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Informed Consent and Medical Law

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ABSTRACT

The present paper vividly elucidates the concept of Informed Consent in Medical Law. The paper begins with an introduction about what is informed consent and then the paper unravels about the different laws on informed consent in India and the jurisprudence of informed consent in medical law is discussed through various case laws in India.

Then the paper shows a cross country analysis on the concept of informed consent in medical laws in India, UK, US and China. Furthermore, the concept of the informed consent is a crucial instrument which determines the fundamental rights of a human being. The paper is concluded with a concluding note which highlights the importance of informed consent in the life of medical professionals and patients.

Keywords: *Informed Consent, Medical law, Health, Doctor, Patient.*

I. INTRODUCTION

Let's start by discussing what being informed means. In general, being informed refers to possessing knowledge or information about something. The person who needs the information should have a comprehensive understanding of the facts and information without any ambiguity before it can be given to them in detail.

The purpose of receiving "informed consent" is to provide patients the knowledge and choices they need to decide for themselves whether to have a medical treatment or surgery, including taking part in clinical trials.

As part of the informed consent procedure, providing patients with all the information they need is a routine and crucial step. The goal is for the patients or whomever is in charge to think carefully about and consider all the treatment's effects. By keeping the safety feature in view, this is accomplished.

A person receives complete health care information and expert advice on the best course of action for the treatment during this process of informed consent.

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II. INFORMED CONSENT AND CONSEQUENCES IN INDIA

(A) Types of Informed Consent

The following are the types of informed consent:

1. Consent- A participant must be at least 18 years old and an adult in order to offer their own informed consent or permission.
2. Parental Permission- When the patient is too young to provide written consent, we must get written consent from both natural parents or legal guardians. A minor needs parental consent since they cannot judge for themselves what is acceptable or unacceptable.
3. Assent- When a child gives his or her informed permission, it means that the form's contents are written in terms that the youngster can understand. The information should be written at a level that is accessible to a youngster aged 7 to 17 years old.
4. Verbal- In this version, the subject reads the material aloud and then vocally confirms their agreement to the terms. Despite the fact that it has all that has been written in it.
5. Short Form- Informed consent is not without its difficulties. In cases when communication is difficult, the abbreviated form must be used. This is a widespread issue in India where a sizable portion of the population has difficulty communicating in English. To ensure that patients fully grasp the implications of the authorised permission, it is provided to them in their native language.

III. LEGAL SCENARIO OF INFORMED CONSENT

Perhaps the one unifying theme in modern healthcare delivery is the importance of patient consent. Self-determination is a fundamental human right, and this concept gives legal and ethical expression to that right. A medical professional may be held accountable in both civil and criminal court if he or she treats a patient without informed permission. The victim of a tort may sue the perpetrator for financial damages. Payment of damages (in the civil realm) and/or jail (in the criminal realm) would result. The patient might initiate legal action against the medical professional by filing a tort claim for trespass to person. Negligence claims might also be filed against the doctor or nurse. Assault and battery accusations could result in jail time, but only in the most extreme cases. As per the common understanding, a battery occurs when one person compels another to come into physical contact with them without their permission. There is no battery if the person who is touched has given their permission, either explicitly or implicitly. Except in extreme cases, such as when a patient's organs are removed without his permission, doctors are almost never held criminally accountable for negligence.

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The amount of force used is irrelevant under tort law; what matters is that it was used on a human being without justification. Under tort law, the doctor will be liable if he tries to treat a patient without permission. There are two types of consent: explicit and inferred. When a patient voluntarily enters a doctor's office for a consultation, such action may be seen as permission for a clinical diagnosis to be made. A patient's assent may be inferred if he or she follows the doctor's directions throughout the diagnostic process. Here we have a perfect case of implied permission in action. It is possible that a vaginal examination will be required at some point during the clinical evaluation. The medical professional should preferably get second consent by verbally asking the patient for permission to do such an exam. Moreover, prior to conducting an invasive examination, the patient's written consent must be sought (such as an incision or the collection of bodily fluid samples).

When written permission is required, doctors usually want very specific orders from patients. It's important to note that the law doesn't try to enforce written authorization but rather only verbal permission and doesn't care if it's in writing or not. The medical facility itself decides if written consent is required. If the patient is to get therapy while experiencing severe pain or undergo local or general anaesthetic, written consent may be helpful. Doctors are not required to always get written permission, and doing so would not protect them from legal consequences. However, in the event of litigation, the doctor would have an easier time showing permission if it were documented in writing. The Medical Council of India (MCI) has published laws mandating the written agreement of a patient before any surgical procedure may be performed, with the goal of standardising the practise. The MCI recommendations only apply to surgical procedures and not to any other forms of therapy. The following are some guidelines that might be used while considering alternative treatments:

- Consent by implication is sufficient for most forms of regular medical care.
- Express oral consent may be required for more complex procedures.
- Complex treatments require explicit written consent.

Article 21, which protects the right to life and personal liberty, includes the concept of autonomy. The right to personal liberty under Article 21 is quite expansive, covering not only the freedom to pursue one's own interests but also the protection of one's own life, health, and freedom from any conduct that results in the permanent or temporary impairment of the use of any portion of one's body or mind. Indian courts frequently apply common law concepts; however, the common law application of consent is still developing. The Indian Contract Act and the Indian Penal Code both have useful guidelines to follow in such situations. A doctor-

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patient connection gives rise to contractual duties since it is a relationship between two persons who are legally able to enter into contracts. According to the Indian Majority Act, a party is considered competent if (i) they are at least 18 years old, (ii) they are of legal age and sound mind, and (iii) they are not prohibited from entering into legal contracts. Furthermore, under contract law, an agreement is not legal if it was reached with the cooperation of a party (here, the patient) under duress, undue influence, error, misrepresentation, or fraud. However, the General Medical Council of England has established a consent age of 16 in its recommendations. A minor may be considered to have decision-making competence and can be treated as an adult. Depending on the child's level of maturity and understanding, he or she may be able to make a decision even if he or she is younger than 16. A parent or legal guardian can ask the court to force a minor to undergo medical examination or treatment if they believe it is in the child's best interests and the minor is old enough to make such a decision on his or her own. It's interesting to note that the situation is different in Scotland, where parents or guardians cannot provide consent for medical operations that their competent kid has rejected.

Naturally, the permission gained after receiving all pertinent information will function under its own set of parameters designed to safeguard the doctor. If the doctor deviates from these guidelines, he does so at his own peril since no more permission is implied. A doctor who proceeded with treatment without permission, even when doing so was in the patient's best interest, may face legal consequences. It was thought that the patient had appendicitis. An procedure was performed on her after proper permission was obtained. Incision revealed, however, that her appendix was healthy and uninflamed. The doctor removed her gangrenous gall bladder for her own good. The patient's kidney was found to be impaired thereafter. Since the doctor had operated without permission, he was found guilty. This body of legislation is also symbolic of the long-standing paternalism in the medical community. It's the idea that doctors should act more like parents and make decisions on patients' behalf. The law, however, does not recognise this idea. The patient's right to autonomy is always important under the law, provided that he has the mental capacity to make his own decisions. If a doctor believes that a certain medical treatment is necessary for the patient's health, then he or she may be forgiven for thinking that the patient's autonomy should be sacrificed in order to facilitate that treatment. In this scenario, the doctor would have been protected since he was acting with the patient's lawful authorization, and because a simple mistake in judgement is not a basis for liability. By operating on her gall bladder without first obtaining her consent, he displayed excessive professional paternalism and blatantly disregarded her right to autonomy. To prevent medical professionals and the general public from acting irrationally during times of crisis, some

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commentators, including Mill, have pushed for paternalism.

The use of proxy consent when the patient is unable to give permission himself has not been the subject of well-developed legislation or guidelines in India. In such a circumstance, the patient's family or caretaker must give permission before the doctor can treat the patient. In one instance, the wife of a patient made it clear to hospital officials that she consented to her husband having bypass surgery, and the hospital accepted her word as final for all purposes.

In another instance, tensions existed between the patient and his wife. A sterilisation operation was performed on a patient. He is a married father of two young children, as he stated under testimony throughout the consent process. In reality, he was having surgery for the sole purpose of financially benefiting from it. His father then claimed that his son was not mentally capable of giving permission to the procedure because of his mental instability. The court ruled that a doctor is shielded from liability provided he has no reason to suspect malpractice or question the patient's mental competence. The examples of these two instances show that a doctor is always protected when behaving appropriately under normal circumstances and is never expected to function as an investigator.

The highest court in the land has handed down a landmark ruling on the subject. In which it was stated that "where a surgeon is consulted by a patient and consent of the patient is taken for diagnostic procedure/surgery, such consent can't be considered as authorization or permission to perform therapeutic surgery, either conservative or radical (except in a life-threatening emergent situation)". In a landmark judgment, an Indian court ruled that a physician's approval for a diagnostic procedure cannot be extended to cover subsequent therapeutic surgery. It was also noted by the court that "where the consent by the patient is for a particular operative surgery it can't be treated as consent for an unauthorised additional procedure involving removal of an organ only on the ground that it is beneficial to the patient or is likely to prevent some danger developing in the future, where there is no imminent danger to the life or health of the patient." This approach, by its very nature, limits the autonomy of the "paternal doctor" in the Indian context. A doctor recommended a laparoscopy for a 44-year-old lady who was experiencing stomach cramps. Several permission papers, including those for admission and operation, were collected from her. The applicable permission form authorised the doctor to do a "diagnostic and operative laparoscopy," with the caveat that a "laparotomy may be needed." The patient's mother gave her proxy agreement for a hysterectomy while her daughter was under anaesthesia in the operating room (and so unable to provide her own). She had surgery to have her reproductive organs taken out. In the subsequent legal case, it was determined that the procedure had been performed without the patient's informed permission, and the physicians were found

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guilty of malpractice.

The precedent set by this case will have far-reaching effects, elevating the field of consent law to new heights. Not only is informed permission necessary right now, but it also has to be "prior informed consent," according to the argument, unless the patient's life is in jeopardy. Furthermore, this ruling limits the extent to which an attendant or the person with parental authority may provide proxy permission.

In the instances listed below, consent must be obtained; else, legal action will be taken:

Patients have a legal right to protect their bodies from any invasive procedures; doctors who perform treatment on patients without their permission will be held legally responsible for doing so. In India, if a doctor wants to conduct anything that, without patient consent, is illegal, he or she must present proof to back it up. Up to a certain point, Indian courts may assume that consent was given implausibly. Beyond that, the court must be given the precise evidence.

The age of majority in India is 18, as established by Section 3 of the Indian Majority Act of 1875. Since this person lacks legal capacity, they can give consent. The parental approval will be regarded as legitimate.

Medical abortion - A minor's or a lunatic's parents must provide consent before the pregnancy may be terminated. According to the Medical Termination of Pregnancy Act of 1971, no pregnancy may be terminated without the consent of the woman. In order to save the person's life, terminations may only be undertaken in good faith.

IV. CASES

1. *Samira Kohli* v. *Prabha Manchanda*

Abdominal hysterectomy and bilateral salpingo-oopherectomy are surgical procedures that need a patient's informed agreement before they may be performed. In this instance, consent was not obtained. Furthermore, the respondent will be found guilty of assault and battery since the abdominal hysterectomy and bilateral salpingo-oopherectomy did not qualify for the exemption of necessity.

This would constitute a service deficit. However, the responder will not be found negligent since his or her conduct passes the Bolam Test and is consistent with previous court rulings. The Supreme Court of India found the respondent guilty of assault and violence amounting to deficiency in service, and it fined him Rs 25,000 and ordered him to pay the appellant Rs 25,000 in damages for the unauthorised operation.

2. The Supreme Court of India adopted the Bolam Test in the case of Vinitha Ashok v.

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Lakshmi Hospital, which held that "a doctor will be liable for negligence in respect of diagnosis and treatment in spite of a body of professional opinion approving his conduct where it has not been established to the court's satisfaction that such opinion relied on is reasonable or responsible."

3. In Indian Medical Association v. VP Shantha, the Supreme Court ruled that medical services fall under the ambit of the Consumer Protection Act. In Dr. Vijil & Ors. v. Ambujakshi T.P & Anr., a similar ruling was made. The court ruled that medical care is a "service" within the meaning of Section 2(42) of the Consumer Protection Act of 2019[12]. Assault and battery is a tort that causes harm to the appellant, therefore the lack of service is obvious.

V. CROSS COUNTRY ANALYSIS

1. UK

a. [2] The 2005 Mental Capacity Act in England and Wales:

The Act provided a legal framework for representing the interests of adults over the age of 16 who lack decision-making ability. It makes clear:

- who has the authority to make decisions for those who are in need of medical care and treatment, particularly those regarding unable to make independent decisions
- how those choices ought to be made

The Mental Capacity Act Code of Practice is required reading for all doctors since it explains how the law should be applied in healthcare situations. Consequently, when:

- determining an individual's capacity
- making a decision that will benefit a disabled person.

b. 1983 Mental Health Act

This law provides a legal framework for when people with mental illness may be forced to get treatment for the sake of their own or others' safety. Information on how patients might appeal the use of restraints before the Mental Health Tribunal is also provided.

c. Act of 2000 Concerning Adults with Incapacity in Scotland:

This Act helps ensure the safety of people over the age of 16 who are unable to make choices for themselves due to a mental disability or communication disorder. It also allows other people

[2] General Medical Council, *Factsheet: Key legislation and case law relating to Decision making and consent*, 1 (2020), www.gmc-uk.org/guidance.

to make choices for them. The Act specifies the procedures to be followed for assessing the needs of people with disabilities, especially those related to medical treatment.

Codes of Conduct, which set forth expectations for law-abiding people like doctors and other healthcare providers who serve adults with incapacity, make up a sizable portion of the Act. Medical care and research-related decisions are covered in Part 5 of the code of practise.

d. Scotland's Mental Health (Care and Treatment) Act of 2003:

The conditions under which persons with mental illness may be subjected to involuntary treatment for their condition are spelled forth in this Act. The Act establishes patient rights and protections (includes a right to seek independent advocate services and the Mental Health Tribunal). Precautions about certain persons and pre-treatment disclosures are also included to safeguard service users' rights and increase treatment compliance. The Mental Health (Care and Treatment) (Scotland) Act 2003 was amended by Part 1 of the Mental Health Scotland Act 2015.

When a person in Northern Ireland lacks the mental capacity to make choices for themselves, such decisions about their treatment and care are guided by the common law.

e. The 2016 Mental Capacity Act (NI): The Northern Ireland Mental Capacity Act of 2016 has not been implemented fully yet. If passed, the Act will create a standardised legal framework for handling matters of capacity and mental health. It will spell out the guidelines that must be followed when making decisions for adults over the age of 16 who lack the mental capacity to do so themselves, as well as the appropriate protections.
f. 1986 Order for Mental Health (Northern Ireland): Currently, mental health patients in Northern Ireland are subject to legal protection, treatment, and evaluation under the Mental Health (Northern Ireland) Order of 1986 ("MHO"). Date of the Mental Capacity Act (NI). The MHO will no longer apply to anyone over 16 years old once 2016 is fully over.
g. CASES:

[3]*Montgomery* v. *Lanarkshire Health Board*, (2015) UKSC 11

The responsibility to inform patients of any significant hazards associated with therapy and any viable alternative treatments.

Mrs. Montgomery, a diabetic, was informed that her unborn child was larger than typical. She

[3] *Id.*

stated fear that this could cause labour problems persisted throughout her antenatal treatment. Her counsellor neglected to warn her that a caesarean section would be necessary if the baby's shoulders had problems passing through the birth canal (shoulder dystocia) during labour. The consultant decided not to share this knowledge because she believed the baby would be unlikely to be harmed in any substantial way.

Umbilical cord blood flow was compromised due to shoulder dystocia during delivery. The lack of oxygen at delivery was ultimately determined to be the cause of the baby's cerebral palsy. He also suffered injury to his brachial plexus.

The Supreme Court ruled that:

- To ensure that their patients are well-informed, doctors must use reasonable care, as established by a recent Supreme Court ruling.
- Physicians have an obligation to use reasonable care in explaining treatment options to patients.
- If the doctor knew, or should have known, that the patient would likely attach significance to it in the given circumstances, or if a reasonable person in the patient's position would likely attach significance to the risk, then the risk was considered to be material.
- As a member of the patient's advisory team, the doctor should discuss the severity of the patient's condition, the benefits and risks of the suggested treatment plan, and any other treatments that may be available.
- If a physician has a good faith opinion that disclosing risk information to a patient would significantly affect that patient's health, then the doctor has the authority to keep such information from the patient. Except in this extremely limited circumstance, doctors are not authorised to conceal information from patients if they feel doing so will lead them to forego treatment that is not in their best interests.

[4] *Wye Valley NHS Trust* v. *B* [2015] EWCOP 60

Offering patients who lack ability the benefit of the doubt on their views and values.

B lacked the mental capacity to determine whether or not he wanted his leg amputated. He was adamantly opposed to the procedure and had been for quite some time. It was believed that if he did not have the procedure, he would die within a few days.

[4] *Id.*

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The following was decided by the Court of Protection.

- B's best interests would not be served by an imposed amputation. The court emphasised the need of giving people who lack ability their wishes, feelings, beliefs, and values.

Re MB (Medical Treatment) [1997] 38 BMLR 175 CA

Considerations that may influence a patient's ability to reject care.

MB required a caesarean section, but she chickened out at the last minute because of her irrational phobia of needles.

The Court of Appeal held the following.

- Fear, confusion, shock, fatigue, pain, and narcotics may all momentarily impair a person's decision-making abilities. It is the responsibility of the treating physician to determine whether or not these extenuating circumstances have rendered the patient incapable of making an informed choice.

2. US[5]

When a court ruled in favour of a competent Mrs. Schioendorff who had consented to an abdominal examination under anaesthesia without being informed about the tumour in 1914, the term "informed consent" was given legal standing for the first time in the United States in Schloendorff v. Society of New York Hospitals. The surgeon removed the tumour without informing Mrs. Schioendorff of the potential adverse outcome. The Nuremberg Code had been in effect since 1947, but it wasn't until 1979 that the United States issued the Belmont Report in response to the scandal surrounding the Tuskegee syphilis study conducted by the Public Health Services Department. The paper focused on three major ethical standards to follow while doing research: respect for people, beneficence, and fairness. When a "prudent" (reasonable or average) patient voluntarily enrols in research after fully understanding the risks and advantages, this demonstrates respect for humans. The patient or study participant must be mentally capable and understand the information presented to them before they may provide their informed consent. A court will use the "prudent patient test" to determine whether a patient or participant was provided sufficient information.

Salgo v. *Leland Stanford University Hospital* (1957). Need to disclose information. The patient claimed negligence on the part of his physician when he was not warned about the risk of

[5] Nandini K. Kumar, *Informed consent: Past and present*, 4 PERSPECT. CLIN. RES. 21 (2013), /pmc/articles/PMC3601698/ (last visited Oct 20, 2022).

paralysis from a novel diagnostic procedure. [‘Informed’ is added to the notion of ‘consent.’]

Natanson v. *Kline* (1960). Another disclosure case: A woman in Kansas who had cobalt radiation treatment after a masectomy filed a lawsuit against the clinic that treated her for radiation burns. She filed a complaint for medical negligence. The guidelines indicate that she had given her consent despite not being fully informed of the risks associated.

Cobbs v. *Grant* (1972). Another California case. Cobbs suffered from duodenal ulcer. His spleen was punctured during the procedure, necessitating further surgery. Then an ulcer formed in his stomach. Cobbs thought he had not been given enough information about the potential dangers of his first procedure. Accordingly, the court shifted the burden of proof from the physicians ("what do doctors generally reveal") to the patients ("what would a competent patient need to know to make a logical choice").

3. CHINA

[6] Only the 1994 revision of the State Council's Regulation Governing the Administration of Medical Institutes mandated the concept of informed consent in China. "Any operation, invasive diagnosis, or treatment suggested by the medical institute should get the consent of the patient, as well as the signature of the patient's family member or the next of kin; in case the patient's permission is not available, the signature of the patient's family member or the next of kin is necessary; in case neither consent nor signatures is available, or in a special emergency, the doctor should prepare a proposal and carry it out only after the proposal is approved by the head of the medical institute or authorised staff," says Article 33 of the Regulation. A new Chinese legislation mandates for the first time that doctors must get permission from the patient or his legal guardian before making a diagnosis. But there's no need to disclose.

[7] Informed consent was reinforced in 1998 by the Law on Licensed Medical Practitioners, which was passed by the Standing Committee of the National People's Congress. Doctors "must introduce patient's position to patient or his family, while avoiding adverse outcome to patient," as stated in Article 26. According to this law, a physician's job is to "introduce," not "inform."

[8] The Tort Law was only approved on December 26, 2009, and it went into force on July 1, 2010. In accordance with Article 55 of Tort Law, "The medical personnel shall communicate the sickness condition and the pertinent medical measure to the patient throughout the diagnosis and the treatment." If a surgery, specialised examination, or other type of specialised care is

[6] Roy G. Beran, *Legal and forensic medicine*, LEG. FORENSIC MED. 1 (2013).
[7] *Id.*
[8] *Id.*

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necessary, the patient must be informed of the potential dangers involved, as well as any contingency plans that have been put in place. They must also seek the patient's written agreement. If the patient is unable to provide written permission, a family member must be notified and sign on the patient's behalf. If a member of the medical staff causes injury to a patient as a result of failing to uphold this duty, the medical centre will be held liable. Article 56 states that "In case of emergency, when the proposed medical plan has been approved by the head of the scientific institute or an authorised person, the essential treatment will take place only if the written consent from the patient or his family member is not accessible."

The Western heritage and culture provide as strong foundations for the informed consent theory. Jewish-Christian philosophy with its emphasis on the person provides the ethical foundation for informed consent, along with the accompanying belief and spirit of autonomy. In contrast, Chinese culture places a premium on group solidarity. Traditional ancient Chinese culture (and arguably that of all of East Asia) placed a premium on family above individuals. In China, family members are often given more weight than patients when it comes to making medical decisions. The patient's loved ones are the ones who are typically briefed about the diagnosis, potential outcomes, and treatment options on behalf of the patient. The patient's loved ones are the ones who make the final decision and give the green light for therapy to continue. Older laws gave more weight to the consent and signature of the patient's family than that of the patient themselves, and this tradition is a big reason why. The Chinese medicine physician may feel at ease informing the patient that they simply have a cold or high blood pressure. However, if the patient has cancer or another terminal condition, the doctor will never provide this information to them. Patients who get honest answers from their doctors may have their loved ones file complaints against them. In most cases, the family of the patient will make the ultimate call. It might be difficult for doctors to decide whether to follow the letter of the law or adhere to established norms.

The problem worsens when the family member has a conflict of interest with the patient or is otherwise unable to make a logical decision on their behalf. In the vast majority of situations, families will make the greatest choice possible for their loved ones. Unfortunately, the patient may suffer consequences when the family is unable to make a sound decision. Ending 2007, China saw what has been known as the "Xiao Zhijun event." Xiao Zhijun was a southern Chinese farmer living in poverty in Beijing. His seven-month pregnant wife fell into a coma after getting pneumonia. After Xiao brought her to the hospital, the physicians advised an urgent caesarean section in order to preserve the mother and child. Xiao did not believe the physicians' advice, therefore he rejected the surgery even after they persisted in trying to persuade him

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otherwise. Neither the mother nor the child survived. It sparked heated debate on whether or not a family should be included in a medical decision. The situation may become more difficult if the patient's best interests and those of the family member conflict.

VI. CONCLUSION

Since a person's health and survival are among their body's most fundamental needs, there shouldn't be any risk relating to that body's health. In India, doctors are revered as being on par with gods because they save our lives and offer us hope when things are at their worst. Since it is believed that doctors are the ones who always serve their patients in whatever circumstance, there shouldn't be any ignorance on their part. In light of the current outbreak of the coronavirus, this is very clear.

Sometimes medical professionals, whether for lack of time, a failure to perform their duties, or for any other cause, forget to sign the informed consent form. Therefore, it is crucial that doctors carry out their duties flawlessly, without any gaps that can cast doubt on their profession. For the average person, health comes first, so any negligence on the part of a doctor would be completely unacceptable. A doctor should conduct themselves responsibly and devote themselves fully to their vocation throughout the entire course of treatment.

The human status of a person determines their rights. In clinical trials, the informed consent is a crucial instrument. The obligations and significance of this assent must be morally righteous and sincere for the benefit of the participant. Informed consent is briefly described in this essay. The significance of the permission form, the legal perspective, and its obligation are all addressed. In India, informed consent regulations should be based on intricate considerations like diversity, culture, educational attainment, and demographic trends.

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