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Original papers, commentaries, news and reviews should be submitted in electronic form to the editor.

Editorial: Ethical decision making

This issue of the journal includes a number of papers on the question of ethical decision making. The paper by Asai et al. examines the way that belief systems, both secular and religious, should be acknowledged in the values of patients in their decision-making. The basic message is to treat each person as their own decision-maker, even if their views are not the same as the health care professionals. Recently I was at an ethics education workshop in Malaysia, where it is apparent that there are persons belonging to many value systems, including a number of classified religious and ethnic groups. However, even within these classifications there is great diversity in the values and principles people use in making decisions. We need to respect each one, and empower persons to critically reflect on their own values and identify what is important for them.

In the papers by Onyemelukwe, and Boyd and Reed, we can see how these principles are enshrined into ethical regulatory systems for research with persons. Principles of bioethics highlight the importance of understanding the values of the persons concerned, before seeking consent, or accepting the choices, that people appear to make. The question of organ transplantation in China is reviewed by Wang and Chen, with some issues of freedom of choice in the donors who are used to provide organs. The paper by Saniotis explores the boundaries of ethics, and will be welcomed by the cosmologists who are exploring different and broader viewpoints in bioethics.

It is time to renew subscriptions to the hard copy issue of EJAIB, please copy and send the form (or email the information) to the editor. ABA memberships are due for 2010, and will secure reduced rates for the ABC11 conference to be held in Singapore mid-2010. Thanks for your support.
– Darryl Macer
The role of religious and non-religious beliefs in medical decisions

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Abstract

The aim of the present paper is to evaluate the role of a patient’s religious and non-religious beliefs in making decisions about medical care. Faith exerts a profound influence on our spiritual lives and our daily actions, including ethical decisions. Religion determines the believer’s fundamental worldview, view of humanity, perspective on life and death, and values. In this paper, we investigated the treatment of medical decisions based on religious or non-religious beliefs. To understand this issue, it is necessary to assess the uniqueness and validity of religious beliefs, as well as the rationality of beliefs. We concluded that decisions based on religious and non-religious beliefs should be treated in the same way and that the distinguishing features of valid beliefs are that they are deeply held and do not cause harm to others. In addition, we stated that the root beliefs we hold, whether religious or secular, cannot necessarily be explained logically, and that patient decisions should be judged by the logical consistency of their reasoning with their beliefs as starting points.

1. Introduction

The aim of the present paper is to evaluate the role of a patient’s religious and non-religious beliefs in making decisions about medical care. The present article does not discuss any religion in particular. Religion is defined as “faith/events that concern either God or some other transcendent absolute being or sacrosanct things that are taboo and separated from secular things” (1). Religious belief or faith is defined as “the act of believing beyond reason, in a being such as God or Buddha as an ultimate source to depend on, to, for example, save one’s lost soul” (2). The term belief will be used to mean “a state of mind that holds firmly to subjective impressions beyond reason.”

Faith exerts a profound influence on our spiritual lives and on our daily actions, including ethical decisions. Thompson argues that each religion presents a particular view of the world, promotes a set of values by which its followers should live, and gives specific advice on how to live – in terms of either rules to be followed or attitudes to be taken (3). Religion determines the believer’s fundamental worldview, view of humanity, perspective on life and death, and values. At the same time, it plays an essential role in forming an individual’s identity and is thought to define his/her purpose in life. A life of faith may provide spiritual stability, purpose, and meaning.

Based on this understanding of religious belief or faith, we investigated the treatment of medical decisions based on religious or non-religious beliefs. To understand this issue, it is necessary to assess the uniqueness and validity of religious beliefs, as well as the rationality of beliefs. We concluded that decisions based on religious and non-religious beliefs should be treated in the same way.

2. Are religious beliefs special?

Theorists have argued for the uniqueness of religious beliefs, thus they should be given greater or different consideration compared to non-religious and secular beliefs. According to these arguments, religion provides meaning to life, is not an individual preference but a reflection of shared values (a religious group), and integrates the individual with the world. Religious beliefs are deeply held beliefs that form the core of an individual’s self-identity (4–6). In other words, religion defines the fundamental worldview, view of humanity, perspectives on life and death, self-recognition, sense of value, and life purpose of those who believe.

We agree that religious beliefs are extremely important; however, we do not agree that people with religious beliefs should be granted a privileged status. We think that secular beliefs can also be deeply held and provide meaning, purpose, and an integrative character to life. A non-religious person can hold firm atheistic worldviews and values and still have a strong purpose in life.

The life of a secular physician who exhibits a firm sense of purpose in rethinking medical practices and reforming medical care from an ethical perspective is of great value. The life of a medical researcher who is actively engaged in research day and night to eradicate an incurable disease is also valuable. The same is true for a life whose purpose is to eliminate world poverty based on utilitarian beliefs, or one whose goal is to improve animal welfare. In addition, making one’s family and
neighbours happy is worthy of respect. Goals that are not based on religion are not necessarily less valuable.

Cahill argues that the one characteristic that most unifies theological approaches to medical ethics is the grounding of ethical argument in religious claims, and in the history and theological traditions of a religious community. For example, virtually every theologically grounded method in Jewish or Christian medical ethics originates from the conviction that humanity is a creature in a created and interdependent natural world; that the Creator is good, just, and powerful; that humanity is sinful, as well as responsible for good moral behavior; and that God offers human beings healing or salvation from moral and spiritual wrongdoing (7). In addition, basic sacred texts offer an understanding of events based on religious traditions and provide rationales for decision-making.

In contrast, an atheistic worldview does not assume the existence of a god; that element which is indispensible for the believer is lacking. Phenomena that an atheist recognizes and understands are extremely different from those of believers, and their deepest beliefs may be mutually difficult to understand and incompatible with each other. In the absence of true understanding, coexistence requires mutual respect instead of deeming one view superior or giving one preferential treatment. Some authors expand the definition of religion to include a non-supernatural worldview such as atheism (5, 6). We, however, think that this expansion can be misleading and unnecessary. We suggest treating both religious and non-religious beliefs equally under the criteria we examine later in this paper.

3. Preferential treatment of religion and secular dogmatism

As Brassington argues, there are cultural expectations that religiously founded opinions are in some way sacrosanct (8). However, there may be non-religious physicians and societies that simply ignore patients or treat them as eccentrics because their decisions are based on a religious belief. As previously stated, we believe that both religious preferentialism and secular dogmatism are inappropriate. Regardless of faith, everyone should be respected as human beings with equal human rights.

If religious and non-religious beliefs were treated differently, what situations would arise in medical settings? Human beings find it difficult to completely free themselves of deep-rooted prejudices. The deeper one’s particular beliefs, the more difficult it may be to openly accept a different way of thinking. When an individual does not accept that “the beliefs of each individual should be respected in principle regardless of whether or not he/she holds a faith,” there are risks of indoctrination, neglect, discrimination, evangelism in the medical setting, or refusal of diagnosis and treatment. In situations of a religious physician and a non-religious patient, a religious patient and a non-religious physician, or when patient and doctor hold religious beliefs that differ, problems are likely to arise due to feelings of superiority of one’s belief system. For this reason, deeply held beliefs should all be treated as equally important.

4. Distinguishing valid and non-valid beliefs

Despite the encompassing nature of the term, many different forms of religion exist. In fact, when viewing the current state of religion, one observes a striking variety. Assuming the existence of an absolute transcendent being, is it one or multiple beings? Assuming it is a single god, what or who is it? Religious sects of the same religion can differ, and occasionally further subdivisions are observed within sects. In this current state of affairs, Bock claims that some religious beliefs are medically valid and worthy of consideration and respect in medical settings, whereas others are not medically valid and should be described as incorrect, unorthodox, bizarre, or idiosyncratic. He further claims that the latter are unworthy of respect and has proposed 4 criteria to distinguish between medically valid and non-valid beliefs (6):

- The belief is shared by a community.
- The belief is deeply held.
- The belief would pass the test of a religious interpreter.
- The belief does not harm others.

We think that beliefs about medical care that strongly affect life and death must not be fleeting but stable and deeply held convictions. They must provide meaning to life, but need not include the existence of a god. We think that human beings are free so long as they do not cause harm to others, and in general, we cannot approve of beliefs or principles that result in harm to others. The no harm principle is the basis for a safe and free society. For these reasons we think that Bock’s second criterion (belief is deeply held) and fourth criterion (does not harm others) are useful for judging whether or not a patient’s beliefs are worthy of respect in medical settings, regardless of their religious or non-religious nature.

Truly knowing the mind of another is difficult and understanding how deeply held a belief is may be impossible. No widely-recognized or established methods exist for evaluating the depth of beliefs. Perhaps judging the firmness of the patient’s decisions and their agreement with his/her other
values and beliefs is the only method. In the absence of reasons to think otherwise, beliefs of others should be considered deeply held and thus respected.

On the other hand, we disagree with the assertion that the more people sharing this belief (e.g., religious group, community, or society), the greater its validity and importance. As previously stated, the importance of a belief is determined by its depth, stability and continuity, and the meaning that it gives to an individual’s life; validity is not determined by the presence or size of a religious group. For example, it is difficult to understand why a national religion is considered more valid than a non-national religion. Suppose that religion A is believed by 90% or more of the people in country X, and that the number of believers of religion B is less than 5% in the same country. Could it be said that religion A is valid, whereas religion B is not and is therefore unimportant? Is it right to recognize the refusal of treatment based on religion A but to make light the same decision when based on religion B? We think not; this attitude is discriminatory.

If a believer of religion A born in country X moved to country Y where religion A was in the minority, would the importance of his/her faith be diminished? Again, we think not. The importance of a religion should not change even if it is a minority view. These issues regarding the number of people sharing a belief are important to politics and vested rights, but not to the individual. Therefore, we think that the presence and size of a religious group are not valid criteria to determine the importance of beliefs.

Assessing the validity and importance of religious beliefs by the size of the community of believers depends on where the evaluation took place and the time of assessment. Any belief based on a new religion would be considered inappropriate; however, all religions and sects would have been supported by only a few believers at the time of inception. Furthermore, even an “incomprehensible” teaching may become “natural” if it undergoes massive social propagation. From this perspective as well, determining the importance of a belief by the number of believers is inappropriate.

Bock seems to state that nothing can be done about the beliefs of a few reformers being ignored, and thus there is no need to dwell on the matter. Bock argues, “(A) few saints may not get the medical care they deserve. But I am not too concerned about ultimate justice here, nor do I think I should be. What I am suggesting is that sharing a religious belief with a larger community makes the belief, prima facie, more virtuous and thus more relevant to the medical establishment than idiosyncratic beliefs. A few admirable reformers might be left out, but if our medical practice recognises a large number of mainstream religious beliefs, then I think the cost is worth it” (6). Indeed, it may be possible to measure the validity of a religion in a society from the number of its supporters and how long it survives; however, caution should be used when applying this idea to medical care based on individual beliefs. It is unjust to exclude or ignore minority beliefs and to give disparate treatment to patients who hold a different ideology.

To demonstrate that religious beliefs that are held by many have greater weight than beliefs that are held by a lone maverick, Bock provides four reasons including benefiting from the epistemic resources available in the community, peer accountability and the regular subjection of one’s beliefs to scrutiny, which helps to eliminate aberrant and antisocial beliefs, availability of knowledge depending on communities of trust relationships, and a support structure of psychic and physical resources that help individuals make choices that they would otherwise be incapable of by a community (6).

People whose beliefs are not shared by others do not have these advantages; however, these four points do not constitute criteria for distinguishing important and unimportant beliefs in medical settings. While it may be beneficial to receive various kinds of help from others, it does not follow that valid beliefs cannot be established without such help. In addition, we think that it is possible to obtain some of these benefits from conversations with medical workers and family members.

Bock also considers passing an examination for religious interpretation as a condition for the importance of a religious belief. A religious or cultural interpreter would serve as a mediator to help clarify the patient’s beliefs, explain them to clinicians, and convey the thoughts of clinicians back to the patient. The interpreter would use the patient’s religion or culture to reach conclusions about treatment. Through the interpreter’s mediation, the beliefs of a patient may become more understandable to clinicians (6).

However, we object to this idea because to believe is to hold firmly to subjective impressions beyond reason. As we describe later, a root belief cannot be judged by knowledge or logic alone. Furthermore, just as we objected to the condition of the sharing of a belief by a large community, we fear that beliefs of individuals or minority cultures that lack interpreters and beliefs of minority religions or religions just started by reformers may also be treated unjustly.

5. Harmfulness/harmlessness of a belief

In medical settings, it is also necessary to distinguish between harmful and harmless beliefs.
using the no harm principle. Regardless of their religious or secular nature, the beliefs of an individual can be differentiated into harmful and harmless beliefs. Harmful beliefs should not be recognized in a medical setting. Bock offered the cases of Laney and Yates, who murdered their own children based on revelations of God or the Devil, as examples of religious beliefs that are harmful to others and should not be recognized (6). Even beliefs from traditional and legitimate world religions can potentially cause harm. Posen discussed a section of a novel in which a terminal cancer patient is put to sleep by a physician with large doses of morphine. Although the treatment was consistent with the clearly expressed wish of the patient, who suffered from uncontrollable pain, the patient’s Catholic relatives objected that “one cannot pray if one is asleep” (9). Establishing the final medical care when a secular physician is caring for a devout patient or family can become a confrontation between medical and religious values. Here medical and religious values are in direct conflict. The doctors and nurses want to relieve the patient’s physical pain and suffering, whereas the religious niece prefers her aunt to remain conscious (even if that means enduring pain) to prepare herself for the ‘life to come.’ The two attitudes are irreconcilable (9).

In the case of a patient suffering from pain, we think that the beliefs of people who request to deny the patient pain relief for any reason are harmful. We cannot recognize such a belief regardless of whether it religious or non-religious, or based on a legitimate or new religion. We cannot recognize it even when the patient’s belief runs counter to the fair distribution of resources (5, 6, 10).

### 6. Irrationality of beliefs

There is a debate concerning whether religious beliefs are rational or irrational (5, 6, 10). We think that the validity of root beliefs that are the primary origins of human action, whether they are religious or non-religious beliefs, cannot necessarily be determined by reason. It has been suggested that unlike secular ethics, religious beliefs lack rationality (10); however, the same can sometimes be said for the major premises of ethical debates. For both ethical and religious views, the premises at their very root can be irrational beliefs.

For example, people believe that life is better than death, health better than sickness, pleasure better than pain, and freedom more important than anything. A major premise states that medical care is conducted in the best interest of the patient. For the patient, life is better than death, longevity better than a short life, pleasure better than pain, and freedom better than coercion; however, it may be impossible to claim any more than this because these premises or beliefs cannot be explained logically.

As Hume states, we eventually reach a point where we cannot answer why we hold a particular position (11). We cannot explain logically why pleasure is better than pain. We may answer that we seek pleasure instead of pain, but as to why we seek pleasure, it is likely that we can only say there is no further reason. Seeking pleasure is a preference that is beyond reason. In this way, the premises we use for ethical inferences ultimately cannot be explained by reason. We may say that they are what the theorist believes is desirable (12).

Of course, even if the initial premises are beliefs beyond reason and cannot be explained using evidence or logic, a person who can arrive at a single conclusion by logical deduction can be considered rational and capable of making decisions. For example, Jansen et al. have stated the following in regards to Jehovah’s Witnesses’ refusal of blood transfusions: “Jehovah’s Witnesses cannot be considered incapacitated to make choices unless there is clinical evidence of such incapacity. On the contrary, these persons usually are quite clear about their belief and its consequences. It is a prominent part of their faith, insistently taught and discussed. Thus, whereas others may consider it irrational, adherence to this belief is not, in itself, a sign of incompetence” (13).

In other words, we think that expressing a choice based on a belief, understanding the outcome of that choice, taking responsibility for the outcome, and logically arriving at a conclusion demonstrates that a patient is capable of making sound decisions. Neither religious beliefs nor the values of secular ethics are founded upon rational premises.

Therefore, we think that although our root beliefs cannot be explained rationally, the reasoning and conclusions based on the beliefs are not necessarily irrational. If the rationality of decision-making is necessary, then the criterion Bock proposes for the importance of a belief—passing the test of a religious interpreter—would correspond to an individual belief that emanates from root beliefs (6).

### 7. Conclusions

We have argued for equal treatment of religious and secular beliefs and conclude that the distinguishing features of valid beliefs are that they are deeply held and do not cause harm to others. In addition, we stated that the root beliefs we hold, whether religious or secular, cannot necessarily be explained logically, and that patient decisions should be judged by the logical consistency of their reasoning with their beliefs as starting points. Considering the difficulty of measuring the depth and rationality of beliefs, we think that patient...
decisions should be judged exclusively with the no harm principle.
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Akhashic Field as a Source of Human Bioethical Behaviour
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Introduction
This is a speculative paper which is based on the recent writings of the renowned systems scientist and philosopher Ervin Laszlo. Laszlo has spent forty years of his life attempting to articulate a theory of everything, which has eluded numerous physicists and other scientists during the twentieth century. In this paper I will attempt to explain Laszlo’s recent ideas of the ‘Akhashic field’ or its scientific derivation – ‘quantum vacuum’. It is in the field of bioethics that Laszlo’s theory is relevant due to the bifurcation point in which the human species presently finds itself in. For example, the anthropologist Richard Leakey has correlated the present human era to the ‘sixth species extinction event’, which is the first extinction event which has been engineered by a living terrestrial species. The end of the Cretaceous period some sixty five million years ago heralded the last species extinction event which culminated with the demise of the dinosaurs. Due to the massive ecological decline of the planet and loss of biodiversity the area of human bioethics needs to be grounded as a possible blueprint for future human ecological and social behaviour. In the first section, I provide an overview of the Akhashic field, the Metaverse, and coherency. Having explained these cutting edge ideas I will discuss them in terms for human bioethical behaviour and how it can inform future human evolution.

According to Laszlo, the Akhashic field is an empty vacuum or void which contains the universe; it is all permeating and embracing of cosmic space and existence (Laszlo 2004, 2006). The Akhashic field is mediated by wavelets which “travel virtually instantaneously throughout space and time, which records the “memory of the cosmos” at all levels” (Combs et al 2006:77). All things which have come into being, which presently exist and will exist in the future are recorded as information by the Akhashic field. Laszlo’s hypothesis has been influenced by
the Hindu idea of the Akhashic record which contains the memory of the entire universe, past and present. “Because the A-field retains the traces of the universe’s entire experience, it retains the memory of everyone and everything that has ever lived” (Bache 2006:116). In Vivekanda’s Raja Yoga he considers the Akasha in the following:

“Where there was neither aught nor naught, when darkness was covering darkness, what existed then?” asked Vivekananda, and answered, “Then Akasha existed without motion…At the end of a cycle the energies now displayed in the universe quieted down and become potential. At the beginning of the next cycle they start up, strike upon the Akasha, and out of the Akasha evolve these various forms…” (cited in Laszlo 2006:89).

Concomitant with the notion of the Akhashic field is the Metaverse which various scientists have cited as being “a vaster and possibly infinite cosmos, that existed prior to the known universe, and which will exist when this universe comes to an end. According to Laszlo the Metaverse is the origin of the universe, and possibly previous universes and future ones. The Metaverse gives rise to local universes which attest to the “remarkable coherence” and order exhibited in the universe (Laszlo 2006: 41). Laszlo explains this as follows: “The same way as the genetic code of human parents informs the fetus …the Metaverse informed the Big Bang, the otherwise inexplicably precise explosion that gave rise to this astonishingly coherent life-bearing universe. It also gave, gives, and will give birth to other universes, producing periodic universe-creating explosions…this kind of evolution we observe in our own universe got under way, and will get under way, time after time” (2006:41).

In short, the known universe with its unique dynamic and life giving propensity and evolution has been informed by previous universes. The Metaverse is the unfathomable “storehouse of information-templates from prior universes” (de Quincey 2006:110). Thus, the universe is one among possible limitless previous universes which is engaged in the “dance of involution and evolution” of the Metaverse (de Quincey 2006:110). As de Quincy explains, “The Metaverse then involves itself in its own creative play by bringing into being a recurrence cycle of universes from big bangs to crashing crunches” (2006:110). This idea correlates with Hindu metaphysics that this universe is a cosmic player in a much grander and infinitely older cosmic play called lila. According to Hinduism, this universe is dreamt by the god Vishnu and exists for one Brahma years, (which equals 311 trillion, 40 billion years) after which it is dissolved and yet another universe is created by the dreaming god. Thus, each universe is the unfoldment of Vishnu’s dream cycles.

The third idea which connects the Akhashic field with the Metaverse is the notion of coherency – the ability for particles to come together and work in a united fashion. Coherence is the reason why all physical, biological and social systems exist. It is coherency that constitutes the interconnectedness of existence, from sub atomic to galactical levels. “An amazing form and level of coherence characterizes nearly everything in the universe, from the largest structures of the cosmos to the smallest particles of the microworld…Coherence is a precondition of life itself” (Laszlo 2006:7). Once again, the notion of coherence is a central tenet of Hinduism and Buddhism. The Hwa-Yen Buddhist depiction of the Jewel net of Indra states:

In the abode of Indra, Lord of Space, there is a net that stretches infinitely in all directions. At every intersection of the net there is a jewel so highly polished and perfect that it reflects every other jewel in the net (cited in Grey 2009:131).

In the human dimension coherence is characterised by the ability for human beings to live together in well-defined social systems which are based on complex moral and ethical structures. Coherence is the integument of human sociality. The evolutionary processes which link the Akhashic field, Metaverse and coherence are exceedingly creative and kaleidoscopic as evinced by the plethora of life on planet Earth. In the human species this evolutionary process has formed a unique kind of reflexive consciousness which enables the universe to become aware of itself. Human self awareness represents a way in which the universe can accumulate experiences, “understanding, and new capacities” (Bache 2006:117). Bache (2006:117), eloquently explains:

We cannot be sure exactly when or where the process began, but somewhere along the way, life seems to have learned how to preserve the learning of individuals and fold that learning into future forms, generating exponential growth and differentiation.

Bioethical Systems as “Coherence Techniques”

So far I have provided an overview of the Akhashic field, Metaverse and coherence. These three elements have been instrumental in the engineering of the human body and human consciousness. As I have stated, human consciousness is endowed with reflexivity, which allows introspection, contemplation, examination, and informed praxis. These elements have expedited human evolution over a two million year period until the present. Evolutionary changes to the human brain, both structurally and neuro-hormonally have privileged the kind of intense
consciousness which humans possess. Ethical systems evolved as a by product of human brain complexity and the need to live practically and harmoniously in social groups which probably spurred the advent of language and pair bonding among other things. The creation of ethical systems in prehistory which worked concomitantly within the ambit of religious and spiritual systems such as shamanism, and later on, in the form of organised religions, was evidence of a transformation in human consciousness based on social coherence.

With the expansion of human societies during the agricultural revolution, and the creation of cities and writing in the middle-east, ethical systems were transformed to account for social changes. At present, the human species is undergoing exponential social and technological change which is unprecedented in human history. Moreover, over population, loss of bio-diversity, and planetary ecological degradation are changing the biosphere. As Laszlo, rightly points out, the human species is at a bifurcation point which will either lead to a new kind of consciousness or an entropic state.

A major problem facing present day ethical systems including bioethics is that the theoretical basis of such systems were devised centuries ago when human societies were different demographically, socially and technologically. For example, the exponential increase of human populations of cities has tended to erode ethical systems since there is a greater likelihood for people to act unethically “outside one’s social circles” (Teehan 2006:752). The danger is that ethical systems may diminish “as societies become larger and more anonymous” (Teehan 2006:757). Moreover, the advent of bio-technologies and inter species gene splicing has blurred the distinctions between human and non-human animals, as well as, between human and machine. What are the ethical implications for these technologies in the short, middle and long term? This has yet to be decided by bioethicists.

At present there is a need to recalibrate bioethical systems which take into account new scientific discoveries into human consciousness and the universe. If the Akhashic field does exist, then, it may become a source for developing new evolutionary ideas, which will promote social harmony and well being on both personal and macro scales. For instance, tapping into Jung’s ‘collective unconscious’ may provide future societies moral tropes for informing their particular evolution. The present development of the global information systems such as the internet is analogous of Teilhard’s ‘noosphere’ – the collectivity of human minds across space and time. Using Laszlo’s idea, the global net is creating new kinds of coherence between people across the planet. In Laszlo’s words “the relatively simple consciousness inherent in every human being in the planet becomes configured and integrated into the far more complex consciousness associated with the planet as a whole.” (cited in Montecucco 2006:133). The creation of new bioethical systems will work concomitantly with the development of a “planetary consciousness” in which people feel united between each other and the non-human world (Montecucco 2006:133).

In this light the resolution of the global ecosystem crisis implicates the transformation of the experience of self from a low to a highly coherent state of consciousness and from egocentric to collective. The key to the entire process seems to be the coherent nature of consciousness. (Montecucco 2006:133).

The possibility for the existence of an Akhashic field has profound implications for human knowledge and understanding the nature of the universe and humanity’s place in it. The idea that we share the universe with a multitude of organisms and that there is a biological coherence between all life forms has possibilities for human growth and well being in ways which we presently cannot conceive. For this reason, it is premature to dismiss Laszlo’s eloquent and timely thesis. It is my hope that future bioethical directions will seriously address Laszlo’s ideas.

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Research Involving Humans in Developing Countries: Expanding the Focus from Ethics to Governance

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Abstract
There has been considerable interest in research involving humans in developing countries as is evident from the growing literature in this area. However, while there has been a focus on the ethics of research involving humans in developing countries, there has been little research on the governance of research in developing countries. Given the emerging governance arrangements in developing countries, a comprehensive focus on this, including the structure and effectiveness of these arrangements, is required. This paper raises questions and issues that research in this area should address.

Keywords: developing countries, domestic regulation, ethics, governance, research involving humans

1. Introduction
Recent years have seen considerable discussion around research involving humans in developing countries. Apart from the part of the discussion that centers on the proportion of health research conducted in developing countries, the 10/90 gap, much of the discussion has focused on the ethics of research conducted in these countries. The increasing awareness of the difference in the circumstances of developing countries and developed countries, the higher burden of disease, and the higher level of poverty and vulnerability of persons in developing countries to exploitation, have prompted concerns about the ethical conduct of research involving humans in these countries.

There have been debates about and criticisms of the conduct of external researchers, as well as allegations of unethical trials by multinational pharmaceutical companies in developing countries, all relating to a failure in many cases to meeting the ethical standards, which such researchers would have been compelled to adopt in developed countries.

Research in this area has, therefore, focused mainly on examining the ways in which the economic inequalities and disparity in access to healthcare between developing countries and developed countries have affected the types of research conducted in developing countries by external sponsors, who dictates the research agenda, including the types of research to be conducted, and how these inequalities and the difficulties in applying the international ethical guidelines give rise to ethical concerns and controversies. Recent literature has focused on the level of research in developing countries, including the adequacy of informed consent procedures in developing countries, the standard of care to be offered to persons involved in randomised clinical trials, access to the benefits of the research, and the inadequacy of ethics review in developing countries.

What is missing in the literature on research oversight in developing countries, however, is a broader analysis from a governance perspective which critically examines the structure and adequacy of any existing governance systems and the effect of these systems on the protection of human participants in developing countries. Understanding the governance arrangements currently in place in developing countries seems particularly important at this time because many developing countries, including African countries, are beginning to take steps to address gaps in the oversight of research and provide protection for participants in research in these countries by establishing domestic regulatory regimes and governance structures. These steps include establishing national ethics review boards, and enacting guidelines and even legislation governing research involving humans.

In this paper, I argue that there is need to take a more comprehensive and systemic view of the regulation of research involving humans in developing countries. There is a need to expand the focus on research involving humans in developing countries to include a consideration of not only the ethical issues, but also examinations of the emerging governance structures in developing countries. I also explore what the perspective of governance would bring to the investigation of research involving humans in developing countries,
and identify the questions and issues that such perspective would have to address. The paper is divided into eight sections. The first is this introduction. The second discusses briefly the ethical concerns with which the literature has mainly been concerned. The third section examines what the governance of research means and entails. The fourth section looks at a few examples of the literature that have developed around research involving humans in developing countries. The fifth section identifies the vacuum in the literature. The sixth section addresses the need for an expanded focus that includes a governance perspective. The seventh section explores and raises the questions that a governance framework or perspective would be expected to address. These question and issues relate to ethics, law, institutional framework and a performance assessment. The eighth section concludes the article.

2. The Ethical Concerns
Before delving into my arguments for the need for a more comprehensive view of the research regulation and oversight in developing countries, it is useful to summarise the major ethical concerns on which recent literature has focused. This summary is necessary to provide some context for the discussion that follows. These concerns revolve mainly around issues relating informed consent, post-trial benefits, standard of care and ethics review. They are discussed briefly below.

2.1 Informed Consent
Informed consent is now accepted as a key concern in every research project involving human participants. While there is general agreement about the necessity for informed consent in research, obtaining it may be difficult. It may be particularly problematic in developing countries because of challenges resulting from such factors as low literacy rates and poverty, gender differences, higher burden of diseases, inability to understand the language of the researchers and translation difficulties, cultural differences, (including those relating to gender roles), lack of familiarity with western research, and different understanding of the concepts of health and disease, all of which must be taken into consideration in seeking informed consent since they may affect the validity of consent. There is, therefore, a greater possibility of exploitation and, arguably, a greater need for oversight to protect participants. There is a significant body of literature on this issue.3

2.2 Benefits of Research
The other major ethical concern in the developing world context relates to the benefits to be derived from the research to be conducted. This is directly linked to avoiding exploitation of research participants and research communities. In developing countries where research is mainly sponsored by external sponsors, research is often driven by economic or academic interests that may not reflect the needs of these countries. Two issues, therefore, arise with regard to benefits. First, is externally-sponsored research justifiable in developing countries, that is, would the research benefit the participants and the wider population? Secondly, what happens with regard to any potential benefit derived from the research after it is over? Considerable attention has also been devoted in the literature to this issue.4

2.3 Standard of Care
Apart from informed consent and access to benefit concerns, the issue of standard of care, which refers generally to the nature of the care and treatment provided during research and includes the preventive or therapeutic treatment provided to the participants in the course of clinical research in developing countries, has also raised problematic ethical concerns. In view of the limited healthcare options available in many developing countries, what standard of care should be offered within clinical research, particularly to control groups? Should this be different in any respect from the standard of care offered in similar research elsewhere in the world, particularly in developed countries? Some argue that it is unethical to conduct trials in developing countries which would never be conducted in developed countries for fear of harm to participants and that doing so creates a double standard, one for the rich and another for the poor, and creates room for exploitation. (Angell M, 2000) The opponents of this argument counter that this would simply not be feasible in many cases due, among other things, to the poor healthcare


systems in many developing countries, and the expensive prices of some of the interventions which, in any case, would be unaffordable for many people in developing countries. Further, they argue that a strict interpretation of the requirement for the universal standard of care as opposed to a national standard of care is unrealistic and may have the devastating effect of preventing research into certain diseases in these countries. It has also been argued that the providing the control arm with effective treatment where available but not readily obtainable elsewhere in the country may compel prospective participants to enroll in the study, thus serving as an undue inducement. (Killen et al, 2002)

These debates have drawn attention to the wider problem of employing ethical standards in developing countries that differ from the standards used in developed countries. Further, these debates have highlighted the difficulty in the application of ethical principles as may be contained in international ethical guidelines such as the Helsinki Declaration.

2.4 Ethics Review

Beyond the ethical concerns and the difficulties in applying the international guidelines, a major concern is the ethics review capacity in developing countries. It would seem that insufficient attention has been paid to the ethics review of research involving humans in developing countries as evidenced, for instance, by findings that some developing countries do not have research ethics review boards (Macpherson, 2001). In 2001, the Regional Committee for Africa of the World Health Organization (WHO) noted that studies involving humans in the Africa Region were not subjected to ethics review (Kirigia et al, 2005). Limited financial resources, inadequate expertise needed for ethics review, and the need for training in research ethics, and issues relating to the independence of the ethics review process, have received some attention in the literature. 

3. Governance of Research Involving Humans

Research involving humans poses physical, social, economic and psychological risks. These possible risks emphasise the need to ensure that research is ethical and as safe as possible. The frequently conflicting goals of ensuring the safety of research participants, and obtaining the results which contribute to the general knowledge that may be beneficial to a wider group of people than these participants, further accentuates this need. In the case of multinational pharmaceutical companies, there is often tension between making profits and ensuring the safety of people on whom new drugs are tested. There is therefore need for oversight of such research. Moreover, researchers require a secure regulatory environment in which to conduct research with the knowledge of what the rules and standards are and, perhaps, the greater possibility of producing research, which is socially beneficial to the wider community. Balancing these sometimes competing priorities (ensuring the safety of research participants on one hand, and providing a stable environment for research on the other) requires a governance system. The central objectives of research governance therefore include the promotion of socially beneficial research and improving the quality of any research and any outcome, protecting and safeguarding the interests of persons on whom research is conducted and building and maintaining public trust.

Governance of research involving has thus been defined as, “the system of administration and supervision through which research is managed, participants and staff are protected, and accountability is assured.” (Samanta and Samanta, 2005, p.235). It has also been defined as “a framework through which institutions are accountable for the scientific quality, ethical acceptability and safety of the research they sponsor or permit.” (Walsh, 2005 p. 468). Further, according to the United Kingdom Research Governance Framework for Health and Social Care, research governance: “sets out principles, requirements and standards; defines mechanisms

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formal legal regulation, in addition to other governance mechanisms, may have advantages for developing countries, not least because with the limitations of other enforcement mechanisms, it may be one of the effective options available as a policing mechanism. 10

Research governance is therefore a broad concept focusing on interactions between different actors, state and non-state actors, and encompassing principles and standards on the one hand, and systems defined by accountability mechanisms on the other. The standards straddle different disciplines. 11 An analysis of research governance thus seems necessarily to entail a discourse on a broad range of subjects and even separate disciplines. An examination of governance systems in the particular context of research involving humans appears more encompassing than a strictly legal perspective because it helps to analyse broadly and in a less reductionist fashion the linkages that come together to form the research governance system, including law. As McDonald observes, “governance issues arise with respect to the appropriate division of responsibilities for the protection of human subjects amongst the agencies and organizations that conduct, sponsor, and regulate research.” 12

Extrapolating from this, understanding research governance requires an examination of the scope and structure of the system, the responsibilities and composition of the institutions within the system, accountability and compliance mechanisms within the system, all of which have implications for ensuring the protection of participants and promoting beneficial research. Research governance systems (which may be formal or informal), may thus include ethics review systems, overarching legislative/regulatory frameworks and policy frameworks.

Examining research involving humans from a governance perspective is helpful because it allows one to ask the question: What regulatory tools and institutions are required to effectively govern research involving humans? The first tool that

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8 National Health Bill, 2004

9 Even in developed countries such as the United Kingdom and Canada, there is legal regulation of only specific areas of research involving humans, such as clinical trials of drugs. However, other countries such as the Netherlands, France, Denmark and Spain have laws which affect research involving humans more generally.
typically comes to mind is ethics review. Ethics review is a process by which research projects and protocols are evaluated by a committee of persons independent of the researchers to assess the ethical acceptability of the projects. These committees are required to safeguard the rights, safety, and well-being of the research participants. Ethics review is now a central part of the research governance systems of many countries and the ethics review system may therefore be mistakenly considered the governance system. Mcdonald describes accurately this tendency to reduce the governance system to ethics review, observing that, “[T]he ethics review process by the REB has come to be, in the minds of the major institutional actors and their constituents, a surrogate for a comprehensive ethical approach to research involving human subjects.” (Macdonald, 2001 p. 9)

The literature tends, therefore, to examine mainly the work of ethics review committees, particularly in developed countries where they have been established for a longer period. However, a broader and more inclusive view of research governance systems may include other components apart from the ethics review system, such as a legal framework, including formal legislation and other forms of law; national and international ethics guidelines; professional associations and codes of conduct; national regulatory bodies such as the ones which regulate pharmaceutical production and the use of human participants, departments of health (of which the drug regulatory agency may be a part); civil society, including non-governmental organizations which promote patients’ rights; the general public, the research participants themselves, and the interactions between these entities. An examination of different jurisdictions will show that these tools and institutions are employed in the governance of research in varying degrees.

Taking a comprehensive perspective allows an evaluation of what these instruments convey about the nature of the relationships between all the policy actors, including such actors as the government, civil society, researchers and research participants. It thus affords, for example, freedom to examine law in the context of different disciplines that bear on research involving humans, such as biomedicine and social science. It permits an inquiry into not only the role and place of law in the system, but also its relationship with other components and key institutions frequently employed in the oversight of research involving humans, such as ethics review committees in achieving the public policy objectives of enabling beneficial research while ensuring the safety and dignity of research participants. It is necessary also to locate and evaluate the place of ethics review alongside other components and instruments.

A related issue that arises and which can fruitfully be examined from the perspective of governance is whether, based on available evidence, these institutions, policies and laws work together and if so how harmoniously, and therefore whether or not they actually form what can truly be understood as a cohesive system. In many countries, developed and developing, the systems of research participants’ protection (with respect to standards, structures, regulations and policies) are not necessarily ordered as a coherent, cohesive and organized structure and consist of fragmented institutions and policies involved in the governance process. The different actors in research governance may employ different forms of governance. For example, funding agencies may have separate criteria for funding eligibility different from those utilized in research institutes, which may themselves have no coercive control over researchers. The universities may also have different guidelines and ways for ensuring compliance which may be different from those employed by self-regulating professional bodies which may exercise significant influence and control over their members or from the powers exercised by the departments of health. The normative weight of international organizations such as the World Medical Association and the guidance they provide, as well as how these have influenced the development of the governance systems in developing countries give room for analysis. The interplay between the different players and the forms of governance requires analysis, especially given that harnessing these subsystems could provide greater effectiveness in protecting research participants. One could then reasonably ask such important questions as how the characteristics of traditional governance (including formal or hard law) can be fruitfully blended with, or be complementary to, less traditional forms of governance, (such as soft law or increased civil society participation), for greater effect where necessary. One could also ask what benefits the different actors – government, research sponsors, researchers, professional bodies, and research participants – bring to the table and how these can be more effectively managed to ensure better governance of research. An examination of research governance in developing countries would thus present a more comprehensive view of the systems available in these countries to protect research participants.

5. What is Missing?

There is increasing interest in the area of governance of research involving humans in

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13 See Commentary to Guideline 2 of the CIOMS Guidelines.
developing countries. However, academic discourse, with its main focus on ethical issues in conducting research in developing countries has, understandably, taken place within a bioethics context. There has been relatively little analysis from a legal or a governance perspective. There is much discussion of ethical principles, and the interpretation, application, and the inadequacies of the international ethical guidelines which contain provisions on these issues. The international ethical guidelines have thus been the subject of a great deal of debate about the principles behind the guidelines, as well as the application of these principles in practice. They focus mainly on the ethics of internationally-sponsored research, that is, research sponsored by developed country sponsors in developing countries. Some recent articles have also attempted to examine ethics review systems in developing countries, including countries in Africa and Latin America. However, although very relevant to the issue of research governance in developing countries their scope remains quite limited.

There are still comparatively few publications that examine the governance of research involving humans in developing countries in a comprehensive way, including the specific role of governments or the legal systems of developing countries in regulating research. For instance, little work has been done that examines the existence, functioning and sufficiency of the legal systems that regulate, and prescribe standards for, appropriate conduct in research. One study has found that among members of ethics review committees in African countries, “knowledge of local legal frameworks governing research was inconsistent and unclear.” (Milford et al, 2006). This may be as attributable to a lack of specific and formal legal frameworks relating specifically to research involving humans, as to a lack of adequate training about them. As others have noted with specific regard to biomedical research, “many developing countries lack regulatory mechanisms and a legal framework for biomedical research.” (Zumla and Costello, 2002) However, it remains necessary to examine other laws which may have implications for the regulation of research in developing countries. It is also necessary to examine law where specifically related to research involving humans as currently exists, for instance, in South Africa. A recent article with specific respect to law relating to research participants’ protection in West Africa observes that: “One difficulty in researching human research subjects laws in West Africa when using law reviews, research journals, and similar sources is that the majority of the articles focus less on actual laws, and more on the need for laws and ethical issues in this area.” (Szabó and Britt, 2007).

Another area that requires more comprehensive analysis is ethics review. There have been efforts recently to investigate ethics review systems in developing countries beyond merely stating that they are insufficient, or that there is a lack of capacity for ethics review committees in developing countries. But even with regard to ethics review committees, Kass et al, (2007) note that, “Most literature examining RECs [Research Ethics Committees] comes from wealthier countries... However, there has been little research examining procedures, strengths, and challenges of RECs in developing countries.” They further note that: “Additional information on how African RECs function, including their staffing, operating procedures, strengths, and challenges would be useful for African and international researchers working within Africa, and for growing efforts to enhance ethics capacity on this vast continent.” (Kass et al, 2007) This gap in the literature is understandable given that many developing countries have, until recently, lacked mechanisms for the protection of research participants, including ethics review committees.

As for regulatory agencies that approve new drugs, these have been largely overlooked in the literature. It is not clear how effective they are in
protecting any research participants who participate in trials for drugs. Luna (2007) points out that this may be because, in fact, they rely on already completed studies in developed countries. However, trials are currently being undertaken in several developing countries for vaccines for HIV/AIDS. The Pfizer incident which generated much controversy and allegations of harm was a trial of a drug in a poor hospital in Nigeria.

There is clearly a need to take a more comprehensive look at governance arrangements of research involving humans in developing countries.

6. Ethics to Governance: The Need for an Expanded Focus

From the foregoing discussion, it is obvious that there are gaps in the research and literature on the governance of research involving humans. One of the possible reasons for this is the previous vacuum in the area of governance systems in developing countries. Some commentators have previously noted the reluctance of many developing country governments to put in place regulatory controls because these may deter researchers from engaging in research in these countries. (Meier, 2002)

There is also an assumption that developing countries lack capacity and can therefore do little to prevent unethical conduct of research and to create governance structures which protect research participants. This assumption may be based on practical realities, including limited resources in developing countries. Nonetheless, while developing countries may be handicapped in terms of available resources to monitor research, there are certainly steps that they can reasonably take to ensure the safety of their citizens who participate in it. Also, implicit in this failure to address critically and comprehensively the governance structures in developing countries is, perhaps, a lack of understanding that there is conceivably a relationship between the need for increased resources for beneficial research in developing countries and the regulation of such research. In this regard, appropriate governance structures may create more room to undertake, and manage, such research. To explain further, there is the possibility that such structures may ensure that such research operates within safe, clearly established parameters. This, in turn, may help create trust between researchers and research participants and the wider community, thus potentially making increased room for research that is more likely to be beneficial to the target population.

In my view, there needs to be a broadening of the discourse around research oversight in developing countries to include discussions of the governance structures in developing countries.

The first important reason a more comprehensive discussion is necessary is the recent steps that many developing countries have taken to address gaps in the oversight of research. Many developing countries, including countries in Africa have taken steps to provide protection for participants in research by establishing or formalizing domestic regulatory regimes and governance structures. These steps include establishing national ethics review boards, and enacting guidelines and even legislation governing research involving humans. They include Uganda, (1997) Kenya (2004), Malawi (2002), Nepal (2001), and India (2000). Others like Bangladesh are in the process of developing national guidelines. Still others have taken steps to develop regional associations of ethics committees such as the Forum for Ethical Review Committees in Asia and the Western Pacific (FERCAP), the Latin American Forum of Ethics Committees in Health Research (FLACIES), and the Pan-African Bioethics Initiative (PABIN). These are exciting and important developments. Some commentators have suggested that the emerging policies are comparable, in theory if not practice, to the older systems in developed countries. (Bhat & Hedge, 2006). This is not surprising, given that while these more recent guidelines may be more wide-ranging and may operate more broadly than the older systems found in some developed countries, they have probably drawn on experiences in those countries while also drawing on local context. In my view, it is therefore essential to investigate these emerging governance systems in order to provide information on these emerging governance systems. Understanding the governance arrangements currently in place in developing countries seems particularly important at this time because of these recent steps taken by many developing countries, including African countries. This importance is not lessened by the fact these systems are relatively recent, and it may be argued, giving little time to analyse sufficiently their adequacy and effectiveness in protecting research participants. The potential of these emerging systems and their possible strengths and weaknesses are, in fact, perhaps best analysed at this point when the arrangements are fluid enough to allow for amendments, and for improvements and developments in different directions. In other words, instead of choosing to repair a broken

21 <http://www.fercap-sidcer.org/>
22 Foro Latino Americano de Comités de Ética en Investigacion en Salud, online: <http://www.flaceis.org>
23 See online: <http://www.pabin.net/>
system, years from now, this may be the best time to point out possible mistakes in these new arrangements which could then be corrected from the outset.

Examining these systems from a governance perspective seems particularly important not only because such examination provides descriptive information on the emerging governance systems in developing countries, but because it moves the discourse from identification of issues to proffering of solutions. The discussion about ethical concerns is important because it addresses the ways in which the conduct of research affects participants. Discussions on the ethics of international research or research supported by developed country sponsors in developing countries and particular ethical concerns remain important, not least because they address important issues of global equity and the practical application of ethical principles. To put these concerns into a context in which action can be taken, however, there is a need for domestic governance structures and systems, including policy guidelines, legislation and ethics review mechanisms. The international guidelines and the new national guidelines will be ineffective without the appropriate mechanisms for their implementation in a domestic setting. The ethical standards set out in the international and national guidelines, though important because they underpin the governance system, are not the same as, and should not be conflated with the governance system—which may include legal regulation and other non-legal guidance and the role of institutions—and its functioning. As some commentators have rightly noted, the international guidelines are by themselves “no substitute for a substantive system of research governance entrenched at the national level.” (Ford & Tomossy, 2004). The domestic governance system becomes even more relevant when one considers the voluntary nature of the major guidelines, which are typically not directly enforceable in domestic law and, which cannot, strictly speaking, be considered as part of international law. The Helsinki Declaration and the CIOMS Guidelines, while widely accepted, are not binding international law, and contain no provisions for legal enforcement. Moreover, there are hardly any rules in international law which regulate the activities of multinational pharmaceutical companies or even generally provide for research ethics.24

Ethics review, an important mechanism of research governance, typically operates within particular domestic systems and contexts. The international guidelines require localisation, application and enforcement in the context of developing countries’ domestic policies, laws and regulations. These domestic systems need to be examined and understood. It allows an evaluation of how well these systems work in practice to provide protections for research participants in developing countries. An analysis of these emerging regulatory and governance regimes and contexts is necessary to understand the context for the local application of ethical principles, and to proactively identify and draw attention to new national systems and practices which are still in the early formation period. As mentioned earlier, it will thus be possible to identify the potential issues, weaknesses and problems that may arise in these new regimes and, in so doing, indicate concerns can perhaps be better addressed in the early formative stages, for instance, what type of ethics review system would work best for the country—a regional or an institutional systems of ethics review. Such evaluation is especially crucial because developing countries without governance systems or in the process of establishing governance systems may want to adopt the procedures now in use in developing countries that have taken early steps in this respect.

In addition, such understanding is especially important because such governance systems govern all research involving humans, not only internationally-sponsored research but also indigenous or domestically-sponsored research. As earlier pointed out, much of the literature on research involving humans in developing countries focuses on internationally-sponsored research in developing countries. There is an emphasis on global economic, health and knowledge disparities. Much of the literature thus fails to address the ethics and regulation of indigenous or domestic research. There is hardly any consideration of indigenous or domestic research in developing countries and on how this is governed or regulated in developing countries or how research participants in this type of research (no matter how little) are protected.

In a similar vein, one may focus on the moral desirability of providing equivalent protections by developed countries when their citizens or companies sponsor or conduct research in developing countries. But discussions of domestic governance systems allow room for a consideration of developing countries’ ownership in the protection of their citizens who become research participants. This shift in focus could also allow for more participation of researchers from the developing world in these important debates.

7. How Could a Governance Framework or Perspective Be Used?

To undertake a systemic analysis as anticipated with a governance perspective, one has to consider broadly the actors and institutions involved in the research governance system. To do this, an examination of the value bases for the system (which are principally located within research ethics) as well as the instruments (the guidelines, legal regulations) and the regulating institutions which attempt to accomplish these value-based objectives is necessary as well as an assessment of their effectiveness based on available evidence. These are discussed respectively below.

7.1 Research Governance: Ethics and Values

Research governance and ethics are inextricably linked. The origins of modern international bioethics can be traced to the abuse of research participants in the second World War and the subsequent enunciation of the Nuremberg Code, the first international declaration of ethical standards for research outlined by the judges at the Nuremberg trials of Nazi doctors in 1947 at the Nuremberg ‘Doctors Trials’ in 1947. The Nuremberg Code was responsible in large part for the inclusion of a provision on the need for informed consent in human experimentation in the International Covenant on Civil and Political Rights, and for the adoption of the World Medical Association’s Helsinki Declaration. The Helsinki Declaration, first adopted in 1964 by the World Medical Association, was intended to provide a statement of ethical principles to guide physicians conducting medical research on human participants.

The interconnectedness of ethics and research governance is also recognisable from some of the major developments in research governance in different countries. The Belmont Report, produced by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research created under the 1974 National Research Act, was enacted in response to revelations about researcher misconduct. It pronounced three guiding ethical principles for research involving humans: respect for persons, beneficence, and justice. These guiding ethical principles serve as the foundation for the ethical conduct of research and provide a rationale for the establishment of oversight systems that ensure that these principles are consistently applied. Thus, ethical standards and principles, have been an important underpinning for research governance.

The international ethical guidelines, including the Helsinki Declaration, the CIOMS Guidelines and the Good Clinical Practice: Consolidated Guideline, ICH Harmonized Tripartite Guideline, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use and, more recently, the Universal Declaration on Bioethics and Human Rights (UNESCO), have therefore been primary instruments for regulating research involving humans. While they have no formal legal character and cannot, by themselves, be considered law, these guidelines may be incorporated into domestic law (Glass & Lemmens, 2001). But, even where they are not so incorporated, they contain some provisions that may bind researchers and research institutions requiring them to adopt certain standards. The use of these guidelines as a basis for governance raises some issues. One such issue is that the formulation of these guidelines is frequently broad, leaving them open to various interpretations and therefore offering little specific guidance to researchers. Also, their standards may differ from legal standards or other domestic policy thereby potentially leading to confusion. Further, the guidelines lack enforcement mechanisms and may therefore have less impact than is desirable, especially when compliance is not linked to access to funding. It seems necessary to examine the normative significance of these international ethical guidelines and the relationship between the ethical principles contained in these guidelines and the legal norms underpinning the emerging research governance systems of developing countries.

Domestic guidelines also require analysis in the context of a study on research governance in the two countries. National guidelines, mostly recent, play a crucial role in research governance in many countries, including Australia, the United Kingdom, Canada, Uganda, India, Nepal, South Africa, and Nigeria. These more recent national guidelines appear, in varying degrees, to be more exhaustive than the international guidelines. This is not surprising given that they are inspired by, and are building on, the foundations already established by these guidelines. From preliminary research, it would appear that the non-legal instruments, that is, the guidelines play perhaps an even greater role than the legal instruments. It would be important therefore to examine also the normative significance of the guidelines and the role they play in the governance of research in developing countries and how well they interact with the legal framework to produce greater effectiveness in governance.

To analyse these guidelines and their impact on the research governance system, one must be able to situate them in context and understand their origins. The analysis of paradigm shifts in the understanding of ethical protections for research participants and research oversight by Emmanuel and Grady in a recent article (Emmanuel and Grady, 2006) is helpful in this regard. They note that research oversight has undergone four major paradigm shifts. These paradigm shifts have occurred as a result of different events signifying the
risks of research and embody different perspectives on the value of research and its potential hazards and different conceptualizations of the objectives of oversight. According to them, “Each period also advances a different underlying ethical principle guiding the protections of research participants, empowers different institutions to implement the protections, and has its own way of balancing protection of research participants against other important values in biomedical research.” (Ezekiel and Grady, 2006) Thus they categorise these four periods, which though distinct may sometimes overlap, as: researcher paternalism, regulatory protectionism, participant access and community partnerships.

Researcher paternalism, the paradigm operating during and immediately after World War II, denotes a period in which a utilitarian approach, an ethical approach which justifies individual sacrifice for the greater good of society, was adopted. (Moreno, 2001). In that milieu, the ethical principle guiding research and research oversight was social value. Emphasis was therefore placed more on the value of research rather than on the safety of participants. It is not surprising, then, that the major mode of research oversight was through self-regulation by researchers, who took on the paternalistic role of determining what was ethical and useful, “weighing social value over individual risk–benefit assessments when they were in tension.” (Emmanuel & Grady, 2006, p. 85). Such paternalism corresponded with the prevailing medical ethics at that time -- the doctor-knows-best mind-set. Professional ethics, codes, and oaths established by physicians, such as the Hippocrates Oath, served as normative standards. Although peer review of research took place in several institutions, it was by no means mandatory. As was made clear by the scandals exposed in articles and books, researcher paternalism far from protecting research participants, in fact, exposed participants to harm. There was with little regard for informed consent and the deception of participants was justified on the basis of the good of society. The scandals led to a paradigm shift to a model of regulatory protectionism or what Moreno (2001) refers to as “strong protectionism,” which was essentially a minimisation of the discretion of researchers in governing their conduct of research involving humans (Moreno, 2001). This paradigm shift led to such regulatory steps as the enactment in the United States of the National Research Act in 1974 and the creation of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which drew up the Belmont Report. The Belmont Report states the ethical principles which should provide the basis for all research involving humans as previously mentioned. 

Further, independent ethics review committees and government regulators such as the Federal Drug Agency (FDA) in the United States became important mechanisms for governing the conduct of research on the basis of the principles elaborated in the Belmont Report. The utilitarian approach thus gave way to an approach of principlism. The ethical principles of respect for persons/autonomy, beneficence/non-maleficence, and justice, stipulated in the Belmont Report, originated from this approach. This approach has gained wide approval and is much employed within bioethical circles.

Further, there has been another paradigm shift from regulatory protectionism to participant access mainly as a result of the HIV/AIDS epidemic, beginning in the early eighties. Participants now see regulatory protectionism as somewhat paternalistic and demand the right to be involved in the decision-making process, most particularly with regards to the right to participate in research which they think will be useful in finding cures to diseases such as HIV/AIDS which as yet have no cure. Hence, as summarised by Ezekiel and Grady (2006), “Individuals did not need to be protected by regulation; rather they should be entrusted to know their own good and interests and be free to pursue them.” The core ethical principle during this period was, then, the right to autonomy.

Ezekiel and Grady (2006) conclude that there is currently a shift from the participant access paradigm to a paradigm of collaborative partnership. Involvement of communities is now argued to be a necessary part of the research approval process. Collaborative partnership recognizes the importance of the social framework in determining both research agendas and priorities, and in negotiating better protections for research participants. Interestingly, this is a trend clearly observed in obtaining approval for biomedical research in developing countries currently. Only recently, a microbicide clinical trial being conducted in Thailand had to stop, partly due to protests by community activists that the communities were not sufficiently involved.

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25 These ethical principles originated from principlism, subsequently formalised by Childress and Beauchamp in their seminal work Principles of Biomedical Ethics. It has however been criticised for being somewhat paternalistic and for its restrictive approach to research involving certain populations, including prisoners and women. Beauchamp TL, Childress JF, (2001) Principles of Biomedical Ethics. Oxford University Press, Oxford (Fifth Edition).

involved in the process of approving the research.\textsuperscript{27} Research partnerships with the community in which the research was being conducted are frequently recommended to protect such communities in developing countries from exploitation was to develop. In developing countries, ethics review committees now frequently have the role of ensuring that benefits are made available to the communities as well as protecting the individual participants of research. Arguments for the research participants' representation on ethics review committees, which are increasingly made in the literature,\textsuperscript{28} can clearly be categorised as falling into this paradigm.

It is important to note that these paradigm shifts overlap to a certain extent and two paradigms may exist at the same time. Moreno, for instance, argues that strong protectionism is the current trend because of scandals as a result of research misconduct and the changes in the research environment, including the increase in private funding of research, the emergence of new areas of investigation, and the complexity of studies. (Moreno 2001, p.175).

The descriptions of these paradigm shifts focus on biomedical research and on western countries, in particular the United States. However, Ezekiel and Grady's characterisation of these paradigm shifts in research oversight illustrates regulatory movements in research governance from self-regulation to increased government role and the use of command-and-control techniques to a collaborative partnership increasingly involving all stakeholders in the research process, including ordinary citizens and research participants. Their characterisation of these movements is also useful for the purposes of raising questions relating to what oversight systems currently exist in developing countries, as well as understanding how they have developed, (for instance, whether they developed in reaction to adverse events), and how these origins have affected the path their development has taken -- the route of voluntary guidelines or a more regulated approach, including the enactment of relevant legislation. In the United States, for instance, the legislative approach was adopted with respect to federally funded research in response to reports of unethical conduct. Several useful questions thus arise from their categorisation in the context of my research. Such questions include: What are the origins -- philosophical, historical or legal -- of research governance in developing countries, especially? What are the values at stake in research oversight generally, and in developing countries particularly? What ethical values underpin these governance or oversight systems? Is there a combination or assortment of values and how are these reflected in the types of research governance systems and the mechanisms currently emerging in developing countries? Thus, prior to an examination of the rules, regulations, policies and institutions comprising the governance system, it is necessary to ascertain the values and underlying objectives of the system. An understanding of the research governance system not only has to do with procedure and processes, but also substantive ethical values. One such value may be respect for persons, thus necessitating a requirement for informed consent. One can then delve into an exploration of whether, and in what way, this value gives rise to concrete governance mechanisms and an evaluation of the function of such mechanisms. Finally, the categorisation also raises the question: What implications do these systems have for the protection of the rights and safety of research participants and what kind of environment do they create for carrying out research?

### 7.2 Research Governance: Legal Context

Apart from the ethical foundations of the governance of research involving humans, law and legal analysis have not been absent from the area of research involving humans. A legal framework is an important part of the governance system, not least because regulation by ethical standards alone leaves much to be desired with regards to enforcement mechanisms. In general, law may, as a form of normative ordering, set standards for behaviour or conduct, and in a positivist sense, act as a formal and concrete means of regulating behaviour. Legal regulation thus has several uses including setting norms, protecting citizens, particularly those in a vulnerable position, for instance, through setting penalties and sanctions for unacceptable action or behaviour and regulating or declaring standards thus providing clarity and certainty in handling controversial areas.\textsuperscript{29} Formal regulation by means of legal regulatory frameworks is useful where the interests of the weak and vulnerable are at stake. (Nielsen, 1998, p.42.) In the case of research governance, it can establish, authorize, and legitimate decision-making and oversight processes. Law may thus regulate research involving humans and normatively,


through its standard-setting aspects, contribute to the promotion of ethics standards. Research governance or oversight should therefore have a legal context.

Much current analysis in the legal context focuses on risk and determining the responsibilities of stakeholders in the research enterprise. Such analysis considers from that perspective, liability under the law of torts, including what actions by researchers, such as failure to obtain informed consent leading to injury, may constitute or be actionable as trespass, (that is, assault, battery) or negligence. Law thus regulates researchers' conduct. The issues of duty of care owed to research participants by others in the governance arena, including the researchers, the government, and the ethics review committees may also be reflected upon within a legal framework of analysis. Such matters as the legal status of the emerging guidelines, the legal protection available to research participants, and the legal liability of ethics review committees responsible for safeguarding the safety and rights of research participants may also be determined within this framework.

However, going beyond specific legal issues, such as duty of care, to a governance perspective which is the focus of the paper, the question arises regarding the role of law in a research governance system. Accordingly, one of the central issues which this paper will examine broadly is the role of law as a social control, the place of law in public institutions and more broadly in governance arrangements, and the limits of law in an evolving, dynamic and special area such as the area of health research involving humans. If law plays a role in the governance of research, what types of legal instruments are employed in governing research involving humans and, what are the reasons behind this choice of instruments?

Law appears to be a purposive instrument, a regulatory tool of oversight, but this is by no means generally applicable. The choice of what legal instrument to employ in the governance of research, if any at all, from a legitimacy point of view depends not only on a formalistic interpretation – a choice between legislation, regulations, administrative guidelines – or on empirical concerns such as effectiveness and political expediencies, but also on the value placed on ensuring that research is conducted ethically. This is made amply clear by the different approaches adopted by different countries towards regulating human research. A few (such as France and Denmark) have enacted specific legislation to regulate the conduct of research involving humans. (Downie & McDonald, 2003) Others have legislation that apply only in specific cases, such as the United States, which has adopted regulations to cover all federally-funded research. Others, however, rely on national guidelines with the law applying only incidentally or to specific issues within the area. As discussed above, one instrument that has been employed in research governance has been international guidelines such as Helsinki Declaration and the CIOMS Guidelines. These guidelines do not, however, have direct legal force in many countries, although no doubt they have influence on researchers. The emerging trend among several developing countries is to go beyond these international guidelines, such as the Helsinki Declaration, to establish national guidelines which further elaborate on the ethics of health research involving humans within a domestic context. But these countries have not, with the exception of South Africa, enacted legislation relating to health research involving humans. Even South Africa's National Health Act, unlike legislation elsewhere (for example, France) is not specific to research involving humans. It covers a wide range of issues unrelated to research involving humans, and only mandates ethics review and creates the national ethics review committees. As has been pointed out elsewhere, the requirements of the international guidelines, including such requirements as submission of proposals to independent ethical review and requirements for the constitution and functioning of review boards are not, by themselves, directly legally actionable. Contractual arrangements made with regard to the conduct of research requiring compliance with ethics guidelines are, however, legally actionable. Can these arrangements therefore be considered legal instruments for the governance of research? What role do private actions in tort play and to what extent do such actions, and arising case law, currently govern research in developing countries?

It is useful, then, to examine whether law plays an explicit or implied role in regulating research. How is this role expressed – through legislation, case law, common law concepts or contractual arrangements? Do these affect only specific issues (for example, facilitation of research through the creation of research institutes, confidentiality or privacy issues or informed consent)? Or do they affect governance arrangements more generally? One could also logically question whether it is even useful for law to play an explicit and formal role in research involving humans, particularly given the lack of specific legislation in many countries, including developing countries. Should ethics review, for instance, be required by law or by

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7.3 Institutional Context

Good governance, according to Macdonald (2001), requires that collective moral intentions (or values) be translated into effective and accountable institutional actions. It is important, then, to examine the institutions that actually implement the rules and guidelines contained in legal and non-legal instruments. What form does the institutional framework take and what is the organisational structure of research governance in different developing countries? One of the key institutions in the governance of research in all countries is the ethics review committee which may be established by institutions like universities or research institutes or by governments. Ethics review is central to most research governance systems. Several questions arise within the context of a governance framework with specific regard to ethics review and include: What form does the ethics review committee structure take? Is the ethics review committee an arm’s length review body that in substance and appearance is independent and objective in terms of membership, processes, and reporting relationships? Who does the ethics review committee report to? Who appoints its membership? Are the interests of prospective research participants adequately represented on the committee and how? Are there lay or community representatives? Are they effective members and do they represent the interests of research participants? Are there transparent and effective accountability relationships to those who set standards? Who, if anyone, addresses gaps and inconsistencies in standards and processes and how? Is there any requirement for any specific expertise, (for instance, ethics expert, legal expert, statistics or clinical research expert) and for lay representation? Do the committees provide approval before, during and after research commences? In other words, is there ongoing monitoring and oversight?

While these questions specifically relate to ethics review committees, the same questions can be raised in relation to other institutional structures involved in research involving humans, such as drug approval agencies -- the institutions that bear responsibility for the drug approval processes in these countries -- and departments of health. It would thus be necessary to investigate whether, based on available evidence, the existing institutions are adequately addressing these governance issues. An investigation of these instruments and mechanisms is also required to determine if they work together in a systematic, coordinated fashion to effectively protect research participants while avoiding unnecessary bureaucracy and creating a stable environment for research.

7.4 Performance of the System

Beyond gaining an understanding of the ethical framework of the governance system, the legal context and the institutional instruments of governance, another important issue that requires consideration is the current and potential functioning of the systems for research governance in developing countries. How well are the systems working in practice and what potential do they have to work well?

Based on available evidence, one could consider issues relating to the scope, clarity, efficiency, and adequacy. Questions that will be asked in this section include: How comprehensive is the system? What aspects of research does it cover? How much public participation is there in the processes? What provisions are made within the system for important matters such as standards, compliance and education? Does the system make for simplicity or is it a convoluted process in which there is no certainty of what the standards are or how things are to be done? Are the rights and responsibilities of actors in the governance system clear? Is it a cost effective and affordable process? Are the conduct and enforcement of oversight adequate and effective? Is there an adequacy of resources and expertise for effective governance?

8. Conclusion

The discussions about the gap in resources for health research in developing countries, or what ethical standards should apply in developing countries, and whether or not developed countries should provide equivalent protections for research participants in research sponsored by organisations in developed countries are very important. However, in my view, developing countries can, and are beginning to, take reasonable steps to establish systems to protect research participants. These developments do not detract from the arguments about ethical concerns and standards, which deserve continued examination in academic literature. But it is also important to examine these new developments in different developing countries, and to give suggestions about improvement.

Thinking of research involving humans in developing countries in a more comprehensive, governance-relevant way, includes asking questions such as: Why are research governance systems needed in developing countries? How is research involving humans currently governed in developing countries? What is (or should be) the role of law, if any, in these systems, and what are the implications of this role or lack thereof on the protection of
research participants? What tools or instruments are required to effectively govern research involving humans in developing countries? What is the role of governments in research oversight? What are the emerging governance models emerging in developing countries? What are the potential issues that these models raise? Based on available evidence, how effective are these systems, and how well do they work in protecting research participants? What should be the future directions of research governance in developing countries?

Finally, a governance perspective would address the existing vacuum in the literature, namely an exposition and analysis of the governance arrangements for health research involving humans in developing countries. Such research would be of value to scholars, research sponsors, researchers and regulators in developed and developing countries who need to understand research governance and regulation in different jurisdictions, particularly the emergent governance regimes of developing countries.

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National and International Guidelines


Department of Health, Research Governance Framework for Health and Social Care (Second Edition) (United Kingdom, 2005), online: <http://www.dh.gov.uk/prod_consum_dh/groups/dh_digit
Soccer is an international sport that serves as a metaphor for clinical research with human subjects. The soccer field is in play all the time. The ball may be sent forward toward the goal or back away from it in order to strategically advance and score. The players work as a team in the strategic play. Infractions of rules by member(s) of one team give advantage to the opposing team albeit temporarily. Fair and competitive play within the rules of the game creates an almost infinite variety of options for players to compete, engage, score and win. If the rules exist to ensure safety and fairness, they do not also dictate what play any team or player must make in the game. Soccer rules, like human subject research regulations are safety boundaries. So long as the rules are not interpreted preferentially for one team over the other, they are mutually protective.

Regulations of research with human subjects have evolved through experience and over time. Egregious unethical use of persons as research “guinea pigs” prompted the Nuremberg Code and soon after, the Helsinki Accord to insist on rules of engagement: scientific worth, informed consent, and ethical review by independent committees. Failing to accept the boundary approach to ethical review led to a proliferation of rules/regulations, including codified regulations within countries such as the Belmont Report and Code of Federal Regulations (CFR) in the U.S.; Council of Europe’s Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine; the United Nations Educational, Scientific, and Cultural Organization’s (UNESCO) Universal Declaration on the Human Genome and Human Rights and the Universal Declaration on Bioethics and Human Rights; the Council for International Organization of Medical Science (CIOMS).

Yet, the multiplication of regulations seeking to regulate research may confuse rather than clarify the rules of engagement. Interestingly, many of the

Ethical Norms and Regulations for Research with Human Subjects

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Acknowledgements

The author would like to acknowledge assistance from the Canadian Institutes of Health Training Programme, which provided funding during the period within which this research was undertaken. The author also acknowledges the advice of Professors Jocelyn Downie and Bill Lahey of the Dalhousie Law School on the project of which this was a part. This paper was previously presented at the Annual Colloquium of the Canadian Institutes of Health Training Programme, and the Osgoode Hall Law School Graduate Students’ Conference in May 2008.
declarations speak in terms of human rights as a duty, as if every nation has accepted and codified the Universal Declaration of Human Rights proposed just after the Nuremberg Code (Eriksson, 2008). Acceptance of ethical codes as guidance gives reviewers and professionals designing and conducting clinical research with human subjects the inspiration to act within the ethical norms (as soccer players perform within the rules). Ethical decisions are context sensitive. Ethical principles, rules, and norms posit ideals; particular protocols require interpretation of ethical norms in its particular context.

Ethical use of principles, such as those proposed by the Belmont Report - autonomy, beneficence, and justice provide guidance and require interpretation within a particular context. A protocol that ignores the process and documentation of informed consent violates the praxis of autonomy (as prescribed in the Nuremberg Code) and should not be approved to proceed, unless, it is impossible to consent the people intended to benefit from the study. For example, a head trauma patient in emergency care with the intent to use an experimental treatment cannot give consent and a surrogate may not be reachable. Absent any proven beneficial treatment, and with the scientific approval and hope of efficacy, the documentation of consent may be waived. In this example it is not reasonable to insist that a strict and formal application of autonomy be immutable. Norms based on principles provide guidance, but they should not impose impractical requirements. In other cases where the “experimental treatment” anticipates significant risk and lacks an empirical evidence of direct benefit, it is harder to justify proceeding without the consent of the subject. Willingness to allow individuals to accept, by virtue of their ‘consent’, a disproportionate level of risk over benefit is equally troubling. Ethics committee members struggle to resolve conflicts between and among ethical norms within each context-dependent protocol.

The Belmont Report recognizes the necessity of interpretation in the use of principles in reviewing protocols enrolling human subjects. “Such rules often are inadequate to cover complex situations; at times they will come into conflict, and they are frequently difficult to interpret or apply….These principles cannot always be applied so as to resolve beyond dispute particular ethical problems” (1979). Belmont is a product of the U.S. that may, or may not adapt well to other cultures. Attempts to codify rules, e.g. CFR, the ethical oversight of clinical research in the U.S. has expanded in recent years, complicating review of multicenter trials and especially making difficult evaluation of international multicenter trials. Abiding by the rules has so far failed to provide any guarantee of agreement or certainty of approval by various institutional ethics committees, eliminate harm to subjects, or avoid scientists’ complaints about time taken up by ethical review.

“Research” is designed to develop or contribute to generalizable knowledge. Improving medical and behavioral health requires research that can only be interpreted by the use of human subjects in clinical trials. Understanding disease pathology and creating preventive or curative therapies ultimately involves human beings, first as subjects, then as patients. The range of research is considerable, including studies of interventions, physical, chemical or psychological in healthy or compromised subjects; controlled trials of diagnostic, preventive, or therapeutic intervention designed to improve human health and wellbeing (CIOMS).

Research seldom follows a linear progression, but as in a good soccer game, moves forward, backward, sideways, in order to move toward the goal. Science is progressive, building upon observation that leads to a revision of understanding in light of the data at hand. Basic research favors controlled experiments, where the number of variables is limited and the contrast between agent and its absence is quantified. The scientific preference for negative control designed research may reflect the placebo control arm in clinical trials. An initial study may justifiably use a placebo because there have been cases in which the placebo subjects had better outcomes than the experimental group. As research progresses, the data from completed trials should inform the design of future expanded studies. As benefit from the experimental drug or therapeutic becomes more evident, returning to placebo control designs raise skeptical eyebrows (Helsinki revisions 2000).

Much ink has been spilled over the prevention of mother to child transmission (MTCT) of HIV following the ACTG076 trial set a therapeutic schedule and dose for antiretroviral therapy in HIV infected pregnant women (Fr/US trial). Subsequent trials intended to discover a less expensive and time intensive therapeutic intervention using a placebo design. Ethical reaction was swift and often severe (refs). Critics complained that when the preventative dose and schedule was known, the placebo arm was unethical, exploitive, and unjust. The counterclaim was that those in the placebo arm were no worse off than persons outside the trial because the therapeutic-known dosage was cost prohibitive. Defenders further asserted that making the trial overly attractive would be coercive. This and other dubious international clinical trials prompted revisions to Articles 29 and 30 of the Helsinki Accord. Article 29 does not exclude use of a placebo in “studies where no proven prophylactic, diagnostic or therapeutic method exists” (Helsinki, 2008).
Therapeutic method did exist but at prices beyond the reach of the host countries. People of good will differ strongly about whose duty it is to provide the best proven therapeutic option and to whom. The Food and Drug Administration responded by removal of references to the Helsinki revised declaration in its regulations in order to avoid limiting use of placebos and increasing responsibilities of sponsors to research participants (Wolinsky, 2006). George Annas disagreed: “It is just totally hypocritical on their [FDA’s] part to follow the Declaration of Helsinki as long as it says what they want it to say, and as soon as it is changed, say it doesn’t mean anything” (Wolinsky, 2006). Despite protests, articles 29 and 30 remain albeit with footnotes added addressing acceptable use of placebo and post-trial access to experimental therapeutic products. Do the footnotes serve those in power, or do they correct the unjust distribution of therapeutic agents to people in need? The revisions in the Helsinki Declaration attempted to reduce exploitation by rewriting the rules, but that did not change the competitive nature of the players.

The principle of justice requires careful attention to more than fair and equitable access to a clinical trial. A subject may want to participate in a trial because he/she believes it is a gateway to therapy that is unavailable elsewhere. Therapeutic hope is not outside the possibility of a research study, but in the main, research by nature must include an element of uncertainty. It is no more just to suggest that a drug is helpful before proof is in hand that it misleads innocent people than to limit access when the efficacy of a new dose or formulation is being evaluated. Justice requires attention to and removal of artificial barriers to access, during and after clinical trials (Kiskaddon, 2005). It may be that what we like to call “ethical complexity” is in truth a tendency to avoid the hard reasoning required to abide by international declarations such as Helsinki, because they expose the ugly ditch separating “technology haves” from the rest of humanity. We add or subtract rules because we don’t like the way the game is being played!

The view of the effectiveness of regulatory oversight may vary depending on where you stand. The investigatory seeks to advance the study, the IRB review concentrates on the level of risk, clarity of consent process, and fair access, often after someone in the regulatory affairs office has decided whether the protocol qualifies for exemption or expedited review. Deciding a protocol is minimal risk is suggested as a way to reduce the oversight process (Kim, et al., 2009). While this one step would effect significant cost and time savings, it is also one topic that has consumed a sustained conversation by members of one IRB on which one of us (Boyd) serves.

International research involving human subjects may well encounter distinctive guidelines on the ethics of medical research, e.g. South African Medical Research Council formulated their regulations in 1979 and have subsequently revised them in 1987, 1993, and 2002, each of which reflect local decisions influenced by national economic and health concerns (Benatar and Vaughan, 2008). Setting priorities on the basis of national health needs flows into the types of clinical trials conducted. In a resource limited context, the strategy is inherently logical. National and international research is shaped by economic and political forces. What may be important to advance knowledge in an area of science may or may not have immediate impact on the local situation. A research study may be made attractive by adding resources such as clinics, training, or simple basic medical care. The host nation has the option to accept or reject a trial sponsored by profit motivated pharmacological companies, foreign governments, or affluent universities. It is reasonable to hope that proposals will have some direct or indirect benefit; otherwise, one expects the host nation to reject the offer. In realistic situations however, the host may accept the study as a way to offer additional resources to an already stretched budget. We dare not assume that a set of ethical guidelines are necessarily leading to uniform or consistent ethical praxis because the guidelines exist in a plurality of forms, each of which is subject to interpretation.

The complexity and cost of doing research is a concern that stimulates discussion about more efficient regulatory oversight. Greater centralized review and acceptance of best practices to reduce unnecessary documentation and lengthy review is desirable. Rules alone will not meet the challenge. The oversight must match the research goals and national-international needs. Recent trends suggest that clinical research is going the direction of other globalization industries (Glickman et al., 2009). Reaching international consensus may require a re-examination of the plurality of oversight guidelines, and an examination of the appropriateness of applying Belmont principles in international research. There is no simple or easy path to universal uniform ethical review of research with human subjects. Guidelines abound without a clear indication of more reasonable and responsible conduct in the field of medical research (Eriksson, et al., 2008). It may be that ethics per se is an art of dialogue which cannot be legislated or instructed but found through mutual interaction and experience.

Universal principles offer important considerations such as the respect of persons,
careful assessment of the risk-benefit ratio (benficence) and justice as fair access, before, during and after the clinical trial. The challenge is more than identifying the elements of a proposed study and its consent document that meet these principles. The difficulty is remaining unbiased to one team over the other such as not yielding to pressure from the sponsor to proceed with a trial without assurance of future availability of the test substance to the host country and its participants. Being satisfied that standards of care differ among persons and places insulates the primary responsibility of subject safety within ethical oversight from the larger justice issues.

The Belmont Report within the US enshrines the autonomy, beneficence, and justice principles as the consideration due any clinical research trial. International documents such as the Declaration of Helsinki also insist that clinical research be beneficent and just. Putting the burden on the participant as a moral agent, free to consent to be a research subject, shifts responsibility from the ethical oversight posited to ensure their safety. Ethical assessment does require knowledge of context and complexity and sensitivity to diverse cultural issues for each particular clinical research trial, but the unique situation is not an excuse to bend or negate ethical principles or rules designed to protect research subject’s safety.

Absent a lexical priority among the principles, the best approach may be to seek an equal portion of autonomy, beneficence and justice. Autonomy as a signed consent form is insufficient to show mutual respect for persons, if after the trial, the subjects lack access to the drug they helped develop. Perhaps the principles of Belmont will be replaced with more respected international ones, but in the meantime, choosing which rules apply, when, to whom, and where is a recipe for chaos.

When players are harmed by infractions of the rules, penalties are imposed and where appropriate the offending player is carded for misbehavior, or even expelled from the game for serious offenses. If the rules were only enforced for certain teams and not for others, one country would always hold the World Cup! The long term impact would be a mistrust of the fairness of the game and loss of participation. World soccer would fade into history like the gladiators of old. In the domain of scientific pursuit for the improvement of human health, we ought to pay attention, while striving for international fairness. Respect deserves equivalent attention, lest history find us inadequate to our task.

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The Status and Ethical Review of Donor and Organ Transplantation Practices in China
Abstract
The shortage of organs for transplantation is severe in China. This paper discusses factors related to this, and the issue of the utilization of the bodies of executed prisoners for organ transplantation. There are also ethical disputes in legislation to set the criteria of brain death, and on commercializing organ and donor compensation.

In China, organ transplantation is now developing quickly. However, despite the various obvious benefits to Chinese society, organ transplantation in our country has experienced some difficulties. From an ethical review of organ transplantation practices in China, there are ethical problems.

On October 13, 1998 when Doctor G, of the Department of Ophthalmology, Hospital R in Beijing, prepared for an operation for the following day, he found the stored corneas to be necrotic. He then went to the mortuary and removed two eyes from a female corpse. The next day, he did cornea transplantation for two patients and both recovered their sight. However, at the crematorium the family of the deceased female learned about the eyes missing and sued Doctor G to the court for compensation of one-half million Chinese dollars.

This case was openly discussed in the mass media and in the fields of medical professionals. On March 5, 1999, the Institute of Philosophy of the Chinese Academy of Social Sciences, and the China Transplantation Development Foundation held a meeting to discuss the case. The presenters included physicians, lawyers, philosophers, teachers of medical ethics, bioethicists, reporters and others. Nearly every physician present showed sympathy for Doctor G, and said they thought that Doctor G worked for the good of the two living patients.

The bioethicists and teachers of medical ethics pointed out that Doctor G violated the fundamental principle of “informed consent” and harmed the integrity of the corpse, as well as the feelings of her relatives. However, the prosecutor decided against bringing a lawsuit against Dr. G because Doctor G did not harm the cadaver with malice. The consensus of this case mirrored the situation in China concerning the shortage of corneas from organ donors, and also the inadequacy of medical ethics education for physicians.

To obtain enough donated corneas or other organs for transplantation in China, all sides urged the Chinese government to enact a law promoting organ donor contributions, and called for a major effort to educate medical professionals about transplantation ethics. After this meeting, the efforts to improve donor and organ transplantation practices were accomplished. Some centers for organ donors have been built in hospitals of the major cities in China and the number of donated organs continues to increase.

The shortage of human organs for transplantation is severe in China. Some traditional beliefs have deterred the donation of organs. “Filial piety (xiao) is the beginning of ren (the sum of human virtues)” (Confucius). “Skin and hair are endowed by parents and should not be damaged” (Book of Filial Piety). Keeping the body intact to extend the existence of ancestors makes people reluctant to donate the dead body for organ transplantation. Confucian and Buddhist beliefs insist on the integrity of the corpse until the moment of cremation or burial. Prevailing attitudes about the need for respect of elders also deters organ removal. As a result, autopsies and donations of cadavers for any purpose are limited, including for transplantation or for use in medical schools.

In the past in China, except for prisoners being executed, there were almost no “voluntary” organ donors. Also, there were almost no conditions or places for the other voluntary donors to give their organs. Due to the severe shortage of donated organs for transplantation, it seems that for a long time in the past the main source of organs in China has been from executed prisoners. During this time, there apparently was no controversy among the general public about the practice of getting organs from executed prisoners.

Some people thought that utilizing the corpses of executed prisoners for organ transplantation was a good thing. Using the organs of a dead criminal to keep other persons alive was considered a worthy practice. People considered it a waste of the otherwise perfectly good organs of the executed prisoners. They thought that it was acceptable to allow criminals to give back to society in that last, crucial way. The public seemed not to consider other possible relevant ethical issues.

However, there was controversy among some Chinese bioethicists. Some voiced objections to the utilization of the corpses of executed prisoners for organ transplantation. The idea of taking organs from executed prisoners for transplantation was criticized by some on ethical grounds. First, prisoners, who by definition have been denied their freedom, do not seem capable of freely consenting to such a procedure. Second, doctors ought not to participate in a process that involves killing.
There were other ethical problems. The first is the ethical dispute in legislating criteria of brain death. The current situation is that the criteria for cadaveric heart death and brain death are interpreted by people according to their own viewpoints. The adoption of criteria for brain death may facilitate options to obtain fresh organs for transplantation. An important principle is that due to the tension between the donor’s death and the recipient’s life, there needs to be a separation of transplantation experts from those diagnosing brain death. The practical problems are a lack of qualified doctors for diagnosing brain death, and instruments and other services for removing and storing organs taken from the body of the donor following brain death.

The second ethical problems was some hospitals that do not yet have the capabilities, had tried to do organ transplantations. That could be seen from there being centers for organ transplantation that are not qualified, and the quality levels of techniques in each center varies sharply. The first reason for this was that many centers for transplantation were motivated by self-interest. A second reason was that a past administration regulation attributed to such. For example, to get a good reputation, the hospitals might reach an index to finish five operations of organ transplantations. This leaded some hospitals to perform by any means to attain the goal. Therefore, measures had been taken to regulate entry into the organ transplantation industry.

The third is the recipient transplantation situation. Organ transplantation in some hospitals was available mainly based on the patient’s financial ability to pay, without considering medical circumstances. It thereby excluded the poor. However, some persons were also able to avoid waiting for organ transplantation because of their power and personal relationships.

Consider the case of Fu Biao a famous Chinese actor. Fu Biao was diagnosed with liver cancer of a later stage on August 2, 2004. He received a liver transplantation on September 2 in Beijing. Because of the spread of cancer, he received a second liver transplantation in Tianjin in June 2005. Due to unsatisfactory effects, he returned to Beijing to get health care services until his death. Points for discussion are several. Why allow Fu Biao, at the later stage of cancer which is not suitable for organ transplantation according to medical standards - to obtain two opportunities for organ transplantation while other patients eagerly wait for one organ transplantation? Is this just? Should there be conditions or criteria for organ transplantation?

A final issue to consider is the prohibition of commercializing organ transplantation and donor compensation. From the perspective of not treating human beings as a means but only as an end, the sale of the body cannot be justified. It violates human dignity and would necessarily result in a society with greater social inequalities. Most countries currently prohibit the sale of human organs. However, the sale of human organs for transplantation cannot be eliminated in practice. So a practical problem is how to regulate such an immoral trade.

Should organ donation be compensated? Organ donors unavoidably suffer some injuries and costs. Donors have to use expensive medicines to recover, lose income during and after transplantation, and need to pay for nutrition, apart from suffering physical injuries. Organ donation is a generous and self-sacrificing act. Should donors not be compensated, especially if the donor is poor? If so, what should be covered in compensation? To what extent, and what standards are there for compensation? And, if compensation is morally acceptable, how can we assure that compensation does not lead to the sale of organs?

To stabilize the confusing conditions, and improve the quality of organ transplantation, a variety of laws for organ transplantation were urgently needed. Despite there being problems, previously there were few regulations or laws relating to organ donor and transplantation in China. However, in July 2006, the Ministry of Health promulgated the “Temporary Provisions of Human Organ Transplanting Technology Clinical Practice.”

Nonetheless, some scholars thought the legislation had shortcomings, such as an unstated legislative goal, an inconsistency with other statutes, allowing inefficiency and unfairness in the distribution of human organs, no special protection of minors, a too general prohibition on the sale of human organs, and no neutral agencies to manage the distribution of human organs, among other issues.

In April 2007, The “Regulation of Human Being’s Organ Transplantation” was enacted and brought into effect in China. The regulation embodies bioethical principles, studied the necessity of doing further ethical regulating of human organ transplantation, and put forward some specific medical ethical principles when performing organ transplantation operations. Among these, the principle of justice and the principle of ethical supervision were especially emphasized. Here, we translate some parts as examples.

(1) The law requires that human organ transplantation done in China follows this law, and have organ transplantation done within the guidelines of bioethical principles. (2) The law prohibits buying and selling of human organs. (3) Organ donors are to have informed consent and not be paid. (4) Hospitals that do organ transplantation
are to have a license issued by the Ministry of Health. Scientific system has begun to be built and it has made some progress, including the setting of entry standards and directives. (5) Hospitals that do organ transplantation are to have an ethics committee. (6) Professionals who do the organ transplantation shall obey bioethics principles. (7) Professionals shall take care of the health of the living human organ donor, and respect the dignity of the corpse. (8) Professionals shall keep confidential the information of donors and recipients. (9) To have ethical reviews by the ethics committee. (10) To have a mechanism for enforcement and sanctions. (11) The government has a responsibility to build a central registration for organ donation and distribution, which prevents transplantation centers from sharing usable organs, and encourage the public to donate the organs for patients. (12) Volunteers have his or her corpse so used with informed consent; or if the family consents. (13) Organ transplantation is available mainly based on the patient’s medical circumstances. This law was enacted in July 2007. The legislation contributes enormously to the future development of donor and organ transplantation in China. Furthermore, the legislation provides more theoretical instruction and practical relevance for the related medical professions. However, the ethical issues and complications of organ transplantation will be dealt with step by step in the future. It is the time for changing donor and organ transplantation practices has been coming in China.

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References
Renzong Qiu, Could organs in China have been from executed prisoners? Medicine and Philosophy, March 2004, p.20

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