

Ethical Issues
for the
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ETHICAL ISSUES FOR THE TWENTY-FIRST CENTURY

PREPARING ETHICS FOR THE FUTURE:
ADDRESSING THE "GLOBAL BASIC STRUCTURE"
IN THE ETHICS OF INTERNATIONAL BIOMEDICAL
RESEARCH INVOLVING HUMAN SUBJECTS

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ABSTRACT: Can there really be a one-size-fits-all approach to ethical standards? In a setting where healthcare is becoming global, rather than local, can there be one set of standards that should apply to all biomedical research involving human subjects, no matter *where* that research is conducted? It seems unlikely that there could be one standard that applies no matter *when*—across all time. How could the ancient Greeks have been held to our current standards? So why think that one set of standards applies to all people no matter where they are, given the vast diversity of people and cultures around the world? Borgerson raises our awareness to the pitfalls and the perils of trying to develop ethical codes that would apply equally (or even justifiably unequally) on a global scale.

Focus has fallen upon the World Medical Association's recent version of the *Declaration of Helsinki* and *The International Ethical Guidelines for Biomedical Research Involving Human Subjects* developed by the Council for International Organization of Medical Sciences (CIOMS) together with the World Health Organization (WHO). The revision process, in conjunction with attention to cases of controversial conduct by HIV-AZT researchers using placebo control groups, has alerted philosophers and the public alike to the existence of these documents, and raised awareness, as well, of the potential effects of proposed changes.

This essay raises a number of issues, and offers only the barest of conclusions in the form of an additional, and currently underrepresented, concern that must play a more primary role in relevant global bioethics debates. That the essay attempts to open up access to issues debated in international health research involving hu-

man subjects marks the author's sense of urgency in making others aware of the premises and assumptions that regularly animate such research debates. The context of international health research involving human subjects, and this should appear obvious, is the human community. As such, basic questions of how human beings *qua* human should be treated by other human beings, particularly in situations of unequal power—e.g., in the form of control, choice, or opportunity—lay at the foundation of related ethical discourse when ethics are discussed at all. Unacceptable treatment from human history can be invoked: codes deliberately reflecting upon these histories are used as standards for creating codes of conduct in order to avoid egregious repetitions of “inhumane” treatment. Yet, the geography, both planetary and human, remains so vast in international health research that the concern for human being, apparently so fundamental and the ground of originary concerns, loses centrality. Excuses are made. Reasons, pragmatic, even heroic, are offered for this loss. But the loss should shock; and the loss, this emptiness at the center of discussions on international health research involving human subjects, should invite critical engagement in an attempt to call attention back to these all too human lapses that guide us into the future.

In the first section of this essay, I trace a narrative that follows upon a recent revision process of international guidelines for biomedical research involving human subjects. I focus, in particular, upon the issue of a standard of care. In the second section, I draw upon philosophers John Rawls, Claudia Card, and Allen Buchanan to discuss concerns regarding the “least advantaged members of society” in the context of global inequality. In conclusion, I mobilize resources in ethical ontology to guide future reflection upon issues emerging from the ethical guidelines for international biomedical research debate.

AT ‘THE BORDERLANDS OF ETHICS’: SOME PLAYERS AND THEIR CONCERNS

Harvard Professor of Social Ethics and Clinical Medicine, Richard C. Cabot, asked in his 1926 book, *Adventures on the Borderlands of Ethics*, “What is the use of a code of ethics?” (p. 79). How is it to be enforced? What of matters that are referred to in the codes but do not fall under legal prohibitions? Cabot suggests that a code of ethics allows a registering of ethical advance in periodic revisions and a brake “on our natural tendencies to slip back.” Whereas those persons involved in recent revisions of the ethical guidelines for international health research involving human subjects appear to believe that such codes have some power to effect research practices, Cabot implies that the insight gained from writing and rewriting codes tells us more about the authors and less about what should be done. Are the current revisions of the international guidelines for biomedical research involving human subjects registering an “ethical advance,” an opportunity to deter our natural tendency to “slip back”? I will not attempt to answer this question here, but I hope to maintain Cabot's insight that in the process of writing codes, the authors are as much a subject of inquiry as the guidelines themselves.

Seventy-three years after Cabot's question, I attended a program on the Ethics of International Health Research at his pedagogically powerful, well endowed, and internationally influential former institution. Researchers, policy makers, academics, heads of international health organizations attended from all over the world. The first day, a lawyer on the program of experts exposed many of us to a new story about the writing of the *Nuremberg Code* (1949), the document of guidelines for about the writing of the *Nuremberg Code* that emerged from the Nuremberg trials of German ethical human subject research that emerged from the Nazi era. The *Nuremberg Code*, the foundation upon which more recent national and international ethical guidelines for research involving human subjects have been built, written the night before the crucial trial date, and designed specifically to convict the particular men on trial for their particular crimes.¹ The language was universal, the speaker suggested, but the purpose of the document was singular. Why should international health researchers be held by the influence of this document?

A primary researcher responsible for AZT-HIV Mother to Child Transmission trials in South Africa spoke. The doctor was under attack for using a placebo control group rather than providing the best proven effective treatment for his control group, as was done during trials in the United States. Marcia Angell, executive editor of *The New England Journal of Medicine*, had refused to publish this investigator's research results after condemning placebo use when “effective treatment exists.” The researcher argued against the often invoked, but what he considered to be illegitimate, concept of “a standard of care” which researchers—regardless of where, with whom, and under what conditions they are working—must uphold and apply to their research subjects. Why should health researchers be bound to provide care to a control group beyond what would have been available to the population otherwise?

Another physician and medical researcher in global health argued that a universal standard or level of care is true-imperialism, requiring under-resourced clinics and researchers to adhere to western standards that not only are unreachable, but limit “below standard” practices that could nevertheless save lives. Several presenters argued that individual informed consent requirements in many cases disregard cultural and contextual norms, including norms of consensus, or at least, hierarchy. “Can a chief,” we were asked in one case-study exercise, “consent for a village?”

ARGUMENTS OF THE PRESENT AS CAUTIONS FOR THE FUTURE

Yale professor and physician Robert Levine has played a strong—though in later discussions, largely invisible—role in the revision process, criticizing existing international ethical guidelines for biases that arise from Western “cultural imperialism” (p. 254). Arguing that international ethics guidelines should be considered global but not universal—“universal” signifying true for all human societies in all historical periods, whereas “global” guidelines will require continual revisions—Levine echoes Cabot's assumption: codes of ethics require periodic revisions. Whereas

Cabot's concern for revisions is to register "ethical advances" or resistance to the tendency to "slip back," Levine's concerns for "advances" are more pragmatic. Research must be done and various guidelines, as written, contain "conceptual errors" and other blockades to research.

Concepts of "personhood" and procedures for individual informed consent form the substance of two such blockades. "Personhood," argues Levine, is a Western concept. In transporting guideline-evoked personhood across cultural lines, well meaning but naïve Westerners engage in cultural imperialist domination. Levine also argues against imposed "imperialist" universal notions of autonomy and individual rights; and in his view, revised versions of the guidelines must adopt a more "pluralist" approach. Levine's arguments often eerily echo post-colonial theory or feminist language in criticizing Western imperialism, lack of attention to context and particularity, and false "universalism." However, Levine's lack of concern for the outcome of his version of pluralism manifests his failure to understand why imperialism and universalism have been so debilitating to subjugated populations. Any new vulnerabilities to which such "pluralist" approaches might subject populations are apparently not Dr. Levine's focus.

Thus, proponents of potentially exploitative—though for the moment rejected—revisions of international ethics guidelines for biomedical research involving human subjects have used context and particularity against concerns for oppression and subjugation.² That is, cultural relativism, not usually a value associated with the scientific community, is here used to support differing standards of care and consent. For example, if current cultural practice in a community does not reflect norms of individual consent, the procedure generally required of researchers for gaining informed consent in Western contexts may be abandoned as intrusive or disrespectful.³

Arguments excusing, deferring, or forbidding individual informed consent procedures raise fears of potential abuses of human subjects. For example, in statements used as apparent arguments against procedures for gaining individual consent—often supported by those with "experience in the field"—a critical listener hears of the difficulty of basic procedural requirements such as gaining access to individuals for information sessions, finding local translators to explain forms or the medical implications of trials, or simply the task of bringing along enough forms. Another species of reason, apparently emerging from the concern to avoid Western imperialism, focuses around potential subjects' inability to understand difficult and technologically advanced medical information, including descriptions of possible effects. Potential subjects are not only, perhaps, unable to read, write, or understand; or found to be embedded in communal or hierarchical procedures of decision-making, but such subjects may also lack the basic intellectual sophistication required to decide for themselves. Such arguments, pragmatic though they may be, cannot avoid parallels to other anti-democratic movements of the past that lobbied, for example in the United States, against voting rights for blacks, women, and the non-property owning public said to be unintelligent, incapable

of individual comprehension, or in other ways lacking in basic qualifications of the mature, adult citizen. It is not that diverse, globally dispersed communities must be forced to become "democratic" in necessary conjunction with a Western model of autonomous decision-making and individual rights that this may entail. Rather—and although the present project defers this work—it is important to track the history of similar arguments and the interests *cui bono*.

In many of what might be considered the most vulnerable geographic locations, researchers and spokesmen, such as Levine, have suggested that "informed consent" and a universal "standard of care" not only slow down and complicate their work, but that guideline processes and procedures may make some research impossible. So what? If maintaining cautionary practices designated to protect human research subjects halts certain research procedures, might this not mean something more than that the guidelines are over-burdensome? Must, or should, such research be done? To ask these questions may mark ignorance, arrogance, and academic distance from crisis situations. There are populations at terrible risk and dying, the frequently stated example being the impact of AIDS in some African countries. The needs are urgent.⁴ Research on new drug therapies offers possible relief, treatments, and cures. New drug therapies also offer the forefront of treatment, sometimes occasioning so-called "compassionate use."

Though the assumption would make the ethical decisions easier, clearly it is not the case that all research goals and drug treatment trials are universally good-willed and beneficent, nor based upon a vision of cooperation for a satisfactory life. Such an acknowledgment, though perhaps unpalatable, occasions consideration of to what extent research goals and drug trials must be related to the long-term development of health in the test-group population. Should a-altruistic, profit-making bodies be allowed to pursue growth, and researchers be allowed to pursue scientific knowledge and enhanced reputations for scientific contribution, in a context of testing scenarios that may, but may not, provide certain populations with access to hope, health, or other resources?

STANDARD OF CARE: SOME CONSIDERATIONS

One of the most basic conflicts between those who favor following a local standard of care (SOC)—which may be recourse to no resources or care at all—and those who do not favor a local SOC centers around the kind of care, both during the trials and after: that will be made available to those upon whom drug trials and non-standard treatments are imposed. Emerging concerns from the anti-local SOC perspective imply that if a local SOC is employed instead of the best proven effective therapeutic method, particularly in the control group, researchers and others with interests in international health research will view this as a justification to 1) save money during trials through removal of requirements for expensive or time consuming care regimes particularly in regard to the control group, and 2) implicitly agree to ultimately longstanding, sub-standard care for populations in which something appears to be better than nothing. Authors of a September 2000 letter

to Dr. Delton Human, head of the World Medical Association, write that failure to maintain the requirement that research subjects shall have access to "the best proven prophylactic, diagnostic and therapeutic method" during the trial will result in "a *de facto* institutionalization of two-tiered research."⁵

A fine line separates new treatments representing an unacceptable substandard care and those treatments for diseases for which curative treatment does exist, but for which researchers believe a process currently conceived of as substandard may prove more effective locally than the imported standard treatment. Dr. Adetokunbo Lucas argues that some treatment protocols that are designed in wealthier developed countries may not meet needs of developing communities (Lucas, 2000). If the standard of care for tuberculosis in developed nations is traditional institutional care in sanatoria, how might a study on an alternative supervised ambulatory care—which would be defined as substandard—be carried out (2000, p. 3)?⁶

Arguments for implementing standards of care that fall below the best proven effective therapeutic method may represent attempts to find workable methods of care at local levels. Currently "below standard" treatment does not necessarily mean worse treatment—in the tuberculosis case the non-institutionalized patients fared better (Lucas 2000, p. 3). Further, should a trial lead to a "better than nothing" solution, such a solution need not be considered the final word in the health care development of that community. This is what Lucas calls "Ethical Progressive Improvement."⁷ Lucas argues that an approach such as his can escape degeneration "into a system of double standards in which people in developing countries receive less protection from ethical guidelines" by assuring a "context of direct responsibility for providing care" (Lucas 2000, p. 3). Such a context of care speaks to the necessity of promoting the research capacities in developing nations and among these nations' citizens. Of course, Lucas's recommendations do not begin to confront situations in which 1) and 2) above appear to be operating, creating mean exploitation in the context of severe inequality.

THE BURDEN OF INTERNATIONAL INEQUALITY

The assumption that health is a virtue and the concomitant "blaming the sick," argues Helen B. Holmes (p. 55), has serious consequences in the context of bioethics' failure to critically examine the assumptions upon which it rests. Similar critical failures lead to a focus upon "treatment" procedures, rather than on prevention. Blaming the sick contributes to a vision, or a representation, of those who live in impoverished, unhealthy conditions. For example, in positing generations of children who might be saved by the sacrifices of human subjects undergoing current research procedures, individuals become reasonable sacrifices, shouldering situationally appropriate burdens, in a utilitarian attempt to gain the greatest good for the greatest number. Further, the impoverished and ill often are described as perfect research subjects. "Everybody is worried that we will use Africa, develop a vaccine there, say thanks and then take it back to Europe and America," said Dr. Peter Piot, the executive director of the United Nations AIDS Program. "I don't believe that will

happen. But we are in a terrible position the process is perilous. It is unfair. And it is filled with inequalities—because the world is filled with inequalities." Americans diagnosed with HIV immediately start drug treatment, hence are useless in testing vaccines, Piot says. "Since people in Uganda cannot hope to afford drug treatment, which can cost more than \$15,000 a year, they are the perfect subjects for such a vaccine test." Thus, an inability to pay for treatment qualifies one for research subject status. Moreover, it is treated as a reason to deny a certain form of care. In the United States' context this reason may sound familiar, but many countries do not treat individual inability to pay as a reason to withhold care.⁹

Given the dangers around blaming the sick and treating ill and impoverished people as ideal research subjects, a familiar question is often raised. Why do drug and treatment testing on these vulnerable populations and in these vulnerable areas? Researchers reply that if a drug, vaccine, or other form of treatment is to be used in an area at all, it must be tested on local populations. Of course, in order for this to be a relevant argument to promote research in vulnerable groups, there must be an assumption that the local population can reasonably expect access to the drug, vaccine, or other treatment once developed. In the best scenario, a vulnerable group is involved in the testing of treatments that will be available to, used in, and benefit their own population. Most international health research does not involve such tidy cases; researchers desire the cooperation of populations before evidence exists for future availability or levels of benefit.

THE LEAST ADVANTAGED MEMBERS OF SOCIETY

In an early attempt to articulate the possibilities for cooperation between the least advantaged members of society and those "more fortunate in their social position," John Rawls wrote,

It may be expedient but it is not just that some should have less in order that others may prosper. *But there is no injustice in the greater benefits earned by a few provided that the situations of persons not so fortunate is thereby improved. The intuitive idea is that since everyone's well-being depends upon a scheme of cooperation without which no one could have a satisfactory life, the division of advantages should be such as to draw forth the willing cooperation of everyone taking part in it, including those less well situated.* Yet this can be expected only if reasonable terms are proposed. (Rawls 1971, p. 15)

We assume here that "willing cooperation" means something like an uncoerced participation based upon an understanding of advantages—understood, perhaps, because of transparency of conditions, expectations, and so on. How seriously the term "everyone" should be taken is also relevant when speaking of the distinctions between individual consent and acting in concert with a group. Cooperation might be accomplished, wrote Rawls, if his two principles were used as the basis for an agreement. That is, a just agreement could be made based upon equality in

assignments of rights and duties, and a check on social and economic inequalities such that inequalities are just "only if they result in compensating benefits for everyone" (p. 15).

Inequalities that are "arbitrary from a moral point of view" contends Rawls, should not figure into the kinds of agreements that can be made, nor upon the terms of the agreements. This important point indicates that many factors that effect the positions of human lives should not influence persons' abilities to enter into important negotiations that influence lifetime opportunities and options. Unfortunately, such inequalities are probably those inequalities that are most relevant and debilitating in the scenario under consideration. That is, morally arbitrary inequalities result from the very conditions most likely to arise in the situations of the least advantaged members of society and under which Rawls's sense of agreement may be impossible. We cannot solve this difficult pragmatic point here, but again, tracking such inequalities certainly will serve a crucial role in any project that hopes to implement a Rawlsian solution to situations of inequality and injustice.

In reference to "natural distribution" of "talents" and the "contingencies of social circumstances," Rawls writes,

The natural distribution is neither just or unjust; nor is it unjust that persons are born into society at some particular position. These are simply natural facts. What is just and unjust is the way institutions deal with these facts. Aristocratic and caste societies are unjust because they make these contingencies the scriptive basis for belonging to more or less enclosed and privileged social classes. The basic structure of these societies incorporates the arbitrariness found in nature. But there is no necessity for men to resign themselves to these contingencies. The social system is not an unchangeable order beyond human control but a pattern of human action. (Rawls 1971, p. 102)

Rawls includes in his unnecessary, or contingent, human scenarios the unjust "basic structure of . . . societies [that] incorporate the arbitrariness found in nature."

Generally, Rawls captures an intuitive sense of many in the realm of bioethics and international health research involving human subjects: no one could have a satisfactory life without the various forms of cooperation that make possible health research. Though little time is given to the compromising context of unjust societies, arguments often mirror Rawls's articulation of the conditions of just cooperation. But are we really in the Rawlsian situation of "cooperation without which no one could have a satisfactory life"? Risks exist in research that may not be balanced by appropriate benefits. Proposing just proportions of benefit and burden to participating parties may require calculations, both quantitative, e.g., DALYs, and qualitative, of questionable validity and value. Moreover, as long as there is some sense in which the vulnerable populations do benefit, researchers often argue that something is better than nothing. Short term, researchers entering a community might point to the availability of vitamin supplements or the construction of a building that will house the temporary clinic. Long-term benefits might include the possibility of valuable knowledge emerging from research that

could aid treatment of disease and ill health in the local population. Given Rawls's articulation of these considerations, however, a "just" undertaking could designate almost any procedure or state of affairs that benefits these populations—and regardless of the magnitude of parallel benefit expected for the sponsoring countries or agencies, in terms of health care improvements, knowledge acquisition, or corporate profits. If inequalities "arbitrary from a moral point of view," some the result of contingencies of social circumstance, are not to figure into "the kinds of agreements that can be made" between the more fortunate and the least advantaged members of society, then the inability of vulnerable populations and countries in situations of desperation to have an influential seat at the negotiating table poses a monumental difficulty in working out terms of agreements.

THE UNNATURAL LOTTERY AND GLOBAL BASIC STRUCTURE

Rawls's inadequate articulations around the "natural lottery" have been noted especially by those concerned with the well-being of subordinated populations, including Claudia Card's attention to the "unnatural lottery," and Allen Buchanan's focus upon unjust global structures.¹⁰ Card writes, "It is not enough to confront the inequities of the 'natural lottery' from which we may inherit various physical and psychological assets and liabilities. It is important also to reflect on the unnatural lottery created by networks of unjust institutions and histories that bequeath to us further inequities in our starting positions and that violate principles that would have addressed, if not redressed, inequities of nature" (Card 1996, p. 20). Where one is born may be a "natural fact," but how the nation or race into which one is born has been treated historically and how various effects emerging from these historical variables will place a newborn are not natural facts. Contingent—though not necessarily accidental—historical circumstances, shaped and held in place by systems of power and status, may be ascribed to the just and unjust functioning of "institutions." Furthermore, such institutions may be as intimately related to an individual as her family relations, her skin color, and her gender.

Allen Buchanan's criticism of Rawls's "law of the peoples" echoes this awareness of underlying structural injustice that effects one's starting point, one's day to day relationships with others, and one's character in morally important ways. Buchanan is particularly concerned with Rawls's inability to address issues of international justice outside a "vanished Westphalian world." Rejecting Rawls's conjecture that, with little regard for resources, "reasonably and rationally organized and governed" societies could become "well-ordered," Buchanan argues that, "A well-governed society might be seriously disadvantaged by the global basic structure" (Buchanan 2000, p. 705). A global basic structure, argues Buchanan, is "a set of economic and political institutions that has profound and enduring effects on the distribution of burdens and benefits among peoples and individuals around the world" (p. 705). Surely then, he writes, such a structure is an important subject of justice. A society may be unable to provide food or health care for its citizens, or to

"determine how wealth is distributed within its borders," failing in what Buchanan calls "economic self-sufficiency" and "distributional autonomy." That is, the way in which goods are distributed, a fundamental aspect of Rawls's "basic structure," creates crucial justice-oriented concerns not simply within autonomous states, but among such states. As much international health research involving human subjects by definition requires agreements, cooperation, and exchange among nations embedded in a global basic structure, inequalities between, and within, states must be honestly and directly attended to.

In addressing the lacunae in Rawls's work, Buchanan raises another point relevant to ethical guidelines for international health research involving human subjects. The populations of states, writes Buchanan, "are collections of different groups, often with different and conflicting views concerning justice and the good" (p. 721). Thus, in seeking access to populations within the borders of countries around the globe, researchers and bioethicists may not rest easy after gaining the opinion or permission, for example, of a country's public health representative, or, alternatively, the head of a country's dominant social group or institution. In both cases, the status or social position of the individual "representative" calls into question his or her ability to speak for others.

Does avoiding western imperialist domination require respecting a centralized authorization as consent for all? Respect for local cultural norms—and not merely claims about feasibility and ease of gaining such consent—it has been suggested, would require putting aside individual informed consent in favor of various forms of consensus or decisions made within an appropriate hierarchy. How, Buchanan might ask, are we to know which group the decision-maker speaks for, what biases the decision-maker might harbor, and which vision of good and justice, in the midst of conflicting visions, this representative represents? Reflecting upon scenarios unveiled in an unnatural lottery, including confronting the institutionalized injustice of the global basic structure, let us turn our concern to the human being in the "subject" of international health research.

ETHICAL ONTOLOGY AND THE HUMAN RESEARCH SUBJECT

Feminist bioethics calls for an awareness of oppression—especially of historically vulnerable groups. How have various principles and forms of reasoning been used to justify exploitative treatment and subordination? How have categories and related representations of race, class, and sex functioned to grant or deny access to certain important resources? Who should be able to decide on behalf of whom when someone, often women or blacks in general, or a non-English speaker in the U.S., is considered not "intelligent or curious" enough to understand relevant risks and benefits (Levine, p. 241)? This section looks briefly at the ethical nature of dilemmas that lead to abstract, rather than human, relations, introducing an approach to human interactions rarely considered in debates around international research.

Caroline Whitbeck's phrase "feminist ontology," emerging from her work on mother-child relations, suggests a model for feminist philosophy generally, occasioning the conjunctions of feminist concerns and experience of particular forms of being (Whitbeck, 1983). "Moral ontology," writes Judith Butler, is "a theory about what being must be like in order to be capable of moral deliberation and actions, in order to lead a moral life and be a moral personality" (Butler 1987/1999, p. 5). A conceptual pairing expresses a concern for the existential phenomenological status of being in the process of pursuing ethical guidelines and addressing ethical practices.

Feminist ethical ontology, the intersection of feminist and moral ontology,¹¹ brings feminist awareness of the subjugated status of certain forms of being to an articulation of ethical theory.¹² Interrelated expressions of being in the world defined in terms of hierarchical dualisms often militate against possibilities for fully human status. This dichotomous mode has given rise to well-recognized, hierarchically ordered dualisms of meaning and being, such as, self/other, white/black, male/female, heaven/earth, civilized/primitive, and rational/irrational that Val Plumwood finds implicated in the "logic of colonialism" (Plumwood 1993, pp. 51–55). Arguably the most basic dualism, self/not self, paves the way for an understanding of the self that is set against the not-self. The self, in central position, defines the not-self as other, and knowledge of the self develops through a self-versus-other epistemology of difference.¹³

This ontological othering has perpetuated particular forms of social relations by subscribing to and reinforcing hierarchical orderings of dualities that throughout history, and within philosophy as well, have favored the male, the white, and the rational.¹⁴ In such a context, those associated with the privileged elements stand in the position to claim knowledge of all that is important to know about those associated with the subordinated elements. That is, the dualistic relation engages with the potential for epistemic closure (Gordon 1997, p. 81). A worldview informed by epistemic closure essentializes being and tends toward creation of a recognizable "authentic" identity while knowing next to nothing "about the typical other beyond her or his typicality" (p. 81). Epistemic closure leads us to believe that we know the other's being completely—who they are and what their purpose is—denying the other status as human being and erasing any possibility for human relationships (for further discussion see Borgerson 2001).

Moral recognition or standing is often denied to those whose human status is contested, particularly in racist and sexist settings of unequal power. Characterizations of typical ways of being and representations of subordinate groups—particularly representations circulating within media culture, but including biomedical and bioethical research literature—rarely contradict, and typically reproduce, versions of subordination.¹⁵ Recent philosophical theorists have written on the relation between identity, identity representation, and ontological status.¹⁶ Some forms of representation that are exoticized, stereotypical, sexist, or racist, damage the reputation of members of the represented group and manipulate their being for

consumption by others. Harm of this type disrupts the represented group's ability to exist as fully human.

Philosophers concerned with ethical norms and behavior have traditionally proceeded as though problematic situations of moral recognition can be handled through constructive definitions of personhood, the formal requirements of universality or universalizability, and substantive demands for impartial or equal consideration (Walker 1998, p. 179). Margaret Urban Walker argues that these three prescriptions lack sufficient conceptual strength to handle representations that often manipulate and damage the identity of subordinate groups. Moreover, because of the kind of problems these prescriptions were meant to handle, not only do they fail to provide sufficiently complex considerations to deal with problems of representations, but damaging representations often fail to qualify as moral problems.

Walker writes that the assumption that people are a kind is propagated and created by representational practices. Representational practices are among those practices that "construct socially salient identities for people" (Walker 1998, p. 178). She argues that if practices of representation "affect some people's morally significant perceptions of and interactions with other people, and if they can contribute to those perceptions or interactions going seriously wrong," Walker on fundamental questions for ethics" (p. 179). By "going seriously wrong" Walker implies that a person influenced by such representations may treat members of the represented group, possibly including herself, as less than human, and underserving of moral recognition. Walker explicates "moral understandings"—forms of interpersonal relation based upon "practices of responsibility"—that she believes can provide ethical guidance in this difficult terrain. Such a project provides an important step toward comprehending, resisting, and moving beyond hierarchical ontological positioning that has ethical import.

OPENINGS AND CONCLUSIONS

The Feminist Association of Bioethics has called for "development of more inclusive theory in bioethics encompassing the standpoints and experiences of women and other marginalized social groups, reexamination of the principles and legitimating functions of the prevailing discourse, and the creation of new strategies and methodologies" (Donchin and Purdy 1999, p. vii). Moreover, Becky Holmes writes, "Constructed from the perspective of an elite group that is blinded to its own partiality, bioethical theory has overlooked such key components of moral life as context, partiality, and relational bonds" (Donchin and Purdy 1999, p. 9).

A crucial point in international health research involving human subjects is the case with which human beings become research subjects and are represented as research subjects, particularly as these subjects tend to exist outside Lucas's "context of care." Moreover, abstract and medicalized relations within research situations challenge human abilities to maintain an understanding of research subjects' full human status, as Nazi-German research protocols and recent stockpiling of children's body parts at the Alder Hey hospital in Liverpool remind us.

Card's concerns emerging from her notion of the "unnatural lottery" and Buchanan's insistence on the international relevance of a moral theory of distributive justice must be included in the discourse addressing ethical guidelines for international health research involving human subjects. Excluding these issues denies core ethical territory. Furthermore, feminist ethical ontology can begin to address questions regarding the status of human being, including the dominant circulating representations of human beings, that must not be excluded from the discourse of mainstream bioethics and international health research involving human subjects. Understandings of human research subject populations, at risk of exploitation, must be formed through practices of responsibility, possibly as conceived by Lucas's "context of direct responsibility for providing care," and including an awareness of the potential damage caused by epistemic closure in the research context. Cabot suggested that revision of ethical codes and guidelines should mark an advance. Without continuing attempts to recognize humanity and human relations in places, and in populations, in which we previously saw abstract research subjects, those who debate the ethics of international health research may indeed be "slipping back."

ENDNOTES

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1. This argument draws upon a narrative told by Robert J. Levine in his work to discredit the Nuremberg Code as an illegitimate document biased by testimony-falsifying United States-based physicians. See Levine, p. 240.
2. This is a concern, for example, regarding women's positions in traditional societies. See Jones, "Culture and Reproductive Health: Challenges for Feminist Philanthropy," in Donchin and Purdy (1999), p. 234.
3. Whereas this particular debate has other aspects, it is interesting to note that similar appeals to a kind of cultural relativism have been made in arenas in which arguments for maintaining certain cultural traditions—while others fade—tend to disadvantage women. See Uma Narayan (1998), "Essence of Culture and a Sense of History: A Feminist Critique of Cultural Essentialism," *Hypatia*, 13 (2): pp. 86–106.
4. Of course, many research efforts have to do with medical and non-medical treatments for longstanding diseases such as malaria and tuberculosis, as well as parasite infestations, such as schistosomiasis.
5. Letter from Peter Lurie, M.D., and Sidney Wolfe, M.D., Public Citizen's Health Research Group, w.citizen.org/hrng/Publications/1538.htm.
6. The *Letter from Brasilia*, a document authored during a forum on the Helsinki revisions held in Brazil, suggests that using new methods of treatment should be allowed "in treating people with progressive, incapacitating or potentially fatal diseases for which treatment does not exist or is not curative."

7. Lucas describes "ethical progressive improvement" in a July 2000 letter to Professor Sir Kenneth Calman of the Nuffield Council on Bioethics. (p. 4).
8. Piot is quoted in a *New York Times* article by Mark Spector, October 1, 1998.
9. Of course, there may be other reasons, perhaps considered more egalitarian that may result in a similar lack of care. That is, the focus falls upon distribution of available resources, rather than on inability to pay. Questions around how and why certain resources are "available" are, of course, another issue.
10. See William McBride, *Social Theory At A Crossroads*. Pittsburgh: Duquesne University Press, 1980 pp. 90-104.
11. See Borgerson (2001), "Feminist Ethical Ontology, or Why Contest the 'Bare Givenness of Intersubjectivity?'"
12. My interest in pursuing a feminist ethical ontology stems from my work on Nietzsche's theories of power and resentment and the relation of the Feminine to both of these in a misogynous, patriarchal world.
13. See Coviello and Borgerson (1999) for further discussion.
14. For a discussion of race, racism, and meaning, see David Theo Goldberg (1993), *Racist Culture: Philosophy and the Politics of Meaning*, Oxford: Blackwell.
15. This concern points to the necessity for an ethics that takes representation seriously, emerging from the ethical significance of ontological divisions and hierarchies and the reality of epistemic closure (Borgerson and Schroeder 2002).
16. See for example, Sandra Bartky (1991), *Femininity and Domination*, New York: Routledge; Judith Butler (1999), *Subjects of Desire*; and Iris Marion Young (1990), *Throwing Like a Girl and Other Essays in Feminist Philosophy and Social Theory*. Bloomington: Indiana University Press.

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