Filling up the New Consent Form

Department of Forensic Medicine & Toxicology
GMCH, Chandigarh
What is Consent

- Consent is an agreement/compliance between two or more parties
- As per S 13, Indian Contract Act, 2 or more persons are said to be in consent when they agree upon the same thing in the same sense

- Except in emergency situations, consent is absolutely mandatory in all other aspects of medical practice
- This is respecting a patient’s autonomy
Medically defined as voluntary acceptance after complete understanding by a competent patient, for a plan of care, after its adequate disclosure in terms of purpose, nature, procedure, risks, benefits & alternatives, by the attending physician/team
There is Nothing like a Blanket Consent

Every specific procedure – be it, examination, taking samples, injecting medicines or doing minor procedure to major surgeries - requires specific consent from the patient.

For medical and medico-legal examination, the age for consent is 12 years & For invasive procedures, it is 18 years.

If patient is conscious, oriented, of sane mind and of consenting age, NO ONE other than the patient can consent on behalf of the patient.
Consent is an interactive dialogue between the patient & doctor/team & is an ongoing process and NOT an event.

Every step of the procedure to be undertaken, is to be properly explained to the patient in a language he/she understands and only then can an informed consent be taken.
Requirements of legally valid consent

It should be

- **Voluntary** (of his own accord)
- **Clear** (unambiguous words)
- **Person & Procedure specific**
- **Direct** (Patient only; No intermediaries)
- **Free**
- **Intelligent** (clear understanding by patient)
- **Personal** (Privacy of patient details paramount)
Components of a Legally Valid Consent
1. **Full Disclosure**: Doctor should inform -
   - What is the patient **suffering from**
   - Various **treatment avenues available & their individual prognosis; cost factor**
   - Why **this particular treatment course over other alternatives**
   - Type of **anesthesia intended, requirement of blood**
   - **Adverse effects/ complications, etc, if any** (complications with high frequency need to be explained completely; others may be mentioned in brief)
   - **What would happen if the patient refuses treatment**
1. **Comprehension** - Dissemination of above information in a language in such a way that patient understands completely

2. **Autonomous choice** - Free will, in absence of outside control by doctor/nurse/relative, etc

3. **Competence** - Patient mentally sound, sane mind, not under influence of alcohol or drugs, of consenting age

4. **Actual consent** - written, signed & witnessed by two independent persons
If after explaining everything, answering all queries of patient to his/her complete satisfaction, if he/she refuses consent, same may be documented in the file as **Informed Refusal**.

Onus now with the patient alone.
The New Consent Form

- The new consent form has been designed keeping the above factors in mind
- It is an exhaustive one, covering 3 pages
- It is in English Language ONLY
- The doctor taking the consent should properly read and understand the contents of the form himself/herself thoroughly first
- If there are any doubts anywhere, please feel free to ask your HOD to arrange for a refresher course by the department of Forensic Medicine & Toxicology
Only if you understand and are without any doubt, what-so-ever, can you explain the contents to the patient **in a language and in a manner that he/ she or the patient’s guardian comprehends completely**
Procedures of documenting consent

GOVERNMENT MEDICAL COLLEGE & HOSPITAL, CHANDIGARH
INFORMED CONSENT FORM

I, ____________ name of the patient,
s/o, w/o, d/o __________ (legal guardian) of
the patient ___________ have (please
tick correct option above and below)
Read
And/or been explained this consent form
in ___________ (name of the language)
which I fully understand and have
understood the information provided
therein.

I understand that I/my ward have/has the
following medical condition(s), as
diagnosed by the treating team of
Government Medical College & Hospital,
Chandigarh, from whom I have sought
consultation:

________________________________________________________________________

For the above mentioned medical
condition(s), I have been advised that I/my
ward require(s) the following operation(s)/
procedure(s):

________________________________________________________________________

(Full name of the operation/procedure(s)
to be performed)

Consent has to be person specific

To be recorded after explanation
in language which patient
understands directly or via
Interpreter

Should mention the purpose of
the procedure, preceded by the
condition of the patient

To be procedure specific and
should explain its nature

Signature of Patient / Legal Guardian Date Signature of Doctor
Procedure of documenting consent

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I have also been informed that the operation/ procedure intended to be performed might be associated with any of the following specific complication(s), even though the treating team would perform the same in “Good Faith” and for the treatment of my/my ward’s above mentioned medical condition(s):

I am now aware of the intended benefits, possible risks & complications, and available alternatives to the said operation/ procedure. I am also aware that the results of any operation/ procedure can vary from patient to patient, and I declare that no guarantees have been made to me regarding success of this operation/ procedure. I am aware that while majority of patients have an uneventful operation and recovery, few cases may be associated with complications. I am now aware of the common risks and complications associated with this operation/ procedure and understand that it is not possible to list all possible risks and complications of any operation/ procedure.

Signature of Patient / Legal Guardian  Date  Signature of Doctor

Should mention each of the complications in specific

Should adhere to principle of full disclosure with regard to all risks and complications, alternatives, prognosis and immediate and future cost of the surgery/ procedure
I understand that anesthesia may be induced as an essential prerequisite for the operation(s)/procedure(s) so that the operation(s)/procedure(s) can proceed smoothly without me/my ward feeling the severe pain associated with the operation(s)/procedure(s). The anesthesia may be general (where a combination of drugs is either injected through the vein in the body or inhaled, making me/my ward temporarily unconscious and relaxing my/my ward's muscles, and the process will be completely returned to normal after the operation(s)/procedure(s) is/are over), regional (where I/my ward will remain awake and only the region in which the operation(s)/procedure(s) will be carried out will be made temporarily numb so that I/my ward do/does not feel any pain in that region of my/his/her body), or monitored anesthesia care (where I/my ward will be temporarily made semi-conscious and painless during the operation(s)/procedure(s)). All these anesthetic procedures, when conducted properly with pre-anesthetic check-up and monitoring, are usually very safe, with only minor and transient side effects like

Indications, type and side-effects of anesthesia should be explained in detail
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hoarseness, mouth or throat pain, and minor injury to mouth and teeth, headache, backache, buzzing in the ears, numbness, etc. I understand that serious adverse events following anesthesia are possible but very rare (usually less than 1 in 100,000).

I also understand that sometimes a planned operation/procedure may need to be postponed or cancelled if patient's clinical condition worsens or due to any unforeseen technical reason(s).

I am also aware that I can withdraw my consent at any point of time at my own risk and consequence, by submitting the withdrawal in writing, before the start of the operation/procedure.

I understand that if medical exigencies demand, further or alternative operative/procedural measures may need to be carried out, and in such case there may be difference in the planned and actual operation/procedure.

To be informed about postponement or cancellation of surgery due to unforeseen circumstances.

Due weightage to be given to the right of the patient with regard to autonomy about withdrawal of consent at any point of time but it should be documented in writing and witnessed.

Signature of Patient / Legal Guardian Date Signature of Doctor
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I am aware that I/ my ward may require administration of blood and/or blood products during or after the operation/ procedure as found necessary by the doctors. I have been explained that in cases of transfusion of blood, despite careful screening tests, as per protocol, amended from time to time, as per the directions of the Government of India, there are still rare chances of life threatening infections such as HIV, Hepatitis, etc. I also understand that sometimes, certain reactions like fever, rash, shortness of breath, shock, and in rare cases, even death may occur. I now understand that these risks may occur despite the stringent preventive measures.

I am now also aware that during the course of this operation/ procedure the doctor will be assisted by a medical and paramedical team and that the doctor may seek consultation/ assistance from relevant specialists if the need arises.

I agree to the observing, photography (still/ video/ televising) of the procedure.

Signature of Patient / Legal Guardian  Date  Signature of Doctor

Complications of blood transfusion in general and about blood borne infections need to be explained.
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(including relevant portion of my body including my diagnosis/ reports
(pathology, radiology etc.), for academic/ medical purposes, provided my/ward’s
identity is not revealed by such acts. I also agree to my/ my ward’s clinical details
being shared for scientific publication provided my/ my ward’s identity is not
disclosed.

I am also aware of the expected course after the operation/ procedure and the
care to be provided and understand that sometimes admission to an intensive Care
Unit and/ or extension of duration of hospitalization may be required and/ or
there may be requirement of extra medicine or treatments, thereby leading to
increase in the treatment expense, depending upon the body’s response to
the treatment/ procedure.

I authorize the hospital for disposal of any
tissue or body part that may be removed
from my/my ward’s body in the appropriate
manner during and for the purpose of
conduction this operation/ procedure.

Consent has to be taken separately, explicitly for utilization of medical
records, videos & photographs for
academic dissemination but with
absolute regards to privacy of patient

Possibility of transfer to ICU should be
indicated but therapeutic privilege
may be exercised depending upon
mental state of patient but without
withholding any information to the
relatives

Signature of Patient / Legal Guardian   Date   Signature of Doctor
Procedure of documenting consent

I declare that I have received and fully understood the information provided in this consent form, that I have been given an opportunity to ask questions relating to my/ my ward’s ailment, the operation/ procedure being performed its risks, consequences, alternatives, potentials complications and intended benefits and recovery and that all my questions have been answered to my entire satisfaction and there are no misconceptions or false hopes in my mind. I further declare that all fields (of this form) requiring insertion or completion were filled in my presence at the time of my signing this form.

For the above mentioned operations(s)/ procedure(s) that I have been made aware of, I give my consent voluntarily to the treating team for carrying out the said operation/ procedure on myself/ my ward, being fully aware of the nature, potential risks and complications, intended benefits and possible alternatives.

I, the above named patient/ named patient's legal guardian, do further hereby declare that I am above 18 years of age as

Signature of Patient / Legal Guardian  Date  Signature of Doctor

Consent has to be of the accord of the patient as per section 90 of the Indian Penal Code, which otherwise is legally invalid.
Procedures of documenting consent

Consent has to be without coercion, influence of doctor, paramedic or relatives as per section 90 of the Indian Penal Code, which otherwise is legally invalid. It has to be a competent choice by a patient who has attained majority unless a minor where consent has to obtained by parent or legal guardian.

<table>
<thead>
<tr>
<th>Signature/Thumb Impression</th>
<th>Name</th>
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</thead>
<tbody>
<tr>
<td>Patient</td>
<td></td>
</tr>
<tr>
<td>Legal Guardian (if applicable#)</td>
<td></td>
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<tr>
<td>Reason for Legal Guardian's consent</td>
<td></td>
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<tr>
<td>Witness</td>
<td></td>
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<tr>
<td>Interpreter (if applicable)</td>
<td></td>
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</tbody>
</table>

# only if patient is a minor or unable to give consent

I, the undersigned doctor, do hereby confirm that I have explained to the patient / patient's legal guardian, the nature, potential risks and complications.

Signature of Patient / Legal Guardian  Date  Signature of Doctor
**Procedure of documenting consent**

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intended benefits, expected post-procedure course and possible alternatives to the planned operation(s)/procedure(s). I have been given to understand that he/she has understood the information fully, as described in this document.

Consent obtained by: Dr. ____________
Designation & Dept. _____________

Signature ____________ Date ____________
(member of the treating team)

<table>
<thead>
<tr>
<th>Signature of Patient/Legal Guardian</th>
<th>Date</th>
<th>Signature of Doctor</th>
</tr>
</thead>
</table>

It has to be an actual consent reduced to writing and signed in date and time by patient, doctor and two independent witnesses.

It is MANDATORY to put signatures on all pages while documenting consent.
Further References

- Latest Judgements on Consent and Medical Negligence
- Samira Kohli Case, which explains that extension of consent is now legally invalid