability, a disease or for familiar reasons, the intervention may only be carried out with the authorization of his or her representative or an authority or a person or body provided for by law. The individual concerned shall as far as possible take part in the authorization procedure.	*Article 31* – (6) If the patient is a minor (under the age of 16), unconscious or incapable to understand the given information, the authority or the representative shall be given the same information by the physician. *Article 32* – (2) If the patient is a minor or incapable to give an informed consent, the informed consent from his or her representative, authority or the body (court) is required.	*Article 15* – (1) If the patient is not able to give the consent, the representative of the patient or the authority should give the consent on behalf of the patient.

The European Convention on Bioethics	Act on the Profession of Physician	The Polish, Physician's Code of Ethics
PROTECTION OF PERSONS NOT ABLE TO CONSENT		
(4) The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, information referred to in Article 5. (5) The authorization referred to in paragraph 2 and 3 above may be withdrawn at any time in the best interests of person concerned.	N.A.	N.A.
The European Convention on Bioethics	**Act on the Profession of Physician**	**The Polish, Physician's Code of Ethics**
EMERGENCY SITUATION		
Article 8 – **When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.**	*Article 33* – (1) The examination or any other medical procedure without patient consent is permitted if the patient requires an immediate medical intervention, or because of his or her health condition or age the patient can not give the informed consent and there is no possibility to contact his or her representative or authority to do it on his or her behalf. (2) For the decision mentioned in paragraph 1 above the physician should consult with another physician. (3) The physician should describe in the patient's medical records the circumstances mentioned in paragraph 1 and 2 above, (7) **The physician may conduct procedures mentioned in paragraph 1 above, without the patient's consent, or the patient's representative or the consent of the authority if the delay of the procedure caused by awaiting the informed consent could create risks for the patient: death, body damage, decreased state of health.** Under such circumstances the physician is obliged to consult it (if it is only possible) with another doctor of the same specialty. *Article 35* – (1) **The physician has the right, without patient's consent, to change the range of the procedure or use another treatment or diagnostic methods if during the surgery, diagnostics or treatment procedures occur circumstances, which if not taken under consideration could cause patient's death, body damage or decreased state of health, and there was no possibility to forthwith obtain the patient's or his/her representative's consent.** Under such circumstances the doctor is obliged (if it is only possible) to consult it with another doctor, of the same specialty.	*Article 15* – The diagnostic, treatment or prophylactic procedures can be conducted without the patient's consent **in emergency situations when patient's or other persons life and health is at risk.**
PREVIOUSLY EXPRESSED WISHES		
Article 9 – The previously expressed wishes relating to a medical intervention by a patient who is not at the time of the intervention, is a state to express his or her wishes shall be taken into account.	N.A.	N.A.

FORMULARZ ZGODY NA BADANIE RADIOLOGICZNE Z PODANIEM ŚRODKA CIENIUJĄCEGO

PROSZĘ PRZECZYTAĆ TREŚĆ FORMULARZA A NASTĘPNIE CZYTELNIE WYPEŁNIĆ POLA 1,2,3 NA DOLE STRONY.

Szanowny Pacjencie,

Lekarze w Wielkopolskim Centrum Onkologii zadecydowali o konieczności wykonania u Pani/Pana badania z podaniem środka cieniującego. Ma to na celu postawienie możliwie pełnego rozpoznania, koniecznego do podjęcia właściwego leczenia.

Środki cieniujące podawane dożylnie powodują polepszenie jakości obrazu rentgenowskiego, umożliwiają uwidocznienie struktur anatomicznych i narządów wewnętrznych i tym samym pozwalają na postawienie właściwej diagnozy.

W większości przypadków podanie środka cieniującego nie powoduje żadnych zauważalnych odczynów, jednak u niewielkiej ilości osób mogą wystąpić objawy wzmożonej wrażliwości na jodowe środki cieniujące, takie jak **wysypka skórna, swędzenie skóry, nudności i wymioty.**

Lekarze z Zakładu Radiologii są przygotowani na wystąpienie takich objawów i potrafią im skutecznie przeciwdziałać. Czas trwania takich dolegliwości nie przekracza zazwyczaj kilkunastu sekund do kilku minut.

Istnieje jednak pewna grupa pacjentów u których częściej występują objawy nadwrażliwości na środki cieniujące; są to pacjenci z takimi schorzeniami jak:

uczulenie na jod,
choroby tarczycy,
zaawansowane nadciśnienie tętnicze,
cukrzyca,
uszkodzenie czynności nerek,
astma płucna,
alergie, katar sienny,
choroby serca i naczyń tętniczych,
niektóre choroby krwi,
osoby u których przy poprzednich badaniach wystąpiły objawy nadwrażliwości.

U tych osób można także stosować środki cieniujące, ale z zachowaniem pewnych środków ostrożności. **Z tego względu konieczne jest poinformowanie lekarza kierującego o występowaniu u Pani/Pana wyżej wymienionych dolegliwości.**

Powyższe informacje mają służyć zrozumieniu przez Panią/Pana czynności podejmowanych przez personel medyczny. Chcemy podkreślić, że wykonanie badania z podaniem środka cieniującego zostało rozważone przez lekarza kierującego i uznane za niezbędne w interesie Pani/Pana zdrowia.

WYRAŻAM ZGODĘ NA WYKONANIE U MNIE BADANIA RTG Z ZASTOSOWANIEM JODOWEGO ŚRODKA CIENIUJĄCEGO.

1. podpis pacjenta..... 2. nr dokumentu tożsamości.....

3. miejsce i data.....

podpis lekarza przyjmującego zgodę.....

INFORMED CONSENT FORM FOR RADIOLOGICAL DIAGNOSTICS WITH CONTRAST MEDIUM

PLEASE READ CAREFULLY THE CONTENT OF THIS FORM AND THEN LEGIBLY FILL IN BLANKS 1,2 and 3 AT THE BOTTOM OF THE PAGE.

Dear Patient,

Doctors of The Great Poland Cancer Centre found it necessary to carry out the radiological diagnostics with contrast medium. The aim of this procedure is to further diagnose your disease, and in a consequence to start treatment sufficient for you.

The contrast medium is delivered intravenously, and its aim is to improve the x-ray image, which allows the doctor to see the anatomical structures and internal organs, consequently allowing the doctor to diagnose your illness better.

In most cases the contrast medium does not cause side effects, however there may be some patients who may respond with hypersensitivity to the iodine contrast medium, reacting with **skin rash, itchiness of the skin, nausea, vomiting**.

The doctors of The Radiological Department of The Great Poland Cancer Centre are fully prepared to respond and to cure these side effects. Those side effects may last from few seconds to few minutes.

There are also illnesses which may make it more likely for patients to be hypersensitive to contrast medium. These illnesses are:

allergy to iodine,
diseases of the thyroid gland,
advanced hypertention,
diabetes,
decreased kidney function, kidney failure,
asthma,
allergies, hay fever,
heart and vascular diseases,
blood diseases,
patients who reacted with hypersensitivity at previous radiological diagnostics with contrast medium.

These patients may still have the radiological diagnostics with contrast medium carried out, however one must take precautions. **Therefore you should inform the physician about the symptoms or diseases listed above.**

The aim of the information given above is to help you understand the activities carried out by the medical personnel. We would like to stress that the necessity of conducting the radiological diagnostics with contrast medium was considered by the physician and acknowledged as an essential examination for your health.

BY SIGNING THIS CONSENT FORM, I AM INDICATING THAT I AGREE TO THE RADIOLOGICAL DIAGNOSTICS WITH IODINE CONTRAST MEDIUM.

1. Patient's Signature..... 2. Patient's ID no.....

3. Place and date.....

Signature of the Physician acknowledging the consent.....

Zgoda pacjenta na radioterapię

Imię i nazwisko pacjenta.....

Adres zamieszkania.....data urodzenia.....

Oświadczam, że dr.....odbył(a) dzisiaj ze mną rozmowę na temat potrzeby podjęcia przeze mnie **radioterapii** i udzielił(a) mi wszelkich informacji o planowanym leczeniu oraz możliwych korzyściach, komplikacjach i skutkach ubocznych z niego wynikających. W trakcie rozmowy mogłem(am) pytać o wszystkie interesujące mnie problemy dotyczące radioterapii, związanego z nią ryzyka oraz innych okoliczności w trakcie i po radioterapii. Uzyskałem odpowiedź na wszystkie interesujące mnie pytania. **Jednocześnie wyrażam zgodę** na proponowane mi leczenie i upoważniam lekarzy do wykonywania czynności, które uznają za stosowne dla ratowania mojego zdrowia i życia w sytuacjach tego wymagających

podpis pacjenta..... nr dokumentu tożsamości.....

podpis lekarza przyjmującego zgodę.....

miejsce i data.....

Informed consent form for radiotherapy

Patient's name and last name.....

Address.....date of birth.....

I declare, that dr..... conducted the conversation with me today, explaining the necessity for radiotherapy as the most sufficient treatment for me. He/She provided me with all the information about the proposed treatment, possible benefits, complications and side effects that may occur during and after the therapy. During our conversation I was able to ask about problems considering the proposed radiotherapy, its risks and other circumstances that may occur during and after the therapy. I received answers to all of my questions.

By signing this consent form I am indicating that I agree to the proposed treatment and I entitle the physicians to do everything that is necessary to save my health and life in situations that require it.

Patient's signature.....Patient's ID no.....

Signature of the physician acknowledging the consent.....

place and date.....

hitherto used informed consent forms belonging to the patient's medical documentation and filled in by the patient at the moment of acceptance to the hospital are not a sufficient proof of his or her agreement to the proposed medical intervention. It may be only considered as a patient's statement, in which he or she agrees for the hospitalization. In terms of law there is no such thing as a general informed consent to a treatment. [14] The informed consent is given to a particular medical intervention.

The recommended procedures requiring formalized (written) informed consent in oncological institutions are [1,4,6–9,12,15–17]:
a) surgery [18–23],
b) invasive procedure (biopsy), biopsy for histopathological examination [24],
c) chemotherapy,
d) radiotherapy,
e) radiologic/investigational procedure, (e.g. radiological examination with contrast medium),
f) blood transfusion,
g) physical examination for teaching purposes (especially in gynecology),
h) palliative care,
i) genetic examination,
j) general anesthesia,
k) experimental methods of diagnostics or treatments,

It suggests that the informed consent should be given to those medical interventions which place the patients at a high risk, both physically and mentally.

Results

The information given to a patient has to be formed in a clear and simple way adjusted for his or her perceptional level. It should be understandable, written or said in lay language. It is suggested that consent forms should be written at the level of elementary school. Perception of ill people is sometimes decreased. It should be written with in a font type minimum size 12. Abbreviations (e.g. TBI – total body irradiation) or difficult medical or legal terms (e.g. radiotherapy – treatment with radiation, chemotherapy – treatment with a drug named..., benign – not cancerous) should be defined. Throughout the informed consent form, the same words should be used (e.g. if the word radiotherapy was used, it should not be changed into irradiation therapy or radiation treatment; if we used the word chemotherapy we should not change it into cytostatics treatment).

Words should be familiar to the reader. Sentences should be short and direct. Important facts should be underlined or highlighted.

The following are examples of consent documents used in The Great Poland Cancer Centre.

Conclusions

The European Convention on Bioethics, The Polish acts of law, the guidelines of The Polish, Physician's Code of Ethics and the standards of The Accreditation Program for Hospitals had a profound influence on the forms and contents of the informed consent for the oncological treatment used in The Great Poland Cancer Centre. The above documents made us realized that the consent of the patient should be an requirement to any medical treatments. The individual must be informed and understand the treatment that he or she will undergo. The patient has to know the advantages (benefits) and disadvantages (risks, potential complications) of the proposed medical intervention. When obtaining the consent the patient should be informed of details of diagnosis and prognosis with or without the proposed medical intervention and the uncertainties and questions should be explained and answered.

The informed consent should involve an ongoing dialogue between the patient and the physician. Only in this way are doctors able to ensure that the rights of patients are protected and the integrality of the informed consent process is maintained. The informed consent is a fundamental right for every individual. It underlines the patient's autonomy, it also builds the trust between the patient and his or her physician, since the decision about the treatment is undertaken mutually in a free and informed way.

Therefore the informed consent forms used in The Great Poland Cancer Centre are not only documents proving that the patient agreed to perform the treatment but are also tools that allow the patient to comprehend the purpose, benefits and risks of the proposed medical intervention and to participate in the decision making process. It can not be denied that the informed consent is needed for legal purposes and it is also important for ethical and practical reasons.

References:

1. Schafer C, Herbst M: Ethical aspects of patient information in radiation oncology. An introduction and a review of the literature, Strahlenther Onkol. 2003; 179(7): 431–40
2. Brody Baruch A: Making Informed Consent Meaningful. IRB: A Review of Human Subjects Research, 2001; 23(5): 1–5
3. Biedlicki M, Kutaj-Wąsikowska H, Surowiec J: Program Akredytacji Szpitali, Centrum Monitorowania Jakości w Ochronie Zdrowia, Kraków 1998
4. Convention for the Protection on Human Rights and Dignity of the Human Being with regards to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, Oviedo, 4 April, 1997, Council of Europe
5. Safjan M: Prawo polskie a Europejska Konwencja Bioetyczna, Prawo i medycyna, 2000, 5(Vol 2)
6. Ustawa z dnia 5 grudnia 1996 r. o zawodzie lekarza, Dz.U. nr 28 poz. 152 z późn. zm.
7. Ustawa z dnia 30 sierpnia 1991 r. o zakładach opieki zdrowotnej Dz. U. nr 91, poz. 408 z późn. zm.
8. Ustawa z dnia 26 października 1995 r. o pobieraniu i przeszczepianiu komórek, tkanek i narządów Dz. U. nr 138 poz. 682. z późn. zm.
9. Kodeks Etyki Lekarskiej
10. Ashford RU, Scollay J, Harrington P: Obtaining informed consent, Hosp Med, 2003, 62: 374
11. Zoll A: Zgoda pacjenta jako warunek legalności leczenia w Prawa pacjenta a postawa lekarza, Polska Akademia Umiejętności, Kraków 1996: 9
12. Schafer C, Dietl B, Putnik K et al: Patient information in radiooncology results of a patient survey. Strahlenther Onkol, 2002; 178(10): 562–71
13. Krajewski R: Zgoda chorego na leczenie, Gazeta Lekarska, 1998; 12: 35–37
14. SN Sygnatura akt I, CR 403/72
15. Verhaak CM, Kraaimaat FW, Staps AC, van Daal WA: Informed consent in palliative radiotherapy: participation of patients and proxies in treatment decisions, Patient Educ Couns. 2000; 41(1): 63–71
16. Liszewska A: Zgoda pacjenta na zabieg leczniczy. PIP Warszawa, 1997; Zeszyt 1(611): 37

17. Thorevska N, Tilluckdharry L, Ticko S et al: Informed consent for invasive medical procedures from the patient's perspective, Conn Med, 2004; 68(2): 101–5
18. Byrne DJ, Napier A, Cuschieri A: How informed is signed consent? British Medical Journal, 1988; 296(6625): 839–40
19. SN Sygnatura akt IV CR 389/79
20. SN Sygnatura akt II CR 421/71
21. SN Sygnatura akt II CR 551/69
22. SN Sygnatura akt I CR 463/73
23. SN Sygnatura akt I CR 43/74
24. SN Sygnatura akt I 188/67