Current Scenario of Informed Consent in India

This whitepaper discusses about Informed Consent (IC), its need and origin. Subsequently, the paper reflects on the essential elements of IC, its current scenario in India and steps that can be taken to improve the quality of IC process in India.

By:
Anupam Sharma
Dr. Shivali Arora

What is an Informed Consent?

Informed consent (IC) is a process or a mean to confirm that the patient or his/her legal guardian has been completely informed by the physician or the researcher about the disease, the treatment procedure planned, complications and/or other adverse effects associated with it. The patient is also informed about the other treatment choices available for the disease and that the patient has made the choice for the treatment voluntarily without any coercion and bias [1]. However, this ethically and legally governed practice of sorting a consent still lacks in protecting the welfare and autonomy of research participants; specifically in developing countries like India.

Informed Consent in Medical Practice

In medical practice, IC is categorized into three types:

1. Implied Consent
2. Expressed Consent
3. Embodied Consent

1. ***Implied Consent:*** This is the most common type of consent used by general and hospital practitioners. It is not in the written form, but is legally effective. The patient implies consent to medical examination, *i.e.*, limited to inspection, palpation, and auscultation, excluding examination of intimate parts (private parts). However, the implied consent possesses a limitation, *i.e.*, there are chances of misunderstanding between the doctor and patient. Implied consent is generally exercised when a patient visits hospital or clinic for treatment in cases such as, a comatose patient requiring rapid initiation of treatment, or a mentally retarded patient admitted to hospital in absence of legal guardian [2, 3].
2. ***Expressed Consent:*** The expressed consent can be obtained both orally or in the written form. Though, oral consent is considered equally valid if witnessed properly, written consent is preferred as it can be easily stored as a proof and permanent record. It is advisable to take oral consent in the presence of an unconcerned party like any literate paramedical staff, for example, pharmacist, nurse, etc. In case, a

patient wishes to withdraw the consent after signing it, it is necessary that the same is documented in the patient's medical record clearly [2, 3].

3. ***Embodied Consent:*** This type of consent is of significant importance especially during the treatment. As per this consent, it is suggested that patient's body language should be assessed for consent to treatment, prior to and during the treatment. However, it is recommended that express consent is also taken before starting the treatment, as the role of embodied consent is limited only during the treatment. Specifically, the body language should be observed during the pre-manipulative hold and assessed for any possible signs, which indicate that the patient may be thinking to reconsider the express consent given by him/her initially. If the body language of the patient indicates that he/she is uncomfortable during the treatment, the doctor should stop the procedure immediately and ask the patient if he/she wants to continue or discontinue the procedure [3].

Informed Consent in Human Experimentation

IC in human research is categorized in to eight different types. **Figure 1** presents the brief description of the types of ICs used in human exp***e***rimentation [4].

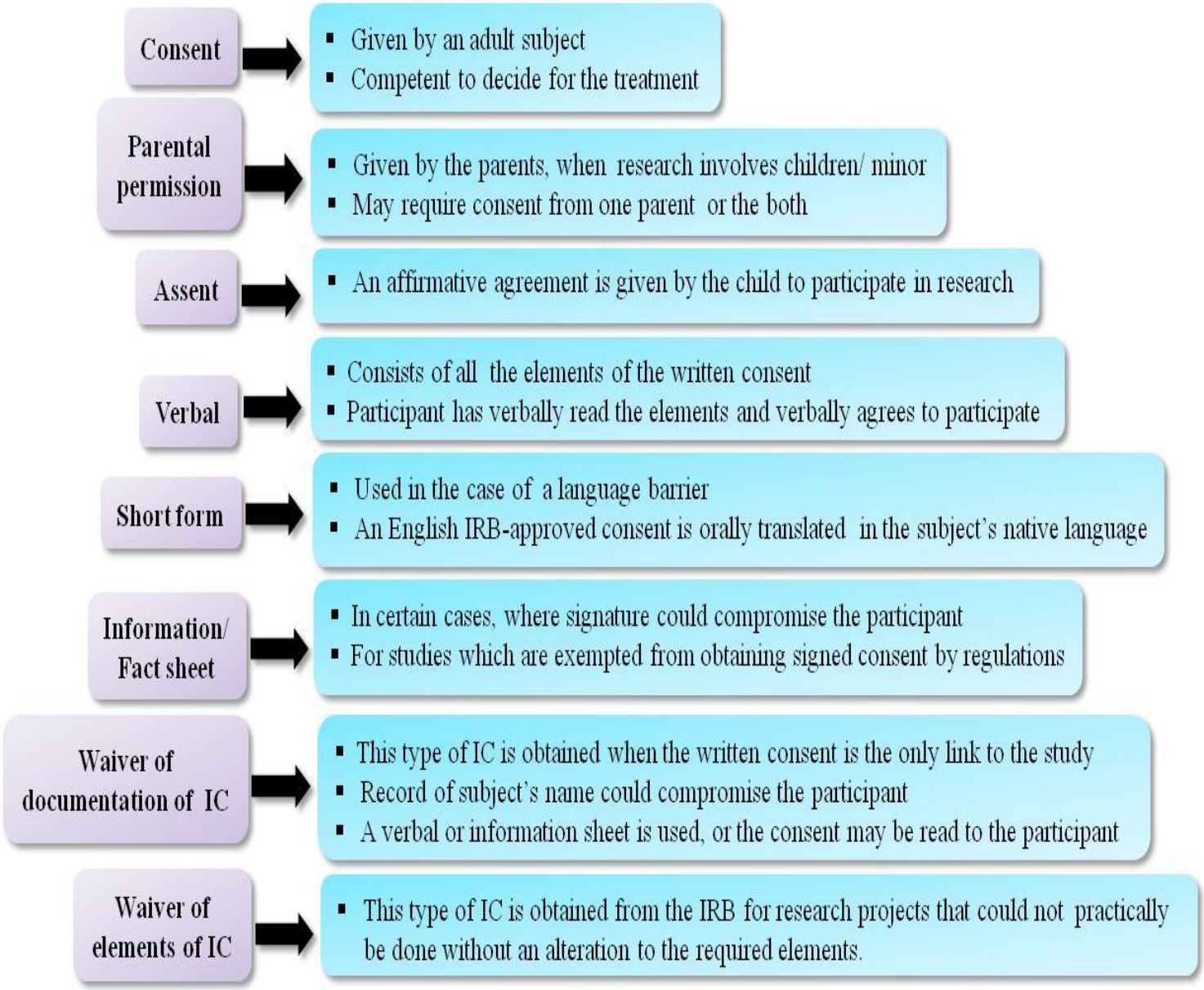
Need of Informed Consent

The paternalistic attitude of physicians has been known to exist since ancient times [5]. Physicians believe that patients should follow the advice for treatment as recommended, thus the perspective of the patient is commonly not considered [1]. It is due to the myriad research experiments conducted unethically in the 20th century; the process of IC came into practice. Therefore, now it is important to obtain consent, both in clinical practice and biomedical research [6, 7].

Origin of Informed Consent

The Nuremberg Code was developed in April 1947, which is a set of principles to be followed for ethical conduct of human experimentation [8]. **Figure 2** presents the origin of IC.

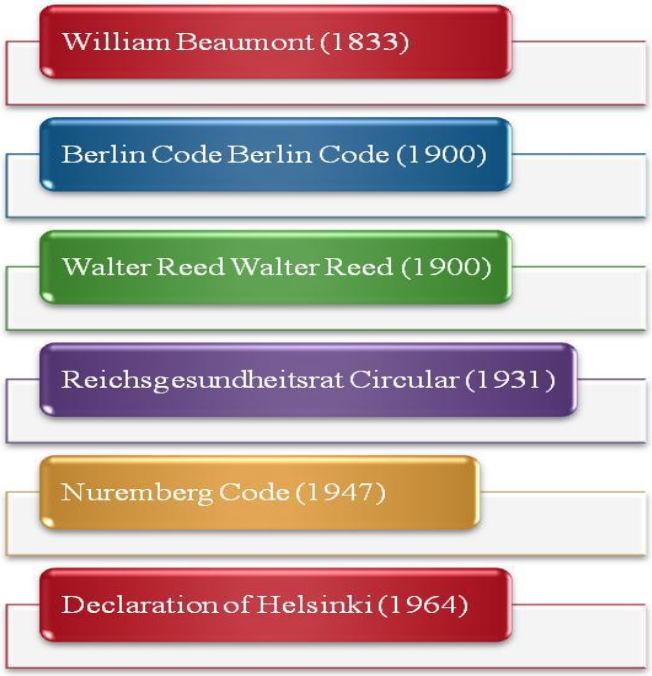
Figure 1: Types of Informed Consent in Human Experimentation



Nuremberg Code was developed as a response to research done on human participants without their willingness by Nazi physicians and investigators [9]. This code consist of 10 principles, the very first of which states that "the voluntary consent of the human subject is absolutely essential." As per the Nuremberg Code, the patient should have the right to make a choice, be legally able to give consent,

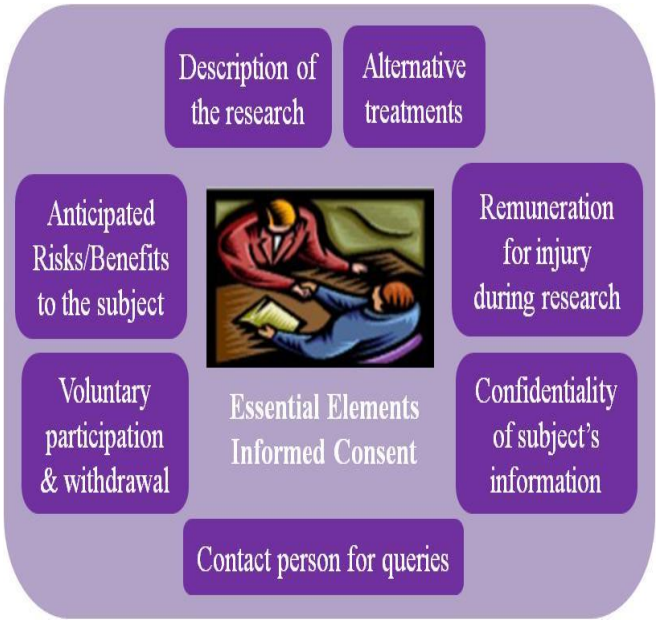
should have sufficient knowledge about the treatment and should not be forced or threatened to participate in the research [10]. Since then the model of obtaining consent has evolved through the Declaration of Helsinki that was adopted in 1964 and has undergone seven revisions and two clarifications [11].

Figure 2: History of Informed Consent Origin



Thus, the paternalistic model shifted to IC in the 20th century, but the situation is still the same in developing countries including India despite the strict rules and regulations governing ethical conduct of research on humans [5].

Essential Elements of Informed Consent



Federal regulations mandate some elements that need to be included in an IC. These are:

1. A sentence stating that the study involves research, details the purpose of research, expected duration of subject's participation in the study, the procedure to be followed and identify experimental products.
2. A description of any foreseeable risks, discomforts, harms, and inconvenience for the subject that may arise and are solely related to the research.
3. A description of benefits to the subject, or to others that could be expected from the research.

If the study is expected to result in no benefit, the patient should be made aware about it.

4. If appropriate, a disclosure of any alternative procedures or courses of treatments other than of the study that would be advantageous to the participants.
5. Information on any remuneration or medical treatments that will be provided to the subject in case of any injury during the study period.
6. A statement demonstrating how confidentiality of subject's information will be maintained. They should also mention that regulatory bodies may inspect the study records.
7. A sentence stating that participation in the study is voluntary, and that their refusal to participate will not lead to any penalty or loss of benefits that they are otherwise entitled to.
8. A statement demonstrating that subjects can refuse to continue participation at any time, and they will not be subjected to any penalty or loss of benefits if they decide to discontinue.
9. A description as whom to contact if they have any questions about the research and research subjects' rights or if there is a research-related injury to the subject.

If appropriate, some additional essential elements that need to be informed to the subjects are:

1. A statement informing about the risks of the research treatment that might occur to the subject, embryo or fetus if the subject is or becomes pregnant during the study; that are currently unforeseeable.
2. A description of circumstances under which the investigator might terminate the subject's participation without regard to the subject's consent.
3. A statement informing that the investigator has a right to withdraw the subjects in case they do not follow the study procedures or instructions as given by the investigator.
4. A statement informing about additional costs to the subject that may result from participation in the research so that he/she can remain prepared for such a possibility.
5. The consequences of a subject's decision to withdraw from the research and procedures for

orderly termination of participation by the subject.

6. A statement on the deleterious effects on the subject's health or welfare in case of withdrawal, there should be a detailed explanation of any withdrawal procedures in the IC that are necessary for the subject's safety and welfare.
7. A sentence informing that the subjects will be informed about all the significant new findings that occur during the course of the research which would be pertinent to the subject's willingness to continue participation.
8. The approximate number of subjects involved in the research [12, 13].

The First Amendment (2013) in the Drugs and Cosmetics Rules provide the requirements for IC in Appendix V of Schedule Y. Kundapura *et al* (2013) conducted a study to assess whether the IC used in clinical trials conducted from 2008 to 2013 in India consisted of all essential elements listed in Appendix V of Schedule Y. The study found that only 30% of the ICFs were in compliance with the content specified in Schedule Y. A total of 26% IC forms were missing the statement that "participation is voluntary, the subject can withdraw from the study at any time; and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled" [14].

This study showed that IC lacks in accuracy of information being given to the participants. This clearly indicates that there is need for stringent rules and regulations to be formed for IC in India. Preparation of IC should be done more precisely.

How to prepare an Informed Consent

Firstly and most importantly, IC should include all the essential elements as described in Schedule Y. The WHO Research Ethics Review Committee (ERC) has developed ICF samples for different types of studies that can be viewed at http://www.who.int/rpc/research_ethics/informed_consent/en/.

Here, are few points that should be considered while drafting an IC:

- Language used in IC should be simple (that of grade 6^{th}/8^{th}).

- Words familiar to non-medical readers should be used.
- Simple, short and direct sentences should be written at all times.
- Paragraphs should be kept short.
- Active verbs should be used often.
- Important points should be highlighted either by making the text bold, underlining it, or by putting them in boxes.
- Acronyms should be spelled out at their first usage.
- Usage of "for example," "so forth" instead of e.g. or etc. is recommended.
- Brand names of drugs/devices, trademark or registered symbol should be capitalized when used for the first time.
- Generic names of drug/device names should be in lowercase.
- Abbreviations that have been accepted as standard in the proposed study (such as HIV and DNA) should not be spelled [15].

It is recommended that the study procedure description should include the following information:

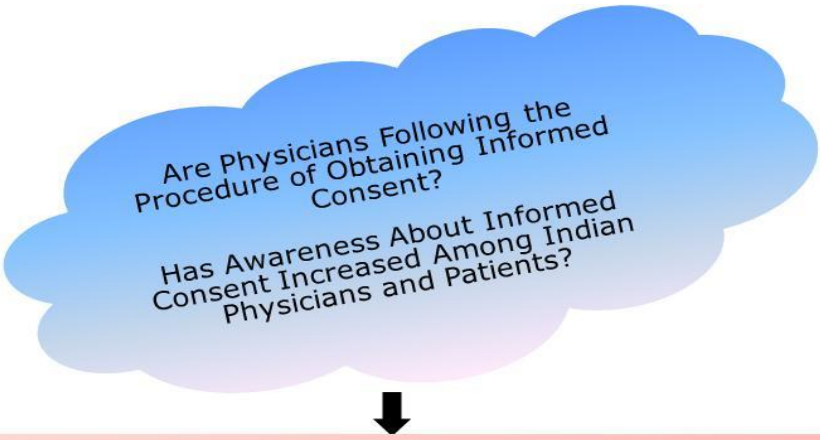
If involved, the amount of blood or other samples to be taken should be mentioned.

- Use of symbols such as ">" instead write "greater than" is recommended.
- Description of the study design should be given when introduced first time.
- Term "study drug" instead of "study medication" should be used and one should avoid using words such as "therapy" or "treatment" for investigational drug.
- "Study doctor" should be written instead of "principal investigator" or "research study" instead of "trial."
- In the consent form, word "participant" should be used instead of "patient." [15]

- There are many websites that provide glossary for lay terms that can be referred while preparing an IC. Some of these websites are:

❖

Current Scenario of Informed Consent in India



Let's have a Look at Current Scenario of Informed Consent in India

Studies in the past have shown that there is still a lack of awareness about the consent process among general population and the healthcare professionals in India [16, 17]. Several factors have been identified which hinder the process of obtaining IC; these include

1. Poor literacy rate of the patients [17]
2. Poverty

3. Paternalistic attitude of the physicians

1. Poor literacy rate of the patients

A study was conducted by Kumar *et al* to assess the perception of IC among patients and physicians. The study concluded that poor literacy was the key obstacle in communication between the doctor and patients. The study suggested that developing audio visual aids and local language versions of IC forms helps the patients to be proactive in taking decisions for their treatment.

One of the doctors suggested that, after training, social workers can be included in the process of obtaining IC. One patient stated that the doctor should spend some time with the patient, because if doctors will visit for only few minutes, the patient might not feel comfortable to ask his doubts freely [17].

2. Poverty

Though, recent data shows that poverty at the bottom of the pyramid has declined, cost of health care is still very high.

For example, data from the Indian Rural Development Report (2013-2014) shows that there is a decline in people categorized as "very poor" from 16.3% to 6.84% [18].

The high health care cost is also contributing in exacerbating poverty, making it difficult for poor people to have adequate access to the health care [19].

These people ignorantly accept the treatment as suggested by the doctor if it is cheap or free as they do not have any other option [20].

Further, subsequent to the relaxation of the Drug Governing Rules in India (2005), foreign pharmaceutical companies are targeting India for conducting clinical trials. It has been reported that hospitals majorly enroll poor and illiterate people for such trials, as they do not have ample knowledge about clinical trials. This is true, even when the protocol clearly states that people from all societies should be included. Sadly, many other cases have been reported in which poor people were not informed or asked about their willingness to participate in such trials. This clearly reflects that poverty and poor literacy are key issues which leads to involuntary participation in India [21].

3. Paternalistic Attitude

As already discussed, the paternalistic attitude among healthcare professionals is known to exist since ancient times. It has been observed that the rural and tribal people in India respect the suggestions, views and instructions of doctors, researcher and scientists and consider them earnestly. It has been reported that people who come in contact with researchers or doctors conducting research give the responsibility of taking decisions to doctors on their behalf [22].

Studies have reported that paternalism exists in other developing countries as well, such as in Saudi Arabia [23].

In India, the IC is based on legal considerations rather than ethical practice [1]. There is critical need to look in to the system of making a decision regarding the patient's treatment.

Recommendations to Improve the Process of Informed Consent

1. Researchers should follow the guidelines by the Central Drugs Standard Control Organization (CDSCO) given in Schedule Y to prepare an IC.
2. ICs have been found to miss the essential elements that are mandated to be included by federal regulations. Thus, IC should be prepared carefully and should include all the essential information of the study that needs to be imparted to the participant.
3. Ethics committee members and all other persons involved with the research should be given training on ethical guidelines so as to improve the voluntariness of participation and protect rights and safety of the participants [5].
4. Ethics committee and regulatory bodies in India need to develop a monitoring system for research studies and should comply with it strictly[5].
5. Government agencies like the Indian Society of Clinical Research and the Forum for Ethics Review Committees in India (FERCI) should regularly organize workshops for investigators and ethics committee members. They should also emphasize on areas for which guidelines need to be developed [5].
6. Awareness programs need to be developed as

7. people in India are illiterate and have less knowledge about IC. FERCI in collaboration with Pfizer has developed a DVD on IC and a speaking book in different languages (English, Hindi, and Telgu) that are helpful in educating people on various aspects regarding clinical trials. More such initiatives need to be taken to increase the awareness about the IC [24].
8. Subsequent to the order of Supreme Court, the CDSCO has made it compulsory to obtain audio video consent of each subject included in the trial in India. This step will surely improve the quality of IC process and will aid protection to both the subjects and the investigators [25].

Conclusion

Lack of awareness about the clinical trials among general public, inability of the patients in taking decision about their treatment, poverty, illiteracy, paternalistic attitude of the physicians and incompliance in the IC forms with the regulatory requirements are the key obstacles in streamlining the process of IC. There is a need of developing robust regulations governing the process of IC in developing countries like India.

References

1. Jacob, K.S., *Informed consent and India.* Natl Med J India, 2014. **27**(1): p. 35-8.
2. Arora, V., *Role of Consent in Medical Practice.* Journal of Evolution of Medical and Dental Sciences, 2013.
3. Shaha, K.K., A.P. Patra, and S. Das, *The Importance of Informed Consent in Medicine* Sch. J. App. Med. Sci., 2013. **1**(5): p. 455-463.
4. *Informed Consent in Human Subjects Research. Available at: http://oprs.usc.edu/files/2013/04/Informed-Consent-Booklet-4.4.13.pdf; accessed on: 4 December 2015*.
5. Kumar, N.K., *Informed consent: Past and present.* Perspect Clin Res, 2013. **4**(1): p. 21-5.
6. Sharma, R., *Informed consent in clinical practice and research: ethical and legal perspective.* International J. of Healthcare and Biomedical Research, 2014. **3**(1): p. 144-151
7. Kegley, J.A., *Challenges to informed consent.* EMBO Rep, 2004. **5**(9): p. 832-6.
8. Vollmann, J. and R. Winau, *Informed consent in human experimentation before the Nuremberg code.* BMJ, 1996. **313**(7070): p. 1445-9.
9. Ghooi, R.B., *The Nuremberg Code-A critique.* Perspect Clin Res, 2011. **2**(2): p. 72-6.
10. *CIRP. The Nuremberg Code (1947). Available at: http://www.cirp.org/library/ethics/nuremberg/; accessed on 19 October 2015.*
11. *WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. Available at: http://www.wma.net/en/30publications/10policies/b3/; accessed on: 19 October 2015.*
12. *UCI Office of Research. Required Elements of Informed Consent. Available at: http://www.research.uci.edu/compliance/human-research-protections/irb-members/required-elements-of-informed-consent.html; accessed on 10 October 2015.*
13. *Rochester Institute of Technology. Ethical and safe Research. Available at: https://www.rit.edu/research/hsro/basic_elements_consent_form; accessed on: 19 October 2015.*
14. Kundapura, S.V., T. Poovaiah, and R.B. Ghooi, *The big Cs of the informed consent form: compliance and comprehension.* Indian J Med Ethics, 2013. **10**(4).
15. *Informed Consent Guidance - How to Prepare a Readable Informed Consent. Available at: http://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/informed_consent_ii.html; accessed on 23 Feburary 2016.*
16. Gupta, V.V., et al., *Knowledge and attitude toward informed consent among private dental practitioners in bathinda city, punjab, India.* Osong Public Health Res Perspect, 2015. **6**(2): p. 73-8.
17. Kumar, S., et al., *How 'informed' is informed consent? Findings from a study in South India.* Indian J Med Ethics, 2012. **9**(3): p. 180-6.
18. Tiwari, R., *Why poverty in rural India is still a concern. Available at: Why poverty in rural India is still a concern*, in *The Indian Express*. 2015.
19. Balarajan, Y., S. Selvaraj, and S.V. Subramanian, *Health care and equity in India.* Lancet, 2011. **377**(9764): p. 505-15.
20. Mukesh Y., T.P. Singh, and R. Pooja, *Role of Informed Consent in India Past, Present and Future Trends.* Journal of Indian Academy of Forensic Medicine, 2014. **36**(4).
21. Lloyd-Roberts, S., *Have India's poor become human guinea pigs?*, in *BBC Newsnight*. 2012.
22. *Trust in Biobanking: Dealing with Ethical, Legal and Social Issues in an Emerging Field of Biotechnology*, ed. P. Dabrock, J. Taupitz, and J. Ried. Springer.
23. Jamjoom, B.A., et al., *Attitudes towards informed consent: a comparison between surgeons working in saudi arabia and the United kingdom.* Oman Med J, 2011. **26**(1): p. 29-33.
24. Kumar, N., et al., *The India experience.* J Acad Ethics, 2009. **6**: p. 295-303.

25. Goyal, S., et al., *New Audio Video Consent Guidelines: Elements For Informed Consent Process For Clinical Trials In India.* International Journal of Information Research and Review, 2014. **1**(2): p. 021-023.

Knowledge isotopes, a medical and communication specialist company, provides a range of medical writing services to pharmaceutical and biotech companies, hospitals and individuals researchers to support them throughout the product life cycle, from development to delivery. For further information please contact info@knowledgeisotopes.com or visit our website: http://www.knowledgeisotopes.com

Knowledge Isotopes Pvt. Ltd., First Floor, Building no. 2, IT Park, Sec- 67, SAS Nagar, Chandigarh.