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Review Article

The Importance of Informed Consent in Medicine

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Abstract: The practice of informed consent has historical roots in various disciplines and plays a critical role in medicine as we are entering the era of patient as a consumer and doctor as a service provider. In India, there has been an increase in the number of malpractice suits that have arisen because of lack of informed consent or inadequate consent from the patients for various procedures. Based on ethical and legal principles of respect for individual autonomy the legal doctrine of informed consent states that "every human being of adult years has the right to determine what shall be done with his own body." All the procedures involving medical treatment, surgical operations, assisting reproductive technologies, treatment of mentally disabled persons and treatment of children should have proper consent in terms of age, mental capacity, free will, and full disclosure. If the patient is not medically or legally competent to give consent, the consent of the parents or guardians or any person present at the time with the patient can be taken. Any researches on a potential subject, removal of organs for transplantation, publication of information obtained during medical examination also require consent of the concerned person. Consent of the patient is not required in situations like medical emergency. Ignorance of law is not a defense in legal cases, so all medical practitioners should be aware of their duties with regard to consent in clinical setting. Any examination by doctor without prior consent amounts to an assault on the patient and liable under the tort and criminal laws. Medical Council of India (MCI) laid down the rules according to which surgical treatment without consent is considered as misconduct and is punishable
Keywords: Autonomy, ethics, Informed consent, law, medical practice, patients.

INTRODUCTION

Informed consent means an agreement, compliance or permission given voluntarily without any compulsion [1]. It can be defined as "the voluntary and revocable agreement of a competent individual to participate in a therapeutic or research procedure, based on an adequate understanding of its nature, purpose and implications" [2].

It is also fundamental and established principle in the Indian law. Self-defense of body (IPC sections 96 to 102, 104, 106) provides right to the protection of bodily integrity against invasion by other. The fundamental principles of autonomy were first expressed in Nuremberg Code of 1947 [3].

Informed Consent is now accepted as the cornerstone of medical practice [4, 5].

World Medical Association in Declaration of Helsinki (1964) emphasized upon the importance of informed consent for medical research by adequately informing the subject of the aims, methods, anticipated benefits, potential hazard, and discomfort which the study may entail [6]. All medical procedures, including examinations, diagnostic procedures and medical research on patients in the absence of consent constitute assault (IPC 351) for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained [7].

Informed consent is the continuous process of providing the patient or, in the case of a minor or incompetent adult, the custodial parent or legal guardian with relevant information by doctor regarding diagnosis and treatment needs so that an educated decision regarding consent for treatment can be made by the patient or custodial parent/legal guardian.

Treatment and diagnosis cannot be forced upon anyone who does not wish to receive them except in statutory sanction.

What needs to be disclosed? - Doctor's legal duty

The Legal Elements of Informed Consent

Complete informed consent from a legal perspective generally requires discussion of the following [8, 9]:

a. The patient's diagnosis
b. The nature and purpose of a proposed treatment or procedure

c. The risks and benefits of a proposed treatment or procedure
d. Alternatives and associated risks and benefits
e. The risks and benefits of not receiving or undergoing a treatment or procedure
f. The special precautions required postoperatively
g. What the doctor recommends

It is essential that this information be discussed in simple terminology that can be readily understood by the patient. It is also essential that the patient be given an opportunity to ask questions about his or her condition and the proposed treatment or surgery. Finally, a doctor should thoroughly document the communications process in the patient's chart. A timely and thorough documentation in the patient's record can be a strong piece of evidence in a court as the communications process in fact took place and that the physician made an adequate disclosure to the patient.

Omission of any of the above information may invalidate the consent of the patient. It is the responsibility of the treating doctor to ensure that the patient fully understands all of the information that has been provided. It is also the responsibility of the treating doctor to provide further information requested by the patient and to answer all questions asked by the patient in a manner that the patient considers satisfactory and in understandable terms [10].

What is the level or standard of disclosure?

Over time, three main models of informed consent have emerged that attempt to articulate what an adequate disclosure of information to patients really means (Table 1) [11].

Table 1: Models of Informed Consent

Model	Definition and problems
Professional model	Disclosure and discussion based on what other physicians would disclose in similar circumstances Problem: Promotes generalizations and diminishes importance of individual patient values and interests
Reasonable model	Disclosure and discussion based on what reasonable patient would want to know Problem: What is reasonable to one patient may be unreasonable to the next
Subjective model	Disclosure and discussion based solely on specific interests, values, and life plan of patient Problem: Difficult to know every important detail of patient's life; cumbersome to implement consistently
Balanced model: Reasonable and Subjective	Disclosure and discussion based on the most important and relevant interests, values, and goals of patient, as identified by both patient and physician

Exceptions to the rule for obtaining consent

There are two exceptions to the common law rule where less information may be justifiable:

- Therapeutic privilege
- Emergency life-threatening situation

Therapeutic privilege

Therapeutic privilege means that a doctor can withhold information if he/she feels that it would be psychologically damaging or harm the patient (e.g. if the patient is suicidal or mentally ill) if disclosed. Even in this case, however, a doctor may not be justified in withholding information if a patient asks a specific question [12].

Therapeutic privilege does not extend to giving doctors the right to lie to their patients. Doctors have an ethical duty to share information with their patients for their interest. However a result in any misadventure is not punishable by law (IPC 93).

Emergency life-threatening situation

The most sacred duty of the medical practitioner is to save the life of his patient. Treatment may be given without any information or consent if it is necessary to protect the patient's life or health. Where a patient is unconscious, intoxicated, and disoriented unable to consent or appreciate what is required, the doctor may administer the necessary medical treatment in good faith or for the benefit of the patient (IPC 92). Failure on the part to provide timely medical treatment to a person in need of such treatment results in the violation of his right to life guaranteed under Article 21.

Requirements for Valid Informed Consent

The practice of medicine is extraordinarily complex and difficult, with little margin for error. In most situations the doctor cannot act without a patient's "informed consent." In order for patients' consent to be "informed" and thus valid, they must be able to make a well-informed logical decision. If they agree to the treatment, understanding what it involves, they have given informed consent.

Informed consent was practically non-existent till the time COPRA [Consumer Protection Act] came into existence. This is seen as more of a legal requirement than the ethical moral obligation on part of the doctor towards his patient [13].

Informed consent is meant to force the doctor to give the patient the knowledge that will make patient to promote individual autonomy and freedom of choice [14].

The principle of self-autonomy of a person is the availability to think, decide, and act on one's own deliberation and without coercion, even if in the end the person involved decides to let someone else guide him/her. The constitution of India in Article 21 provides a right to life and personal liberty [15].

What are the Ethical Elements of Informed Consent?

There are two ethical justifications for the claim that doctors should get consent from patients for tests or treatments.

The first is based on the moral (and ethical) principle of autonomy, according to which a person has a right to determine the course of her own life and to be free (within limits that must themselves be justified) from interference by others. A central aspect of this right is a person's right to bodily integrity. It is impermissible for any person (including a doctor) to invade or manipulate the body of another without permission.

The second is based on the ethical principle of beneficence, according to which doctors should act out of compassion or concern for their patients and aim at doing what will be best for them. Patients are typically the best source of information about what will make their lives go better.

What are the Criteria of Valid Informed Consent?

Consent from a patient is generally considered to be valid if (and only if) the following criteria are satisfied [16]:

1. The patient has **decision-making capacity**. (The ability to take decisions regarding consent and degree of ability of the patient to understand the nature and consequences of the treatment offered)

2. The patient has been **adequately informed**. (Means that sufficient amount of information about the nature and consequence of the treatment has been disclosed to the patient).

   There are three 'standards of disclosure' for adequate informing.

   a. Professional Practice Standard. The amount of information disclosed is determined by the traditional practice of a professional community, such as a community of physicians or clinical psychologists.

   b. 'Reasonable Person' Standard. The pertinence of a piece of information is measured by the significance a hypothetical reasonable person would attach to it in deciding whether to undergo a procedure. The physician must disclose all information the reasonable person would judge relevant.

   c. Subjective Standard. Adequacy of information is judged by reference to the specific beliefs, desires and fears of the individual patient. Typically, it is expected that a physician will meet (ii) and, where she has (or should have) information about a particular patient that would shed light on the desirability for that patient of additional information, (iii) as well.

3. The patient has not been coerced. The patient must consent to treatment voluntarily. If she is forced to agree or threatened with grave consequences if she refuses, her consent is not valid.

Informed Consent is a continuous process, which includes the exchange of information and development of choices. If after due information the patient gives contradictory or doubtful signals in a particular procedure, then he also has the right to withhold consent at any point of time of the ongoing procedure.

The Constitution of India in its Penal Code (IPC) provides protection to the doctors against legal actions in any misadventure that had happened during a procedure which is done in good faith after taking well-informed consent of the patient or his/her relatives or legal guardian in case of minor or an insane (IPC 87, 88, 89) [17].

As per Section 90 of IPC, if any consent given under the following circumstances will not be true consent.

1. By a person under fear of injury or,
2. By a person who is under misconception of the facts and person who obtain consent knows or has reason to believe that or consent was given inconsequence of such fear / misconception.
3. By intoxicated person or,
4. By a person who is of unsound mind or, unable to understand the nature and consequences of that to which he gives consent.
5. By a person who is below the age of 12 yrs.

At the international level there are six major hindrances to genuine informed consent:

1. Confusion and forgetfulness: some lay patient may have difficulties in remembering and

understanding details relating to treatment comparisons. This may lead to the patient consenting without appreciating the risks [18].
2. Cultural barriers: these may include presumed differences in the construction of personhood, language differences, and economic power [19].
3. Psychological forgetfulness by patient in respect of undesirable information especially related to risk [20].
4. Situational pressure on the patients may be occasioned when they are involved in several procedures [21].
5. Implicit forms of coercion such as the manner in which benefits are presented may threaten the patients [22].
6. Procurement of informed consent may pose challenges to the doctors' assumed beneficence, thus leading to some resistance [23].

These factors can affect the quality of doctor patient interaction. Thus, doctor should pay greater attention to this issue so that patients can be better informed and have greater comprehension about the informed consent documents that they are required to sign. Furthermore, doctor should take all the steps necessary to ensure that patient fully understand what is being stated in the consent form.

For practical purpose, we divide the consent into implied and expressed form depending upon the circumstances.

Implied Consent

This is the trust and empathy that a patient develops with his doctor when he first comes in contact and due to this empathy he allows history and examination of himself. This empathy and trust forms the basis of implied consent and is the most commonly employed type of consent in general and medical setup.

Implied consent is limited to the examination up to inspection, palpation, and auscultation, excluding examination of intimate parts (private parts). Whereas several European countries have defined the intimate parts, which generally include all the natural orifices of the body and genital parts including breast examination in females. In UK, oral cavity has been excluded from the list of intimate parts as for the requirement of DNA sampling [24].

The limitations of implied consent are that there is always a scope for misunderstanding between the doctor and patient on what was actually implied by the patient's actions.

Expressed Consent

An expressed consent can be written or verbal. This is taken when any material risk is involved. Expressed consent includes informed consent, which is the ideal form of consent because it includes all aspects of meaningful decision-making where he/she can make a balanced judgment.

It is appropriate to make an entry in the patient's clinical record which may be of use in future as corroborative evidence to support the defense taken by the doctor.

Patients may wish to withdraw their consent although they might have signed a consent form earlier. In such a case, documentation in patient's medical record is important.

Oral expressed consent, when properly witnessed, is as valid as written expressed consent, but latter has the advantage of easy proof and permanent record.

Tacit consent is failure of the patient to disagree or dissent [25]. This form of consent is open to interpretation and is therefore less reliable upon legal scrutiny.

Embodied consent is assessment of the patient's body language for consent to treatment, prior to and during treatment [26]. Since express consent is initially recommended for treatment interventions e.g. cervical manipulation, embodied consent becomes important during the treatment. The body language of the patient should be observed specifically during the pre-manipulative hold and assessed for indications that they may be reconsidering the initial express consent that was given. If the therapist observes body language that may indicate the patient is uncomfortable with proceeding, the therapist should stop the procedure and ask the patient if it is acceptable to continue.

Role of hospital

"Does the hospital have a responsibility to ensure that the patient received adequate disclosure?" Under the theory of "Respondent Superior", an employer (hospital) could be held jointly liable with an employee (doctor) whose failure to obtain informed consent could be shown to have caused injury and damage to a patient. A hospital policy must govern the procedure by which consents are obtained. A patient can withdraw consent after signing a consent form. Though this is the rule, but there are practical limitations. In such cases, if patient is admitted in a hospital, it is the obligation of the hospital to make sure that no member of the hospital staff performs the refused procedure.

Who can give consent?

The legal age for giving a competent consent in India is 18 years as per the Indian Majority Act [27]. Whereas in children between 12 and 18 years consent for physical examination and treatment [17]. For a person under 12 years of age, or of unsound mind, his/ her guardians / person in whose lawful custody he / she is, can give consent (89 IPC) [28]. Treatment of children is

mainly under the consent of parent or guardian or under the doctrine of in loco parentis.

Locoparentis: "*To act in loco parentis* [in place of the parent]" has come to mean not only "to act as a *surrogate* for the parent," but also, implicitly, "to act with the devotion, motivation, and dedication of the parent" in the best interest of the child.

In a emergency involving children, when their parent or guardian are not available consent is taken from the person in charge of the child for example school teacher can give consent for treating child, who become sick during picnic away from the home town or the consent of the principal of a residential school.

There are other situations like legally separated parents or sole custody authorized to one parent or unmarried mothers, where the consent could be obtained from the mother or who is legally entitled.

None of the children should be operated for organ transplant or tissue removal until he/she is minor (less than 18 years) as per the guidelines of Human Transplant Amendment Act 2011[29].

No one can give consent for any treatment on behalf of adult, but it is advisable to be on the safer side that the doctor should take the consent of the next of kin of the patient. Local guardian can give consent on behalf of a person only if the treatment is an emergency one. Unconscious / Unknown patient when admitted in hospital, the medical superintendent / In charge of hospital can give consent for treatment.

Pathological autopsy should not be carried out without the consent of next of kin of the deceased. In case of consent for donation of organ after death the will of the deceased is enough. Not taking consent is considered as deficiency in medical services under the section 2(1) of the Consumer Protection Act.

Consent of one's' spouse is not necessary for the treatment of other. Husband or wife has no right to refuse consent to any operation, which is required to safeguard the health of the partner.

Sections dealing with consent under Indian law

Sections 87 to 91 of Indian penal code deals with consent. Section 88 of IPC lays down that an act is not offence if it is not intended or not known to be likely to cause death, which causes any harm to a person from whose benefit it is done in good faith with his consent to suffer it. Thus after a valid consent if surgeon operates on patient and patient dies on the operation table, then the surgeon cannot be held guilty of murder. Persons who are non-qualified in medical profession are not allowed to take the plea of this section, as they are not said to do the act in good faith. IPC 52 says that an act is only done in good faith if it is done with due care and attention. Section 91 of IPC serves as a corollary to sections 87 to 89. It states that the exceptions contained in sect 87 to 89 do not extend to acts, which are offences independently of any harm, which they may cause to the person, giving consent. Thus causing miscarriage (unless caused in good faith for the purpose of saving the life of the women) is an offence independently of any harm which it may cause or be intended to cause to the women and the consent of the women or of her guardian for causing such miscarriage does not justify the act (91 IPC) [28].

Any medical procedure except physical examination requires written consent. Written consent should refer to one specific procedure and not blanket permission on admission to hospital. It is on the safest side to take the consent of a spouse if the operation destroys or limits sexual function. While not legally necessary it is good medical practice to consult with relatives of patient in patient's best interest and ones this has been established then doctor can continue to give treatment in good faith.

Upto1972, there was no provision in the Criminal procedure code under which court can compel the accused person to get himself medically examined. Consequently police faced lots of hardship in investigations especially dealing with criminal cases. Law commission in its 41st report recommended that provision be made in the code of criminal procedures for making lawful the medical examination of the accused at the request of the police. Eventually, bearing all these aspects in mind the parliament included a new provision in the code of criminal procedure 1973 in section 53 [30].

Prisoners and persons released on bail can be treated without their consent in the interest of justice of society. A registered medical practitioner can examine an accused by using reasonable force if the examination is requested by the investigating police officer not below the rank of police sub inspector (CrPC53). (Force should be applied by police.) Under subsection 2 of CrPC 53 which lays down that, whenever the person to be examined is female the examination shall be made only by or under the supervision of female registered medical practitioner. The obtaining of such evidence, it has been held, is not violative of article 20(3) of constitution, which grants protection against self-incrimination. Consent of the patient cannot be defense to medical practitioner in negligence [31].

Procedure to obtain consent

Consent must be obtained before treatment begins. Preferably, the ideal timing of consent is at the time of admission for a particular procedure [32]. Asking the patient for consent while treatment is in progress may adversely influence the patient's decision-making and is not recommended [33].

For changes in treatment (introducing a different type of technique), the full process of informed consent must be undertaken and consent explicitly obtained verbally or in writing.

Patient should also be made aware that this ongoing consent (voluntarily) can be withheld at any point of time during treatment or procedure.

It should also be borne in mind that merely signing the consent form does not exclude doctor's responsibility if he is negligent in carrying on his duties [34].

When a form is utilized, it is best to use simple words and phrases, avoiding technical terms, so that it is readily understandable to a lay person. Broad statements such as "any and all treatment deemed necessary…" or "all treatment which the doctor in his/her best medical judgment deems necessary, including but not limited to…" should be avoided. Courts have determined it to be so broad and un-specific that it does not satisfy the duty of informed consent.

The following should be included in "informed consent" form [35]:

1. Name and date of birth of pediatric patient
2. Name and relationship to the pediatric patient/legal basis on which the person is consenting on behalf of the patient
3. Description of the procedure in simple terms
4. Disclosure of known adverse risk(s) of the proposed treatment specific to that procedure
5. Professionally-recognized or evidence-based alternative treatment(s) to recommended therapy and risk(s)
6. Place for custodial parent or legal guardian to indicate that all questions have been asked and adequately answered
7. Places for signatures of the custodial parent or legal guardian, dentist, and an office staff member as a witness.

Refusal of Consent

A competent adult has a right to refuse treatment When this situation occurs, it is important to consult and discuss with all those who are concerned about the patient except in a very few circumstances like issues associated with public health, military personnel or prisoners. All discussions and actions taken should be documented in the patient's healthcare record.

Pediatric Informed Consent

It is generally assumed that parents will act in the best interests of their children. Parents have the legal right and obligation to make decisions on behalf of their children in matters of health and well being. For that reason, parental consent is required in pediatric care and in the care of minor who is not yet free from the care and custody of parental control due to being under the age of majority minors.

Consent of maternity patients

Consent to obstetric procedure should be discussed during the antenatal period. If the doctor finds that the wishes of the pregnant woman are unusual, these should be noted carefully in the antenatal record.

In Assisted Reproductive Technologies that include fertilization involving manipulation of gametes outside the human body and the transfer of gametes or embryos into the body, informed consent should be taken from the spouses as well as the donor, as the case may be, for possible side effects, and the risk of treatment. As per the Delhi Artificial Insemination Act 1995, written consent of both husband and wife seeking artificial insemination and also consent for single screen semen for HIV through enzyme-linked immunosorbent assay (ELISA) should be taken [36].

For contraceptive sterilization, consent of both husband and wife should be obtained. Consent given for an illegal act is not valid e.g. Criminal abortion. Doctor is punishable if he performs such an act even with consent from the patient.

Consent in Psychiatry

Mentally disabled persons or the persons who have diminished ability to consent for any of the medical procedures should be checked in terms of capacity and the capacity of the person who gives consent. Where there is no durable power of attorney or appropriate next of kin, it may be prudent to petition the courts to provide a guardian to protect the interests of the patient. This is especially important when conflicting interests are present. It is expected that the patient's interests can and will be adequately protected by any surrogate decision maker. They can be admitted or treated or discharged from a mental hospital as per the guidelines laid in Indian Mental Health Act 1987 [37].

As far as the emergency is concerned they are supposed to be treated under the protection of IPC 92 and Article 21 of the Indian Constitution. None of such insane persons should be operated as far as he/she is alive for the organ or tissue donation [38].

Privacy and Confidentiality

One of the conditions on which informed consent rests is that patients privacy will be respected. Privacy refers to "persons and to their interest in controlling the access of others to themselves" [39]. Safeguarding this information is a key part of the relationship of trust and respect that exists between the doctor and the patient. Depending on the type of treatment whatever data are collected, doctor may take several steps to ensure the confidentiality of their patients' information by use codes.

DISCUSSION

Barring physical examination, informed consent is necessary for every medical examination and surgical procedures, which should be obtained in or in the presence of disinterested party.

Informed consent is also required in anesthesia (local, regional, or general) with explanations regarding the procedure of anesthesia, its complications during the procedures, and it's after effects. If during the ongoing procedure any extension of the procedure is required which is not covered, fresh consent should be insisted.

All the radiological investigations which involve isotopes, dyes, or other image enhancers should be done with informed consent. Similarly, treatment by chemotherapy and radiotherapy should involve consent for treatment after proper disclosure of side effects and further disabilities. Research studies or clinical trials should be conducted and have informed consent as per the guidelines laid by Indian Council of Medical Research [40].

Separate care should be taken in case of blood transfusion during the procedure and patient should have proper information about the amount of blood to be transfused.

It is on the safer side to take the consent of spouse if the operation destroys or limits sexual functions.

All the transplants involving human tissue or organ should have consent based upon the guidelines of Transplantation of the Human Organ Act 1994 and Transplantation of Human Organ (Amendment Bill 2011) [41]. For cadaver donor transplants, informed consent from next of kin should be taken. If prior consent for organ donation before death is given in the presence of two or more witnesses, then transplantation of the organ should be presumed and is permissible without seeking further consent [42].

In the era of advancement of knowledge and technique the belief that the patient will be misguided, if the doctor is not having reasonable care and skill. Consultation, consent and clinical confidence will never put the doctor in Medical litigation.

While it is not legally necessary it is good medical practice to consult with relatives of patient in patient's best interest and ones this has been established then doctor can continue to give treatment in good faith.

CONCLUSION

The informed consent promotes the rights of a patient as autonomous beings to ensure that they are treated with justice, beneficence, and respect. Neglecting its importance can lead to unethical behavior and the loss of patient's rights.

Patients nowadays no longer want to be treated as passive recipients of medical care. Medical litigation and demands for medical accountability is the trend of the day.

To avoid negligence and breaching, the doctor should exercise his skill with competence in accordance with accepted practice. He should discuss his diagnosis and treatment plan with the patient. If the patient inquires about the risks of proposed medical treatment, the doctor must disclose the material risks to the patient. It is good practice to document contemporaneously his advice to which the patient has consented. In doubt, it is prudent for the doctor to seek a second opinion from his colleagues professing a similar skill [09].

It can therefore be concluded that Informed Consent should be taken seriously by all clinicians and medical researchers in the broader interest of patient-doctor relationship and there should be no compromise in providing information that is not "reasonable" in the eyes of the court.

In the event of an adverse medical outcome written records of such discussions can be doctor's best defense as the court can demand relevant documents/ X-ray films of the patient [43, 44].

Informed consent process can be improved by 8 ways [45]:

1. Work on your rapport - The importance of good rapport between the patient and doctor cannot be overemphasized. The level of rapport is a better predictor of the risk of litigation than the actual content of any particular discussion
2. Discuss all treatment options with regardless of insurance coverage - Determining what should be disclosed as a *material* risk in the consent process can be challenging.
3. Use the ABCDEF mnemonic which is useful for guiding and documenting your discussion with the patient:
    - **A**lternative therapies available
    - **B**enefits of the therapy proposed
    - **C**ommon but not devastating risks
    - **D**evastating but not common risks
    - **E**xtra considerations specific to this patient
    - **F**acial expressions, body language, and questions.
4. Decide how much medication information the patient needs
5. Discuss how test results will be communicated - Laboratory or radiology investigations and their results introduce a unique set of issues. Particularly for non-routine lab work, it is prudent to discuss the advantages,

disadvantages, and limitations of the test being ordered or recommended.

6. Keep a record of referrals - A patient generally has the right to refuse specialty treatment or referral to a specialist, once informed of the risks of delay or lack of treatment after making such a decision. If a patient still refuses referral, document the decision in case it results in a delayed diagnosis or an adverse outcome.
7. Avoid making guarantees about procedure - All procedures, including associated anesthesia, require a discussion of risks and benefits. If appropriate, also discuss available alternative procedures and your reasons for not recommending them
8. Document, document, document - Documentation is a necessary, final step. It records the process that is vital to good patient care and it may be the only proof that a discussion took place. Legal case opinions shed little light on what represents adequate documentation.

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