

## Commentary

# The Belmont Ethos: The Meaning of the Belmont Principles for Human Subject Protections

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### Abstract

The Belmont Report is central to human research ethics. It is not a policy nor regulatory legislation. It addresses more the *being* of research integrity than its *doing*. The impact of The Belmont Report is in its significance as a living tradition. This paper will reflect on the implications of Belmont's three principles: Respect for Persons, Beneficence, and Justice. These form the fundamental *ethos* underlying human subject protections. These three principles must be interpreted anew in each age and each context so that research is shaped by the preservation of human dignity. In this way research itself is shaped, preserved, and protected as a process leading to truly human and humane progress.

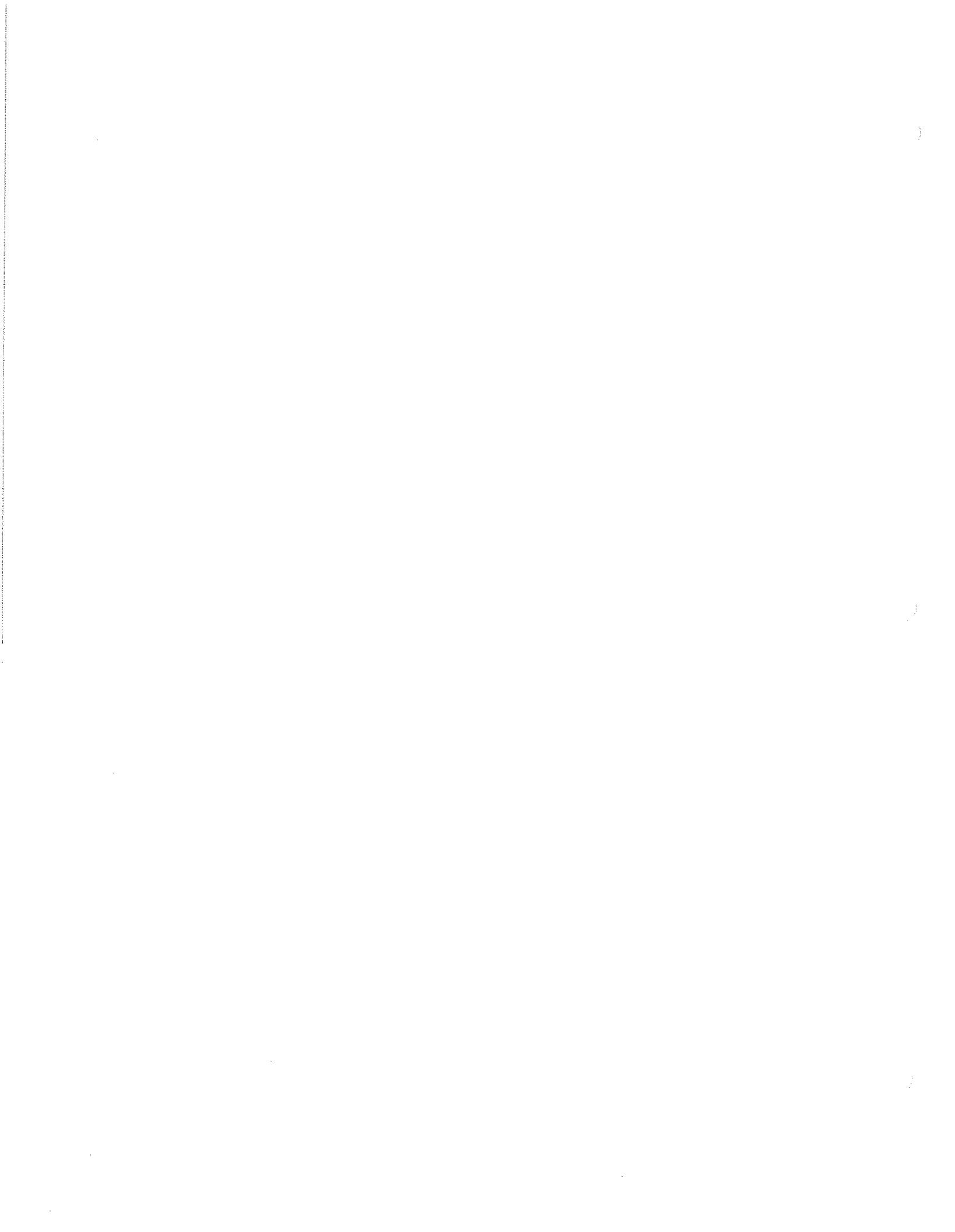
### Introduction: Belmont as Ethos

History, whether of individuals or cultures, is a never ending process of milestones and

markers each building upon or veering away from the experience of each other. Sometimes, these markers and milestones stand out and seem to capture the very essence of a person's life or the soul of a culture. Americans look to the signing of the Declaration of Independence and

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the Emancipation Proclamation as two exemplar events that have marked the conscience of a nation struggling to evolve from a noble experiment to become an experience. In this light, there are any number of historical markers that vividly bring into high relief the profound significance of human subject protections in the evolving history of research. One of the most significant is The Belmont Report of 1979.

On 12 July 1974, the National Research Act was signed into law and established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Among other charges, the Commission was directed to identify and articulate the ethical principles that must form the basis of all human subjects protections in research. Over a four year interval, the Commission convened physicians, behavioral and biomedical researchers, academic theologians, ethicists, philosophers, and lawyers to discuss from a wide variety of perspectives the common bases from which could be articulated the fundamental ethical principles for protecting human participants in any form of research. In April 1979, the Commission issued The Belmont Report and in it identified its three principles that are the foundations for the protection of human research subjects: respect for persons and their autonomy, beneficence, and justice.

Memory and perspective are curious human phenomena. The work of the Commission and its principles are often unfortunately discussed in popular experience from a particular bias favoring *law* or *regulations*. However, the work of the Commission was clear that the principles of respect, beneficence and justice are not *ethical codes* as one might find in other documents. They are not black and white regulations or easy minimalist standards. Rather, these principles and the Report itself are an analytical framework or *paradigm* better understood by the origin of the word ethics itself.

The term ethics comes from the Greek *ethos*. Ethics are sets of regulations or standards against which behaviors can be measured. *Ethos* is the fundamental character of a person, an institution, a society, or a culture. In the ideal, ethics or codes should be born from the originator's *ethos* (i.e. fundamental character). *Ethos* is something profoundly more fundamental than any set of regulations. The three principles articulated

in The Belmont Report are three fundamental markers of the ethos of human subjects protections.

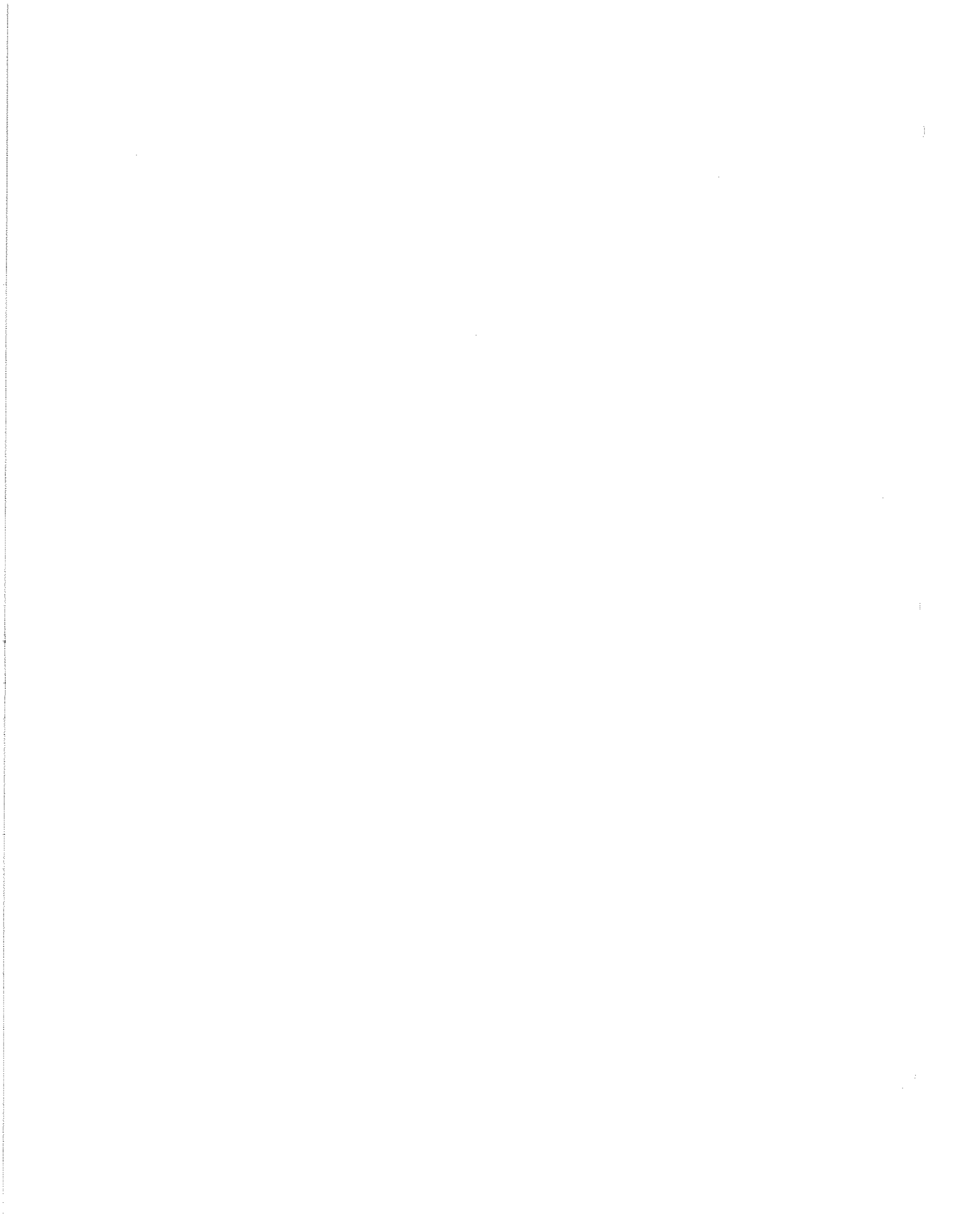
All paradigms are subject to the process of *hermeneutics*, namely, the act of interpretation. Under this process, the three principles of "*The Belmont Ethos*" must undergo a hermeneutic and thereby be understood anew in each age and each context so that research efforts are tempered and shaped by human dignity and integrity. Research is best preserved and protected in this manner as a humane pathway always leading investigators, institutions, human participants, and society toward the good and always away from anything less.

### **Respect for Persons**

Respect for persons is the first of the three foundational principles of The Belmont Report. For all who read The Belmont Report, the principle of respect for persons will conjure up nostalgically the values learned in education and home rearing. Respecting others is basic, and one of the normative lessons of life in the ordinary family or school setting. Respect for others and their personhood is so basic that the nostalgia and ordinariness of this life lesson are what can anesthetize people from its significance in human subjects protections. While the principle of respect for persons is basic, it is far from commonplace and can never be presumed.

Respect for persons has two elementary parts. First, this principle refers to the inviolability of the autonomy of another person. Second, the Report indicates that respect for persons means a special obligation to protect those who have a diminished capacity for making autonomous decisions and self-determination. In essence, each human being has a right to individual autonomy and self-determination that cannot be diminished by the will of another.

The principle of respect for persons as understood by the 18<sup>th</sup> century had sought to elevate the dignity and worth of the individual human person over tyranny. Evolving gradually over time, the rights of the individual were a crowning achievement in Western thought and formed part of the very cornerstone of the American experiment itself. The implications of this profound principle have not been exhausted and never will. The cultural discussion regarding the protection of equal rights and individual



autonomy is far from over. In each age and context, human beings must carefully and honestly look for the emergence of the darker side of human experience that is capable of exploitation, manipulation, bigotry and power. Protecting individual autonomy and those with diminished capacity is as old as civilization itself and has been traditionally one of the major measures of the moral centeredness of a society and its leaders.

The impact of this foundational principle for research and research populations has grown and expanded in line with new insights regarding the inherent dignity and autonomy of women, men and children. New experiences of what it means to be human and humane provide re-interpretation for this first of the three foundational principles of The Belmont Report.

To discover for ourselves what it means to revere this principle of respect for persons, one need only look at the origin of the term. *Respect* comes from Romance language roots that mean *to look back* or *to regard again*. An image may prove helpful to understanding what is meant here. Assume you are riding at full gallop down a road. You come upon a country scene that simply takes away your breath. At full gallop you turn your attention away from the road to "look again" or "look back" simply because you cannot resist the scene. Sometimes, the price for being so transfixed is obvious. But the reality of what is seen cannot be resisted and ultimately seems to be worth the price of falling off one's horse.

Respect for persons occurs when the absolute worth of other human beings suddenly arrests one's attention away from mundane concerns of daily living. One suddenly becomes aware of an *other* and the magnitudeness of this *other* constitutes a manifestation of humanness itself. It invades the perceptions and senses. Strange how this occurs at the most inconvenient times and upends one's assumptions and one's activity. History is replete with stories and examples how the most inconvenient and unlikely of characters became themselves messages about the dignity of human nature to those who were too busy to see and remember. The lowly in these stories unexpectedly invaded the sensibilities of the *busy* making them stop and wonder and be amazed.

In the act of human subjects research, genius and industry meet in a relationship between

researcher and enrollee. In that meeting there always must be something that arrests the attention and makes one wonder. For after all, to be in the presence of another woman or man or child who generously would give of themselves in research to benefit human welfare is certainly enough to make one look back or regard again.

For an Institutional Review Board (IRB) whose mission is clearly the protection of the ethical rights and welfare of human subjects from research risks, the responsibility found in respect for persons is immense. It is to uphold the rights and dignity of individual persons in any culture as pre-eminent over the charging energies arising from the research enterprise. To uphold the autonomy and rights of persons is sometimes an inconvenient "stop" in the busyness of research. In the research culture where *produce or perish* can be the whisper heard by new investigators, an IRB has a moral obligation to voice more loudly a deeper wisdom: *Protect or perish*. While one practically must be concerned about what is produced in research for sponsors and for the public trust, to violate or leave unprotected the personhood and rights of human subjects, especially the vulnerable, is, as T.S. Eliot might image it, the deepest treason of them all.

### **Beneficence**

Beneficence is the second of the principles articulated in The Belmont Report. For many, the meaning of beneficence seems rather immediate or familiar. *Bene facere* is the Latin root phrase that forms our English term. Literally, it means *to do well* or *to do the good*. The Report clearly grounds beneficence, the *doing of the good*, upon respect for persons, its first ethical principle. Respect for persons and their autonomy necessarily must give birth to doing the good. However, in the discussion of this second ethical principle, the Report engages in a series of reflections that take the reader far deeper than a reminder to have the best interests of other people firmly in mind. In what can only be deemed an act of sheer wisdom, the Report's discussion concerning beneficence draws the reader to consider the balance between *doing no harm* and *always doing the good*.

There is always an element of risk in human research regardless of discipline. As part of the inherent risk in research, it is not always easy to



maintain a definitive difference between what constitutes the avoidance of harms and the embrace of doing the good. It is entirely possible that to do the good means to take risks that are above and beyond what is routinely met in daily life. A doctor certainly wants to heal a patient suffering from an infection. But the most effective and lifesaving therapy will require a needle stick and the painful disinfection of a wound. Healing does not always guarantee freedom from pain. Medical research history is filled with examples of ingenious and life saving discoveries brought into being because someone, somewhere took a risk. Risk is at the very heart of human subjects research. Beneficence ensures that the risks of the act of research are kept within the essential context of the commitment to *do the good* for the benefit of others. But how does one approach this way of understanding beneficence? How does a researcher or an IRB itself understand the critical and delicate interplay between avoiding harms and doing the good?

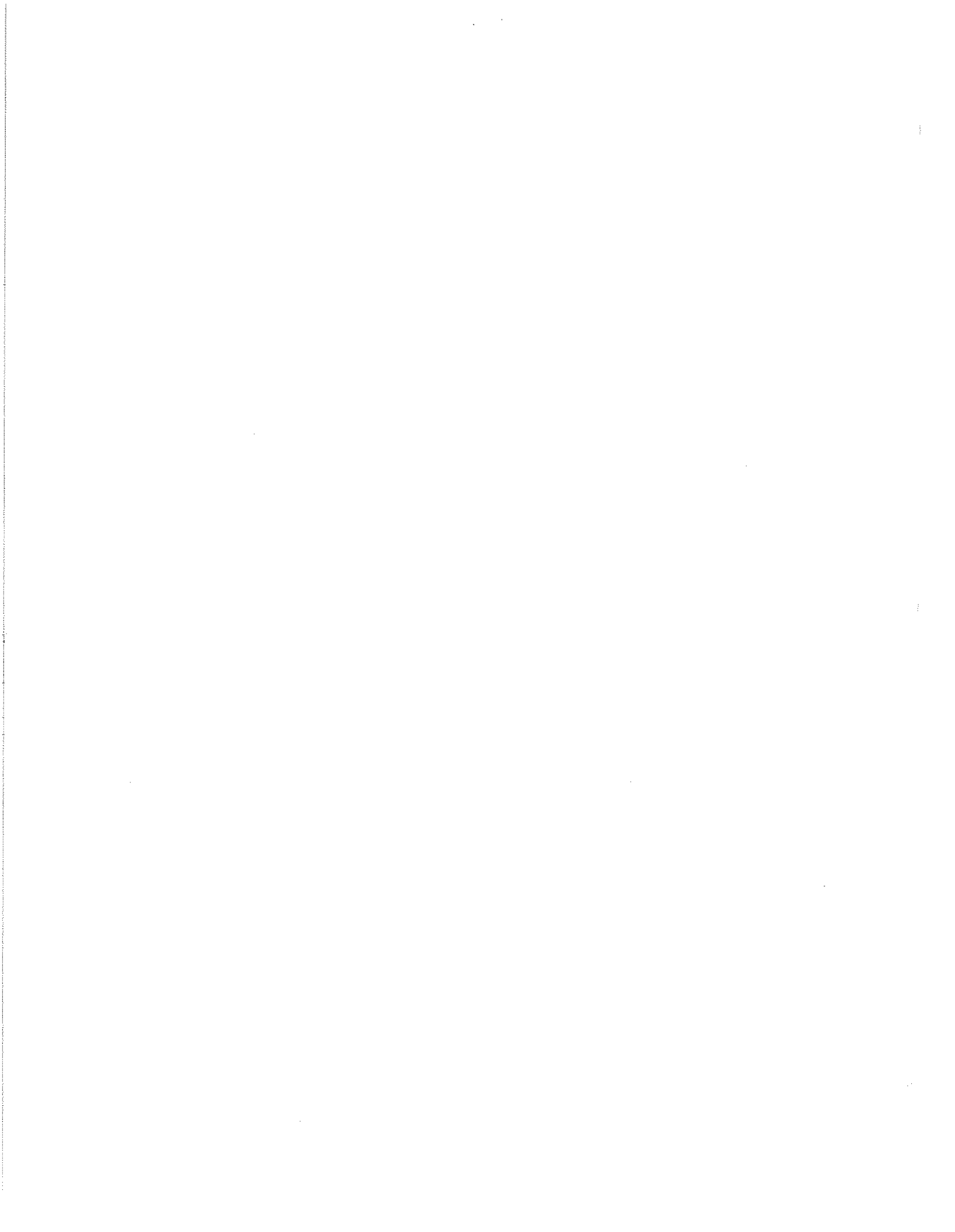
Since 1991, the importance of human subjects protections has exploded into the world of research in a way completely unanticipated. Even in the aftermath of the Holocaust and the Nuremberg Trials, many American researchers and medical professionals did not consider that such things could ever happen in this nation. Little did many realize that research tragedies and problems were occurring in our own communities where such things *never could happen*: Tuskegee, Willowbrook, Fernald etc. Yet even in the face of these events, there still abides an unarticulated bias that IRB procedures have something to do with administration, or secondary scientific review, or institutional safeguards, or legal compliances. In its bald articulation that one must approach human subjects protections as a balance between risks and benefits, between avoiding harms and embracing the good, the principle of beneficence says something completely different regarding the purpose of an IRB and the mandate to protect the rights and welfare of human research participants. IRB's are not about the business of administration or secondary scientific review. Their primary purpose is not safeguarding institutions, institutional officials, or legal standards. Rather, IRB's are to be about the act of ethics: the discernment of what is best

for human participants who freely enroll in the act of research which itself has inherent risks. IRB's then do not engage in the facile world of simple black and white standards. They must delve into the gray fog that comes with human circumstance and perspective. And it is in the "fog" that IRB review is an act of balance and a beacon of beneficence and safety despite inherent risks.

For human beings, learning how to balance things is a life long process. It begins with balancing ourselves. It grows as we learn to carry objects. It develops greatly with the challenge of balancing a checkbook. Some of us first saw the beauty of balance, along with its dangers, when we held our breath during circus high wire acts. There we gaped and gasped as women, men and children danced and twirled—caught between the free flight of air and the ever present possibility of harm and danger below. Somehow we learned that true *balance* comes about when one can juggle both: the high call of the ethers and the pull of gravity. Researchers, institutions, and IRB's are called to do exactly the same. In the spirit of beneficence, IRB's call researchers and the act of research itself to a deeper sense of balance between risks and benefits, between avoiding harms and doing the good, between the strong headiness of advancement and the looming practical ground of human welfare, safety and goodness.

### **Justice**

The third of the ethical principles articulated in The Belmont Report is Justice. As philosophers would say, a many *meaninged* term. Linguists remind us that language is absorbent. Words accrue and sop up diverse meanings over time. As human experience expands and unfolds, the words we use take on new, sometimes even ironic, or contradictory, meanings. For many people, the term *justice* conjures up an image of a blindfolded Greek woman bearing weighing scales. Court rooms and legal briefs become the easy images that appear when the word *justice* is articulated. But is that the fundamental meaning of this critical term in human social experience? Does justice in the human protections sense refer to civil entitlements arising from a common consensus that is the assumed basis of democratic law?



To understand justice, it is important to appreciate its roots in the Greco-Roman and later traditions of philosophy. As Western society evolved in its understanding of human nature and the place of the individual in society, the concept of justice equally grew and developed. Philosophy, especially after it emerged from medieval neo-scholasticism, increasingly though slowly addressed the fundamental dignity and freedom of the human individual. This dignity and freedom eventually evolved into a deeper cultural understanding of inalienable human rights. These rights are part of one's fundamental nature and therefore are owed by society itself to each person under the virtue of *justice*. With the coming of the Renaissance, the Reformation, the emergence of nation states, and the beginnings of the scientific and industrial revolutions, women and men increasingly claimed life, liberty and the pursuit of happiness as matters owed to them under the virtue of justice. Justice therefore is a virtue that admits that each woman, man and child is, in the spirit of our American heritage, "endowed with inalienable rights."

Justice as an ethical principal of The Belmont Report is something far deeper than simply a legal protection. As the human dignity and freedom of each volunteer must be protected indiscriminately above all things, Belmont's concept of justice means that the risks of research can never be made to sit unfairly on any one part of the population. Justice, in tandem with respect for persons as well as beneficence, requires that special attention be paid to vulnerable individuals who will be more prone to risks because of their age, incapacity, social status, or any other circumstance. Belmont's concept of justice also means that the benefits of research cannot be distributed unequally. The benefits of research cannot become the property of the privileged while others share risks with greater proportion.

Justice can be seen to challenge the mission and service of IRB's in a very different way. Respect for persons challenges the central vision of the research act. Beneficence challenges the means by which risks and benefits are to be *calculated*. One way of understanding justice is in its challenge to the *telos* or *end* of research itself. In its search to assure that both the risks and benefits of research are distributed equitably, there is a question as to what is the final *end*

of research and who owns it. In saying that the risks of research can never be borne inequitably by one part of a population and the benefits are not the privilege of another, IRB's point investigators and their institutions to the reality that research itself in the final analysis can never belong to the scientist, the university, the industry, or the sponsor. It belongs to the public trust. Research, unlike alchemy of old, is not a secret industry hidden from human scrutiny and awareness. It belongs to the entire human community. Its *telos* is human progress but never at the expense of human protections or the expense of the widest possible benefit to society. When an IRB weighs inclusion and exclusion criteria in a protocol, inherently—albeit often unconsciously, an IRB is challenging investigators as to the proprietorship of research inquiry. In an age of consumerism where a simplistic and uncritical preoccupation with metrics and benchmarks can turn human subjects into *data* to be *mined*, this is an enormous challenge. In essence, the discernment of justice in human research leads one back full circle to the Belmont principles of respect for persons and beneficence. Justice poses the inherent challenge: Why are we doing this anyway? Are we doing it with integrity?

Hence, justice is not a *thing*. Like all three of the Belmont Principles, it is a process with a pervading and even disturbing energy. Assuring a level playing field regarding risks and benefits as part of the process of justice is not an easy task especially in a day and age of increasing human rights and human equality sensitivities and initiatives. It is of paramount importance that researchers, IRB's, institutional officials, research associates, key personnel, and sponsors be keenly aware that justice requires careful ethical discernment of all factors that would affect research participants. Such factors go well beyond the physical or medical. Justice further requires critical reflection upon the ultimate purpose of the research act in question. Justice stings the researcher with the awe-filled responsibility that comes when asking others to take part in that fragile and vulnerable act of human inquiry we call research.



## Conclusion

In any principled society, there is always a need to enact regulations and laws that will keep people safe from harm and protect the heartbeat of human existence. The older we get, however, we learn that protecting human life and making human choices are not merely about complying with laws and regulations. Human life and human choices are more about the shades of gray that one finds in fog. Like travel through a fog, the journey of ethical decision-making in human subjects protections is a matter of discernment not mere compliance. But words do not come easy in fog. As Eugene O'Neill reminds us in *Long Day's Journey Into Night*, "Stammering is the strange eloquence of us fog people." The ethical discernment of human subject protections necessitates some stammering before we can articulate with precise eloquence any directions, judgments, decisions, and parameters for a protocol, an informed consent docu-

ment, a continuing review, or a final report. Human research protections is not a facile process. It is far, far deeper than punching the right tickets, making the administrative grade, or ensuring one has met the minimal requirements of a regulation or precept. Hence, today we are beginning to speak increasingly more and more about establishing in the research community not a culture of compliance or conscience, but a culture of integrity. This is highlighted in the quest to understand what it means to apply and practice the principles of human research ethics found in The Belmont Report. These principles remind the world of research to render to each research subject what is their utter and inalienable due: the protection of life, of liberty, of freedom. . . the dignity that comes to mind whenever one utters the word *human*. And when we ensure that this is the foundation for any and all forms of human participation, then we are more surely on the pathway to real *progress* in any act of research.