



De nasjonale
forskningsetiske
komiteene



Den nasjonale
forskningsetiske komité
for medisin og helsefag
(NEM)

Samtykke basert på autonomi og tillit

FEK/SIKT seminar 02.11.2023

Kari Milch Agledahl,

leder av Den nasjonale forskningsetiske komité for medisin og helsefag (NEM)



Grey's Anatomy, ABC



De nasjonale
forskningsetiske
komiteene



Den nasjonale
forskningsetiske komité
for medisin og helsefag
(NEM)

INFORMED CONSENT TO SURGICAL PROCEDURE

It is very important to your doctor that you understand and consent to the treatment your doctor is rendering and any surgery your doctor may perform. You should be involved in any and all decisions concerning the surgical procedure. Sign this form only after you understand the procedure, the risks, the alternatives, the risks associated with the alternatives, and all of your questions have been answered. **Please initial and date directly below this paragraph indicating your understanding of this paragraph.**

Patient's Initials or Authorized Representative

Date

I, _____, hereby authorize Dr. _____ and any associates or assistants the doctor deems appropriate, to perform (circle one: LEFT, RIGHT, BOTH, UNILATERAL) _____

I consent to have _____ (name and title) perform the following tasks (list): _____

The risks and benefits associated with the procedure have been explained to me. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure(s). I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well being and safety.

The risks and possible undesirable consequences associated with the procedure have been explained to me including, but not limited to, blood loss, transfusion reactions, infection, heart complications, blood clots, loss of or loss of use of body part or other neurological injury or death. Other risks may include: _____

I understand that if I need blood or blood products these carry a risk of contracting HIV/AIDS, Hepatitis, or reactions such as the symptoms of fever, chills, hives or in more severe reactions, the destruction of the transfused red cells (Hemolytic Transfusion Reaction), antibody stimulation, bacterial infections or, in rare situations, death.



Affix Patient Label

Informed Consent to Surgical Procedure, Side Two

In permitting my doctor to perform the procedure(s), I understand that unforeseen conditions may be revealed that may necessitate change or extension of the original procedure(s) or a different procedure(s) than those already explained to me. I therefore authorize and request that the above-named physician, his assistants, or his designees perform such procedure(s) as necessary and desirable in the exercise of his/her professional judgment.

The reasonable alternative(s) to the procedure(s) have been explained to me. The alternatives include but are not limited to: _____

I hereby authorize my doctor to utilize or dispose of removed tissues, parts resulting from the procedure(s) authorized above. I consent to any photographing of the procedure(s) that may be performed, provided my identity is not revealed by descriptive texts accompanying them. I also consent to the admittance of student equipment representatives to the procedure room for purposes of advancing medicine and obtaining important product information. As required by the Safe Medical Device Act, I consent to the release of my name, address, and social security number to the manufacturer of the device I receive.

By signing below, I have had an opportunity to ask the doctor all questions concerning risks, alternatives, and risks of those alternatives.

Date	Time	Signature of Patient or Authorized Representative	Relationship of Representative
------	------	---	--------------------------------

- The Patient/Authorized Representative has read this form or had it read to him/her.
- The Patient/Authorized Representative states that he/she understands the information.
- The Patient/Authorized Representative has no further questions.

Date	Time	Signature of Witness
------	------	----------------------

CERTIFICATION OF PHYSICIAN:

I hereby certify that the facts, risks, the risks associated with the alternatives of the procedure(s) described in this form have been discussed with the individual granting consent.

Date	Time	Signature of Physician
------	------	------------------------

9030-02 R11 06 R03 07 J/FORMS / Consent-Informed General online Page 2 of 2

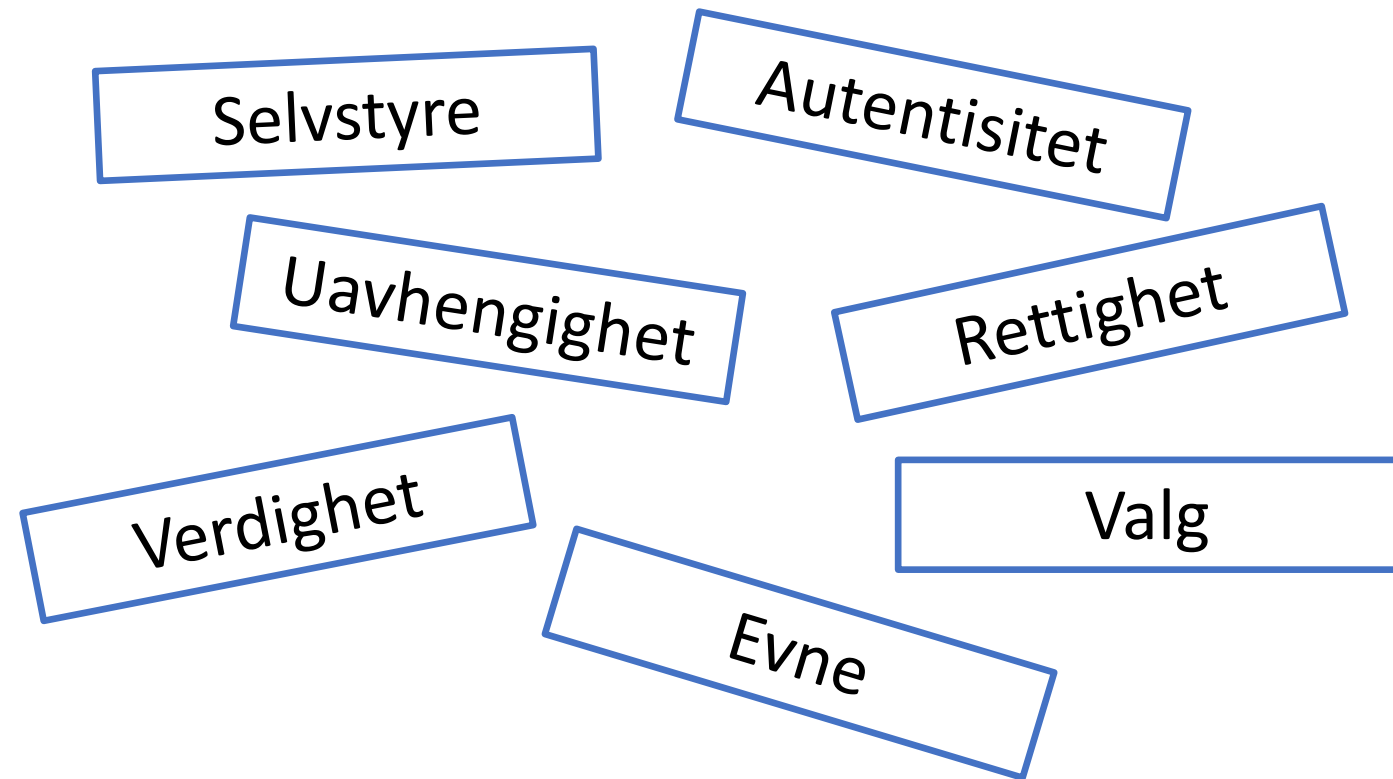


Affix Patient Label

“Sign this form only after you understand the procedure, the risks, the alternatives, the risks associated with the alternatives, and all of your questions have been answered.”

Samtykke

- Hva er samtykke?
→ Uttrykk for autonomi
- Hva er autonomi?



Et bilde holdt oss fanget. Og vi slapp ikke ut av det, for det lå i språket vårt, og det virket som språket gjentok det for oss, ubønnhørlig.

Filosofiske undersøkelser, § 115

Informert samtykke

- Helseforskningsloven:
- Det kreves samtykke fra deltakere i medisinsk og helsefaglig forskning, med mindre annet følger av lov.
- Samtykke er en frivillig, spesifikk, informert og utvetydig viljesytring fra deltakeren

- Bredt samtykke
- Stedfortredende samtykke
- Passivt samtykke
- Kollektivt samtykke

INFORMED CONSENT TO SURGICAL PROCEDURE

It is very important to your doctor that you understand and consent to the treatment your doctor is rendering and any surgery your doctor may perform. You should be involved in any and all decisions concerning the surgical procedure. Sign this form only after you understand the procedure, the risks, the alternatives, the risks associated with the alternatives, and all of your questions have been answered. **Please initial and date directly below this paragraph indicating your understanding of this paragraph.**

Patient's Initials or Authorized Representative

Date

I, _____, hereby authorize Dr. _____ and any associates or assistants the doctor deems appropriate, to perform (circle one: LEFT, RIGHT, BOTH, UNILATERAL) _____

I consent to have _____ (name and title) perform the following tasks (list): _____

The risks and benefits associated with the procedure have been explained to me. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure(s). I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well being and safety.

The risks and possible undesirable consequences associated with the procedure have been explained to me including, but not limited to, blood loss, transfusion reactions, infection, heart complications, blood clots, loss of or loss of use of body part or other neurological injury or death. Other risks may include: _____

I understand that if I need blood or blood products these carry a risk of contracting HIV/AIDS, Hepatitis, or reactions such as the symptoms of fever, chills, hives or in more severe reactions, the destruction of the transfused red cells (Hemolytic Transfusion Reaction), antibody stimulation, bacterial infections or, in rare situations, death.



Affix Patient Label

Informed Consent to Surgical Procedure, Side Two

In permitting my doctor to perform the procedure(s), I understand that unforeseen conditions may be revealed that may necessitate change or extension of the original procedure(s) or a different procedure(s) than those already explained to me. I therefore authorize and request that the above-named physician, his assistants, or his designees perform such procedure(s) necessary and desirable in the exercise of his/her professional judgment.

The reasonable alternative(s) to the procedure(s) have been explained to me. The alternatives include but are not limited to: _____

I hereby authorize my doctor to utilize or dispose of removed tissues, parts resulting from the procedure(s) authorized above. I consent to any photographing of the procedure(s) that may be performed, provided my identity is not revealed by descriptive texts accompanying them. I also consent to the admittance of student equipment representatives to the procedure room for purposes of advancing medicine and obtaining important product information. As required by the Safe Medical Device Act, I consent to the release of my name, address, and social security number to the manufacturer of the device I receive.

By signing below, I have had an opportunity to ask the doctor all questions concerning risks, alternatives, and risks of those alternatives.

Date Time Signature of Patient or Authorized Representative Relationship of Representative

- The Patient/Authorized Representative has read this form or had it read to him/her.
- The Patient/Authorized Representative states that he/she understands the information.
- The Patient/Authorized Representative has no further questions.

Date Time Signature of Witness

CERTIFICATION OF PHYSICIAN:

I hereby certify that the facts, risks, the risks associated with the alternatives of the procedure(s) described in this form have been discussed with the individual granting consent.

Date Time Signature of Physician

9030-02 R11 06 R03 07 J/FORMS / Consent-Informed General online
Page 2 of 2



Affix Patient Label

“Sign this form only after you understand the procedure, the risks, the alternatives, the risks associated with the alternatives, and all of your questions have been answered.”



Samtykke i klinikken

- Krav om forsvarlig behandling
- Makt asymmetri
 - Kunnskap
 - Portvokter
 - Definisjonsmakt
- Tillatelse
 - **Tillit**



De nasjonale
forskningsetiske
komiteene



Den nasjonale
forskningsetiske komité
for medisin og helsefag
(NEM)

Samtykke i forskning

- Forskningen er oftest ikke til deltagerens beste
- Informasjonen enda vanskeligere å forstå
- «Den terapeutisk misforståelse»
- Bør stille høyere krav til samtykke
 - **Tillitsdimensjonen enda viktigere**



Samtykke i forskning

- Forskningen er oftest ikke til deltagerens beste
 - Informasjonen enda vanskeligere å forstå
 - «Den terapeutisk misforståelse»
 - Bør stille høyere krav til samtykke
- **Tillitsdimensjonen enda viktigere**



Paula Fjellheim, Lisa Løkken, Sara Paulsen, Alfred Mjøen og Morten Mortensen.

Foto: Ukjent. Eier: Sverre Fjellheim



De nasjonale
forskningsetiske
komiteene

Takk for oppmerksomheten