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The theory of informed consent forms the backbone of all ethical guidelines for medical experimentation with humans. Every person is considered as autonomous and unique who has the right to determine about oneself and has full privilege of body autonomy. Any therapy or research done against these rights is violative of the basic human rights of that individual. Beginning with the Nuremberg Code, almost all jurisdictions has made ethical guidelines to protect individual rights of human beings involved in medical experimentation.

Understanding the driving forces, values, ethics, morals promoted in the social, cultural, political and economic setup in a society will help us in understanding the nature, extend and the restriction on the right of self determination and the liberty to exercise body autonomy principles that are accepted, followed and promoted in health care scenario of a society.

Analyzing these factors may provide an insight into future studies. It is necessary to analyze each and every concept relating to autonomy and self determination to understand why consent to medical research need to be an informed one and how much it is essential and important in medical research.

The participants before entering into research may be provided with adequate information. The consent obtained after informing all the vital material facts to the research participant is known as informed consent. There are specific guidelines to determine what are the material factors which need to be informed.

Making the research participant understand and implementing these guidelines and principles needs proper networking between the research organizations and the prospective research participants. It is within the framework of liberal western thinking that this theory and practice of informed consent has taken shape. Informed consent gives importance to the right of determining about oneself, this legal requirement is similar to the moral doctrine of respecting a person’s autonomy.
The rationale of the legal protection of self determination is based on reasoning that the state has a duty to protect the body autonomy of every individual. The right to make an informed choice is very essential to carry out the research in human beings which attains more assertiveness because medical research is non-therapeutic in nature.

Obtaining informed consent in its true sense is not simply a matter of common sense; it requires a thorough understanding the process involved in the medical experimentation. Whether and to what doctrine extends this doctrine may be applied and implemented to the poor, illiterate and the vulnerable mass in the Indian Society is the bare fact which need to be addressed. This is an evolving and complex area.

**Rationale of the Doctrine of Informed Consent**

Informed consent is a legal theory which has been formulated by courts in Western Europe and North America as a result of experiences over many years. The reasoning of the theory of informed consent is that the research participant voluntarily decides whether to be a part of the medical research or not right after going thoroughly through the procedures of the proposed research.

The research subject may be informed not only about the risks involved but also the anticipated results of the proposed research. Only if all the information is made available to the research subject he can make a proper decision whether to be a part of the research, to continue or to choose an alternative method of treatment.

The basic principle behind recognizing the theory of informed consent as basis of medical research with humans is because of the relevance, importance and respect given to personal autonomy. Respect for autonomy enjoys a similar pervasive influence in the world of health care policy. It provides the research subjects the information about his health status and requires that the researcher also respect his decision to what to do with his own body. The basic principle of the theory of consent recognizes a valid consent as one without any vitiating elements like coercion, force, deceit, undue influence or fraud.

The definition of the term informed consent as given in the Nuremberg Code specifies that it is a consensus between the parties on all information about the procedure to
be carried out. It is also specified that the agreement need to be made only with the person who are competent and has legal capacity to enter into an agreement made without any of the vitiating elements to get consent.

Generally recognised vitiating elements of free consent in almost all jurisdictions are force or compelling a person, making a person to behave affirmatively through a fraudulent act, deceit, duress, coercion etc.

Concept of "informed consent" is embodied in WMA Helsinki Declaration in 1964. The main ingredient of the 2008 version of the Declaration with respect to informed consent is:

Every medical research involving humans,

1. Research participant may be properly and clearly be given the details regarding objectives, process and the data concerning the funding of the research.

2. The research participants may also be given information on any anticipated conflicts of interest.

3. The information about the institution to which the researcher is affiliated may also be given to the researcher.

4. The information on the anticipated advantages and the possible risks involved in the study and the resultant discomfort which may arise from the research may also be informed to the research subject.

5. The research participant may also be informed about the liberty to enter and move out of the research study at any time without any hindrances.

The Belmont Report mentions about informed consent as: respecting a person’s autonomy means making him capable to decide what may be done with his body. The research participant is given this opportunity when informed consent standards are properly followed.

There are many doubts surrounding the procedure and the nature in which informed consent is obtained. A proper informed consent includes providing information, proper comprehension of the available information and voluntarily agreeing and accepting the terms and procedures involved in the proposed medical research.
The doctrine of informed consent forms a crucial prerequisite to research. It specifies that physicians acquire informed consent from the research participant before performing medical experimentation. It is essential that this need to be given voluntarily. The main features of the informed consent are the elements of a valid consent like,

1. Volition,
2. Information and
3. Capacity.

It envisages that the decision to consent must be free one. The research subject may have attained sufficient information about the procedure. The research subject may have reached the age of maturity and intelligence.

In case of those who involved in research not having required age and not have the capacity to consent, the guardian or the parent need to act similar manner as if the concerned person would have acted if, he had proper maturity and mental balance. In short every decision and action done for the research participant by the guardian or the parent may be for the welfare and in good faith.

A consent given after getting adequate information is respecting body autonomy of the individual concerned or a voluntary decision to permit medical research or to involve in the research. Thus from the part of the researcher respecting the body autonomy and from the side of the research participant making a voluntarily decision to permit an experimentation to be conducted on his body makes the process of informed consent a valid one.

Thus consent may be defined as freely given and specific which indicates the desire and will of the research subject through which he specifies his decision to dilute his autonomy of personal information.

**Judicial Interpretation of the theory of Informed Consent.**

Doctrine of informed consent, emphasizes on the essentiality of a valid consent originated from the case of Rogers v. Whitake. In this case the appellant gave importance to the theory developed by the UK courts in the case of Bolam. The curx of the judgment of this case was regarding the fixing of liability on the physician.
The court pointed out that the physician may not having any liability under negligence if his conduct are in accordance with what is accepted during that particular time as appropriate by his peers, even when other medical experts follow some other practice.

The main content of this judicial pronouncement was that the evaluation of whether there was a proper standard of care adopted or not is always a matter of medical judgment. Only in emergency situations or in cases of utmost necessity any medical intervention may be conducted without having information and consent by the patient.

It made a crucial change in the way the information disclosure is handled in the law. It makes a balance between the obligation of the researcher to disclose all matters relevant for the research and the research subject.

When we trace the history of informed consent through judicial pronouncements, we find during 1767, it was considered that is fair to impose liability on a physician who doesn’t follow the required standard of care. So the court used to uphold what is today recognized as the reasonable practitioner standard. Later on, the idea that consent had to be given voluntarily developed.

Only by 1957, the expression of consent as something more than simply assenting to a procedure took form. A general notion developed among the physicians that it is proper to make a physician liable if he doesn’t disclose any material facts which are essential for getting an informed consent. It can be said that, the term informed consent was formulated and used for the first time in this case.

During this time two cases also emerged with same set of principles. The court described the doctor’s duty as required a reasonable disclosure of the manner and natural outcome of the prescribed or recommended treatment. This principle of disclosure of information was much elaborated by Justice Mc Nair.
The physician may not be liable for negligence if his actions are in pari with the practice recognized as up to the standard by a prudent group of medical experts skilled in that specific area. So the standard of care is that standard adopted by a reasonable group of physicians.

A contrary view was also adopted in which respect for patient’s right for self-determination was upheld apart from a standard formulated for physicians. It requires a physician to tell patient what an ordinary man would consider as crucial while taking a decision. We must acknowledge and grateful to the historical grounds for society’s concern, and also the genuine and anticipated nature of physician's power, regarding doctrine of informed consent.

**Historical circumstances of the advancement of the practice of Informed Consent.**

Historical background of the practice of informed consent forms an essential feature in most interdisciplinary areas that include law, philosophy, social and behavioural science and also in ethical and moral aspects of medical science.

Informed consent is sine qua non to research ethics. The key factors being provisions that voluntary consent of the research participant is necessary, and retraction from the research is permitted if the subject is not satisfied on the research study through which he is going through. One among the early exponents of principle of informed consent was Dr Albert Moll. He published many cases of medical research as illustrations.

The doctrine of informed consent came up with the Nuremberg code of 1947 as an end to the malpractices towards the human beings by Nazi medical researchers. The immoral practices done by the researchers under the cover of experimentation for the discovery of new medicines were brought to lime light at Nuremberg.

The consent requirement originated along with the research ethics was later on extended to all other medical procedures. The principle behind the theory of informed consent very much recognize individual autonomy. Requirement of informed consent makes research subject to act autonomously to be a part of the medical experimentation or not.
The history reveals that the advancement of the process of the practice of informed consent. It is very much related and developed based on liberal social, economic and political background of Europe. The basic theory behind the legitimacy of transactions is the claim that freely given consent legitimates any actions.

Abusive treatment of humans for experimentation in the pre-war Nazi Germany and later on in the concentration camps resulted in the prosecution of the doctors. The Nuremberg code was drafted to support the arguments of the prosecution in 1947, by Dr. Andren Jvy and Dr. Leo Alexander. Initially the code consists of six points defining the legitimate research.

The verdict of the Nuremberg Tribunal reiterated these points and extended it into ten, which subsequently recognized and established as Nuremberg code. The informed consent requirement, embodied in the code which was formulated as research ethics, was later on extended to clinical practices also.

Making the medical professionals accepting and recognizing the doctrine of informed consent was not an easy task, but later on the horrors committed on the marginalized and the vulnerable groups in the name of progress to medical science in various countries especially in US and UK demanded for the extension of the doctrine beyond any boundaries. The rationale behind such an extension was not to treat patients paternalistically.

The Tort of Battery

The theory of informed consent originated from the wrong of battery. An action that specifically, intentionally, recklessly or negligently results in certain bodily contact with any other individual without his consent. A tort is a wrong for which remedy is fixed under civil liability.

The law relating to theory of informed consent originated from this tort. It safeguards a person from unlawful touching of the body without consent. The consent may be express or implied. To bring a claim of battery the touching may be by an individual who does not have the right to act in such a manner.
Battery is results medical research while some act is done by a researcher without the consent of the research subject. It can also be battery when a researcher performs a different procedure than what has been told to the research subject and for which he has given consent. If the researcher goes beyond the scope of the consent which has been informed to the research subject, then also it results in battery.

Two caveats can be derived from this definition:

1. The legal system doesn’t provide a remedy for all civil wrongs. Only select infringements on another person’s rights, such as malpractice and its resultant injury may be compensated.

2. This area of law does not address things like contracts or criminal law, so the only sanction available in the realm is monetary damages.

So the theory which emerges is, when an individual has given an express consent then there can be no claim of battery.

Battery consists of a direct act of the defendant which causes contact with the plaintiff’s body without the plaintiff’s consent. When the researcher does anything without the consent of the research subject it will result in battery.

Thus, as the theory of informed consent became an acknowledged ground for researcher’s liability, the courts made decisions with implications with the effect that, any acceptance to be a part of a medical research without adequate information is not a valid acceptance or consent and is not legal because of fraudulent concealment of material facts and results in battery.

The Judiciary made an attempt to explain the different realms of the practice of informed consent like:

1. The patient may be explained of the characteristics about the disease or condition,

2. The procedures involved in the trial to be conducted and the chance of success.
3. The details regarding the prevailing risk and its nature.

4. Potential advantages and disadvantages of various therapies which can be seen as alternatives.

5. The patient shall finally be offered a choice of no treatment.

The patients understanding of the above information may be assessed and the liberty to select among the medicinal choices without any vitiating elements of free consent must be assured.

Informed consent is mainly interpreted in terms of freedom from interference. Freedom to choose is given much and paramount importance. It is a form of absolute autonomy.

**Autonomy and Self determination**

The right to autonomy and self determination are given legal expression through the law of consent. Autonomy is an ethical requirement that the approval for conducting research given by the research subject be adequately informed and freely given, without any inducement.

The principle is highly invoked where the research participants right to consider whether to be a part of research or not. Self rule is the basic feature of the concept of autonomy as its word meaning suggest. The notion rest on the fact that all individuals have the capacity of making free choice and can make decisions.

The body autonomy principle of research subject describes acknowledgement of the right to decide on their method of actions with regard to their needs. Respect towards research subject’s right to autonomy is very much related to recognizing their ability to decisions voluntarily. Thus the principle of autonomy is the underlying factor behind the reasoning of the practice of taking consent in an informed manner.

The informed consent in almost all research consisting of vulnerable samples and sensitive aspects are continuous procedure and not sole requirement and condition to be satisfied for the collection of information from the research participants.

This is due to the fact that they are often not clear on certain questions till put to them clearly. Even though at the early stage of the research, option is given to withdraw from the
experimentation process at any time, the researcher should evaluate the research participant’s comfort while being a part of research process and willingness to continue or withdraw from the research study.

Informed Consent principle and theory forms the basis of all health care rights. The principle also justifies the reasoning behind the law and ethics and the inalienable privilege to have autonomy and self-determination. The concerns of power, liberty, and individuality all are essentials of the theory of autonomy. As a result of these features attributed to the concept of autonomy, it is essential to evaluate its nature, value and limits. The theory gives every person the right to decide what procedure or therapy may be done on his body. Self determination requires a capacity to act rationally.

The reasoning based on a rational thinking may become defective when the person attempts to give reasoning misjudges or misrepresent what others can follow. Thus the reasoning of an individual while deciding what is good for him is open to scrutiny and it deserves respect only if the ends are accessible to others. That reasoning may be in the form of critical evaluation of oneself. Thus, the personal autonomy of a person and the right of a person to determine about oneself are choices that permit the subjects of experimentation to feel that they are in control of their destinies. Such beliefs or feelings are very much essential to human dignity.

The theory of autonomy also stipulates to safeguard the rights of the persons with diminished or lack of autonomy because of any vulnerability or being a dependent on a guardian or legal representative. Even though body autonomy is considered as an absolute right of every individual, the only reason for which the authority may be legitimately applied over any person of a civilized society, contrary to his will is to restrict injury to others.

In spite of the fact that, the theory of individual autonomy is commonly accepted and recommended in theory, it’s feasible ramifications for the doctor-patient relationship are contentious. Individuals utilize their autonomy during medical decision process by arranging for needed professional services. In the domain of medical findings and therapeutic care there is lot of opportunity for reasonable divergence of ideas and observations.

A researcher may not be held as negligent simply because his opinion and the consequent actions are different from the opinion of the professional men. If one researcher has shown
less skill and knowledge than others, it doesn’t mean he is negligent.

The true test to determine and to establish the liability of negligence is any procedure in which the researcher has not displayed ordinary standard and skill if he has done the procedure with ordinary care.

**The Limits of Autonomy**

The right to body autonomy is not an absolute rule. There are some principles that may justify a limitation on the individual’s autonomy. They are,

1. The harm principle,
2. Prudence,
3. Offence to others,
4. Self harm and
5. Morality.

Respect for autonomy and the law of consent allows the subject an absolute right to provide, or not to give consent to forms a part of medical experimentation, but whether or not the subject can give or withhold consent, depends largely on the individual circumstances of each case.

Personal autonomy is seen as a combination of thought, will and action. Along with the principle of autonomy, some more principles where also developed from a pluralistic, albeit American thinking like;

1. Principle of beneficence,
2. Principle of justice and
3. Respecting the individuality and personality.
The National Research Act was passed U.S in 1974. It was because of the revelation about the study conducted in 1972 on Tuskegee Syphilis. It is supposed to be the first federal law to protect the basic rights of human beings involved in medical experimentation.

Under the U.S National Research ACT, A National Commission for the protection of Human Participants of Biomedical and Behavioural Research was created. In response to the commission’s report in 1981, the U.S Department of Health and Human Services and the FDA codified the recommendations as Title 45 Part 46 of the code of Federal Regulations. The code of federal regulation specifies constitution of Institutional Review Board (IRB). The understanding of the features of voluntariness of the research subject while taking the consent is absolutely essential. It is pertinent to examine the concept of voluntariness and its limitations.

**The concept of Voluntariness and its limitations**

The concept of voluntariness surrounds around the concept of voluntary informed consent. It depends greatly on chances of exploitation of the research participant. The Belmont Report defines “voluntariness” as an agreement to participate in research which is given voluntarily.

A person competent to participate in a medical research may decide to participate or not after receiving getting knowledge about the features, aims, and the time period of the research of the research, the procedure and the ways through which it is going to be performed.

All difficulties as well as hardships which may result need to be informed to the research participant. He may also be informed about the effect of any procedure involved in the research upon his health or person. The participant may not be compelled or subjected to force, fraud, deceit, duress, or coercion.

The research subjects may have certain questions including who’s in charge of the research, what are the risk and the benefits? and what’s the actual procedure which is going to be conducted on me and all. The person involved in the experimentation procedures may have the capacity to give consent.
He may be given a freedom to choose and have the power and capacity to choose what he really wants without any intervention of any of the vitiating elements. He may have enough and sufficient information and understanding of the material factors of the procedures of medical research making him to take an informed decision.

Making an understanding decision means, before recognizing an affirmative judgment by the research subject, he may be informed, the nature, the time span and objectives of research, methods and means of conducting the experimentation, all possible risks and hazards involved, and the effect of experimentation on the health of the research subject. Only if a research subject acted in such a manner, he could be said to act voluntarily.

Voluntariness implies, what is embodied in the maxim, volenti non fit injuria, no injury is done when the research participant is consenting to the said procedure or therapy. The informed consent requirement may specify that the research subject himself is in control of his body. It ensures body autonomy.

The Nuremberg standards on informed consent were open to a wide range of criticisms. The main criticism was that whether it enough to ensure that research subjects has enough capability to provide a lawful consent.

The Nuremberg Code specifies that tacit or implicit consent would meet these standards, provided that those to whom it was ascribed had legal capacity and could act on his freewill. The requirement is that anybody whose consent is given should have sufficient awareness and the capacity to comprehend the features of the relevant matter to make an enlightened judgment.

There are many challenges to voluntariness. The condition of an agreement by the partner to participate in research violates the right to make autonomous decisions of research subjects and their right to keep certain personal facts confidentiality. U.S National Bioethical Advisory Commission (NBAC) specifies that requiring spousal agreement is permissible only when it is not possible to perform the medical research as not receiving those proxy permission. Again if the circumstances are such that the failure to perform the research may not give its benefit to women then spousal agreement is permissible.
The Doctrine of Informed Consent and Cultural Context

The documentation involved in the procedure of informed consent may vary based on cultural and social contexts. The social and cultural context of the research may affect a person’s ability to voluntarily consent to participate, continue, or withdraw from the research.

Beyond the formal aspect of general consent, the real consent is based on the confidential fiduciary connection between research participant and the researcher, based on a trust that scientists are behaving ethically and in the interest of the public.

Justice Benjamin Cardozo opines that, all adult individual having sane mind may be given the liberty and privilege to decide to what his body may be subjected to. We have gone from a time we were comfortable with the idea that the “doctor knows best” to one where the line “trust me I am a doctor” is assured of a laugh from a time where the patient contributed little to clinical encounter to one where the patient often demands and gets whatever they want. Thus an intervention without consent is an assault.

Gender inequalities prevailing in some societies play a great deal in the process of informed consent. It very much affects the aspect of voluntariness. The question of who shall make a decision on whether to be a part of experimentation or not is a difficult question to answer in such cases.

Low literacy among the study group very much prejudicially affect the smooth procedure of research environment and may result in taking consent without giving enough information. It may also affect proper communication between the researcher and the research subject.

Economic backwardness may also negate the concept of voluntariness. It can be said that the doctrine of informed consent is built from a complex interrelation of medico legal and ethical principles. Appelbaum states that generally informed consent whether to treatment or research, falls into three categories. Voluntaries, disclosure and competence.

Voluntariness implies that research subject must be acting of their own free will when
they agree to participate in research. Disclosure specifies that, the information on the basis of which potential subjects may make an informed choice. Disclosure includes disclosure of features and objectives of the experimentation, the possible merit and demerits of revealing the privilege to discontinue participation in the study etc. Informed consent also requires certain competency.

**Recording of Visual images and the audio of the different process involved in informed consent.**

Through an order dated 19th November 2013 the office of the Drugs Controller General (India) has been made audio visual (AV) recording of the informed consent mandatory for the conduct of all medical research or clinical trials in India. This order was made as a result of the order of the Supreme Court dated 21st October 2013 which made mandatory the recording of visual images and the audio of the process of informed consent. While adhering to the principles of confidentiality. Even though the court had made such an order, the technical specifications relating to the audio visual recording was not mentioned or clarified by the court.

There are many advantages in these type of recording, but the experts of this field raises several issues concerning the procedure to carry out the audio visual recording which needs to be discussed elaborately from different perspectives.

The purpose and objective in implementing audio visual recording of informed consent process is mainly to guarantee the research participant that they are adequately informed about the whole procedure involved in the medical research process, the pros and cons, the risk and the benefits, chances of the failure of the intended result etc.

The main aim is to ensure that the research subject understood the details of the study. When all incidents related to the informed consent process is recorded, it become a good piece of evidence in case of any litigation or dispute. It becomes effective evidence that the informed consent has been taken according to the prevailing rules and laws. Theoretically where
uneducated patients are enrolled for clinical trials or medical research, mandatory audio visual recording of informed consent procedure becomes important for the patients’ rights and safety.

The practical application of this theory becomes difficult to implement because of many factors involved as there are many hindrances faced by the patients to face the Camera. Confidentiality, privacy all plays a big role.

From the perspectives of an investigator lack of guidance on the procedural aspects of conducting and managing the records, the type of equipments to be used, maintaining the confidentiality etc is problematic.

The processes involved in the audio visual recording are time consuming and complex. It also increase the cost involved in the clinical trial or medical research. The recording of the audio and the visual process involved in informed consent procedure has doubled the responsibilities of the researcher.

**Eliciting Informed consent and competency**

Getting consent through an informed manner is applicable only when the research participant is a competent person and has the capacity to decide for his own needs. Consent from the research subject is not needed when decision making capacity is permanently damaged or incapable to give it (minors, unconscious patients, etc). Consent is not needed also when researcher uses only records of the previously done research; and also when human tissues are stored and used when need arises.

In the instances of those who are incompetent there are often legislative and other rules and procedures for how to obtain the consent to medical research. The sensitive issues regarding humans has always confronted with many ethical arguments and questions that often researcher may be confused with.
The intensity of the issue gets double when the research participants are children or when certain intimate issue regarding the life of the respondent is involved. More precisely when dealing with the issues of sexual or emotional abuse. Generally these two issues have certain unique features like:

1. Firstly it may be possible that certain revelations are happening and it is for the first time and there are all possibilities to be emotionally questioned.

2. Secondly, experimentation on these issues by its very nature and content always involve certain risks to respondent’s life.

**Legal Guardian**

The consent of the legal guardian is an important factor when a research is going to be conducted with a person who does not have the capacity to give informed consent. Informed consent recognizes a person’s liberty of choice and provide safeguards to person’s autonomy. When the informed consent principle and the principle of body autonomy joins together, it educates the prospective research participant about his health conditions and gives full information about the procedure of the research. This makes him competent to take a valid informed decision.

The taking part in medical research may be without any vitiating elements and thus, the research participant may be thoroughly educated of all the possible harm which may arise during the research procedure. The patient must be told about the likelihood of success of the treatment.

Most people wish to receive knowledge on their medical facts but a majority does not want to take a decision on their health issues or even to be a part of the decision making process in a very significant manner. Translating the abstract ethical requirements of the informed consent to every research subject and making him understand the need and the practical implications of the informed consent is a very difficult task of the researcher.

Onora O’ Neill states that, “Informed Consent is one hallmark of trust between strangers”. It is not the basis of trust, rather it presupposes and expresses trust, which we may already place
to assess the information we are given. Legally and ethically the concept of understanding is the corner stone of health care decision making.

Appelbaum distinguishes four types of competency.

1. First the subject must be able to evidence a choice regarding decision at hand. The choice need not be expressed verbally, but the subject must be able to communicate their preferences in some manner. The choice must be sustained over time. The inability to maintain a consistent choice overtime may reflect deficit mental status to be a part of a medical experimentation.

2. Secondly, the research subject must have a factual understanding of the information that has been presented before him.

3. Acceptable levels of understanding may vary depending on the risk involved in a proposed research project. Thirdly, research participants may also be able to rationally manipulate the information, which is not impaired by their illness. They must have ability to reason through the information presented to come up with a logical decision.

4. Finally, the subject must have a realistic appreciation of their situation.

Certain patients due to their ailments may not be able to appreciate actually and precisely what is done to them. The appreciation must include some awareness and understanding of the fact that the study involves research and not treatment, and so may not bring any substantial and direct advantages to that person.

Wittgenstein opines that understanding doesn’t simply means understanding the words and their order in a sentence, it also means something deeper. He hints at understanding being like understanding a poem which entails not only understanding the words and their meaning but also their deeper significance. Understanding involves both of these concepts.

The US court laid down the criteria to be followed when research involves participation of mental patients in research in which high-risk is involved. The dispute before the court was
regarding the state agencies exercising supervision over the sanctioning of research using human incapable to give consent. The research participants involved in the research included adults and minors. All were mentally challenged, retarded persons etc. The trial court accepted the conditions of the legal guardian of the research participants. The court granted a partial summary judgment to that effect.

The trial court agreed with the representatives of the subjects, granting a partial summary judgement to that effect.

The court explained the effect, risk and possible benefits of participating mentally challenged individuals in the experimentation which involved very high risk. The court tried to explain the relevance of the said research in question and pointed out that the procedures are limited to identify the cause of stroke, heart attack, convulsions, hallucinations, or other diseases and disabilities including death.

The court also accepted that the research may bring benefits to a large group of possible sufferers of these types of ailments. Even though that being the case, the research have no direct therapeutic benefits and advantages to the research participants and also because of the existence of risk more than minimal. The research with mentally challenged and incapable cannot be justified.

The issues around informed consent remains problematic even after much judicial analysis over many years. Consolidating the rules and principles relating to informed consent is not an easy task because of different factors. The concepts involved in the doctrine of informed consent like decision making capacity, voluntariness and freedom to decide are difficult to perceive clearly. Almost all are indistinct.

It can become clearer only through further elaboration and specification in the context in which they are used. Making common people understanding all these concepts and getting consent is very difficult. The manner of conveying and by whom the matter is conveyed also really matters.
Understanding the Doctrine of Informed Consent through Various International Documents

Ethical Guidelines for Biomedical Research on Human Participants, given by Indian Council of Medical Research mentions about Informed consent as, “Adequate information about the research may be given in a simple and easily understandable unambiguous language in a document known as the Informed Consent Form with Participant/ Patient Information Sheet.

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Specifically in the area of human biological materials, world health organization has issued Guidelines for setting consent in an informed manner in 2003

Human biological materials are scientifically proved to have the potential for medical research. There is still no consensus about the rules that govern bio banks in ethical or legal terms. Thus W.H.O has formulated a unified model of informed consent. It was a unique mode for eliciting informed consent intended for research studies and future use. The informed consent form may specify:

1. Information relating to storage of biological samples and concerning data,
2. Manner and objectives of the research to be carried out;
3. General information about research that may be carried out in future in
4. Specific information on privacy issues of the research subjects, and on donor authorization to use anonymous samples and data for scientific publications, teaching purposes or commercialization;

5. Specific information on the right of the donors to request and obtain details of the status of the work and general study results;

6. Specific information about the right to withdraw consent and request the destruction of samples and data.

In the area of genetic research, UNESCO bioethics program issued two guidelines, Universal Declaration on the Human Genome and Human Rights (1997) and international declaration on Human Genetic Data (2003). In Universal Declaration on the Human Genome and Human Rights (1997), the research, which has an effect on the person’s genome, may be taken only after rigorous and prior assessment of the possible advantage and disadvantages.

It is mandatory to obtain prior, free and informed consent of the person. In case of not in the position to give consent, authorization may be obtained. The research may be carried out only for his health benefit.

When there is no direct benefit then the research may be exposed to minimal risk and burden. The research need to be in compatible for safeguarding the individual’s human rights. The information regarding the research needs to be confidential.

Any research concerning human genome shall not sacrifice the respect for freedom, dignity of human beings. All may be made eligible to get the benefits of the research concerning human genome. Freedom to conduct research is very much needs to be promoted for the progress of knowledge. It forms a crucial component of thoughts and thinking. Through such research relief shall be given to the sufferings and also to improve the health of persons and humankind at large.
The responsibilities present in the actions of researchers includes:

1. Taking appropriate care,
2. Caution,
3. Honesty and
4. Integrity in carrying out their research.

These qualities need to extend even to the stage of presentation of research and also while utilizing the findings of the research.

The ethical and social effect of the research may always be kept in mind. While making policies on these issues, the state may foster all conditions favourable for carrying out human genomic research.

As a welfare state one among its prime duty is to adopt appropriate steps to encourage medical experimentations. The state shall make enough resources for training and accumulate information to increase the awareness level of the society regarding the question of human dignity brought up by the research relating to biology, genetical and medicinal application.

The state shall also generate international opinion taking into account the social, philosophical, cultural and religious viewpoint and opinions. Genetic information of human beings shall be accumulated, presented and processed only when the object of such procedure is for:

1. Diagnosis and health care
2. Medical and scientific experimentation
3. Genetic studies based on population
4. For epidemiological experimentation
5. Anthropological research
6. For any civil and criminal proceedings
The collection of genetic data of human beings and samples of biological nature through any type of procedure invasive or non invasive need to obtain free prior, express and informed consent. If as per the law of any jurisdiction the person involved in research lack the capacity to consent or are disabled, the best interest of the person concerned shall be taken care off.

There is still no ethical consensus about the legal framework that deals with bio banks. The informed consent form may specify information regarding the storage of samples of human body parts, and about the procedures involved in the research study.

The research subject also need to be informed about the chances of conducting another study in the future based on the results derived from the present study. Privacy issues, authorization given by the donor, the information that those who are participating in the research has very much the right to withdraw during the course of trial also need to be informed.

Consent may be lawfully legitimate and professionally adequate only where the research subjects or the legal guardian have the competency to give consent. Even though the minor can understand the various steps and stages of medical experimentation the consent of the guardian or the parent need to be attained along with the consent given by the minor. The level of understanding of the minor cannot be equated to the level of understanding of an adult person.

The process of understanding, according to Stewart and Biegler, maybe formalized into three phases:

2. To have a belief over the information collected
3. Balancing it with other elements to arrive at a decision.

The existence or nonexistence of a person who care very much influence an individual’s nature manner and clarity of attitude and willingness towards the research. When
we consider the totality of the issues, the nature of environment and the relationship of the process of making decision may all contribute to detract from the person’s individual decision making in furnishing informed consent.

**Surrogate Consent / Proxy consent in Medical Research**

The ability or the capacity to give consent to be a part of a medical research is determined by the requirement of competency. Competency of a person generally increases with age. It is not always considered as depending primarily on age, but on the capability of a person to understand and weigh up options. Especially the aftermath of being a participant of any intervention needs to be analyzed. The evaluation of this information to arrive at a decision is pertinent for free consent.

The manner and the mode of how the information is being communicated to the prospective research subject to arrive at a decision are also crucial. If a person possesses the capacity for all these process, then he is considered as competent to give consent for the purpose of medical experimentation.

Informed consent process is generally considered to be the backbone of medical experimentation involving minors as children only in the exceptional case of certain adolescent conditions have the capacity to consent. Great caution and care is needed in determining whether to involve a child in a medical experimentation.

**The Doctrine of Informed Consent and Medical Research Involving Children**

With regard to non therapeutic research involving minors, the informed consent procedure in such trials are not totally analyzed by the judiciary.
The US court has once opined that, while the enforceability and authority attached to the consent agreement, the enforceability of the agreement as a contract, the truthfulness of the relationship of the child with the guardian, any contract entered by the researcher with any organization making him to conduct the research are important factors which need to be looked into when research is conducted with children.

The court was of the opinion that the protocol of the medical research is also important similarly as that of getting informed consent from the legal guardian. The concept of getting consent from the guardian of the child was developed as an ethical and moral responsibility of the researcher.

Thorpe J reflects on this issue that, if the person is having the capacity to comprehend the manner, purpose and effects of the operation in question. If the situation is satisfied the person in question is considered as competent. The reasoning for accepting that another person may give consent for the person who undergoes the research or experimentation that to be a part of medical experimentation is crucial that the research participant need to give his consent. If he is not competent to give consent, then any one on his behalf for his best interest.

This theory of best interest of the research participant may not work well with medical experimentation because it is non – therapeutic in nature. Even this argument is being rationalized based on various ethical theories stating public good and the benefit of the society at large. In United States In Re Martin the Michigan Court of Appeals explained competency as:

1. Having sufficient mental capacity to understand the situation.
2. Able to comprehend the inherent features
3. Effect of making such choice
4. Ability to make an informed choice
5. Capability to act voluntarily
6. The factor that consenting not because of any coercive element.
Rationality and ability to consent

Where rationality is the underlying criteria to determine the capacity of the individuals there may be vast variance between individuals. The object of rationality is to suffice consistency in justifying emphasis on the output of the reasoning procedure. Every individual’s self-awareness is generally better than any others. Thus competent persons have the freedom to take decision for their own matters that influence their lives.

Compartmentalizing, evaluating, and rationalizing the risks of involved in the research study are very difficult procedures when the research is one that involves newborn babies, minors, and adolescents. Special care and caution may be taken in the case of this group, as they are not able to express their needs. They lack the capacity to give consent and defend their interest similarly as that of others.

Physiological and psychosocial status of the children is very unique. Conducting an evidence-based treatment in children is also essential as that of matured. Only after a thorough evaluation a medicine can be licensed for children. Many factors need to be determined. In determining competency evaluating certain factors are important.

The factors like:

1. The persons knowledge that they have a discretion to choose
2. Their capability for evaluating the options which are available
3. Merits and demerits
4. Cognitive capacity to evaluate the factors
5. Pathological perceptions
6. Delusions
7. Depression
8. Dependence on others
9. Awareness of other perception on making such a decision.
These factors need to be evaluated to determine whether a person is competent or not.

The Royal College of Paediatrics and Child Health (RCPCH) considers medical experimentation involving minors as important for acquiring more improved evidence-based health care for prospective children. In the process of acquiring such health care standards, it is also essential that highest ethical standards need to be followed.

Good clinical practices (GCP) has set a standard which is based on ethical principles and scientifically proved designing for carrying out and recording the research process that involves human beings. G.C.P points out certain matters which an investigator may ensure before conducting research in children.

a. If the proposed research may be carried out with adults then children may be avoided form undergoing the research procedures;

b. A medical research may be conducted involving children only for generating knowledge essential for the health needs of children. In order to evaluate the efficacy of a new medicine, it may be administered in children only after conducting phase III trials in adults. It is essential that the proposed research involving children has certain therapeutic advantages in children;

c. Either the legal guardian or the parent of the child needs to give proxy consent;

d. If adolescents and mature minors are involved in the research study, depending on the child’s capability he may be given information about the proposed research and the consent may be obtained;

e. Medical research may be carried out in such background and backing so that medical and psychological assistance may be provided when and if it is needed;

f. Any procedures intended to be carried out on children need to justify in connection to anticipated risks and advantages arising out of the study;

g. If the child disagrees to the proposed research, the child’s denial to be a part of the research
needs to be respected. In cases in which there is no other tested therapy then with the consent of the parent or the guardian the medical research may be carried;

h. Procedures which are intended to be carried out are likely to benefit the each and every child participant of research than presently available intervention.

i. It is also necessary to look into the factor of risk. The foreseeable risk to the child research participant is very low when balanced with the advancement of medical science and the awareness that it is to be acquired from the proposed research.

Making decisions for oneself is difficult or impossible for incompetent persons. Excluding those category of persons completely from the research purpose as their decisions are irrational and inconsistent, is depriving them and also the community at large the benefit of the potential research.

Medical experimentation need to be done in those categories or groups when new drugs or therapy is introduced for their benefit and use. To identify efficacy of the proposed drug or therapy it need to be tested in those groups or categories of human beings.

In such cases, parent or other guardian or the person who is having legal custody of the person may give surrogate consent and that must be for the best interest of the person. Even though, researcher seeks permission of parents in almost all cases they also need to concentrate on the objectives of providing adequate care.

In cases in which parent refuses to consent and if the patient is at risk, the physician can approach the court and ask for legal intervention. It is also the duty of the doctors to acknowledge the needs and rights of the patients and their surrogates.

The same principle can be extended to the medical research also. A researcher who acts in accordance with accepted ethical principles relating to best interest is unlikely to be found to have acted unlawfully, despite the lack of informed consent, especially if the incompetent is not expected to become competent later.

If they resist participating then they may not be compelled or forced. The principle of absolute body autonomy is limited in such cases. The purpose of restricting autonomy of each individual is to restrict harm to other individuals. Thus the justification in interfering with the body autonomy of another person may only to prevent harm. This suggestion as to include a
research subject who doesn’t possess the capacity to decide for oneself departed from the guidelines specified in Nuremberg Code.

The Nuremberg Code provide for the research participant’s voluntary informed consent, in cases of medical research with less risk factor involved and those which offers a direct benefits from the proposed research. In England the consenting age is 16 years old as per the regulations of General Medical Council.

The rule also says that the factor of capacity to decide also depends on general understanding of the child regarding what is the procedure involved. If a child with general understanding is refusing to participate in medical research, that need to be decided on the basis of evaluating whether it is for the best interest and welfare of the minor.

In United States the Agricultural Department under 7CFR1c, Subpart A, states the general requirement for informed consent. It states that, no researcher may include a human being as a participant without properly obtained informed consent from the research participant or from his lawful guardian. The researcher shall give sufficient choice to the prospective research participant whether to involve in a medical research or not.

There may not be any element of coercion or any other vitiating element of free consent. The descriptions of the procedure to be conducted shall be made in a language which can be understood by a prospective research participant. All these are specifically mentioned as precautionary measures to be taken while conducting medical research including children.

The Department of Agriculture under 7CFR1c, Subpart A mandates that every research subject may be given certain information like, that the procedure is a research, the need for experimentation, anticipated time span of the involvement of research subject in the process of experimentation and also an explanation of the steps to be taken during the course of the medical research. An explanation of risks that are foreseeable, details of the any benefits to the research participant may also be informed.

A divulgence of suitable measures of choice of procedures during medical research that may be beneficial to the research participant is also specifically mentioned. A description of extend of confidentiality may also be disclosed. In cases of medical research consisting of more than minimal risk, a description of compensatory measures may also be properly
informed. The details of the authorities to be contacted for clarification on their rights and experimentation. These rights may be disclosed to the research participants.

An assertion that involvement of the research subject is purely based on free will and the denial to partake may not incur any sanction or loss of benefits which the participant is otherwise entitled also may be specified in the informed consent form. It may also be mentioned that the participant may withdraw from the study at any time during the course of the medical research at any stage and that too without penalty.

It is specifically mentioned that all federal agencies that encourage or carryout medical research consisting of children may, however, choose to take up the defence of these regulations. The factor of risk is categorized on the basis of minimal, greater, whether it was anticipated, immediate benefit to the participant of the research etc.

Medical research that consisting of not much minimal risk to a child participant. Research that consists of considerable smaller amount of risk but that is rationalized by the foreseeable advantages to the research subject. Cases in which there is research consisting of children may be legitimizied while considering certain factors like:

1. Whether risk factor is minimal or high
2. Whether there are chances of benefit to the research participant
3. Whether the research is on any situation suitable for children’s health benefits
4. Whether the research will yield any vital information on children’s disorders.

Section 46.407 allows to conduct research in certain exceptional circumstances which is not otherwise acceptable, if it represents a situation to assume, stop, or avert a significant problem influencing child’s health or benefit and may carry out in relation to sound ethics and values. These provisions specifically mention certain protections. Special care and protection is needed in case of medical research involving children because of their vulnerability.
In 2001 The Boston Globe brought up a report that 45,000 minors are made part of an experimentation process that year, compared to 16000 in 1996. Research institutions where offered and taking monetary benefits to recruit minors for medical research. The legal guardians who were not informed about the amount of risk inherent in the research were offered monetary benefits.

Children are being recruited aggressively as research subject in experimentation for certain conditions which children do not have. In such a procedure the minors were exposed to high risk with an ulterior intent to expand the progress of paediatric medical market.

Children were made part of research without considering pain and their sufferings. The eye experimentation conducted in South Florida University resulted in many complications. Presently available method of surgery was adopted in one eye and newly developed technique was experimented on the other eye which resulted in unusual bleeding in the eye. This was an instance of unreasonable manner of exposing children to pain and suffering.

On August 16 2001, the Mary Land Court of Appeals made a deep rooted judgment for protecting the rights of children. The court stated that whatever is the interest of the parent and whatever the interest of the community at large to carry out a research the prime importance may be given to the welfare of the child. A healthy child may not be put into a non- therapeutic situation benefiting all children.

In this case a research conducted by an affiliate of the John Hopkins University, babies of normal health and youth were exposed to lead paint poison. An appeal was filed by the plaintiff whose children had been subjected to the research, before the Maryland Court against the lower court judgment.

The court pointed out the wordings and the guidelines of Nuremberg code and Helsinki reiterating the importance of basic human rights of every individual. The court made the judgment to the effect that when there are chances of high risk of harm children may not be exposed to non- therapeutic experiments. The court also opined that the parents have no right to subject the children to any non therapeutic research nor do the researchers.

The court observed that, certainly the law and ethics of the medical research involving human beings is well stocked with cautionary advice that all research subjects especially
when including people from vulnerable and disadvantaged sections informed consent is
mandatory. The importance and significance of Nuremberg code was also looked upon by the
court. It also considered the code as an apt, absolute and reliable framework of informed
consent for medical research involving human beings.

Nuremberg code is an international common law. It can be made applicable to both
civil and criminal matters in all jurisdictions in United States. It is not possible to find a
precedent to support any case of medical research involving human rights which makes the
codes like Nuremberg very important.

The Medical Research Council has laid down certain guidance on medical research consisting
of children. The objective behind framing the guidelines is to constitute a frame work of
general principles that may be made applicable to all situations. All national and international
guidelines relating to medical research in children has certain guidelines in common like;
welfare of the research participant may conquer over those of society.

When conflict arises, the research may have capacity to accumulate scientific knowledge that
may form the backbone for developments in human health and welfare. There need to be a
balance between foreseeable harm and benefits to the research participant. Researchers may
only move further if they have received voluntary informed consent from the research subject
to be a part of the medical research. It is also necessary that an independent research ethics
committee may review and agree the terms and conditions of the research proposal.

Ethical Principles relating to research involving children consist of certain guidelines
like children may be participated only when the particular knowledge may not be obtained by
conducting research in adults. The objective of the research may be to receive and generate
information needed for the health related issues of children.

Only competent children may be involved after obtaining their informed consent from
the legal guardian or parent beforehand. If a minor refuses to be a part in the experimentation
process, that may be respected. If a child becomes nervous or upset during the course of the
medical research as a result of any procedure which is followed, that may be considered as a
valid denial to participate.
Researchers may include the parents or legal guardians of the child in the decision making process. Any factors that pressurize and may motivate to be a part of medical research may be avoided. A certificate of participation may be issued to the child or to the family, recognizing that the research involves a relationship with the child or the family. They may be given information about the different phases involved in the research. The researchers may consider the progressive, therapeutic, passionate, social and psychological aftermath of the child’s involvement in medical research.

In United States, considering the need for safeguarding the rights of children who participate in medical research and also because of the hue and cry from the public for extending safeguards to medical research consisting children, resulted in a report formulated by the Institute of Medicine.

Certain topics were specifically pointed out like:

1. Effectiveness of rules regarding medical research of minors of different categories
2. Interpretation of legal framework for validating medical research
3. Methodology for getting parent’s and children’s consent to be a part of research.
4. The speculation and understanding of minors and guardians on the matter of volunteering in experimentation
5. The suitability of payments regarding the minor’s involvement in experimentation process.
6. Adhering to the applicability of federal regulations
7. Specific roles and duties of institutional review boards.

The 2000 edition of RCPCH guidelines doesn’t have a difference between research which have therapeutic benefits and non therapeutic benefits. The main principle which was pointed out was that children may be made part of medical experimentation for the welfare and benefit of all children.
It was also provided that a research which may not directly beneficial to the child is not unethical if the findings results in the benefit of future generation of children. In conducting medical research if there is no therapeutic advantages to the child participant the extend of risk need to be very minimal.

The common law concerning medical research involving minors are confusing, unclear as well as difficult in identifying the rules on this issue with complete accuracy. Eckstein is of the opinion that there are no specific statutes or judicial interventions concerning research on children.

It is inevitable to participate children in research, as it is not appropriate, scientifically fair and overall unethical to conduct medical research in adults and apply those findings to ailments which only arise in children. Diseases occurring in children are different from that of adults, to understand those diseases in detail, research in children becomes relevant. The body physic of children is not similar as that of adult human beings.

The age related differences in drug handling may be better understood only through medical research in children. Many disorders arising in children need to be evaluated in the circumstances and stages of child growth. In order to make a medical procedure effective, its application may fit with their requirements.

Certain ailments that are considered to have their genesis in early life may be understood through the research with children. When research does not involve children, the advancement in the therapeutic care of children may be damaged. The children may not be given treatment that is potentially unsafe.

In United Kingdom, presently there are two legal frameworks functioning in parallel. For research not coming under medical research regulations, the common law is applicable. Medical research for finding drugs for human ailments comes under regulations for medicines for human use. As per the stipulations of medical research regulations, the age limit for majority is 16. The age of majority is 18 as per common law.

Common Law Considers those young people between 16 and 18 who are about to
reach the age of majority as competent to give consent. The young population, who have enough knowledge and understanding to comprehend the procedure involved and balance the information in arriving a decision, can give consent to the procedures of medical research.

As there is no judicial interpretation which predominantly deals with medical research Gillick’s judgment may be extended and applied to medical research cases also. However the nature of understanding varies depending on the complexities of research. The medicines for Human Use (clinical trials) Regulations 2004 are the law which regulates medical research in UK.

This regulation offers extra safeguards for a person under 16 who is being involved in a medical research. The regulation emphasis that for a person below 16 in order to get involved in a procedure of medical research may obtain consent from legal guardian or a parent and the concerned person may withdraw such a minor anytime while undergoing medical experimentation.

A child may not be participated without parental responsibility if he is found incompetent to participate in research. The children Act 1989 and the children Act (Northern Ireland) order 1995 formulated rules for rights of the parents and also for the right of the parent to furnish consent for the child while participating in the research.

The children (Scotland) Act 1995 includes measures for instances in which a minor cannot give valid consent. The adults and incapacity (Scotland) Act 2000 mentions the therapeutic measures and advantages to person over the age of 16 who are not able to give consent.

According to the Indian Good Clinical Practices, measures need to be adopted to ensure that persons or communities selected for medical research is choose in a manner which distribute the risks and benefits of the proposed research. The experimentation related to genetics may not result in racial differences and conflict. The individuals who are from a poor social and economic background may not be used for the advantages of those who are in a better position.

The interest and benefit of mentally disabled and differently able individuals who are not able of provide informed consent or those who have behavioural problems may be safeguarded. Enough justification is needed for the participation of research subjects such as
prisoners, students, subordinates, employees, and service personnel etc. who have diminished autonomy as research participants.

Alliance for Human Research Protection (AHRP) launched a programme to help common man to safeguard themselves from harmful or unwanted medical research. AHRP warns the participant of the medical research that the researcher do not always inform the research subject nor his family regarding the nature of the possible known and the foreseeable risks, discomfort, and the possible adverse consequences of medical research. AHRP urges anyone who thinks to become a part of the research to be informed to speak up and ask certain questions and the doctor conducting the project may provide the answers in writing, to certain questions.

The questions may be as follows:

1. The objective of the research, effect of research on the day to day life of the participant , whether the research subject need to be hospitalized and if yes how long ?

2. Will research participant have to be hospitalized and how long?

3. Whether the research procedure consists of any painful or uncomfortable procedures?

4. Whether the research subject’s sleep will be affected?

5. Who is the authority which sponsors the experimentation ?

6. Does the person conducting the research or other members of the research institution affiliate with the experimentation get a “finder fee” to bring the patients into the research procedure? If yes, nature of the fee?

7. Does the person conducting the research or the members affiliated with the experimentation is a paid representative to any pharmaceutical firm?

8. What are the risks and the side effects that can be foreseeable ?
9. Number of other people who have taken the said experimental drug along or before the research subject? Nature of their present status. Did anyone die as a result of the participation in the study?

10. Whether information can be furnished about anyone who had earlier or presently participated or participating in a similar experimentation?

11. For the purpose of the research does some patient get a new drug while others get a sugar pill [placebo]?

12. If I get a placebo, what is the benefit for me from participating?

13. Is this study designed to benefit me by testing a product or procedure that has a probability of improving my condition? Or, it in a non therapeutic experiment designed to learn about tolerance levels or the physiology of illness?

14. Does the study require that I stop taking all medication [drug washouts] for how long?

15. If my symptoms return whether I will be given proper medication which help me to recover, and who is authorized to prescribe those medicines?

16. Does this study in any psycho stimulant drug that will likely to include psychosis and worsen any condition, and what is the potential risk and hazards involved?

17. Who is the responsible authority for monitoring my wellbeing and also to make certain whether proper safeguards are being followed?

18. Is there any independent doctor who is not connected with the research term?

19. Is there any advocate to help me and what shall be his authority?

20. Will I be provided with a statement which discusses the risk and benefit of the denouement of the result?

21. Are there procedures that involve radiation (e.g. . . PET scans) in this study? Does that exposure conform to community safety levels for radiation?
22. What exactly does the informed consent cover and how long?

23. Does it cover more than one project?

24. Is this umbrella consent from that will allow several procedures to be performed at the same time or successively?

25. What will be the situation if I am injured or harmed?

26. Who is responsible for my aftercare?

27. Are subjects of research are protected by an insurance cover?

28. Will I get any compensation?

29. What alternative care treatment is available to me if I don’t choose to be a research subject and what are the advantages and disadvantages of each?

30. If the drug proved is beneficial to me, what assurance do I have that will continue to get the drugs after completing the study?

31. If there are any benefits from the study will my medical records indicate these findings and will those records be sending to the doctor who is going to treat me later in order to take decisions about my follow up care?

32. Will I and my family be informed about these finding in writing?

33. What follow up care is offered to those who complete a study? To those who drop out?

34. Who is authorized to available during business hours [e.g. night during a holiday or weekend] to help me if problems arise or should I wish to withdraw from the research?

35. Do I have the right to my medical records and will they be send to me or my doctor on my request?

To make a doctor to answer these questions is only one among the many action in the ongoing process of informed consent. When taking a decision
on the health care issues of young parties, both the parents and physicians have a joint responsibility. It is essential to seek permission to parents before medical experimentation. An informed parent is a responsible parent. It is not a mere permission by the parent. He has to undergo a thinking process before arriving at a decision.

AHRP requires a parent who gives permission for research on your child, to ask certain questions to the researcher. Some of the usual questions are:

1. What the medical condition of my child is and whether it needs medical attention and care?

2. Is there any treatment for this ailment already exists?

3. What are the foreseeable unfavourable health outcomes of that condition if no treatment is given?

4. Whether the child may overcome the condition normally without any medical attention? Etc are some of the questions among many.

Several national and international ethical standards guide the conduct of medical research involving human beings. These standards put forward schemes to respect the individuality of each and every individual and prohibits the use of one for the benefit of other.

Not respecting the autonomy of people who are competent is to inflict harm to these persons. There are many national as well as international guidelines to guide an ethics oriented human research. All these point out respect towards every individual in the society. They prohibit using the patients just as a means to attain an objective. They further establish a moral duty to consider the autonomy of the participant through a consent which is not affected through any vitiating elements.

With the advancement of medical science while conducting medical research the main objective is also to ensure safety of those persons participating in research. Very little of the clinical trials are adhering to the trial protocols. Many are not even conscious of formalities like informed consent from the patient.

Researchers need to be well informed about the ethical concerns attached with
informed consent, indemnifying the research participants, ensuring confidentiality, publication of research results and international collaboration. Giving transparency to the medical trials will minimize chances of malpractices, public must be adequately informed about the stages of each trial and its advantages to the society.

The recommendations of the committee based on ethical and moral considerations may be made binding on the institute conducting the research. The representatives from the media may be given the duty to make the public informed about the proposed trial.

The contemporary discussions of research ethics, commonly refer to later emerged declarations and reports like, The Declaration of Helsinki 1964, The Belmont Report etc.

The 2004 Helsinki Declaration consists of a very strict and fair consent. The method of obtaining informed consent from research subject has been made strict as compared to Nuremberg code. Explicit written document is made mandatory for attaining and requesting consent. Consent need to be obtained for the proposed research projects.

Art.20 the participants of the research must be volunteered without any vitiating elements and must be informed about the research project.

Art 22 : A research involving human being need to satisfy certain criteria before proceeding further with medical experimentation like:-

Person participating need to be specifically informed about

1. Aims
2. Procedures
3. Nature of funding
4. Chances of any conflict of interest
5. Institutions under which the researcher carrying out the particular research.
6. Foreseeable advantages and the nature of the risk involved in the study.
7. Possible discomfort that may result from the study.
8. The participant may be given information on his right to abstain from participation in the study or can withdraw consent at any time.
9. The researcher needs to ensure that the participant has understood all the information.
10. If the participant can’t furnish consent in writing, that need to be formally documented and witnessed.

Giving transparency to medical trials will minimize chances of malpractices, public must be adequately informed about the stages of each trial and its advantages to the society. The recommendations to the committee based on ethical and moral considerations may be made binding on the institute conducting the research. The representatives from the media may be given the duty to make the public informed about the proposed research.

The quest for higher standards for informed consent has introduced many vigorous problems to health care ethics. The idea behind the doctrine of informed consent implies strong commitment to participants of the research. It involves comprehension of issues and concerns pertinent to obtaining meaningful informed consent from participants. The consent may be a legally valid one only if it is given upon a thorough evaluation and understanding of the facts and ramifications of treatment and research.

Earlier, The Doctrine of Informed Consent set the standard of care as a matter of medical judgment, however now it shift the perspective in favor of warning the participant regarding the inherent risk on the proposed method of research. In a proper informed consent there occurs a proper communication between the patient and doctor. It is necessary to discuss the nature, the procedure, the risk involved and the result and benefits. It is essentially required to provide full information to the patient, and such communication shall be in an understandable language.

The patient shall be explained of the type of the disease or condition, the features of the trial which is going to be carried out and the chances of receiving advantages and benefits from the study. Further the details regarding the involvement and the characteristics of the factor of risk involved, possible advantages and disadvantages of the available methods of therapy shall be given.
The patient shall finally be offered a choice of no treatment. The patients understanding of the above information may be assessed and be made free to make choice among alternative medical facilities without any vitiating elements must be assured.

Thus informed consent is mainly interpreted in terms of freedom from interference. It is a form of absolute autonomy. Indian Good Clinical Practices defines Informed Consent as, an action based on one’s own free will.

A written consent of a participant’s readiness to be a part of medical research and in its documentation. The consent of the research participant may be obtained only after giving information about the procedures of the medical research. A statement regarding aims, anticipated benefits, disadvantages and inconveniences, any other presently available method of treatment also need to be mentioned to the research subject.

**The Risk Factor and Informed Consent**

Medical research in human beings constitutes a desire to inquire for the scientific advancement of the society at large. Medical research has enhanced the lives of the people and will carry on doing so. A medical research with a well designed protocol may always benefit the society. Research always attempts to find the unrevealed. In identifying unrevealed matters the risk is a hidden factor.

In Roe v. Ministry of Health the judge opined that ,In cases in which the anaesthetists had anticipated that the ampoules may be cracked and the cracks may not be find with bare eyes even with a thorough inspection , and consequently resulted in contamination, it is very difficult to foresee such cases as negligence.

It is not a difficult job to consider an instance as negligence after it has happened even if it was only a misadventure. Judiciary need to be a guard against such happenings to protect the rights of the professionals of health care sector. Medical science has bestowed tremendous advantages to the mankind. All these are achieved by overcoming considerable risks in every stage.
A surgeon confront with risk in every surgical operation. Benefits and advancements in technology may not come without risk. Medical professionals, like any other system of knowledge, have to acquire knowledge by experience which usually teaches in a very hard way. Occasionally some acts may go wrong, may show weakness. Later through experiences what is gone wrong earlier will become right.

In Medical research involving human beings there is a need to reconcile a wide range of interests and also balance potential benefits and harm. It is a difficult task to ensure that the medical research being conducted, do not risk the life of the participants of the medical research. The amount of the risk involved in a medical research may be identified only after its completion. Although medical research in developing countries leads to much risk of exploitation to persons and to the society, the benefits deriving from such research are passed to the people in developing nations.

Risk forms an unavoidable factor in medicine related or biological research. Even though not very high, in behavioural research also, the factor of risk cannot be avoided. The intensity of emotional consequences of the exposure to research is very high.

The researchers may be held liable for negligence if not obliged to the duty to pass material factors relating to the research to the participants. A prudent researcher should warn the subject about all those risks involved which a reasonable person demands to know. The researcher may appreciate the right of the research subject to be informed; otherwise the researcher may be morally and legally censured.

Deciding on the risk-benefit ratio is considered as the hardest ethical concern which the ethical committees address. Usually, a comparison is made between the risks of injury from involving in a medical research to its accompanying benefits. In most cases the research consisting of more than minimum risk of harm. The researcher may guarantee on advantages of the experimentation clearly override the risk of harm.

The advantages of the research are not purely bestowed to the research subject, in most cases but it goes to the society at large. New knowledge in medical science leads to advancement of
health care sector which benefits the society at large.

The duty to make certain that the involvement in medical research dispense a beneficial balance of anticipated benefits and harm to the research participant is essential when upholding the ethical reasoning of beneficence. Any treatment or procedure carried out on an individual in the absence of consent of the research subject, could amount to a criminal offence, unless it is carried out with good faith and belief that it will result as beneficial to that person, so the Doctrine of consent is frequently the key to approach health care.

In United States, The Institutional Review Board is the authority for protecting research participants. An obligation is bestowed on IRB to see that the Risk to the research participants is minimized and also risks are sensible with regard to the anticipated benefits.

As per federal regulation an approval to medical research involving children can be justified only when the probability and intensity of risk or any discomfort as a consequence of research may not be higher than one encountered during the routine physical check up or examination. Physicians have a duty to respect the autonomy, right and preferences of their patients and their surrogates. The advantages and harm arising from the research may be balanced and shown to be in a favourable ratio.

Risk involved in medical research is not a matter of concern for the research subject alone. It may adversely affect the whole community and also future generation. Morgan defines Risk as a disclosure to a possibility of harm or loss. The chance relates to uncertain and unpredictable events. The harm or deprivation includes any consequences for which the person who is acting has no utility.

Risk factor is a multifaceted and complex concept consisting of dual magnitude, a probability and a certainty of happening of certain unwanted harm to the research participant. The consent of the research subject will be legally valid only if it is given upon an appreciation and after evaluating of the facts and after effects as a result of research. The subject may be exposed to all harm and certain advantages as a consequence of the involvement in medical research.
The research subject thus may be properly informed. Informed consent is obviously a patient centred one. It requires disclosure of two major types of risks. Firstly it is the general and significant risk and secondly it is the specific and particular risks applicable to the patient. The first comes in the category of objective or reasonable patient approach and the second in the subjective or particular approach. In fact the concept of informed consent combines both types of approaches.

Lord Scarman enunciated three grounds as the basis of informed consent in Sidaway’s case;

1. Firstly, it is a basic concept that an individual who has completed the age of majority and has a sound mind has a right to choose what may happen to his or her body.

2. Secondly, the consent is the informed exercise of a choice and that it entails a possibility to elucidate knowledgably the resources available and the risks pertinent on each.

3. Thirdly, the doctor must therefore disclose all material risks.

What risk are material is determined by the prudent patient test, which elucidates what a common and prudent patient in the same situation of the plaintiff may attach significance to, in coming to a decision on whether to participate in an experimentation procedure or not. Thus it is the duty of the researcher to evaluate the facts and decide what all are material risks.

Risk means a harm which has a possibility to happen. The features of risk cover the possibility of its happening, as well as its degree and time span. The risk factor may be differentiated based on its intensity of consequences like;

1. Minimal risk
2. Low risk

3. High risk

In Minimal risk various measures are adopted and explained to the research subject in advance. In order to identify material risk, the researcher has to think like a reasonable and prudent man. Commitment to avoid risks or reduce them as much as possible can also be stated as nonmalefence.

For every research, there is a need to look at risk-benefit ratio. There may be a proper balancing between risk and the likely benefits. There are direct, collateral benefits to the research subject is possible from research. Benefit is direct when the benefit of intervention is received. The benefit is collateral when benefit is received even if one doesn’t receive the intervention. The benefit is aspirational when the benefit goes to the society at large.

Risk involved in the experimentation may be of different forms like Economical risk, Physical risk, social risk, psychological risk. The harm which may cause based on a minor risk are categorized as:

1. Minor or serious,

2. Temporary or permanent,

3. Immediate or delayed.

It may also result in emotional sufferings; it may result in some aberrations in behavior. The research participation may expose the subject to any type of social stigmatization. Financial burden may also arise as the result of research participation.

Research needs to be conducted by professionally competent persons to reduce risk to the participants. If the risk is foreseeable then its happening may be reduced to the maximum possible extend. The potential benefit as an outcome of the research and furthering of information may outweigh the risk which is foreseeable.

The factor of risk is comparatively higher when conducting medical research involving children. In US authorities in charge of designing and sponsoring medical research plays a commendable role in designing ethical policies to safeguard human involvement as
research subjects.

The Secretary’s Advisory Committee on Human Research Protection structured certain observations which need to be followed for carrying out the research on an ethical manner when the research involves children. In examining the possible risk or harm caused due to research procedure that involves children, the researcher may interpret minimal risk taking into account the normal experiences of average, healthy, normal children.

The world of medical research has become outmost competitive and commercialized. Clinical research is essential to determine the efficacy, adverse effects, interactions and cost–effectiveness of drug therapy in various patient populations. Every year about 80000 medical experimentations carried out throughout the world comes up to the cost of about 12 million $.

Though the Helsinki Declaration, specifically states that the priorities of the research participant may always dominate over the interest of the medical science or welfare of the society at large\textsuperscript{iii}. The facts show many cases in which laws are not taken care off. The controversy over the medical research conducted in 2001 at the Regional Cancer Center (RCC) Trivandrum, Kerala of anti cancer drugs, nor–dihydroguaiaretic acid (NDGA) and its tetra –o –methyl derivative (M4N) illustrates the inadvertent and reckless manner of conducting experimentation on human beings.

The total market for clinical research activities in India was 1.5 – 2 billion in 2010.\textsuperscript{xiv} It is also predicted that within the next two years 30 %of the global clinical trials will take place outside the U.S, it is likely that India would emerge as a favorable destination.\textsuperscript{xv}

Medical research consists of greater risk than ordinary therapy therefore cautions and precautions are needed. The doctrine of informed consent reflects some moral value which needs to be protected for the welfare of the community at large and also for protecting individual research subject. The report of the Institute of Medicine (IOM) indicates that thousands of patients die in hospitals every year because of errors committed by doctors and hospital authorities.
On March 14, 2002, the joint commission on Accreditation on Healthcare Organizations (JCAHO) has lounged a national campaign “SPEAK UP” to bring forward the patients to take up active participation in their own health needs. The main motto was to be active, involved and informed participants\textsuperscript{xvi}.

**Flizer’s Ethics Programs Relating to Informed consent.**

The initiate was to point out the importance of conducting medical research with internationally accepted ethical principles of medical research. Flizer formulated a “speaking book” for uneducated individuals to describe the basis and importance of being a part of medical research. It consists of cartoons to explain the content along with the test. It teaches uneducated patients and their dependents to have a general knowledge of these concerns.

In addition to these Flizer conducted debating competition for high school students. It included exposure of a large variety of young individuals and generates meaningful discussion on the ethics of medical research. Flizer assumes that only through a grassroots level understanding the concept of informed consent may become meaningful, practicable and provide true protection.

The law protects the individual’s right by requiring the doctor to disclose information on the risks and benefits emanating during different stages of experimentation to the subject. To balance the potential benefit and risk needs a good understanding of both. The problem is that, it may be for the first time that the research subject is realizing how poor his skill or capacity to understand things is. Thus the detailed information about the aims, methods and the procedure adopted during the trial may sometimes cause distress to the research subject.

The research subject may also understand the implications of randomization. He may come to know that neither he nor the researcher understands which medical procedure they may undergo and also that the researcher himself don’t know which is the better method. To force unwanted information on a research subject may adversely affect him\textsuperscript{xvii}.

The information of the objectives and results of medical research already done may sometimes prejudicially affect the way of approaching the therapies or questionnaires which come later. The object of the research may fail with a biased attitude of the participants of research subject.
On question of free and informed consent in medical experimentation, there were always two types of physicians. One group of physicians insists on free and informed consent at all times; another group tends to be more flexible. They are of the consensus that, free and informed consent may be obtained whenever the risk is slight.

Jean Bernard, illustrates an issue of informed consent as, Here is a 25 year old man, a diabetic. He knows his illness in detail such matters as blood sugar, sugar in the urine, and acetone and alkaline reserves. He is perfectly capable of understanding both the advantages and inconveniences of any proposed new treatment. He can give a free and informed consent, but another man also of 25. He has the ailment of leukaemia. There is no effective treatment known.

When invited to participate in the trial of a new drug, he is given information something like this: “your leukemia most likely will kill you in about four months. This new treatment may (and no one knows for sure) give you two or three months more. Do you want to join the trial? Putting a proposition like that to an already doomed patient might even hasten his decline.

Jean Barnard, asks how could his patient already so ill, respond objectively? A patient whose physical and mental condition affected because of an ailment may not respond positively when asked for informed consent. He may not understand the nature and the consequences of the said research procedure even if explained to him.

So more acceptable proposition relating to informed consent is informed and free consent need to be specified and obtained when the risk factor involved to the patient is slight. But on the other side there is an argument which says that medical progress may adversely affect by giving much importance to the liberty of the individual.

With the full publications of the objectives and benefits and the risks involved, the research subject may refrain from doing their duty to serve the societal interest which may lead to improper functioning of the research. There are several instances in history which can be seen as an example.

Many research study where carried out giving significance and importance only to the welfare of the society. In the Tuskegee Syphilis Case\textsuperscript{xviii}, the advancement of science and
generation of knowledge was immensely placed before the research participant’s welfare and best interest. The research subject may be well informed about the procedure involved in the research process.

**Conclusion**

When we evaluate the nature of eliciting informed consent in our nation, there are many suspicious situations. Does anyone really explain the procedure of trials to participants? There is a need to change the methods and procedures, the process of taking informed consent, so that researcher gets enough time to explain to the participants the nature of informed consent procedure in a manner understandable to the research subjects.

In cases in which the things are being explained, the researcher may explain to the research participant that this is the procedure, we may use this medicine, we suppose it may work and suddenly in almost all cases the research subject responds that, he agrees to the treatment. This is the response of research participants irrespective of public sector or private sector.

Many thinks that in private health care sector the consumers are more knowledgeable, but the position is more or less same. Those who approach the health care sector believe that the physicians are doing something for their good. It is essential to follow the ethical guidance and the essential mandates of the doctrine of informed consent when a doctor plays the role of a researcher while conducting medical research.

Whatever may be the justifications, the non-therapeutic research has the sole object of acquiring knowledge, in most cases without any benefit to the subject of research. Hence it warrants a strict application of the principle of informed consent. It is essential to ensure that the medical research involves minimal risk and harm to the particular who has enrolled for research and the procedures conducted has the potentiality of benefiting significantly to the mankind.

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3. Should I have a proposed operation? Should I buy this car or this computer? In each case I need to assess what is offered, but may be unable to judge the information for myself.
Patients who have impairments in their reasoning in addition to their primary symptoms like cognitive deficits, concrete thinking, inability to abstract etc might have difficulties in this regard.

Patients with schizophrenia, for example, who do not believe they are ill will have a limited appreciation of why they are being enrolled in a study.

Section 46.404, Ibid.

Higgins Vs Kennedy Krieger Institute, Inc.


Ibid.


Physical Harm Or Psychosocial Harm Like Breach of confidentiality, Stigmatization, Discrimination. Studies Involving DNA Banking, Genetic Studies Or Involving Psychiatric Illness Need To Ensure That No Psychosocial Harm Occur To The Participants.


World Medical Association – Declaration of Helsiniki.

According to a study by consultancy Major Erust & Young.

Aparna Ramalingum, 3 Sep, 2006, Times News Network.

http://www.jcaho.org/news frm.html