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Legal Safeguards in Surrogacy: Clinical Permission and Informed Consent in the Indian Context

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Abstract: *Right to privacy and bodily autonomy is an established Fundamental right in India. Right to bodily autonomy includes within its fold multiple rights including the right to decide what medical procedure can be performed on one's body and right to know in advance the consequences of these procedures. However, most medical procedures are performed by obtaining an undertaking form, from the patient and there exists a doubt whether the patient has actually understood the medical procedure and the consequences it will have.*

Surrogacy is a medical process wherein the surrogate mother carries the child for a full term in her womb, which she agrees to give away upon birth to the intending couple for whom the surrogacy is carried out. With advancement of science and technology and the advent of techniques like test tube babies and In Vitro Fertilisation (IVF), surrogacy became one of the sought-after methods to obtain a child who is genetically connected to the intending couple. Earlier surrogacy was performed for helping the intending couple and had emotional angle attached. However, in under developed and developing countries it became a source of income for women who were ready and willing to rent their womb. Hence surrogacy became an interplay of science, economy, and contractual legal obligations leading to the popularization of commercial surrogacy. Due to lack of legal control surrogacy started operating like a business with little regard to the rights of the surrogates especially right to health and informed medical consent.

The present paper is an attempt to explore the right to health and informed medical consent of the surrogates with special reference to Surrogacy (Regulation) Act, 2021..

Keywords: Surrogacy, IVF, Informed Medical consent, Right to health

I. INTRODUCTION

The presumption that the surrogate did not provide informed consent and was coerced into entering the surrogacy contract is the core argument for prohibiting commercial surrogacy in India and around the world. This presumption is the basis for the prohibition. Informed consent is a concept that is both ethical and legal. A dual informed consent is required for surrogacy, which includes agreement from both the medical community and the contracting party. Nevertheless, in the context of a surrogacy arrangement, it is presumed that neither of these consents has been obtained. The significance of medical and contractual permission, as well as the ideas underlying them, are discussed in this study paper. After doing our fieldwork in this region, the researcher is currently seeking to determine whether or not these essentials are present by utilizing the results of the fieldwork undertaken. To determine whether or not surrogates provided informed consent before engaging in surrogacy arrangements, the researcher employed a technique known as planned interviews, conducting interviews with both surrogates and doctors. Following an examination of informed consent from a medical point of view, the researcher will then examine free consent from the point of view of contract law, and ultimately, the researcher will concentrate on the results of the fieldwork.

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Informed Medical Consent

Every patient has the right to know what to expect from their process, before, during, and after their treatment or medical surgery. This includes any potential benefits or drawbacks of the therapy.It is essential for the practitioner to obtain the patient's informed consent in the field of medicine, as the practitioner may be subject to legal repercussions in the event that any treatment or operation is administered to the patient without the patient's consent. It has developed into an essential part of the practice of medicine, and it plays a significant part in safeguarding the legal rights of patients. All of the actions that can be done with the patient's body are up to the patient to decide.[1] For the benefit of the general public, informed consent can be defined as the consent, acquiescence, and authorization to a medical procedure or treatment that is provided without the use of pressure or force. A capable individual or patient's voluntary and revocable consent to participate in the treatment, therapy process, or study after having a comprehensive understanding of the nature and consequences of the same can be characterized as the concept of informed consent. The patient's confidence and faith in the medical practitioner may be increased if they are provided with adequate information regarding the treatment that they are required to undergo.

It is possible to convey comprehensive information to the patient either vocally or in writing while communicating with them. A key component of conducting medical research with participants' informed consent was highlighted in the World Medical Association's Declaration of Helsinki. According to the statement, for individuals to give their informed consent, they must be adequately informed about the aims, procedures, anticipated findings and advantages, as well as potential downsides and hazards associated with the study activity. Any surgical procedure or medicine that is administered to the patient or subject without the patient's or subject's comprehensive informed permission is considered an assault and is penalized under Section 130 of the Bhartiya Nyaya Sanhita, 2023 regulations. The provision of comprehensive information to the patient regarding the diagnosis and treatment is included in this process. This allows the patient to make an educated decision regarding their medical care.[2] Ethical considerations that respect the patient's physical autonomy and are consistent with the patient's treatment goals are included in informed consent, in addition to the legal difficulties that are involved. The physician is required to provide such disclosures due to the doctor-patient fiduciary relationship. Furthermore, it has therapeutic effects such as increased patient compliance and a reduction in the length of time required for recovery.[3]

The medical practitioner's disclosure should cover diagnosis, therapy, benefits and risks, alternative therapies, precautions, and physician recommendations. As a result of the fiduciary relationship that exists between the doctor and the patient, the physician is obligated to disclose such disclosures. Additionally, it offers therapeutic effects, such as greater patient compliance and a reduction in the amount of time needed for healing.

The disclosure made by the medical practitioner should include consultation of the diagnosis, the nature of the therapy, the related benefits and dangers, information on alternative therapies and their merits and disadvantages, any necessary precautions, and the recommendations made by the physician. It is imperative that this information be communicated to the patient in a straightforward manner, ensuring that they can comprehend it and have sufficient opportunities to inquire about it with the medical practitioner. Furthermore, the physician is obligated to maintain a comprehensive

[1] Daniel E. Hall, Allan V. Prochazka, Aaron S. Fink, Informed consent for clinical treatment, Canadian Medical Association Journal vol 184(5), 2012, March, DOI 10.1503/cmaj.112120, pg. 3, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3307558/, accessed on 8th September 2022 at 10:08 AM IST

[2] Kusa Kumar Saha, Ambika Prasad Patra, Siddhartha Das, The importance of informed consent in medicine, Scholar Journal of applied medical science, ISSN 2320-6691, 2013, volume 1(5), pg. 455, available at: https://saspublishers.com/article/5596/, accessed on 8th September 2022, at 15:55 pm IST.

[3] Steven B. Dowd, The legal, ethical, and therapeutic advantages of informed consent, Journal of nuclear medicine technology, vol 24(2), June 1996, pg. 129, available at: https://tech.snmjournals.org/content/24/2/129, accessed on 8th November 2022 at 19:36 pm IST

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written record of the aforementioned facts. An informed consent requires the physician to provide the patient with comprehensive knowledge regarding the medical treatment and procedure. This gives the patient the opportunity to make an independent decision without being subjected to any type of coercion or fear. In accordance with Section 28 of the Bhartiya Nyaya Sanhita, 2023, permission is deemed to be illegitimate if it is obtained via the use of intimidation, material damage, or a misunderstanding of the facts. Furthermore, if the person who is requesting permission is aware that it is being granted under such conditions, or if it is granted by someone who is under the age of 18, under the influence of alcohol, or who is not of sound mind, then it is regarded to be invalid. [4]

The primary objective of informed consent is to provide patients with the ability to make decisions that are rational and autonomous regarding the treatment alternatives available to them. However, this objective is not achieved in the majority of cases.

It is generally accepted that the following factors constitute obstacles to the process of obtaining informed consent: [5]

Distraction and Uncertainty

Cultural challenges.

Several psychological issues, including selective amnesia in relation to unfavourable circumstances.

Circumstantial stress is an indirect form of coercion that compels the patient to participate in therapy.[6] The patient has the option of expressing their consent overtly or implicitly, or it can be codified. The patient visits the physician with self-assurance, trust, and compassion for their condition. It is apparent when it is inferred from the patient's body language and gestures

prior to and during therapy.[7] Additionally, it is articulated when it is conveyed through written or spoken formats. As a result, the patient may directly provide it by rolling up his sleeves and consenting to an examination. However, in certain circumstances, formal authorization from the patient is required, particularly for procedures that are hazardous or pose a risk to the patient's life.[8] It is advisable to obtain the patient's consent prior to initiating treatment. As a result of the potential for the patient's decision-making to be hindered and negatively impacted, obtaining authorization during the procedure of continuing treatment is typically not recommended. Within the context of the informed consent procedure, it is necessary to notify the patient that they have the ability to withdraw their consent at any time during the treatment process. The patient, the patient's spouse, and the donor are all required to give their informed consent in cases involving assisted reproductive technology (ART). [9]

A number of different models can be utilized in order to successfully obtain informed consent. In accordance with the professional model, the disclosures include information that would be provided by other medical professionals. In accordance with the reasonable model, the physician ought to convey to the patient the information that they would

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[4] Ibid pg. 457

[5] Daniel E. Hall, Allan V. Prochazka, Aaron S. Fink, Informed consent for clinical treatment, Canadian Medical Association Journal vol 184(5), 2012, March, DOI 10.1503/cmaj.112120, pg. 4-5, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3307558/, accessed on 8th September 2022 at 10:08 AM IST

[5] Kusa Kumar Saha, Ambika Prasad Patra, Siddhartha Das, The importance of informed consent in medicine, Scholar Journal of applied medical science, ISSN 2320-6691, 2013, volume 1(5), pg. 457, available at: https://saspublishers.com/article/5596/, accessed on 8th September 2022, at 15:55 pm IST.

[6] Kusa Kumar Saha, Ambika Prasad Patra, Siddhartha Das, The importance of informed consent in medicine, Scholar Journal of applied medical science, ISSN 2320-6691, 2013, volume 1(5), pg. 457, available at: https://saspublishers.com/article/5596/, accessed on 8th September 2022, at 15:55 pm IST.

[7] Ibid

[8] Steven B. Dowd, The legal, ethical, and therapeutic advantages of informed consent, Journal of nuclear medicine technology, vol 24(2), June 1996, pg. 129, available at: https://tech.snmjournals.org/content/24/2/129, accessed on 8th November 2022 at 19:36 pm IST

[9] Kusa Kumar Saha, Ambika Prasad Patra, Siddhartha Das, The importance of informed consent in medicine, Scholar Journal of applied medical science, ISSN 2320-6691, 2013, volume 1(5), pg. 460, available at: https://saspublishers.com/article/5596/, accessed on 8th September 2022, at 15:55 pm IST.

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typically anticipate finding out. When it comes to the data that is offered by the subjective model, the patient's specific interests and his intentions for the future serve as the foundation.[10] The approach that is considered to be well-rounded has aspects from both the rational and the subjective perspectives. As a result, informed consent operates differently depending on the jurisdiction and the field of practice, and there are no rules that are universally accepted.[11] For example, when a patient is about to have surgery, medical professionals are obligated to provide them with thorough information regarding the process, which should include any potential risks. When it comes to the risks that are involved with surgical procedures, it is of the utmost significance to provide patients with accurate information. It is essential to take into consideration any specific circumstances, such as commitments related to one's job, concerns over one's family, religious beliefs, and insurance policies. It is of the utmost importance to involve a member of the patient's family or a close friend who is able to interact with the patient in circumstances when there is a language barrier. [12]

A study conducted in the United States and Canada found that patients saw this process as an opportunity to trust their doctors more and take a leap of faith. As a result, the two parties work together in a partnership, with the patients and doctors agreeing that neither should have too much say in the matter. Although it is ultimately the patient's responsibility to make their own decisions, both countries found that patients saw this process as an opportunity to take a leap of faith. [13]

Due to the fact that patients previously adhered to their physicians' directives without question, the notion of Informed consent has become more pertinent as the number of lawsuits filed against physicians has increased. Furthermore, consumer protection legislation have an effect on the medical business since it has switched its focus to the patient. This movement influences the industry. [14]

[10] Ibid pg. 456

[11] Daniel E. Hall, Allan V. Prochazka, Aaron S. Fink, Informed consent for clinical treatment, Canadian Medical Association Journal vol 184(5), 2012, March, DOI 10.1503/cmaj.112120, pg. 3, available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3307558/, accessed on 8th September 2022 at 10:08 AM IST

[12] Melissa Hanson and Dennis Pitt, Informed consent for surgery: risk discussion and documentation, Canadian Journal of surgery, vol 60(1), 2017, doi:10.1503/cjs.004816, pg. 2, available at: https://pubmed.ncbi.nlm.nih.gov/28234594/, accessed on 8th November 2022 at 19:53 IST

[13] Ibid pg. 6

[14] Steven B. Dowd, The legal, ethical, and therapeutic advantages of informed consent, Journal of nuclear medicine technology, vol 24(2), June 1996, pg. 131, available at: https://tech.snmjournals.org/content/24/2/129, accessed on 8th November 2022 at 19:36 pm IST