THE CENTRE FOR BIOETHICS
Improving health care through Bioethics

The Centre for **Bio**ethics

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Editorial

In this issue we focus on Research ethics. This is an important area for several reasons. Research has become an integral part of most disciplines in the current world, but probably none more important or immediately touching human lives as research in medicine. In fact, Ana Iltis makes a sweeping statement as her opening line in the book, Research Ethics, “Medicine in the twenty first century will be defined by biomedical research” It is critical then that research ethics keep pace with the advances in biomedical technology and the consequent research that comes in its wake.

Another reason for bringing research ethics into the limelight is the terrible abuses committed in the name of research in the 20th Century, none worse than the Nazi studies during the 2nd World War. These and other atrocities pitchforked research ethics into mainstream medical ethics. In this issue, we will look at informed consent in research especially as it interacts with decision makers in community in societies that are less individualistic; the role of Institutional Research and Ethics Committees; and the importance of Research Indemnities. We hope that these articles will stimulate your thinking and challenge your interaction with the way research is being and ought to be practised.

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ETHICAL ISSUES IN RESEARCH

Dr. Mitra Dhanraj

Mrs xx 24 yrs G1 2A1, un-booked with 38 weeks of gestation had reported with labour pains to the XN hospital for delivery. Patient delivered immediately. It was decided to include the patient in an ongoing clinical trial. And cord blood was collected for research purposes and APGAR of the baby was noted.

Title: Cord blood Vs APGAR to diagnose intra-partum Asphyxia

The objective of the study was to determine the efficacy of cord blood analysis Vs APGAR Score in determining Foetal asphyxia. The sample strength was 50. Patients who delivered vaginally after 38 weeks of gestation were included in the study. The APGAR score was assessed immediately after birth. Cord blood was collected and analysed for acid base status of the foetus. The analysis was done to find out whether Apgar scores correlate well with cord artery pH in cases of intra-partum asphyxia.

Ethical issues

A. IRB approval – whether the study was approved by the internal review board or ethics committee

B. Written Informed consent – whether obtained from the patient?

C. If the data shows abnormality what is the investigators responsibility?

D. Whether compensation is involved for using the tissue.

E. Permission to publish the data of the study

Discussion of ethical issues

A.IRB approval – Ethics committee approval was taken prior to the start of the study

1.Updates to IRB may be necessary if required by them.
2.Final report should be sent to the IRB

B. Written Informed consent – whether obtained from the patient.

1.Un-booked patient VS booked
2.Patient is in labour- not the ideal time to recruit participants for study
3.Not enough time/state of mind of patient in labour to understand
4.Time to explain is not adequate

C. If the data shows abnormality what is the investigators responsibility?

Disclosure to the parents –the investigator must discuss with the parents the results of the analysis and inform if there are any problems
Should the investigator or hospital bear the expenses? The cost of analyzing the cord blood should be borne by the investigator
It will be ethical to treat the infant in case it is needed.

D. Whether compensation is involved for using the tissue.

E. Permission to Publication of the data – Confidentiality –permission must be got from the patient and confidentiality should be maintained.

Conclusion:

- The study should be one which is beneficial
- Appropriate ethics approval should be obtained
- Written informed consent should be obtained from each participant
- It is the responsibility of the investigator to get informed consent and to meet the cost of testing cord blood
- Compensation need not be given
- The data should be pass word protected and confidentiality should be strictly maintained.

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THE INTERACTION BETWEEN AUTONOMY AND COMMUNITY FOR INFORMED CONSENT IN RESEARCH

- Satish Thomas

Informed consent is one of the pillars of research ethics. The Nuremberg Code considers informed consent as an ethical imperative (Iltis, 2006). The underlying philosophical basis of the doctrine of informed consent is respect for persons, for their autonomy, as a fundamental moral principle. Autonomy is anchored in a requirement to see patients as “ends in themselves” in the words of Immanuel Kant who was hugely responsible for formulating the philosophical basis of respect for human beings in a secular setting. According to Kant a person is being exploited when he or she is being used “merely as a means and not simultaneously as an end in itself.”(Emanuel, 2008) The remedy for this Kantian type of exploitation is provided by the informed consent process. Kant based this requirement for respect for human beings on their rational nature. The problem with laying the basis there is that while it justifies the need for respect to the human race as a whole, it can lead to discrimination between individuals, for people obviously differ in their rational ability and their capacity for self-determination and self-governance. A more robust anchoring of the philosophical basis for respect would be the biblical assertion that all human beings, irrespective of physical and mental capacities are created in the image of God and therefore worthy of equal respect in relation to each other and much more in relation to all other life forms.

Principle of Beneficence as basis for informed consent

Beneficence or utility is an important principle that is upheld by the informed consent process by facilitating interventions most beneficial to patients/participants and promoting their general well-being. The Principles of Autonomy and Beneficence can lead to different and sometimes conflicting conceptions of informed consent. As long as a procedure has no significant harmful effect on a subject, the Principle of Beneficence does not require an informed consent. However, when the Principle of Autonomy becomes the foundation of informed consent, irrespective of whether there is possibility of harm or not, an informed consent is mandated just so as to protect and enhance the subject’s right to self-determination. Health care professionals are strongly influenced by the Principle of Beneficence as part of their training and practice of clinical health-care, so that the many implications of an autonomy-enhancing conception of informed consent often are not fully considered. When the Principle of Autonomy is acknowledged as the moral foundation, there occurs a whole different perception - a shift from focusing on risks and benefits to majoring on protecting and enhancing patient autonomy. Informed consent then becomes more a matter of equipping and elevating subjects to a position where they become equal partners in the decision making process rather than just being seen as a mechanism to protect one from legal tangles.

Characteristics of informed consent

For the informed consent process to uphold a participant’s autonomy, it has to fulfill certain conditions. Sufficient information must be provided to subjects in a manner that they understand so that they can then make a meaningful decision. Consent must be voluntary and free from coercion. For research purposes the participants must first of all understand that they are being asked to participate in research and not personalized health care, and they should be made aware of the difference between the two situations. Additional elements necessarily addressed in an informed consent are the nature of the study, the purpose of the study, the risks and benefits associated with participation, and the alternatives to participation. Also in order to be truly voluntary, the subjects should know that their treatment with the existing physician would not suffer adversely in any way from choosing not to participate in the study and that they have the freedom to withdraw from the study at any point without loss of benefits.

Possibly the biggest drawback of the informed consent procedure is that it can be reduced to a documentation of legal protection to the researchers without adequately fulfilling its primary role. The primary purpose which is to uphold autonomy and beneficence of subjects is better served by paying greater attention to the consent process rather than the consent form (Emanuel, 2008).

Challenges in the informed consent procedure

There are many challenges to a participant's autonomy in the informed consent procedure. The key elements of an informed consent being voluntariness and comprehension, its efficacy will depend on the extent of their realization in the participants' decision making. There must be a full or adequate disclosure on behalf of the researchers, but that does not always translate into sufficient comprehension on behalf of the possible participants. Some of the hindrances that stand in the way are therapeutic misconception, therapeutic optimism, unfamiliarity with technical terms and jargon, and so on. Vulnerable populations like children, pregnant women, prisoners, mentally challenged or the economically poor, are more prone to exploitation and so the principle of respect necessitates that they be given special privileges and protection over and above the informed consent process.

There is yet another major issue that autonomy as the foundation to informed consent throws up. Some people believe that autonomy is too much of a Western concept that is not relevant to societies in the developing world that are more community oriented. Holding on to Western values for informed consent in other cultures that do not share these values amounts to ethical imperialism. This is a matter of much debate and one that merits some scrutiny.

Is autonomy merely a Western concept?

How does the socioeconomic and cultural milieu of the developing countries impact the requirement of individual informed consent from participants? Taking the case of India for example, there is a wide disparity in society. The upper and middle socioeconomic classes are literate and may be able to fulfill the criteria for informed consent in a similar way to those in the developed societies. The lower socioeconomic classes are illiterate and also have language barriers. However, these need not necessarily be barriers to a valid informed consent process. While they may be illiterate, they are not uneducated because they have life experiences which empower them. If researchers are sensitive and innovative enough, they can modify the consent process in such a way that potential subjects understand content before consenting. The main goals and ideals for humanity are the same in most cultures, namely respect of individuals and the value of life. So while it is true that some of the Western bioethical principles may not fit in if imported intact, it does not mean that therefore we lower the standards which are universal. All they require is an adaptation to the sociocultural values of the study population

Individual autonomy and community

So then, how does individual autonomy play out in societies where community plays a major role in decision making? In many societies of developing countries like India, there are power hierarchies within families and communities that have a bearing on individuals being empowered to make decisions by themselves. Obtaining an ethically meaningful and valid informed consent in such a setting would be a great challenge. In such a scenario, there are different suggestions on approaching the process of informed consent. Some authors suggest a community based approach where the decision making is by the community leaders. This issue has even prompted some to propose the addition of respect for communities as a fourth moral principle to the three principles - respect for people, beneficence and justice - put forward in the Belmont report. According to them the interests of the community is worthy of moral status and this may sometimes be in conflict to the interests of the individual (Iltis, 2006).

Acknowledging and accepting the differences in how individuals perceive themselves with respect to community, researchers can then sensitively build modifications into the way consent is sought so that respect for persons is upheld. Though this process might be challenging and tedious, it is worthwhile because the painstaking effort itself is evidence of respect for research participants and the communities they belong to. Community consultation and community consent are proposed to supplement, not replace the process of individual informed consent. Information given at the hospital setting with a view to get consent immediately would be highly inappropriate in community settings. This would be especially relevant when women are potential participants since in most of these societies, men are the sole or major decision makers concerning their wives and children.

Collaborative partnership with community

One of the benchmarks for ethical conduct of research is collaborative partnership between the researchers and the community where research is envisaged and conducted. This is because ultimately clinical research is meant to serve a social good, to enhance the health and healthcare of people. This principle recognizes that community should participate in the research endeavor. It then follows that the community decides for its members whether a particular research is acceptable and relevant to its health needs. This sort of collaborative partnership has many other benefits. It increases the likelihood of a community not being exploited, of it receiving fair benefits, and of the research having greater impact. If collaborative partnership is a benchmark that is followed in clinical research, then it automatically solves a lot of problems related to the conflict between individual autonomy and community in decision making. The community leaders and decision makers would already be sensitized to the research and would have given their consent in general.

To summarize, informed consent is a key procedure and process in clinical research that upholds individual autonomy and thereby respect for a person. While there may be cultural differences in perceptions of individual autonomy vis. a vis. community, the fundamental principle of respect for human personhood is a universal value that must be upheld. It is necessary to be sensitive to local cultural issues while upholding the universal ethical principles.

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ETHICS COMMITTEES IN INDIA AND ITS CHALLENGES

-Roopa Jewel

The past few years have seen a tremendous rise in the number of clinical trials conducted in India. This is attributed to the huge patient population, genetic diversity, and rich technical pool in our country. However, the economical upsurge in the clinical trial industry has also caused concerns pertaining to the efficiency of the regulatory agencies and Ethics Committees (EC). These few years have seen a steep rise in the number of clinical research studies in India. The biopharmaceutical world all over are turning toward India, given its rich technical resource pool, ease of patient recruitment, and sheer diversity inherent in our country's genetic texture (Bound, Kirsten, 2012)

However, the exodus of international clinical trial projects to India have also brought concerns about the quality of clinical research, sighting timelines for regulatory approval, deficiencies found in the functioning of the ethics committees, and an unethical approach to the recruitment of trial subjects (Kadam, 2012). It has been more than 30 years since the establishment of ethics committees in India, as the first official guidelines for the formation of ECs was issued by the Indian Council for Medical Research (ICMR) in February 1980 (Kadam, 2012).These guidelines included recommendations for membership criteria and ethical standards for review, which laid down the foundation for the establishment of ECs in India. This was followed by release of the ICMR guidelines in bioethics in the year 2000 and further revised in 2006.

Despite the establishment of ethical guidelines since a long time, the IEC s (Institutional Ethics Committees) in our country are still grappling with basic issues like inadequate or no standard operating procedures (SOPs) and noncompliance with the Schedule Y recommendations. The IEC has the prime responsibility of regulating clinical research and safeguarding the rights and safety of research participants. However, the institutions and hospitals that focus on enhancing their research facilities tend to ignore the EC, which approves their research. IEC s have to deal with basic issues such as lack of trained manpower, heavy workload, inadequate space allocated for EC operations, lack of administrative support, and inadequate remuneration offered to members serving on IEC boards. These issues culminate into reluctance of trained individuals to serve as members of the IEC (Kadam, 2012). IEC s also have to cope with problems such as insufficient space allocated to them for operations and archival of records, thus posing problems during audit procedures. As per the Bulletin report of the World Health Organization (WHO) there are less than 40 ECs in our country, which are properly constituted and functioning (Kadam, 2012). It is also observed that many IEC members are ambiguous about their roles and responsibilities, during a review process. IEC members comprise of highly educated and experienced representatives from non-scientific communities, but most of them are silent observers during meeting proceedings and do not participate in scientific or ethical deliberations in the review procedures. Lack of formal training in bioethics leads to a limited knowledge of complex ethical issues such as reduced autonomy, distributive justice, subject vulnerability, and subject compensation. IEC members see their responsibilities limited to providing approval to research proposals submitted for review and are oblivious to the need for a continuous review (Kadam, 2012). Very rarely do IEC s undertake detailed monitoring of studies and scrutinize the informed consent process.

Training of IEC members is essential as they come from varied academic and research backgrounds and may not be aware of the ethical principles and technical requirements of the IEC review process. A national training program in bioethics needs to be introduced and made mandatory for every functional IEC member. This should be coupled with strategic workshops, organized by the local ethics committees and research institutes. Training programs should emphasize on the codes of ethical conduct, principles of GCP (Good Clinical Practice), compliance with applicable regulatory guidelines, developing SOPs, composition of IEC s, roles and responsibilities of the members, and review procedures. The IEC members should also be trained on complex, but important, topics in clinical research, such as, the rights of vulnerable populations, therapeutic misconception, informed consent process, and issues related to subject compensation and insurance. The content of the programs should be designed keeping the nonscientific EC members in perspective, and thus equip them to discharge their responsibilities efficiently. Bioethics should be introduced as a subject in medical, life sciences, pharmacy, and other relevant curriculums to sensitize our future researchers to this topic. The strong need for IEC s in our country is to focus on capacity building. Members of IEC s should be trained in the principles of bioethics, local regulatory guidelines, and GCP. The isolated existence of the IEC s and the lack of communication framework between the IEC s and the regulatory bodies make it essential for IEC s in our country to come together and work in a collaborative manner to develop a uniform code of conduct. The members of various ethics committees need to reflect on their roles and responsibilities and come up with solutions for issues faced during the IEC review process. Ethics committees need to interact with each other and share their experiences and observations with an aim to update themselves and refine their functions. The IEC members need to understand that their responsibilities are not merely restricted to the ethical review of research, but toward the well-being of the community they represent. This advocates the need for IECs, which can serve as platforms to address the issues and problems faced by them. It takes an educated committee to write good policy and provide meaningful consultation, educated caregivers to carry out policies and recommended courses of action, and educated patients and families to appreciate the institution's policies and make meaningful personal choices.

While the necessary scope of IEC members' background in medicine and ethics is controversial, they certainly need a foundation in clinical ethical theory and practice, medical law relevant to various issues to deal with the issues well. Increasingly, the inequalities of access to care, the inequalities of care once accessed, and the high cost of many life saving interventions-some in short supply - are likely to force IECs into the discussion of costs, especially in light of health care reform. The question of how IECs should participate in the discussion and how they should use financial information in their consideration of patient care and policy remains unanswered. IECs should know what role their individual institutions expect them to play in the hospital's larger agenda, and ensure that the ethical criteria for its policies and practices are not subverted by other interests. The IEC can promote the hospital's healing mission where others serve the bottom line, and it can examine head-on the issue of cost containment in selective policy and case review, providing the institution with a clear understanding of the difference between ethics and economics.

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Research Indemnity

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International Clinical trials are investigations carried out on human beings by pharmaceutical experts, in order to discover or verify the clinical and pharmacological effects of any investigational medicinal product(s) with the object of ascertaining its safety and/or efficacy. During clinical trials research participants could have adverse events including death. In India, financial compensation to research participants who sustain injury including death, while participating in clinical trial is not guaranteed. There is lack of clarity on the norms on which eligibility for compensation is decided. It is largely subjective and the basic data comes from the very investigators who are involved in conducting the trial[1].

Whenever there is injury or Severe Adverse Event, the aetiology of the same has to be looked into, to determine if it was due to negligence, oversight, and lack of communication, omission or commission, not adhering to the protocol, inadequate infrastructure and lack of facilities to attend to injury. Currently countries vary from one another regarding insurance cover- investigators and /or sponsors to indemnify research participants against trial related injury or death. When insurance does exist, the indemnity limit and the quantum of compensation would depend on the terms and conditions of the insurance. Ultimately it is left to the discretion of the sponsor or clinical trial insurer.

"An **indemnity** is an obligation by a person (indemnitor) to provide compensation for a particular loss suffered by another person (indemnitee)"[2]. "An *indemnity* contract arises when one individual takes on the obligation to pay for any loss or damage that has been or might be incurred by another individual. The *right to indemnity* and the *duty to indemnify* ordinarily stem from a contractual agreement, which generally protects against liability, loss, or damage[3]".

Research indemnity is a legally binding promise whereby a party undertakes to accept the risk of loss or damage another party may suffer. Insurance is a legal contractual method of risk transfer, by one entity to another, in order to protect or transfer its liabilities that may arise through the course of its activities. The arrangements are defined through a procured policy or product, and are subject to terms and conditions including limitation on aggregate liability and deductible levels[4]. Indemnities form the basis of many insurance contracts.

Compensation for research subjects in clinical trial has been in practice for over 200 years[5]. It was offered to recruit research subjects, to retain them to the end of the study and to compensate for wages lost etc. "Some of the ways used to determine the amount payable are the market model, the wage model, reimbursement model and the appreciation model"[6]. Compensation raises ethical concerns such as undue inducements, disproportionate burden on the poor and commodification. Also it could have detrimental effects on vulnerable population such as children, economically disadvantaged and mentally challenged.

Indian Supreme court's finding is that, “India's Central Drugs Standard Control Organisation (ICDSCO) has failed to protect the rights of the participants in trials”[7]. ICMR's National Institute of Medical Statistics has set up The Clinical Trials Registry to promote transparency, accountability and accessibility of clinical trials[8]. The new regulations to set right the above-mentioned has resulted in less number of applications by sponsors and less number of trials being approved. The regulations seem to be barriers for conducting clinical trials. India's new regulations entitle injured clinical research subjects to “free medical management as long as required” as well as “financial compensation “over and above any expenses incurred on the medical management of the subject”[9]

Section 37 Drugs & Cosmetics Act 1940 reads as follows: “Protection of action taken in good faith.—No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act”[10]. In the presence of this act, is it essential to indemnify explicitly?

ICMR Ethical Guidelines for Biomedical Research on Human Participants[11]and Indian Good Clinical Practice guidelines[12] favour compensation to research participants who suffer physical injury. There is lack of consistency among various norms. “India's new regulations provide for the compensation of injury or death arising from "the failure of [an] *investigational* product to provide intended therapeutic effect" [Rule 122-DAB (5)(c)]and from "the use of a placebo in a placebo-controlled trial" [Rule 122-DAB (5)(d)]. Both provisions are counterintuitive and violate the principle of equipoise”[13].

International guidelines vary – Association of the British Pharmaceutical Industry (ABPI) and CIOMS guidelines have laid down compensation in an elaborate manner, but earlier guidelines such International Conference on Harmonisation GCP and declaration of Helsinki mention compensation briefly. Concern has been voiced in the research ethics literature that under U.S. federal regulations U.S. sponsors, particularly the NIH, are not required to provide compensation for the treatment of research-related injury for trial participants or to allow grant funds to be used by investigators for appropriate insurance[14].
The ICH-GCP guidelines state that compensation should be paid and /or treatment be made available to the subject in the event of trial-related injury. If required by the applicable regulatory agency, the sponsor should provide insurance or should indemnify (legal and financial coverage) the investigator/ the institution against claims arising from the trial, except for claims that arise from malpractice and /or negligence on their part”[15]

In order to protect the research participants, proper insurance coverage should be in place before the start of the research. It might be essential for Institutional Ethics Committee (IEC) members also to be indemnified. However it is unclear if it is appropriate to have sponsors of the research to indemnify IEC members as this could influence their decision making process or could negate the independence of the committee. Therefore a viable option could be for the IEC members to be indemnified by the institution that has constituted the IEC.

Collated from interactions on indemnity, in the institutional ethics committee (iec) exchange google group

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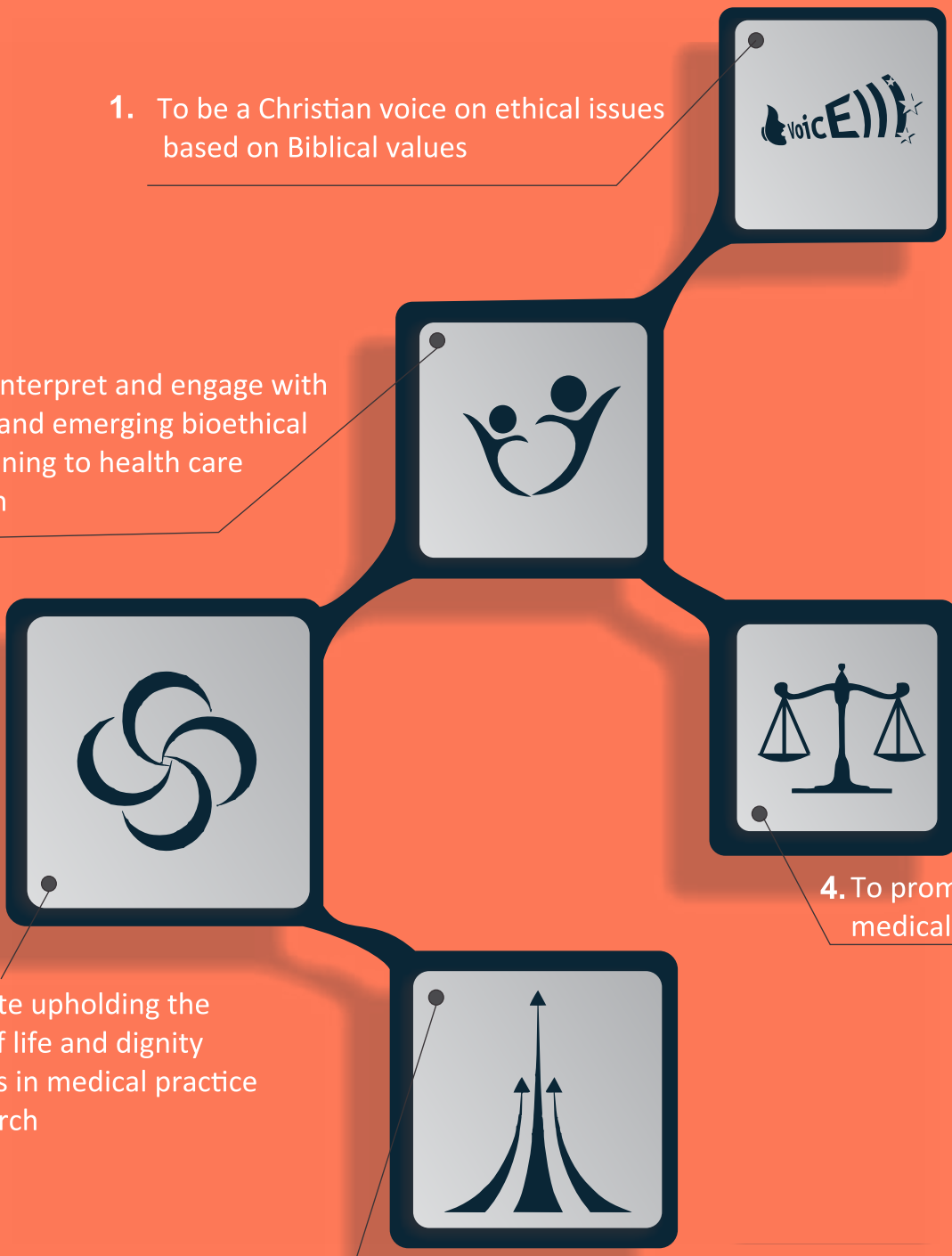
Aims & Objectives of TCB



1. To be a Christian voice on ethical issues based on Biblical values

2. To analyze, interpret and engage with the existing and emerging bioethical issues pertaining to health care and research

3. To facilitate upholding the sanctity of life and dignity of humans in medical practice and research

4. To promote ethical medical practice

5. To build leadership in the field of Bioethics, in the areas of Medical education, Medical practice and Medical research

Prayer support:

TCB needs constant prayer support of churches and individuals alike for the success of its mission and we request all our like-minded believers to kindly uphold us in prayers for God's leading and wisdom. We will appreciate you being in touch with us through face book, website, email or post.

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