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Institutional Ethics Review Committees: Bridge not Barrier to Humane Research

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Introduction:

A brief history of ethics committees:

In the Hippocratic texts, the dominant figure of the essentially male physician taking virtually all decisions pertaining to the life or death of a patient has been portrayed. In these texts, the person taking these decisions is almost in all cases depicted to be a person of very high wisdom and one whose integrity in making these decisions cannot be suspected. In the modern context, priority of many contemporary consultants is not to be doctors of medicine. The earlier texts show that even though the Hippocratic authors counseled the use of consultants in hard cases, they did not seem to anticipate a non-physician consultant whose sole function was ethical rather than medical assistance (Ackerman, 1989). Moreover there are other concerns such as justice and autonomy that guide the ethics consultants of today whereas most of the early ethical issues were those of values of non-malfeasance and beneficence (Moreno 2010). However, this article proceeds to reflect that the manner in which ethical considerations have needed legal backing has led to the formation of institutional ethics review committees. Thus law has supported the cause of ethical review committees. Law has created avenues for the enforcement of the stipulations and recommendations of the ethical committee. This article seeks to explore this relationship between the ethics committees and law.

In the beginning the Ethics committees were not as rigidly structured as they are now. These committees were less procedural and were not necessarily controlled by non-physicians (Moreno, 1995)

US scenario:

It would be interesting for the purpose of this article to trace the trajectories of the institutional ethics review boards and how they have always needed the support of legal cases and maxims to further their cause.

In the 19th century, sterilisation committees in the US were composed mostly consisting of those trained in mental health care. Their role was to make decisions regarding the avoidance of social burdens such as inherited ‘idiocy’ through prevention and by their perspective, they took these decisions very objectively. These were extremely ethical decisions to take.

The later example would be the committees formed in the 1960s when dialysis machines were in short supply, which kidney patients with terminal illness should have access to these machines. The issue of allocation of a scarce life resource in a situation where the demand exceeds the supply, was indeed a perplexing issue that brought the matter of ethical dilemmas to the forefront. The debate of having a fully competent ethics review committee arose from there. The famous 'God committee' attracted wide spread media attention, at a Swedish Hospital in Seattle, Washington in the 1960s. The experience of allocation of scare life resources was brought to the forefront through this committee (Alexander 1962)

Also, until the 1970s, abortion selection committees took the highly subjective and controversial decision of identifying those with medical or psychiatric ailments and warranted elective termination of pregnancy.

In the landmark ruling of the New Jersey Supreme Court; in the case of Karen Ann Quinlan the Judges stressed upon the need of having ethics committees in place. The judges also relied on the Law review article of Karen Teel which was published in 1974 where she stated that numerous hospitals often used the ethical committees to make complicated decisions. The Judges agreed in the judgement that if the ethics committee had reviewed the case and reached a conclusion that had been recommended a certain set of people, which made decision makers exempt from civil and criminal liability. Moreno (1995) is of the opinion that the judges seemed to have been unclear about the functioning of the ethics committees and confused them with prognosis committees, which are more traditional and technically driven. Thus, the ethics committees have always worked in tandem with the existing laws or have needed to include newer laws.

Next in the series of events which led to the formation of the ethics review committees as they are found in the present context are the Reagan administration's attempt in the 1980s to secure for severely handicapped newborns, aggressive treatment regulations that included reference to 'infant care committees (Moreno 1987)

The United States has a mix of both the optional model and the mandatory model of institutional ethics committees. A large number of committees in the U.S. operate on the optional basis for the purpose of case review. Thus, whether a case is brought to the attention and approval of the ethics review committee, is optional and not mandatory. The advice of the committee is also optional, i.e. the physician is not bound to follow the advice of the committee.

However, in some states in the U.S. this is not the case and state ethics committee's main objective is to comply with mandatory legal requirements. For example, it is mandatory under special law in New York state to obtain consent from the patient or her appropriate surrogate for a physician's DNR ('do not resuscitate') order. A dispute resolution committee is to be formed to solve any disputes that arise between the surrogate and the physician, and some ethics committees accomplish this function. Dispute resolution mechanisms are also part of some state laws concerning the assignment of durable powers of attorney for

health care, and again ethics committees can be convenient venues for this role. (Moreno 2010)

One of the possible role of ethics committees which was not anticipated during the mid-1970s is that of resource allocation. Health-care around the globe is witnessing mounting financial pressure suggesting that, explicit rationing is a looming possibility. No less figure than the editor of the Journal of the American Medical Association has suggested that ethics committees help develop practice guidelines for their institutions to identify when treatment may be withheld on grounds of (so-called) futility (Lundberg, 1993)

Moreno (1995) has argued that bioethics has to be recognized on equal footing as social scientists understand various other social institutions i.e. as a set of social practices.

In a survey conducted by Fox and Stocking (1993), of the ethics consultants, they found great difference of opinions with respect to various scenarios. During the survey 154 ethics consultants were questioned regarding their reactions to a particular case where the patient is in a persistent vegetative state who was artificially administered food and fluids. Out of various scenarios where non-treatment was considered to be an option, the one that the consultants tended to agree (87%) was the one where the patient left specific instructions that she would not want any life-prolonging treatment, which her family had also consented too. In other cases where there was a difference of opinion between the patient and their family members, has seen less than 50 per cent agreement to stop treatment.

International development of Institutional Review Boards:

In the USA, there was huge uproar after the reported revelations in the Tuskege Syphillis Study initiated in 1932, wherein, about 400 African-American men were medically followed by public health officials for decades, without revealing to them their diagnosis even when treatment was available, following which, the National Commission for the Protection of Human Subjects of Biomedical and Behavioural research, issued the Belmont Report, which articulated the guiding ethical principles of human subjects research in USA. The three main principles of the Belmont report are:

1. Respect for persons
2. Beneficence and
3. justice

Based on this, the regulation for the protection of human subjects were issued in the code of federal regulations in 1981 (http://www.hhs.gov/oh rp/humansubjects/guidance/45cfr46.html)

The research grants Division of the Public health Service, issued a memorandum in 1966, which outlined the need for research ethics review in USA. It stated as follows:

No new, renewal, continuation research or research training grant in support of clinical research and investigation involving human beings shall be awarded by the Public Health Service unless the grantee has indicated in the application in the manner in which the grantee institution will provide prior review of the judgement of the principal investigator or programme director by a committee of his institutional associates. This review should assure an independent determination: (1) of the rights and welfare of the individual or individuals involved, (2) of the appropriateness of the methods used to secure informed consent and (3) of the risks and potential medical benefits of the investigation. A description of the committee associates who will provide the review shall be included in the application. (Confrey, 1968)

Ethicists and other critics have argued that the rules for ethical research as operationalized by IRBs have actually become **'rules of policy'** designed to protect the institution from risk, rather than ethical 'first principles' designed to protect research volunteers from potential harm (Downie and Cottrell, 2001; Flicker and Guta, 2008; Office for Human Research Protections, 1993; Solomon and Piechowski, 2011). Benjamin Sachs, a bioethicist, argued that the seven rules for research (i.e. informed consent, right of withdrawal, etc.) should more accurately be understood as policy norms rather than ethical norms (Sachs, 2010). He elucidated that ethical rules echo ethical facts while rules of policy are applied to achieve a specific goal. Ethical facts should be applied uniformly around the globe, whereas policies which are frequently enforced universally, may not serve in attaining the best ethical choice in any given context.

Relation between Ethics committees and law:

Law has had a historical relationship with bioethics and research. When ethical dilemmas were faced by researchers, law has come to the rescue by offering to provide sanctums of legal rules and regulations that define the frameworks of legally valid research. However, of late there have been many discussions and debates about the role of law in bioethics. Some researchers say that bioethics has developed under philosophy and theology and law has had no role to play in the process (Jonsen A.R. 2000 describing the start of modern bioethics by saying that, "Gradually, scholars from the two academic disciplines that had traditionally studied morality, philosophy and theology, began to join the scientists," though acknowledging that a broader range of disciplines including law eventually entered the field as well)

Some authors have also said that not only law has shaped bioethics, but that bioethics has also shaped law (Loyola of *Angeles Law Review* 27 (1993)25-40, 32**)** However, if one were to assess the process of evolution of ethics in research, the role of law will be hard to overlook. The safeguarding of the rights of participants in a research and ensuring the codification of best practices and watertight rules have been the contribution of law in research and bioethics. The field's attempts to avoid future atrocities with respect to human research have relied primarily on federal regulation. (the central, though not only, federal regulation is the Common Rule, found at 45 C.F.R. pt. 42 (2003) Attempts to empower patients and families at the end of life have involved legislative recognition of advance directives (A. Meisel and K.L. Cerminara, me Right to

Die:The Law of End-of Life Decision making (New York: Aspen Publishers, 3d ed. 2004): chapter 7**).** The background to ethics in research is full of recourse to law and its sanctums of binding authority that has led to thousands of judgements, recourse to the **U.S.** Supreme Court. Attempts to prevent human reproductive cloning have been based primarily around federal law and regulation, state law, the laws of other countries, and international agreements. T.L. Hafemeister et al., "The Judicial Role in Life-Sustaining Medical Treatment Decisions," Issues in Law and Medicine (1991)

Wolf has argues that law has created a practical path for the development of bioethics. She has shown that the pragmatic approach forward in the quest for implementable bioethics was through that shown by law. Wolf further argues that protection of the most vulnerable sections in the field of research i.e. the patients, researchers and those without access to care has been possible only through legal frameworks that have been put in place. Without law providing for logical reasoning and watertight rules and procedures the concept of consent, through consent forms, disclosure, voluntariness, confidentiality and many more could not have been put in place. These terms have always been the basis of bioethics. They have always been a part of the discussions however, never before a part of the mainstream because they could not be defined categorically, till law codified such terms into definable terms to be used in a uniform manner by all concerned.

Meaning of the ethical principles:

There are certain principles on which the premise of ethics is settled. These are unalterable truths for the practice of institutional ethics review boards. They area enumerated briefly in the following paragraphs:

The first ethical principal is that of beneficence; which is the ethical obligation to improve the welfare of others (Ross, 2002 [1930]). In research settings, this is the responsibility which is associated with the welfare of participants, which might include physical health, psychological well-being, and social reputation.

The second ethical obligation, justice, has two essential components. In most research settings, justice primarily implies that there be a unbiased selection of research participants and perfect distribution of risks and benefits. This is commonly known as distributive justice. The second component of justice, known as procedural justice, is concerned with fairness in the processes for resolving disputes, making decisions, and allocating rewards (Tyler and Blader, 2000). Safeguarding the autonomy of all people has been identified as the third ethical obligation which is achieved, by treating them with respect, which undergirds informed consent, an exchange that requires understanding by the community or individual of the relative risks and benefits of participation. This principle is consonant with the ethical obligation Ross (2002 [1930]) defines as 'non-maleficence' or 'do no harm'

Gaining confidence necessitates learning to communicate across differences, and developing the skills to address ethical and operational issues when these arise, as they inevitably will (Chavez et al., 2008; Leung and Srinivasan, 2010) demonstrate the commitment to self-evaluation and self-critique in order to

redress power imbalances and to develop and maintain mutually respectful collaborative relationships. Inequality may spread through the practices of IRB, beyond interpersonal interactions. Researchers and community groups have appealed for lenient protocols and IRB review procedures in order to respect cultural values, community timelines, and emergent research design (Bradbury and Reason, 2006; Downie and Cottrell, 2001; Patterson et al., 2006). Developing flexible protocols would involve two things from IRBs: understanding qualitative and emergent research methodologies becomes imperative to create protocols that facilitate high quality and ethical research; and secondly, changing standard IRB submission and review procedures to be more flexible. Both of these would mean that the IRB is expected to act on its ethical obligation for self-improvement. For all parties, understanding the ethical obligation to self-improvement, as well as respect and procedural justice, can help highlight the need for each to share and educate others as well as to listen and learn from others. In Phase II, ethical guidelines would focus on strategies and procedures (not policies) for creating trust and mutual learning through identification of the research needs of the community (Brown and Vega, 2008; Downie and Cottrell, 2001; Minkler, 2005).

While regulations establish several facets of IRB structure and function, interpretation and application of the regulations can vary considerably between IRBs. Since approximately 30 years of the formal birth of IRBs, much has been understood about the pros and cons of the IRB system (Grady, 2010; Hamburger, 2004; Rice, 2008) Moreover, no aspect of human subjects research review requires that IRBs play an adversarial role, longstanding perceptions notwithstanding (Steinke, 2004). Instead, the shared metaphysical foundations articulated in Nuremberg and Belmont present as 'first principles' a robust regard for the shared humanity of researchers and research participants. The presupposition that undergirds the notions of beneficence, justice, and respect for persons is precisely that researchers, IRBs, and prospective research participants are all members of a mutual community of moral agents who voluntarily engage in the discovery process. As such, communication, collaboration, and a shared effort to protect the safety, rights, and welfare of research participants – as individuals or communities – is a basis for responsible conduct of research for both traditional research and CBPR. There is nothing in this vision that cancels adaptation of IRB review, but it requires a concrete effort to reconstruct review of human subjects research within a framework that is more collaborative, more flexible, and more attuned to the perspective of the communities and research participants that are invited to be a part of the process.

The Law has also been instrumental in creating ethics review policy in the areas of community based participatory research (CBPR). In traditional research, three types of risk to individuals are assessed – process risks to well-being, outcome risks to well-being, and risks to agency (Ross et al., 2010b). In CBPR projects, communities, such as a tribal group, might also face process risks to well-being (risks to group structure and function because of research processes), outcome risks to well-being (risks to the group's structure based on research findings), and risks to agency (undermining the group's moral and sociopolitical authority) (Flicker et al., 2007; Ross et al., 2010a). We expand this argument further, noting that when researchers work with communities, all the ethical principles of justice, beneficence, and respect necessarily expand in scope to include the community in

addition to individuals (Downie and Cottrell, 2001; Ross et al., 2010a). There is needed to be a shared effort to recognize a broader ethical perspective.

This includes:

- Recognition that IRBs ought not simply to 'tell' researchers or communities what is ethical/appropriate; they are partners in a collaborative process aimed at responsible conduct of research. Often, determining what is the best way to achieve a particular ethical objective is to seek the advice of community members or those who are most likely to be impacted, not simply superimpose an 'outsiders' construal (O'Neill, 1985; Strand et al., 2003).

- The research community must commit to discussing the ethical priorities of each party (researcher, community, IRB) as protocols are being developed and as studies are being conducted.

- Where ethical priorities appear to be in conflict, a shared discussion of management plans to ensure best practices must ensue, with the primary aim being to ensure respect for the safety and well-being of the community in question, not that of the institution conducting the research or reviewing the IRB protocol (Cross, Pickering and Hickey (2014) Community based Participatory Research, Ethics and Institutional Review Boards: Untying a Gordian knot. Critical Sociology, Sage Publications

CONSENT is a major part of the ethical research process. In fact it forms the basis of responsible and accountable research. For consent to be available, it is very important that certain prerequisites should be in place. The first and foremost is capacity. The word capacity is sometimes interchangeably used with 'competence'. Grisso and Appleabum (1998) define capacity as a complex construct that refers to the presence of a particular set of "functional abilities" that a person needs to possess in order to make a specific decision.

Also the law comes into play when the debate is between the ethical principle of beneficence and respect for the patients's or research participant's autonomy. In many cases the research participant may not want to divulge certain information even though the research is for a greater common good. In such scenario the conflict between the autonomy of a research participant and the beneficence arising from the positive results of the research are in contradiction. (Hope et al. 2003) have stated that in western society, the liberal tradition emphasizes the importance of liberty and freedom for the individual and, in particular, freedom from the interference of others. In this context the principle of beneficence will be trumped by autonomy. Such decisions shall be made under the aegis of the concerned law in place.

The main weaknesses of Institutional Ethics Boards:

It is seen on a general basis that those ethics committees are usually successful which engage in the day to day clinical and educational activities. Usually ethics

committees are created amid great excitement and optimism about their anticipated contributions to institutional culture, education and morale, but usually after some time, most ethical committees suffer from what the bioethicist John Fletcher calls the ethics committees' 'failure to thrive' syndrome (Fletcher, 1995: 228). Usually, the reason for this is the passive style of the functioning of such committees. The committees which are more successful tend to be those that actively insert themselves into everyday clinical and educational activities, creating relationships with staff members and the sense that the committee is a vital resource for everyone concerned.

Despite the remarkable growth and undeniable popularity of ethics committees, there are many unanswered questions about ethics committees. For example, what is the legal status of an ethics committee's non-binding recommendations in a court of law? Should hospital lawyers be voting members of the ethics committee? Who should be able to bring a case to the committee? Should a designated patient advocate sit in the ethics committee? What about the hospital's risk manager? Should an ethics committee record its recommendation in the patient's chart, or only that it discussed the case and offered some assistance? (Moreno 2010)

There could be major flaws in the manner in which some institutional ethics review boards function. There are some inherent ethical conflicts which are embedded in common IRB practices which reveal the need for a paradigmatic shift in how the practices of institutional ethics review boards. Power centers are created as exclusive units of generation of knowledge, through the Institutional Ethics Review boards, which is an avoidable trend in research. By creating a deadline for submissions and obtaining approvals and by setting time oriented targets, the institutional ethics boards render the community timing as irrelevant to the research (Chavez et al, 2008; Israel et al, 2008; Stoecker, 2008)

In the same manner, if the Institutional Ethics Board requires a letter of recognition or of support for its functioning and day to day governance for the procedural aspects of the institutional ethics board then the rigidity of this process may diminish the value of the work of the Board.

The initiatives taken by organizations with of institutional structures more familiar to IRBs are favored over initiatives taken (schnarch, 2004). When the IRB accepts the epistemology of Western science as the only legitimate paradigm, then alternative forms of knowledge construction held by the community are subjugated to the researcher's epistemological domination as illustrated by Dr. Markow who claimed she was doing 'good science' but the Havasupai Tribe felt violated (Harmon, 2010). The fact that the IRB requires that consent be obtained from each individual research subject means that protections are predetermined not to extend to communities and cultures (Ross et al., 2010b). What was initially justified as a protection for human subjects looks much more like assertions of privilege and power when viewed through the lens of CBPR (Chavez et al., 2008; Israel et al., 2008; Smith, 1999). However, the very principles of

CBPR that enhance ethical conflict between researchers, communities, and IRBs also provide the answer – participatory processes.

However, now in modern times, there is a tacit understanding amongst policy makers that ethics committee members should be from areas of expertise, such that there are diverse perspectives, and not only physicians. Thereby meaning that the idea of democratic liberalism has to be maintained in the constitution of ethics committees, which includes the ideas that ethical problems are best solved in the backdrop of the idea of a good life, through a process that takes into account multiple perspectives (Moreno 2010).

RELATIONSHIP BETWEEN ETHICS COMMITTEES AND COURTS:

Education, development of policies and guidelines and consultation and case review (Cranford and Doudera 1984). The relation between ethics and law can be described best with the aid of the concept of co-production. The term co-production has been used to describe the complex process by which science and society interrelate to influence each other and develop together. **S.** Jasanoff, "Ordering Knowledge, Ordering Society," in ***S.*** Jasanoff, ed., ***States of Knowledge: The Co-production of Science and Social*** Order (New York: Routledge, **2004):**13-45

This term can be easily used in the context of the relationship between bioethics and law. Only when the need is felt by a society to enable it to have a codified framework for its protection, law steps in to provide a coherent and pragmatic solution. The same process has led to the formation of ethics committees when the need to protect the rights of the research participant was pointed out by various sections of the society. According to Wolf (2004) the field of bioethics is a collaborative production of lawyers and non-lawyers who are all working with a set of tools, some legal and some non-legal. The concept of Fundamental right to live with dignity and the right to life and liberty are all legal maxims that have come into the picture as and when the issues of bioethics have developed.

S.M. Wolf, **"Shifting** Paradigms in Bioethics and Health Law The **Rise** of a New Pragmatism," ***American Journal Of Law and Medicine 20*** **(1994): pg. 395-415** David Orentlicher's has discussed how principles are translated into practice in both law and ethics. D. Orentlicher, ***Matters of Life and Death: Making Moral Theory work in Medical Ethics and Law*** (Princeton, NJ: Princeton University Press, **2001).**

Roger Dworkin also takes an interesting look at the relationship of law and bioethics in R.B. Dworkin, ***Limils: The Role*** *of* ***Law in Bioethical Dworkin Making*** (Bloomington, IN: Indiana University Press, **1996).**

The alliance between research ethics and law is complex and intriguing. Through the course of time researchers have realized that law is not only liberating and a vision of rights talk, individual liberty and protective regulation. Law can also be used as a force of the state to ban scientific and medical practices, laws to criminalise scientific research and threaten imprisonment. Robert Cover, found law at the core of violence, and not just any violence but violence of the state. (R. Cover, "Violence and the Word," in M. Minow, M.Ryan and A. Sam, ***Narratiue, Violence, and the Law: The Essays of R o b Cover*** (Ann Arbor, **MI:** University of Michigan Press,**1992): 203-38.** Cover writes: "Legal interpretation takes place

in a field of pain and death.... **Legal** interpretive acts signal and occasion the imposition of violence upon others: A judge articulates her understanding of a text, and **as** a result, somebody loses his freedom, his property, his children, even his life .... Neither legal interpretation nor the violence it occasions may properly be understood apart from one another." ***Id.*** at **203.** Thus it can be easily said that law and ethics are deeply connected.

Moreover, Institutional Ethics Boards are a relatively new phenomenon in University campuses internationally (Sachs 2010). Also, for the fulfillment of the above functions of ethics committees, it is vital that the committee is well conversant with all aspects such as legal, scientific, research based etc. to arrive at the correct and coherent result. It is undeniable that the role of the ethics committee member is a terribly complicated one requiring a broad range of skills. They must be well conversant with the facets of medicine, law and ethics and must be interpersonally skilled and cognizant of social-psychological issues. (Moreno 1991)

- Ethics committee to be viewed as a legal requirement for protection and not as a barrier to research- Assessment of any decision taken by the ethics committee through the legal filter not only safeguards the researcher but also the Principal investigator is insulated against any future litigation that may arise.

- Ethics committees are therefore intricate mini institutions of power and tremendous capacity to make decisions that strengthen laws and policies.

WHY IS IT SOMETIMES TERMED AS THE IMPOSSIBLE PROFESSION?

However when one approaches this topic, it is evident that the ethics consultant's role is a extremely complex one, which requires a broader range of skill set than that can be found in nearly any other field. At a minimum, the competent ethics consultant must speak the languages of medicine, law and ethics, must be interpersonally skilled and cognizant of social-psychological issues and must have the ability to inspire confidence among patients and their families as well as her medical colleagues (Moreno, 1991).

CASE STUDY:

1. A researcher goes to the interior parts of India to do his research and builds trust and goodwill amongst the local inhabitants. He finds that one of the research participants is very depressed but refuses any discussion on the subject. The researcher encourages him to see the psychologist but the person refuses any help or treatment. He shares with the researcher the social stigma that is attached with being seen with the psychologist at his clinic. People will declare him mad and imbalanced and cut off social ties with him and his family. Not just him but his family will also suffer.

   In this scenario the researcher is in a dilemma as to whether to let the situation rest as it is or to help the research participant. The ethical law says

that the privacy of the research participant has to be maintained. The researcher also feels constrained to himself report the matter to a mental health consultant because he feels that this could be a breach of trust between him and the research participant.

In such scenario some out of the box thinking is usually required because the law is very clear on the concepts of consent and voluntarism. The law upholds these as against the ethical principle of beneficence. In such scenario the conflict between the autonomy of a research participant and the beneficence arising from the positive results of the research are in contradiction. (Hope et al. 2003) have stated that in western society, the liberal tradition emphasizes the importance of liberty and freedom for the individual and, in particular, freedom from the interference of others. In this context the principle of beneficence will be trumped by autonomy.

Thus, we see that the law comes to recourse in times of moral dilemma. It also protects the researcher from making a judgement based on subjective considerations and provides the framework for an objective assessment in which the privacy of the research participant is maintained.

However, having stated the above, it is still possible for the researcher to help the participant by suggesting some alternatives such as by encouraging the participant in seeking help in a nearby community where he will not be recognized. Making some appointments for the participant so that the initial hesitation is over.

2. A researcher 'X' is working on his research project related to old age home inhabitants. He notices that one of the usually cheerful and helpful inhabitant of the old age home 'B' gets rather nervous when his son visits him in the old age home. He interacts less, contributes lesser in the research etc. The researcher has witnessed loud arguments between 'B' and his son. The researcher is concerned about the safety and well being of his research participant and feels distressed and helpless seeing the condition of 'B' but there are no tools and mechanisms available for them to handle such ethical dilemmas that arise in the course of their research.

Anstey and Wagner (2008) have developed a code of ethics for community health after a working group round table discussion attended by approximately 200 people from 40 community based provider agencies, which was finalized in 2003. These principles provide researchers with relevant concepts that help them to identify and articulate ethical issues and conflicts based on a common language within the community context. The worksheet has four sections that are identified by the acronym 'IDEA':

- Identify the facts
- Determine the ethical principles in conflict
- Explore the options

- Act on your decision and evaluate

Using the above toolkit, the researcher collected the relevant facts, including 'B' perspective on the matter. 'B' persistently maintained that everything was well. A responsible person from the old age home was involved by the researcher who established the conflict between 'B' and his son and the adverse effect that it had on 'B's life. Next it was communicated in no uncertain terms by the old age authorities to the son that legal action would be taken if this treatment to 'B' would continue.

Thus, the researcher has acted within ethical boundaries and tried to resolve the situation while adhering to the ethical research principle of confidentiality and consent.

3. Dr. A is a general practitioner in Indore and has an extensive patient list. He is approached by researchers who wish to carry out a full scale study into a medical area. He is requested by the researchers to provide the vital statistics of all his patients with a High blood pressure problem. He is assured by the researchers that the research ethics committees of both his local university hospital and the researchers' own institution has approved the study. He is offered payment for the administrator's time required to prepare this data.

   The following shall be the main concerns of the Doctor:

   Should the data that belongs to so many patients of Dr. A be shared with the researchers. It may be stated that the assurance given by the ethics committee that the research has their ethical clearance should be of tremendous solace to Dr. A. However, to take added precaution, he could make it generally known that the data that they leave with him could be used for medical research purpose. This would also help the researchers in legal protection in case a party approaches them with litigation in future. Also, Dr. A has to assure himself that the risk to patient's interests has been minimized.

   Thus, it can be seen that law has over a period of time, very systematically defined the role of Institutional Ethics Review Boards. The role of the Institutional Ethics Review Boards becomes even more important in todays time and age when more and more artificial intelligence is being used in research and the subjects of research may be totally unaware of the methodology, import and implications of research. The mechanics of Institutional Ethics Review Boards can be defined through specific tenets of law that have been evolved over a period of time.

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