

**PROGRAM PASCASARJANA
MAGISTER HUKUM KESEHATAN**

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Nomor : 00024/B.7.3/MHK/IX/2011
Lampiran : -
Hal : Pra Survey

30 September 2011

Kepada:
Yth. Direktur RSUD Kraton Pekalongan
Jl Veteran No 31
Pekalongan

Dengan hormat,
Dalam rangka penyelesaian Tesis Program Studi Magister Hukum Kesehatan Universitas Katolik Soegijapranata Semarang untuk mahasiswa tersebut di bawah ini :

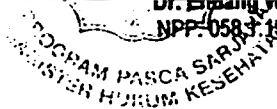
Nama : dr. Hari Suko Wihandono,
N I M : 09.93.0048
Judul Tesis : **ANALISIS TERHADAP PERSETUJUAN TINDAKAN KEDOKTERAN PADA TINDAKAN ANESTESI DI RSUD KRATON PEKALONGAN**

Bersama ini kami mohon kesediaannya untuk membenarkan ijin serta informasi ataupun data yang diperlukan oleh mahasiswa tersebut untuk mengadakan survey penelitian di institusi yang Bapak/Ibu pimpin.

Demikian surat permohonan kami sampaikan, terima kasih atas perhatian dan kerjasama yang diberikan.

Sekretaris Program Studi,


Dr. Endang Wahyati Yustina, SH., MH.
NPP: 0583.1984.0006





PEMERINTAH KABUPATEN PEKALONGAN
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Jl. Veteran 31 Telp. (0285) 421621 – 423523 Fax. 423225
PEKALONGAN

Pekalongan, 3 Oktober 2011

Nomor : 4234 / 437 / 2011

Lamp :

Perihal : Balasan Pra Survey

Kepada

Yth. Sekretaris Program Studi Pascasarjana
Magister Hukum Kesehatan Universitas
Katolik Soegijapranata

di -

Semarang

Menindaklanjuti Surat Saudara tanggal 30 September 2011 Nomor : 00024 /
B.7.3 / MHK / IX / 2011 Perihal Pra Survey.

Sehubungan hal tersebut dengan ini kami sampaikan bahwa pada prinsipnya
pihak kami tidak keberatan mahasiswa Program Pascasarjana Magister Hukum
Kesehatan Universitas Katolik Soegijapranata Semarang melaksanakan Pra
Survey RSUD Kraton Kabupaten Pekalongan.

Demikian untuk menjadikan maklum dan terima kasih atas kerjasamanya.



**DIREKTUR RSUD KRATON
KABUPATEN PEKALONGAN**

dr. SITANTO SETIABUDI, M.Kes
Pembina Utama Muda
NIP: 19590614 198511 1 002



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Pekalongan, 21 Nopember 2011

Nomor : 800/1092/2011
Lampiran : -
Perihal : Penelitian

Kepada Yth,
dr. Hari Suko Wihandono, Sp.OT
RSUD Kraton Kab. Pekalongan

di -

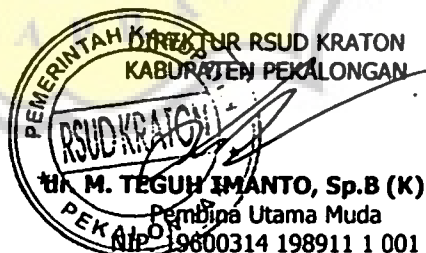
PEKALONGAN

Dengan hormat,

Dasar surat Komite Medik Nomor 007/ KM/ XI / 2011 Tanggal 17 Nopember 2011 Perihal Penelitian dr. Hari Suko Wihandono, Sp.OT.

Sehubungan hal tersebut dengan ini disampaikan bahwa penelitian yang dilakukan atas nama dr. Hari Suko Wihandono, Sp.OT dapat dilanjutkan.

Demikian surat pemberitahuan untuk dapat dipergunakan dipergunakan sebagaimana mestinya.



PERSETUJUAN TINDAKAN KEDOKTERAN

Saya yang bertanda tangan di bawah ini:

N a m a :

Umur/jenis kelamin :

A l a m a t :

Bukti Diri / KTP :

Dengan ini dengan sesungguhnya telah menyatakan:

PERSETUJUAN

Untuk dilakukan Tindakan Kedokteran berupa :

Dan Anestesi :

Terhadap :

N a m a :

Umur/Jenis Kelamin :

Alamat :

Bukti Diri/ KTP :

Dirawat di :

Nomor Rekam Medik :

Yang diagnosa, prognosa, sifat, tujuan, perlunya tindakan kedokteran tersebut diatas, resikonya, kemungkinan perluasan tindakan dan komplikasinya telah dijelaskan secukupnya oleh dokter dan saya telah mengerti sepenuhnya.

Demikian Pernyataan Persetujuan ini saya buat dengan penuh kesadaran dan tanpa paksaan.

Pekalongan, , 20 . . .

Dokter Anestesi

Dokter Bedah / Operator

Yang Membuat Pernyataan

(Saksi dari RS)

(Saksi dari RS)

(Saksi dari Keluarga Pasien)

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PENOLAKAN TINDAKAN KEDOKTERAN

Saya yang bertanda tangan di bawah in:

N a m a :

Umur/jenis kelamin :

A l a m a t :

Bukti Diri/KTP :

Dengan ini dengan sesungguhnya telah menyatakan:

PENOLAKAN

Untuk dilakukan Tindakan Kedokteran berupa.....

Dan Anestesi :.....

Terhadap :

N a m a :

Umur/Jenis Kelamin :

Alamat :

Bukti Diri/ KTP :

Dirawat di :

Nomor Rekam Medik :

Yang diagnosa, prognosa, sifat, tujuan, perlunya tindakan kedokteran tersebut diatas, resikonya, kemungkinan perluasan tindakan dan komplikasinya telah dijelaskan secukupnya oleh dokter dan saya telah mengerti sepenuhnya

Demikian Pernyataan Persetujuan ini saya buat dengan penuh kesadaran dan tanpa paksaan.

Dokter Anestesi Pekalongan, , ,20 ...
Dokter Bedah / Operator Yang Membuat Pernyataan

() () ()
Saksi dari RS Saksi dari RS Saksi dari Keluarga Pasien

() () ()

LEMBAR PERTANYAAN

NOMOR LEMBAR PERTANYAAN :
 NO REGISTER / RUANG PERAWATAN :
 TANGGAL OPERASI :
 DAFTAR PERTANYAAN :

Mohon dijawab yang menurut anda paling sesuai, dengan melingkari huruf di depan pilihan yang anda pilih.

No	Pertanyaan	Ya	Tidak
1.	Apakah anda memperoleh informasi bahwa operasi yang dilakukan akan disertai dengan pembiusan atau anastesi?		
2.	Apakah anda memperoleh informasi resiko yang dapat terjadi bila tidak dilakukan tindakan anastesi?		
3.	Apakah anda memperoleh informasi resiko yang dapat terjadi dari tindakan anastesi yang dilakukan pada anda?		
4.	Apakah anda memperoleh informai kemungkinan perluasan tindakan anestasi yang mungkin dilakukan pada anda?		
5.	Apakah anda merasa berhak untuk memperoleh informasi tentang tindakan anestaesi yang dilakukan pada anda?		
6.	Apakah anda memperoleh kesempatan menyetujui atau menolak tindakan anestesi yang dilakukan pada anda?		
7.	Apakah anda merasa berhak memperoleh kesempatan menyetujui, menolak tindakan anestesi yang dilakukan pada anda ?(
8.	Apakah anda merasa hak asasi anda untuk memperoleh informasi dan menentukan nasib sendiri pada tindakan anestesi sudah terpenuhi		

Universal Declaration of Human Rights

Fifty years ago, the United Nations General Assembly adopted the Universal Declaration of Human Rights as a bulwark against oppression and discrimination. In the wake of a devastating world war, which had witnessed some of the most barbarous crimes in human history, the Universal Declaration marked the first time that the rights and freedoms of individuals were set forth in such detail. It also represented the first international recognition that human rights and fundamental freedoms are applicable to every person, everywhere. In this sense, the Universal Declaration was a landmark achievement in world history. Today, it continues to affect people's lives and inspire human rights activism and legislation all over the world.

The Universal Declaration is remarkable in two fundamental aspects. In 1948, the then 58 Member States of the United Nations represented a range of ideologies, political systems and religious and cultural backgrounds, as well as different stages of economic development. The authors of the Declaration, themselves from different regions of the world, sought to ensure that the draft text would reflect these different cultural traditions and incorporate common values inherent in the world's principal legal systems and religious and philosophical traditions. Most important, the Universal Declaration was to be a common statement of mutual aspirations – a shared vision of a more equitable and just world.

The success of their endeavour is demonstrated by the virtually universal acceptance of the Declaration. Today, the Universal Declaration, translated into nearly 250 national and local languages, is the best known and most cited human rights document in the world. The foundation of international human rights law, the Universal Declaration serves as a model for numerous international treaties and declarations and is

incorporated in the constitutions and laws of many countries. Drafting the Universal Declaration

The preparatory work for the Universal Declaration of Human Rights is a remarkable and early example of the Organization's capacity to bring about international cooperation and consensus. The text was drafted in two years – between January 1947, when the Commission on Human Rights first met to prepare an International Bill of Human Rights, and December 1948, when the General Assembly adopted the Universal Declaration. An eight-member drafting committee prepared the preliminary text of the Universal Declaration. The committee, chaired by Mrs. Eleanor Roosevelt, widow of the former United States President, agreed on the central importance of affirming universal respect for human rights and fundamental freedoms, including the principles of non-discrimination and civil and political rights, as well as social, cultural and economic rights. The Commission then revised the draft declaration, in the light of replies from Member States, before submitting it to the General Assembly.

The General Assembly, in turn, scrutinized the document, with the 58 Member States voting a total of 1,400 times on practically every word and every clause of the text. There were many debates. Some Islamic States objected to the articles on equal marriage rights and on the right to change religious belief, for example, while several Western countries criticized the inclusion of economic, social and cultural rights. On 10 December 1948, the United Nations General Assembly unanimously adopted the Universal Declaration of Human Rights, with 8 abstentions. Since then, 10 December is celebrated every year worldwide as Human Rights Day. The adoption of the Declaration was immediately hailed as a triumph, uniting very diverse and even conflicting political regimes, religious systems and cultural traditions. During 1998, the fiftieth anniversary of the Universal Declaration is being commemorated all over the world as Human Rights Year.

For the first time in history, the international community embraced a document considered to have universal value – "a common standard of achievement for all peoples and all nations". Its Preamble acknowledges the importance of a human rights legal framework to maintaining international peace and security, stating that recognition of the inherent dignity and equal and inalienable rights of all individuals is the foundation of freedom, justice and peace in the world. Elaborating the United Nations Charter's declared purpose of promoting social progress and well-being in larger freedom, the Declaration gives equal importance to economic, social and cultural rights and to civil rights and political liberties, and affords them the same degree of protection. The Declaration has inspired more than 60 international human rights instruments, which together constitute a comprehensive system of legally binding treaties for the promotion and protection of human rights.

The Universal Declaration covers the range of human rights in 30 clear and concise articles. The first two articles lay the universal foundation of human rights: human beings are equal because of their shared essence of human dignity; human rights are universal, not because of any State or international organization, but because they belong to all of humanity. The two articles assure that human rights are the birthright of everyone, not privileges of a select few, nor privileges to be granted or denied. Article 1 declares that "all human beings are born equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood." Article 2 recognizes the universal dignity of a life free from discrimination. "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status."

The first cluster of articles, 3 to 21, sets forth civil and political rights to which everyone is entitled. The right to life, liberty and personal security, recognized in Article 3, sets the base for all following political rights and

civil liberties, including freedom from slavery, torture and arbitrary arrest, as well as the rights to a fair trial, free speech and free movement and privacy.

The second cluster of articles, 22 to 27, sets forth the economic, social and cultural rights to which all human beings are entitled. The cornerstone of these rights is Article 22, acknowledging that, as a member of society, everyone has the right to social security and is therefore entitled to the realization of the economic, social and cultural rights "indispensable" for his or her dignity and free and full personal development. Five articles elaborate the rights necessary for the enjoyment of the fundamental right to social security, including economic rights related to work, fair remuneration and leisure, social rights concerning an adequate standard of living for health, well-being and education, and the right to participate in the cultural life of the community.

The third and final cluster of articles, 28 to 30, provides a larger protective framework in which all human rights are to be universally enjoyed. Article 28 recognizes the right to a social and international order that enables the realization of human rights and fundamental freedoms. Article 29 acknowledges that, along with rights, human beings also have obligations to the community which also enable them to develop their individual potential freely and fully. Article 30, finally, protects the interpretation of the articles of the Declaration from any outside interference contrary to the purposes and principles of the United Nations. It explicitly states that no State, group or person can claim, on the basis of the Declaration, to have the right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth in the Universal Declaration.

International Bill of Human Rights

Once the Universal Declaration of Human Rights was adopted, the Commission on Human Rights, the premier human rights

intergovernmental body within the United Nations, set out to translate its principles into international treaties that protected specific rights. Given the unprecedented nature of the task, the General Assembly decided to draft two Covenants codifying the two sets of rights outlined in the Universal Declaration: Civil and Political Rights and Economic, Social and Cultural Rights. The Member States debated the individual provisions for two decades, seeking to give explicit endorsement to certain aspects of the universality of human rights only implicitly referred to in the Universal Declaration, such as the right of all peoples to self-determination, as well as reference to certain vulnerable groups, such as indigenous people and minorities.

Consensus was reached in 1966, and the United Nations General Assembly adopted the International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights that year. The preambles and articles 1, 2, 3 and 5 are virtually identical in both International Covenants. Both preambles recognize that human rights derive from the inherent dignity of human beings. Article 1 of each Covenant affirms that all peoples have the right of self-determination and that by virtue of that right they are free to determine their political status and to pursue their economic, social and cultural development. Article 2, in both cases, reaffirms the principle of non-discrimination, echoing the Universal Declaration, while Article 3 stresses that States should ensure the equal right of men and women to the enjoyment of all human rights. Article 5 of both Covenants echoes the final provision of the Universal Declaration, providing safeguards against the destruction or undue limitation of any human right or fundamental freedom. Two Optional Protocols elaborate certain provisions of the Covenant on Civil and Political Rights, one providing for complaints by individuals, the other advocating the abolition of the death penalty.

When they entered into force in 1976, the two International Covenants made many of the provisions of the Universal Declaration

effectively binding for States that ratified them. These two International Covenants, together with the Universal Declaration and the Optional Protocols, comprise the International Bill of Human Rights.

Over 60 human rights treaties elaborate fundamental rights and freedoms contained in the International Bill of Human Rights, addressing concerns such as slavery, genocide, humanitarian law, the administration of justice, social development, religious tolerance, cultural cooperation, discrimination, violence against women, and the status of refugees and minorities. The following four Conventions, relating to racial discrimination, torture, women and children, are considered core human rights treaties, together with the two International Covenants:

The International Convention on the Elimination of All Forms of Racial Discrimination (adopted in 1965/entry into force 1969) was a ground-breaking treaty defining and condemning racial discrimination. Calling for national measures towards the advancement of specific racial or ethnic groups, the Convention also makes the dissemination of ideas based on racial superiority or inspiring racial hatred punishable by law.

The Convention on the Elimination of All Forms of Discrimination against Women (1979/1981) specifies measures for the advancement and empowerment of women in private and public life, particularly in the areas of education, employment, health, marriage and the family.

The Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (1984/1987) bans torture and rape as weapons of war. In 1998, in a major effort to help torture victims and to step up international attempts to end torture, the United Nations declared 26 June as the annual International Day in Support of Victims of Torture.

The Convention on the Rights of the Child (1989/1990) is the most universally ratified human rights Convention. Only two Member States, the United States and Somalia, are not yet parties to the Convention, which protects children, among other things, from economic and sexual exploitation.

Some 14 States have incorporated provisions of the Convention on the Rights of the Child into their constitutions, while 35 have passed new laws conforming to the Convention or amended laws related to child abuse, child labour and adoption. Other Member States have extended the length of compulsory education, guaranteed child refugees and minority children special protection or reformed juvenile justice systems, as stipulated by the Convention.

World Conference on Human Rights

The United Nations designated 1968 as the International Year for Human Rights to mark the twentieth anniversary of the Universal Declaration on Human Rights, and convened an International Conference on Human Rights in Tehran, Iran, to enhance national and international human rights efforts and initiatives. After evaluating the impact of the Universal Declaration on national legislation and judicial decisions, the Conference approved the Proclamation of Tehran, which formulated a programme for the future, addressing the problems of colonialism, racial discrimination, illiteracy and the protection of the family. The Tehran Proclamation emphasized particularly the principle of non-discrimination, condemning the policy of apartheid as a "crime against humanity", and urged the international community to ratify the International Covenants on Civil and Political Rights and on Economic, Social and Cultural Rights adopted by the United Nations two years earlier.

Twenty-five years later, the World Conference on Human Rights, convened in Vienna in 1993, reassessed the progress of United Nations human rights work over the years. The Vienna Conference was marked by an unprecedented degree of support by the international community. Some 7,000 participants, including delegations from 171 States and representatives of more than 840 non-governmental organizations, gathered for two weeks to set out a revitalized programme for global

human rights action. There was broad consensus that, with fundamental rights codified and the essential machinery in place, it was time to implement the established human rights standards and norms with greater vigilance.

In adopting the Vienna Declaration and Programme of Action by consensus, the World Conference reaffirmed the centrality of the Universal Declaration for human rights protection, and recognized, for the first time unanimously, the right to development as an inalienable right and an integral part of international human rights law. The Conference also emphasized that, as human rights are universal and indivisible as well as interrelated and interdependent, they should be promoted in equal manner. The delegates rejected arguments that some human rights were optional or subordinate to cultural traditions and practices. The Vienna Conference thus gave high priority to preserving the integrity of the Universal Declaration. Giving new impetus to the worldwide implementation of human rights norms, the Conference emphasized that most violations could be addressed by forcefully implementing existing norms through the mechanisms already available.

Stating that the protection and promotion of human rights are the "first responsibility" of Governments, the Vienna Declaration recognized democracy as a human right, thus strengthening the promotion of democracy and the rule of law. Also, giving high priority to the universal ratification of international human rights treaties, the World Conference urged States especially to ratify promptly the Convention on the Rights of the Child and the Convention on the Elimination of All Forms of Discrimination against Women. Similarly, the Conference took innovative steps to protect the rights of vulnerable groups and to bring women's rights into the mainstream of United Nations human rights work, supporting the establishment of a Special Rapporteur on violence against women and calling for an international decade of the world's indigenous peoples.

The World Conference had a catalytic role in revitalizing the human rights programme of the United Nations. The Vienna Declaration and Programme of Action provides the international community with a new framework of planning, dialogue and cooperation that enables an integrated approach to promoting human rights. The recognition of the interdependence between democracy, development and human rights, for example, laid the groundwork for increased cooperation among international development agencies and national organizations in promoting human rights. The Vienna Declaration states, for the first time explicitly, that all organs, programmes and specialized agencies of the United Nations system should have a central role in strengthening human rights. Its key institutional recommendation, however, was the establishment of the post of United Nations High Commissioner for Human Rights to coordinate all human rights activities system-wide. The World Conference also called for a comprehensive five-year review of the progress made in the implementation of the Vienna Declaration and Programme of Action in 1998. This review coincides with the fiftieth anniversary of the adoption of the Universal Declaration of Human Rights

Declaration of Helsinki (1964)

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfilment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient. "

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects. In the field of biomedical research a fundamental distinction must be recognised between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the law of their own countries.

I. Basic Principles

- 1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.**
- 2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially**

appointed independent committee for consideration, comment and guidance.

- 3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.*
- 4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.*
- 5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.*
- 6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.*
- 7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.*
- 8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.*
- 9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely given informed consent, preferably in writing.*
- 10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who isn't engaged in the investigation and who is completely independent of this official relationship.*
- 11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national*

legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

- 12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present declaration are complied with.*

II. Medical Research Combined with Professional Care (Clinical Research)

- 1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgement it offers hope of saving life, re-establishing health or alleviating suffering.*
- 2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.*
- 3. In any medical study, every patient- including those of a control group, if any- should be assured of the best proven diagnostic and therapeutic method.*
- 4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.*
- 5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (1, 2).*
- 6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.*

III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)

- 1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.*
- 2. The subjects should be volunteers- either healthy persons or patients for whom the experimental design is not related to the patient's illness.*
- 3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.*

- In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.*





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Jl. Veteran No.31 Pekalongan Telp. (0285) 421621 – 423523 Fax.423225

KEPUTUSAN DIREKTUR RSUD KRATON
KABUPATEN PEKALONGAN
NOMOR : 445 / 029.b / 2011

TENTANG
KEBIJAKAN *INFORMED CONSENT* / PERSETUJUAN TINDAKAN
KEDOKTERAN
RSUD KRATON KABUPATEN PEKALONGAN

DIREKTUR RSUD KRATON KABUPATEN PEKALONGAN

- Menimbang** : a. Bahwa *Informed Consent*/Persetujuan Tindakan Kedokteran di RSUD Kraton Kabupaten Pekalongan diperlukan untuk memberikan informasi yang sejelas - jelasnya kepada pasien dan keluarga mengenai keuntungan dan resiko dari tindakan yang akan diberikan;
- b. Bahwa *Informed Consent*/Persetujuan Tindakan Kedokteran di RSUD Kraton Kabupaten Pekalongan diperlukan untuk memberikan pilihan kepada pihak keluarga pasien terhadap rencana yang akan dilakukan (disetujui / ditolak);
- c. Bahwa *Informed Consent*/Persetujuan Tindakan Kedokteran di RSUD Kraton Kabupaten Pekalongan menghindari adanya gugatan/tuntutan baik dari pasien atau keluarganya terhadap tindakan yang akan dilakukan;
- d. Bahwa bahwa untuk tercapainya tujuan sebagaimana dimaksud pada huruf a,b dan c, perlu ditetapkan dengan Keputusan Direktur RSUD Kraton Kabupaten Pekalongan Tentang Kebijakan *Informed Consent* / Persetujuan Tindakan Kedokteran RSUD Kraton Kabupaten Pekalongan;
- Mengingat** : 1. Undang-Undang Republik Indonesia Nomor 36 Tahun 2009 tentang Kesehatan (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 144);
2. Undang-Undang Republik Indonesia Nomor 44 Tahun 2009 tentang Rumah Sakit (Lembaran Negara Republik Indonesia Tahun 2009 Nomor 153);

3. Undang-Undang Republik Indonesia Nomor 29 Tahun 2004 tentang Praktik Kedokteran (Lembaran Negara Republik Indonesia Tahun 2004 Nomor 116);
4. Peraturan Pemerintah Nomor 32 Tahun 1996 tentang Tenaga Kesehatan;
5. Peraturan Menteri Kesehatan Republik Indonesia Nomor 290 / Menkes / Per / 111 / 2008 Tentang Persetujuan Tindakan Kedokteran Menteri Kesehatan Republik Indonesia,
6. Peraturan Menteri Kesehatan Republik Indonesia Nomor 159.b/Menkes/Per/II/1988 tentang Rumah Sakit;

MEMUTUSKAN

Menetapkan

- Kesatu** : Kebijakan *Informed Consent* / Persetujuan Tindakan Kedokteran RSUD Kraton Kabupaten Pekalongan
- Kedua** : Kebijakan *Informed Consent* / Persetujuan Tindakan Kedokteran di RSUD Kraton Kabupaten Pekalongan dimaksud adalah sebagaimana terlampir dalam Keputusan ini yang merupakan satu kesatuan dengan Keputusan ini.
- Ketiga** : Surat Keputusan ini berlaku sejak tanggal ditetapkan dan akan ditinjau kembali pada saat diperlukan atau sampai ada ketentuan lain yang mengaturnya.
- Keempat** : Apabila dikemudian hari ternyata terdapat kekeliruan dalam Keputusan Direktur ini akan dilakukan pembetulan sebagaimana mestinya

Ditetapkan Di : Pekalongan
Pada Tanggal : 17 Maret 2011


DIREKTUR RSUD KRATON
KABUPATEN PEKALONGAN
dr. **ANTO SETABUDI, M. Kes**
Pembina Utama Muda
NIP. 19590614 198511 1002

**KEBIAKAMAN MENGENAI INFORMED CONSENT /
PERSetujuan Tindakan Kedokteran**

Lampiran I
Keputusan Direktur RSUD Kraton
Kabupaten Pekalongan
Nomor : 445 / 029.B / 2011
Tanggal : 17 Maret 2011

LATAR BELAKANG :

Di dalam suatu sistem kesehatan, interaksi yang nampak menonjol adalah interaksi antara dokter dan pasien yang mungkin juga melibatkan unsur-unsur lainnya. Dalam sistem kesehatan yang menonjol adalah profesi kedokteran karena menurut anggapan umum seseorang yang mempunyai profesi ini adalah menyenangkakan yaitu dianggap merupakan profesi yang mulia.

Dalam aspek hukum kesehatan, hubungan dokter dengan pasien terjalin dalam ikatan transaksi atau kontrak terapeutik. Masing-masing pihak, yaitu yang memberi pelayanan dan yang menerima pelayanan mempunyai hak dan kewajiban yang harus dihormati. Dokter mempunyai kewajiban untuk melakukan diagnosis, pengobatan dan Persetujuan Tindakan Kedokteran yang terbaik, tetapi pasien atau keluarga pasien mempunyai hak untuk menentukan pengobatan atau Persetujuan Tindakan Kedokteran.

Namun akhir-akhir ini profesi kedokteran sering mendapat kritikan-kritikan yang cukup pedas dari berbagai lapisan masyarakat, beberapa media massapun ikut mengangkat berita-berita ini sampai ke permukaan.

Berbagai upaya hukum yang dilakukan dalam melakukan perlindungan menyeluruh kepada masyarakat sebagai penerima pelayanan, dokter sebagai pemberi pelayanan banyak dilakukan. Salah satunya dengan adanya persetujuan Tindakan Kedokteran.

RSUD Kraton Kabupaten Pekalongan merupakan rumah sakit umum daerah yang ikut berperan dalam terciptanya Persetujuan Tindakan Kedokteran antara dokter dan pasien. Untuk terjaminnya pelaksanaan Persetujuan Tindakan Kedokteran sesuai dengan yang direncanakan, maka terlebih dahulu dibuat perjanjian Persetujuan Tindakan Kedokteran antara dokter dari pihak RSUD Kraton Kabupaten Pekalongan dengan pasien.

Dari uraian tersebut diatas, maka RSUD Kraton Kabupaten Pekalongan perlu membuat Kebijakan Mengenai *Informed Consent* / Persetujuan Tindakan Kedokteran.

TUJUAN :

- Memberikan informasi yang sejelas - jelasnya kepada pasien dan keluarga mengenai keuntungan dan resiko dari tindakan yang akan diberikan.
- Memberikan pilihan kepada pihak keluarga pasien terhadap rencana yang akan dilakukan (disetujui / ditolak).
- Menghindari adanya gugatan/tuntutan baik dari pasien atau keluarganya terhadap tindakan yang akan dilakukan.

KEBIJAKAN

A. PERSETUJUAN TINDAKAN KEDOKTERAN

1. Semua Persetujuan Tindakan Kedokteran yang akan dilakukan terhadap pasien di RSUD Kraton Kabupaten Pekalongan harus mendapat persetujuan.
2. Persetujuan mengenai tindakan tersebut dapat diberikan secara tertulis maupun lisan.
3. Persetujuan mengenai tindakan tersebut diberikan setelah pasien mendapat penjelasan yang diperlukan tentang perlunya Persetujuan Tindakan Kedokteran dilakukan.
4. Dalam hal persetujuan lisan yang diberikan dianggap meragukan, maka dapat dimintakan persetujuan tertulis.
5. Setiap Persetujuan Tindakan Kedokteran yang mengandung risiko tinggi harus memperoleh persetujuan tertulis yang ditandatangani oleh yang berhak memberikan persetujuan.
6. Persetujuan tertulis dibuat dalam bentuk pernyataan yang tertuang dalam formulir khusus yang dibuat untuk itu.
7. Dalam keadaan gawat darurat,
 - a. untuk menyelamatkan jiwa pasien dan/atau mencegah kecacatan tidak diperlukan persetujuan Persetujuan Tindakan Kedokteran
 - b. keputusan untuk melakukan Persetujuan Tindakan Kedokteran tersebut diputuskan oleh dokter atau dokter gigi dan, dicatat di dalam rekam medik.
 - c. Dalam hal dilakukannya Persetujuan Tindakan Kedokteran tersebut dokter atau dokter gigi wajib memberikan penjelasan sesegera

mungkin kepada pasien setelah pasien sadar atau kepada keluarga terdekat.

8. Persetujuan Tindakan Kedokteran dapat dibatalkan atau ditarik kembali oleh yang memberi persetujuan sebelum dimulainya tindakan.
9. Pembatalan Persetujuan Tindakan Kedokteran harus dilakukan secara tertulis oleh yang memberi persetujuan.
10. Pemberian Persetujuan Tindakan Kedokteran tidak menghapuskan tanggung, gugat hukum dalam hal terbukti adanya kelalaian dalam melakukan Persetujuan Tindakan Kedokteran yang mengakibatkan kerugian pada pasien

B. PENJELASAN PERSETUJUAN TINDAKAN KEDOKTERAN

1. Penjelasan tentang Persetujuan Tindakan Kedokteran di RSUD Kraton Kabupaten Pekalongan harus diberikan langsung kepada pasien dan/atau keluarga terdekat, baik diminta maupun tidak diminta.
2. Dalam hal pasien adalah anak-anak atau orang yang tidak sadar, penjelasan diberikan kepada keluarganya atau yang mengantar.
3. Penjelasan tentang Persetujuan Tindakan Kedokteran sekurang-kurangnya mencakup :
 - a. Diagnosis dan tata cara Persetujuan Tindakan Kedokteran;
 - b. Tujuan Persetujuan Tindakan Kedokteran yang dilakukan;
 - c. Alternatif tindakan lain, dan risikonya;
 - d. Risiko dan komplikasi yang mungkin terjadi; dan
 - e. Prognosis terhadap tindakan yang dilakukan.
 - f. Perkiraan pembiayaan.
4. Penjelasan tentang diagnosis dan keadaan kesehatan pasien dapat meliputi :
 - a. Temuan klinis dari hasil pemeriksaan medis hingga saat tersebut;
 - b. Diagnosis penyakit, atau dalam hal belum dapat ditegakkan, maka sekurang-kurangnya diagnosis kerja dan diagnosis banding;
 - c. Indikasi atau keadaan klinis pasien yang membutuhkan dilakukannya Persetujuan Tindakan Kedokteran;
 - d. Prognosis apabila dilakukan tindakan dan apabila tidak dilakukan tindakan.

5. Penjelasan tentang Persetujuan Tindakan Kedokteran yang dilakukan meliputi
 - a. Tujuan Persetujuan Tindakan Kedokteran yang dapat berupa tujuan preventif, diagnostik, terapeutik, ataupun rehabilitatif.
 - b. Tata cara pelaksanaan tindakan apa yang akan dialami pasien selama dan sesudah tindakan, serta efek samping atau ketidaknyamanan yang mungkin terjadi.
 - c. Alternatif tindakan lain berikut kelebihan dan kekurangannya dibandingkan dengan tindakan yang direncanakan.
 - d. Risiko dan komplikasi yang mungkin terjadi pada masing-masing alternatif tindakan.
 - e. Perluasan tindakan yang mungkin dilakukan untuk mengatasi keadaan darurat akibat risiko dan komplikasi tersebut atau keadaan tak terduga lainnya.
6. Penjelasan tentang risiko dan komplikasi Persetujuan Tindakan Kedokteran adalah semua risiko dan komplikasi yang dapat terjadi mengikuti Persetujuan Tindakan Kedokteran yang dilakukan, kecuali :
 - a. risiko dan komplikasi yang sudah menjadi pengetahuan umum
 - b. risiko dan komplikasi yang sangat jarang terjadi atau yang dampaknya sangat ringan
 - c. risiko dan komplikasi yang tidak dapat dibayangkan sebelumnya (*unforeseeable*)
7. Penjelasan tentang prognosis meliputi
 - a. Prognosis tentang hidup-matinya (*ad vitam*);
 - b. Prognosis tentang fungsinya (*ad functionam*)
 - c. Prognosis tentang kesembuhan (*ad sanationam*).
8. Penjelasan harus diberikan secara lengkap dengan bahasa yang mudah dimengerti atau cara lain yang untuk mempermudah pemahaman.
9. Penjelasan dicatat dan didokumentasikan dalam berkas rekam medis oleh dokter atau dokter gigi yang memberikan penjelasan dengan mencantumkan tanggal, waktu, nama, dan tanda tangan pemberi penjelasan dan penerima penjelasan.
10. Dalam hal dokter atau dokter gigi menilai bahwa penjelasan tersebut dapat merugikan kepentingan kesehatan pasien atau pasien menolak diberikan penjelasan, maka dokter atau dokter gigi dapat memberikan penjelasan tersebut

kepada keluarga terdekat dengan didampingi oleh seorang tenaga kesehatan lain sebagai saksi.

11. Penjelasan diberikan oleh dokter atau dokter gigi yang merawat pasien atau salah satu dokter atau dokter gigi dari tim dokter yang merawatnya.
12. Dalam hal terdapat indikasi kemungkinan perluasan Persetujuan Tindakan Kedokteran, dokter yang akan melakukan tindakan juga harus memberikan penjelasan

C. YANG BERHAK MEMBERIKAN PERSETUJUAN TINDAKAN KEDOKTERAN

1. Persetujuan diberikan oleh pasien yang kompeten atau keluarga terdekat.
2. Penilaian terhadap kompetensi pasien tersebut dapat dilakukan oleh dokter atau dokter gigi sebelum Persetujuan Tindakan Kedokteran dilakukan.
3. Dalam hal terdapat keraguan persetujuan yang diberikan oleh pasien atau keluarganya, dokter atau dokter gigi dapat melakukan permintaan persetujuan ulang.

D. PENOLAKAN PERSETUJUAN TINDAKAN KEDOKTERAN

1. Penolakan Persetujuan Tindakan Kedokteran dapat dilakukan oleh pasien dan/atau keluarga terdekatnya setelah menerima penjelasan tentang Persetujuan Tindakan Kedokteran yang akan dilakukan.
2. Penolakan Persetujuan Tindakan Kedokteran tersebut dilakukan secara tertulis.
3. Akibat penolakan Persetujuan Tindakan Kedokteran menjadi tanggung jawab pasien.
4. Penolakan Persetujuan Tindakan Kedokteran memutuskan hubungan dokter dan pasien.

E. KETENTUAN PADA SITUASI KHUSUS

1. Tindakan penghentian/penundaan bantuan hidup (*withdrawing/ withholding life support*) pada seorang pasien harus mendapat persetujuan keluarga terdekat pasien.

2. Persetujuan penghentian/penundaan bantuan hidup oleh keluarga terdekat pasien diberikan setelah keluarga mendapat penjelasan dari tim dokter yang bersangkutan.
3. Persetujuan tersebut harus diberikan secara tertulis.

Ditetapkan Di : Pekalongan
Pada Tanggal : 17 Maret 2011

DEKRETUM RSUD KRATON
KABUPATEN PEKALONGAN



dr. SUTANTO SIKHABUDI, M. Kes
Pembina Utama Muda
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**RSUD KRATON
KABUPATEN PEKALONGAN**

**Standar Prosedur
Operasional
(SPO)**

**PERSETUJUAN TINDAKAN KEDOKTERAN
(INFORMED CONSENT)**

Nomor Dokumen

Nomor Revisi

Halaman

0

Tanggal Terbit

Sehatpikan,
Kepala
RSUD KRATON
dr. Sutanto Setiabudi, M.Kes
NIP. 19590411905151002

Pengertian :

Persetujuan Tindakan Kedokteran adalah persetujuan yang diberikan kepada pasien / keluarganya atas dasar informasi dan penjelasan mengenai Persetujuan Tindakan Kedokteran yang akan dilakukan terhadap pasien tersebut.

Tujuan :


Sebagai pedoman bagi seluruh dokter dalam melaksanakan ketentuan tentang Persetujuan Tindakan Kedokteran.

Kebijakan :

- Keputusan Direktur RSUD Kraton Kabupaten Pekalongan Nomor: 445/029.b/2011 tentang Kebijakan Informed Consent/Persetujuan Tindakan Kedokteran RSUD Kraton Kabupaten Pekalongan
- Keputusan Direktur RSUD Kraton Kabupaten Pekalongan Nomor: 445/340a/2008 tentang Pemberlakuan Pedoman Pelayanan Medik

Prosedur :

1. Dokter memberikan penjelasan dan informasi kepada pasien dan keluarganya tentang Persetujuan Tindakan Kedokteran yang akan dilakukan.=
2. Pembertan penjelasan tersebut dapat di delegasikan kepada dokter lain atau perawat atau bidan.
3. Pasien atau keluarganya menyampaikan keputusan apakah menyetujui ataukah menolak dilakukannya Persetujuan Tindakan Kedokteran tersebut.
4. Bila pasien menyetujui atau menolak maka pasien menandatangani atau membubuhkan cap ibu jari tangan kiri pada formulir yang sesuai dengan jenis Persetujuan Tindakan Kedokteran yang akan dilakukan, diketahui dan ditandatangani oleh dua orang saksi (perawat bertindak sebagai salah satu saksi).
5. Jika pasien menyetujui maka dokter melakukan Persetujuan Tindakan Kedokteran yang dimaksud.
6. Penarikan kembali persetujuan Persetujuan Tindakan Kedokteran dibuat secara tertulis dan ditandatangani oleh orang yang telah memberikan Persetujuan Tindakan Kedokteran dan dua orang saksi (perawat bertindak sebagai salah satu saksi).
7. Penarikan kembali Persetujuan Tindakan Kedokteran dapat dikabulkan dengan syarat Persetujuan Tindakan Kedokteran dimaksud belum sampai pada tahap pelaksanaan yang berdasarkan pertimbangan medik tidak mungkin lagi untuk dibatalkan.

 <p>RSUD KRATON KABUPATEN PEKALONGAN</p>	PERSETUJUAN TINDAKAN KEDOKTERAN (<i>INFORM CONSENT</i>)		
	No. Dokumen	No. Revisi 0	Halaman 2/2
Unit Terkait :	<ul style="list-style-type: none"> • Instalasi Gawat Darurat • Instalasi Rawat Inap • Instalasi Rawat Jalan • Instalasi Bedah Sentral • Intensif Care Unit • Rekam Medik 		

