

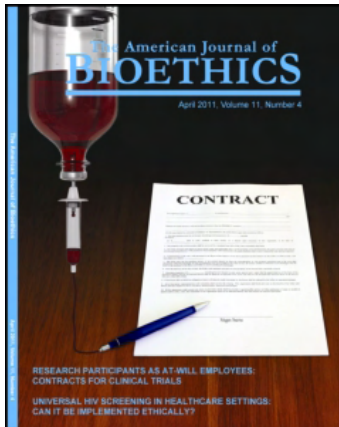
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### Social Contexts Influence Ethical Considerations of Research

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Target Article

# Social Contexts Influence Ethical Considerations of Research

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This article argues that we could improve the design of research protocols by developing an awareness of and a responsiveness to the social contexts of all the actors in the research enterprise, including subjects, investigators, sponsors, and members of the community in which the research will be conducted. "Social context" refers to the settings in which the actors are situated, including, but not limited to, their social, economic, political, cultural, and technological features. The utility of thinking about social contexts is introduced and exemplified by the presentation of a hypothetical case in which one central issue is limitation of the probability of injury to subjects by selection of individuals who are not expected to live long enough for the known risks of the study to become manifest as harms. Benefits of such considerations may include enhanced subject satisfaction and cooperation, community acceptance, and improved data quality, among other desirable consequences.

**Keywords:** biomedical research, cultural studies, human subjects research, IRB (institutional review board), research ethics, social science research.

The prevailing paradigm for assessment of proposed research involving humans as subjects is, in our view, incomplete because it does not afford sufficient attention to the social contexts of all who are involved. Others have noted that many persons may be unfairly deprived of opportunities to participate in research or to profit from its benefits owing to such factors as race, age, gender, disability, culture, sexual orientation, lifestyle, and socioeconomic status (de Melo-Martin 2008; Evans 2007). However, such factors do not stand out in isolation; the selection of which "social factors" to study is shaped by researchers and clinicians, among others, who direct attention to the "contextual variables" they choose to study (De Vries 2009; Turner 2009).

Social interactions within and between groups inevitably affect how research is proposed, approved, carried out, and applied (De Vries 2009). We are not the first to recognize that the social contexts in which the involved parties make their research-related decisions strongly influence the ethical and even the scientific quality of any study (Hoffmaster 2001). We argue here that a valid ethical analysis of research involving human subjects must pay attention to the complexity of the social contexts in which it takes place.

The Research Ethics Working Group at the Yale Interdisciplinary Center for Bioethics, in which all authors of this paper participated, undertook a detailed analysis of an

HIV vaccine case study. The study, which entailed inoculation of human subjects with HIV, was designed to minimize the risk of injury by selecting as subjects persons who were expected to die before the most serious of these risks, development of clinical AIDS, would occur. We undertook this case study with the goal of determining whether the conduct of such a study would be ethically permissible and, if so, under what conditions. We intended to concentrate on such traditional issues as justification of risks in terms of anticipated benefits, informed consent, and equitable selection of subjects. As we pursued each of these issues, we found ourselves agreeing repeatedly that we might reach different conclusions depending on certain contingencies that we now group under the rubric of social context.

Members of the working group noted that risks were proportional to anticipated benefits but conceded that others might disagree about whether or not this study was ethical depending upon who they were, how they were situated, and the social contexts in which their decisions would be made.

For example, in one study patients with cancer were willing to undergo intensive chemotherapy with substantial side effects for a 1% chance of cure, compared to oncology nurses who said they would need a 50% chance, doctors who would need a 10% chance, and the general public who

Colleagues who participated in the discussions that led to the development of this paper include Julius Landwirth, Douglas Olsen, Carol Pollard, and Christine Slaughter. Authorship is listed alphabetically; all authors contributed equally to the article. Address correspondence to Robert J. Levine, Yale University, 31 Beach Point Drive, Milford, CT 06460, USA. E-mail: levinerj@sbcglobal.net

said they would need a 50% chance of cure. Healthy institutional review board (IRB) members and critics are likely to view studies with few benefits and greater risks unfavorably, yet patients might view the same studies as having a risk-benefit ratio that they are willing to accept or even welcome (Agrawal and Emanuel 2008).

Such issues raised the topic of social context so frequently that we split off a subset of the original Research Ethics Working Group to consider varying social contexts and their relevance to the design, review, approval, and execution of research involving humans as subjects. This subset became the Social Context Working Group, and this paper is the product of its deliberations. Without the experience of membership on the Research Ethics Working Group, the Social Context Working Group and this paper would not have been created. In thinking about our own situated actions, it became clear that social contexts have so many facets, the choice of which factors to examine is challenging. In this paper, we provide some examples of the factors we considered while pondering our provocative case study.

## THE CASE STUDY

### Purpose

This study is designed to determine whether a vaccine developed to prevent HIV infection produces mucosal immunity. Mucosally induced immunity has shown promise as a form of preventing systemic infections (Akiko Iwasaki personal communication). So far, however, only a few vaccines specifically target this locus of the immune system.

### Study Design

HIV seronegative and antigen-negative subjects will receive a single injection of the candidate vaccine. Six weeks later their blood will be drawn to determine whether they have developed antibodies to the vaccine's HIV antigen. If so, subjects will next be inoculated with live HIV virus applied to the mucosa of the rectum or vagina. Subsequently, their blood will be drawn weekly for 4 weeks and tested for the presence of the inoculated HIV antigen. A positive test indicates a failure to induce effective mucosal immunity; negative results would be consistent with the induction of effective mucosal immunity.

### Selection of Subjects

Eligible candidates for participation in this protocol would be adults with intact immune systems who are likely to live long enough to complete participation in the protocol (3 months) but, because of their disease(s), are not likely to live long enough (2 years) to develop clinical AIDS. Individuals with various illnesses were considered, including those with certain types and stages of cancer; congestive heart failure (e.g., with left ventricular ejection fractions below 25% and concomitant renal insufficiency); end-stage liver disease; relentlessly progressive neurological diseases (e.g., amyotrophic lateral sclerosis [ALS]); and the "end stages" of such conditions as lung disease. After careful considera-

tion of a number of factors that are discussed in a separate article we decided to limit enrollment to patients with ALS (Levine et al. In preparation).

The idea of limiting risk by selecting as subjects persons who are expected to die before the anticipated harms will occur may startle some readers; it is, however, not without precedent. For a specific proposal and a review of the literature in the field, see Pentz and colleagues (2003).

### Risks

The most significant risk in this study is that the vaccine may not induce immunity. Therefore, some subjects could become infected with HIV and consequentially develop one or more of its serious complications. Although they are highly unlikely to develop full-blown AIDS, any subjects becoming infected with HIV would experience some detriments to the quality of their lives; they would, for example, be required to observe precautions to limit the risk of transmitting the virus to others.

### Informed Consent

Patients must be capable of informed consent; no surrogates or proxies can be accepted.

### Financial Considerations

Payments will be limited to reimbursement for out of pocket expenses. In the unlikely event that a subject becomes infected with HIV or develops AIDS, all costs of treatment will be paid by the sponsor of the research.

## FRAMING SOCIAL CONTEXTS

As noted earlier, the task of defining the social contexts in which AIDS vaccine research is designed and carried out requires consideration of the social interactions of the groups and actors involved in the research. Our considerations are complicated further by the fact that the social worlds in which actors interact can themselves change quickly, thus affecting resources and practices in unanticipated ways. We realize that each individual who agrees to become an investigator or subject in this study will be uniquely located in his or her "life world". But some features of that world are shared. To address the case before us, we had to question how we conceptualize and identify the relevant social contexts. This is easier said than done (Evans 2007).

The etymology of the words "social" and "context" illuminates the problem at hand. According to the *Oxford English Dictionary*, the term "social" comes from the Latin *socialis* from *socius* friend, companion, associate. In the 21st century, in organizations that themselves compete for power, recognition, funding, prestige, and status, the people interacting within them cannot assume that their social worlds or organizations are composed only of friends or allies. Given this recognition, our use of the word "social" represents the need to take account of the social interactions and processes that influence the proposed study—not only those that occur within the organization in which the study

is developed, but also with other individuals, groups, and organizations outside the organizations in which the study will be housed.

Linking “social” with “contexts” makes this need evident. The word “context” turns attention to the circumstances that form the setting for an event, statement or idea. It originally denoted the construction of a text: from Latin *contextus*, from *contexere* to weave together. Knowing this explains why there is not one agreed upon definition of “the social context.” Clearly there are alternative variables that can be woven together and studied by a particular research group in any time and place. This fact complicates our task since other groups can claim to take into account what matters in ways that differ from our own.

We therefore turned attention to the question of how we take account of varying definitions of the situation while shaping our considerations of the social contexts in which the decision to do or not do the research laid out in our case study may be made (Thomas and Thomas 1928). Consideration of any proposal to do research should begin with the recognition that there are multiple social contexts that need to be taken into account. A description of those that involve the actors (sponsors, investigators, IRB members, etc.) will enable others to better understand their choices regarding the proposed research.

### Public Opinion

Our discussion of varying social contexts generated by our case study added to the traditional paradigm by facilitating a consideration of the concerns of relevant observers along with those of the investigators and the human subjects. It seems likely that even if the hypothetical study has substantial medical and scientific worth, certain groups may have major concerns about it because they will judge it by other criteria. Such concerns can be aired publicly. How then do we take account of the impact of public opinion upon the proposed research?

On the one hand, it was clear by 1989 that some of the world’s peoples observed AIDS as a terrifying epidemic that has killed millions and would continue to kill at an alarming rate (Gordon and Pavlis 1989; Mann 1989). The secondary effects of this epidemic on children, families, economies, and nations are profound. In 2010 the development of a vaccine remains an extremely high international priority. This definition of the situation could be necessary, but is it sufficient enough for us to assume that it is the only definition of the social context that we need to consider? Other questions arise.

First, how should the concerns expressed by those who support AIDS vaccine research such as the study we are considering be balanced against the important ethical quandaries and emotional concerns that are characteristic of such research? In public considerations of the design and description of research involving sensitive matters, the emotional quality and social context of research can be as important as methodological and design issues (Berkley 2009). Our case study is such an example. Because the stakes are high

and the issues are emotionally and ethically charged, competing and varying views of what should matter call for careful consideration. The impact of varying social contexts, both internationally and locally, must be recognized, aired, debated, and explored by all involved stakeholders in this research enterprise.

We noted that members of concerned publics have negative perceptions of those who exploit the dying for any reason. There is, for example, ambivalence concerning donating body parts and selling tissues and body fluids; concern about whether physicians engaged in organ transplantation are trustworthy and capable of accurate prognostication; and concern about whether scarce medical resources, such as vaccines and medications, are allocated equitably. The most advanced medical technologies are not available for vast numbers of people; this is among the reasons that many hold negative perceptions of the pharmaceutical industry (Relman and Angell 2002).

The members of the public are also aware of concerns about the troubled legacy of human subjects research (Beecher 1966; Levine 1988; Moreno 2000; Schaller 2008). As a result, ethical standards have been developed and published as international codes of ethics: Council of International Organizations of Medical Sciences: *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, World Medical Association: *Declaration of Helsinki*, and U.S. national regulations 45 CFR 46 and 21 CFR Parts 50 and 56 (Office for Human Research Protections 2011).

However, the public at large has not shown confidence in the research enterprise despite seeing greater regulatory and community oversight (Fost and Levine 2007; Levine 2001). Instead, the public perception of research appears to have changed for the worse during the past decade (Koepsell 2006). The principal reasons include reports of unethical behavior of prominent scientists (e.g., undisclosed conflicts of interest) and concerns related to such highly charged religious issues as those associated with stem-cell research, cloning, and the therapeutic transplantation of tissues removed from aborted fetuses. Other relevant factors include intense scrutiny by investigative journalists and attention by the media (Snyder et al. 2009); skepticism regarding the motivation and values of physicians, scientists, and academics; concerns about financial and other incentives related to sponsorship of research; and the sensitivity of issues and populations that are being studied can be found in print and online. As the media influences what people know and can shape varying social contexts in which research is accepted or rejected, we next turn our attention to the media.

### The Media

The effect of the media (including the electronic media) on the public’s perception of scientific research is so strong that it must often be taken into account in the design and implementation of research. Some describe the interest of the media in scientific content as ordinarily shallow, and tending to escalate when a story involves sex, money, politics, or scandal (Allan 2002). There is also great media interest

in exploring and exposing such problems as unexpected harm to participants, conflicts of interest, fraud on the part of researchers or their sponsors, and the potential misuse or misallocation of funds (Interlandi 2006). We realize that no research team can control all of what may or may not be communicated to whom as the study is considered or takes place, but we need to be aware that such communication matters.

One prominent example of media interest was the case of the Twins Study at Virginia Commonwealth University (VCU) (Botkin 2001; Rubin 2001). The father of one adult female subject happened to read the survey instrument and saw questions about the physical characteristics and physical and mental health of family members. The father was upset by these questions, some of which concerned very intimate matters. He protested that his daughter was not the only subject of this research, that he and other family members were also subjects (as defined in federal regulations), and that their informed consent should have been obtained before the research began. When the Office for Protection from Research Risks (OPRR) (now the Office for Human Research Protections, OHRP) reviewed the minutes pertaining to the VCU IRB's review of the Twins Study, it found no evidence that the IRB had considered whether the father, mother, or other family members should be regarded as research subjects whose consent to participate would be required. OPRR faulted the IRB for its failure to decide whether, in this case, family members were or were not research subjects.

Because the OPRR criticized the VCU IRB for failing to decide this question and for failing to record its decision in the meeting minutes, it is widely and incorrectly believed that the suspension of research operations at VCU occurred as a consequence of this study. Actually, the initial complaint by the father occurred during a period of ongoing investigation of VCU by OPRR and probably did not influence the decision to suspend research (personal communication from Charles McCarthy). However, extensive coverage in the media created a legacy for this study, first that one might unknowingly become a subject of research and second that highly sensitive and personal matters may be probed without informed consent (Levine 2008).

In this case the combination of media and subsequent congressional interest brought national prominence to this example of apparently flawed survey methodology. Some of the judgments required to analyze our case study must necessarily be influenced by an awareness of the media's responses to issues similar to those in the VCU case that can influence the social contexts of people who could be subjects in our study. It is to these subjects that we now turn.

### The Subjects

The literature attests to the importance of individual characteristics for subject recruitment and participation. We first examined some examples of the many ethical considerations arising from the identity of each potential subject. For example, the potential meanings of death differ from one

individual to another and may change for any one subject during the course of the research. The fact that the potential subjects are known to have a life-threatening disease also shapes the social context in which their lives take place.

Herman Feifel (1959) has called attention to several relevant variables including psychological maturity, coping techniques within reach, and such demographics as age and socioeconomic status. The patient's past and current experiences of the health care and other helping professions may have powerful influences on the individual's response to the near possibility of dying. An open, sensitive discussion of these past experiences is likely to encourage a potential subject to engage in the necessary demanding discussions of what the future may hold. The way that such social interactions take place also shapes the definition of situations. Such difficult social contexts may or may not encourage people to become subjects in this study, depending how they view themselves in time.

Other cultural variables and social interactions are also important. Failure to address them led, for example, to the withdrawal of an AIDS prevention trial in Cambodia. The proposed trial was an investigation of whether daily oral tenofovir would be safe and effective for the prevention of sexual transmission of HIV infection (Page-Shafer et al. 2005). The authors concluded that there is a need for "innovation in communication" for which they knew of no textbooks or guidelines. Additional closures of tenofovir trials in Nigeria and Cameroon led a correspondent (Newman 2006) to suggest the development of a "science of community engagement." The goal of the development of such a science would be to incorporate a systematic understanding of the communities' social contexts (see also Levine et al. 1991).

Another set of important factors arises from the individual's clinical course. In addition to the usual relentless physical deterioration in ALS, the prevalence of cognitive impairment has been recognized recently (Rippon et al. 2006). Almost a third of 40 consecutive patients with ALS were found to have cognitive impairment following a pattern of frontotemporal lobar dementia unrelated to site of their ALS onset or their length of survival. Clearly, this finding is relevant to understanding the differences in the social contexts of possible subjects who may be considered for AIDS vaccine research studies.

Religious identity is another key area. Pelikan (2003) has pointed out that there have been some 200 creedal formulas among Christians and that most groupings professing the same formula are far from homogeneous; however, some generalities can provide at least initial guidance. Lo and other members of the Working Group on Religious and Spiritual Issues at the End of Life (Lo et al. 2002) have developed a useful tool for discussion of religious and spiritual issues at the end of life.

A series of seven essays published in *The Lancet* in 2005 provides brief accounts of how the major faiths are likely to influence their adherents' attitudes toward death and dying. Although they are directed toward giving informed support and assistance to individuals near the end of natural life,

these essays also provide a useful basis for understanding how the proposed study would be most effectively presented to potential subjects. Summarizing the series very briefly, Hindus strive to make of life a preparation for a good death (Firth 2005). For Muslims one lives in stewardship of his or her body as a tenant and death comes only by God's leave (Sachedina 2005). One Jewish perspective values responsible choice in the care of one's body, which is God's creation (Dorff 2005). Buddhism emphasizes compassion, mindfulness, and respect, seeing death as integral with life (Keown 2005). A focus on union with God as the goal of human life marks the Christian view (Engelhardt and Iltis 2005), while a Roman Catholic view is rooted in human dignity and community (Markwell 2005). Finally, there are individuals with a humanist perspective rather than a religious one who assert that a responsible moral life is in itself desirable (Baggini and Pym 2005). Each of these articles illustrates that the adherents of any one tradition exhibit variety within the commonality that distinguishes them from the others. Thus, there are several social contexts to be found among the faithful within any one religion.

Also, it would be well to bear in mind the findings of Kubler-Ross (1969) regarding how people cope with learning that they are dying. For example, in the "bargaining" stage one might be unduly prone to consent to research. On the other hand, a depressed individual might embrace the role of subject as a para-suicidal behavior. Denial may be in some way helped toward resolution through engagement in a discussion based on one's terminally ill status. Anger might prematurely preclude participation. Keeping Kubler-Ross's model in mind should prove useful both for admitting study subjects on a sound basis and assisting them to persevere.

Note that the decision as to whether or not individuals become subjects reflects the situation created for them by those who have the power to decide who will or will not be in a study. Sometimes these decisions are individualized, but sometimes they are not. The exclusion or inclusion of women in clinical research studies also illustrates this point.

Until the mid-1990s, many clinical investigators tended to exclude women as research subjects. Among the reasons that women were not included as study subjects was a concern about the possibility of pregnancy and exposing the fetus to the risks of research (Merton 1993). Although there is a clear ethical obligation to consider whether participation in clinical research trials may endanger potential offspring, exclusion from a research protocol assumes that women lack any control over their childbearing potential while participating in clinical trials. Furthermore, if a research protocol could cause permanent risk to the capacity to bear healthy children, the question then arises as to why the analogous concern would not be raised with regard to men.

Especially given this history, an unanswered question is whether gender influences a potential subject's likelihood to participate when asked, and motives for and expectations from participation. Recent relevant reports and reviews inform the answer to this question by documenting the consistently high prevalence of women who step

forward to provide care for others in need (Vanderwerker et al. 2005; Zhang et al. 2008) and to volunteer for charitable causes at higher rates than men even when differences in income, age, and education are controlled (Mesch et al. 2006). Other reports indicate the high degree of women's altruism in care giving (Aronson 1992) and in giving of themselves through prosocial behaviors (Beutel and Marini 1995) at all levels of personal cost (Andreoni and Vesterlund 2001). Some postulate that this broad and significant degree of apparent altruism develops as a function of defined gender roles (Kidder and Parks, 2001) that place responsibility on women to provide care (Risman and Feree 1995) and result in an attendant sense of personal obligation to contribute to the care of others (Aronson 1992). Stockard and colleagues (1988) suggest that although all women may not always behave in a manner consistent with traditional gender roles, such roles nonetheless "prescribe that women should cooperate with others and should contribute to the social good." These reports document that "on a cultural level women are expected to donate themselves in the form of time, energy, and body" (Raymond 1990). In sum, gender potentially affects recruitment and participation as well as health outcomes and, as such, must be considered in our ethical and responsible conduct of research (Merton, 1993).

Finally, a variant of the therapeutic misconception (Appelbaum et al. 1982) may arise due to the choice of dying patients for research. Although they understand that no direct alleviation can be expected for their primary condition, they may reckon with some validity that having the status of research subjects may enhance the care they receive. This could mean an expectation of longer survival, with a chance, however remote in reality, of being alive when a cure for ALS is discovered. As is often true, then, the present study design calls upon investigators to monitor for signs of this expectation. Clearly, the social interactions that we discussed with possible subjects demonstrate the need to attend to the social contexts of the investigators as well.

### The Investigators

The social contexts of the investigators will be influenced by the fact that they would be addressing as prospective subjects a group of individuals chosen on the basis of their prognosis of death within a short time. Since this is unusual, it would be well to give some specific attention to how this reality might bear on the design and conduct of the research. Now entitled "end of life," this area of medicine and medical ethics was for a generation at least called "death and dying." This probably reflected the influence of Kubler-Ross's choice of this title for her work. This name change is of uncertain origin, but it may well reflect the long-recognized fact that in particular physicians as a group tend to deny the reality of death as an outcome for themselves or their patients. Kubler-Ross recounts how she and her students, having resolved to learn about dying patients, initially had to search a major urban hospital for quite some time before finding any physicians who would acknowledge that they had dying patients under their care.

Kasper (1959) suggests that significant numbers choose to pursue medical studies in response to very early experiences of self-doubt, going on to describe behaviors he has seen among medical students that indicate their uneasiness with the implications of mortality. Becker (1973) makes comparable observations and suggestions in his often-quoted *The Denial of Death*. While the prevalence of the denial of death among some physicians is no longer news, its impact may remain hidden when physicians make decisions as to who will be treated with the aim of producing a cure or remission and who will be given palliative care.

Finally, investigators must take account of the social contexts of sponsors. For example, in 1986 the National Institutes of Health (NIH) attempted to respond to the pressing need for information on women's health by offering new guidelines suggesting that women be included as subjects in NIH-supported clinical research. In June 1990, however, the General Accounting Office (GAO) reported that attempts to increase the participation of women in NIH-funded studies had not succeeded (USGAO, 1990). Subsequently, a provision was included in the NIH Revitalization Act of 1993 (U.S. Public Law 103-43 1993) requiring that NIH-funded research must include women and minority groups as subjects. Because of NIH's influence as the single largest source of biomedical research funds in the nation and its role as the standard setter in the field, this change in policy has brought about a significant transformation in the recruitment of women as subjects in clinical research (U.S. GAO 2000). Who pays for what to whom, when, and how requires us to be aware of the changing social contexts of investigators as well as subjects.

## CONCLUSION

Evaluation of proposals to do research involving human subjects customarily entails assessments of whether the plan is adequately responsive to the ethical principles of respect for persons, beneficence and justice. In this paper we argue that such evaluations would in most cases be enhanced if the evaluators were aware of and responsive to the social contexts of the parties to the research including, among others, sponsors, investigators and subjects. Evaluation and discussion of social contexts will in many cases lead to a recognition of interactions that may not have come to light during the planning and evaluation of research as it is customarily carried out. Recognition of some of these complexities can enable the sponsors and investigators to make changes in protocols that will enhance the conduct of the research. Attention to the variability of social contexts over time can also identify situations over which the sponsors and investigators have no control. Awareness of such complexities may enable sponsors and investigators to deal more sensitively with concerns of subjects, the observing publics, the media, and others, even though they cannot control the issues that give rise to these concerns. We of course have not exhausted the ways in which social contexts can be shaped or understood. However, we have concluded that the need to understand people in their social worlds can be facilitated

by attention to the social contexts in which human actions, including ethical actions, take shape. ■

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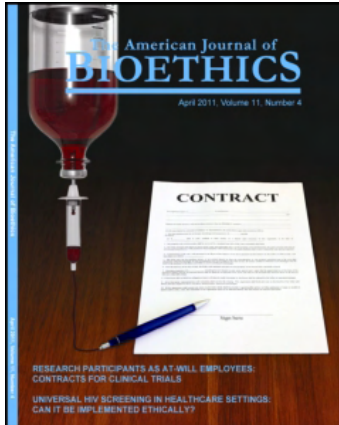
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### Social Considerations in Research: Consider Them but Don't Use Them

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Open Peer Commentaries

# Social Considerations in Research: Consider Them but Don't Use Them

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Notwithstanding the benefits from the analysis of social contexts of any given research program, this inquiry ought not be employed to import general limitations on scientific research. Consequently, while it is nevertheless essential in science communication efforts—particularly with an apprehensive lay public—to recognize and acknowledge the social contexts and the popular understanding of the research in question, in order to properly convey the research to the general community, these important and valuable assessments ought to be made expressly in the context of reporting to the public, not as an effort to determine whether to curtail or change the general direction of scientific research. Further—and importantly—the aforementioned concerns as to how research will be perceived in our current culture and relayed in society should be viewed as separate and distinct from the ethical and moral concerns that compel a more complex and comprehensive analysis in a considered manner.

This seemingly elitist position—to some extent dismissive of lay attitudes to the general direction of science and its context within society—has served the United States well in the development of a robust biotechnology sector.

Using patenting levels as a proxy of national innovation, the United States consistently leads the world in biotechnological development. The American pharmaceutical industry accounts for more than half of global sales; U.S. biotechnology companies are responsible for three-quarters of all biotechnology sales, and are developing more than twice as many biotechnology products as the Europeans. A generation or so ago, however, Europe dominated the pharmaceutical market and invented most of the world's new drugs (Fuller and Reeve 2007).

U.S. patent law has successfully fostered this diverse innovation by allowing nearly all possible inventions to fall under the rubric of patentable subject matter—irrespective of social considerations and contexts.

How does it work? In general, The U.S. Patent and Trademark Office (USPTO) employs numerous bars to patentability, each designed to prevent the acquisition of monopoly rights on non-inventions or for which the

quid pro quo of public disclosure by the inventor in exchange for limited property rights is not adequately fulfilled.

The first and lowest bar to patentability is the patentable subject matter analysis: Is the innovation constitutionally barred from being patented? This is “the first door which must be opened on the difficult path to patentability” (*In re Comiskey* 2007). This bar has for decades been a low barrier: Effectively, “anything under the sun that is made by man” provided that it is a machine, manufacture, composition of matter, or a process and is not an abstract idea, law of nature, or natural phenomenon, is patentable. This “shoot first, ask questions later” tactic particularly benefits the advancement of cutting-edge technologies.

The courts have gone so far as to repudiate moral or ethical limitations to patenting (*Juicy Whip* 1999), and the U.S. PTO's decisions as to patentability are supposed to be devoid of any ethical considerations (*Ex parte Murphy* 1977). As such, the United States has typically allowed more controversial innovations to be patented than other patenting regimes like those of Japan (Patent Law 29) and the European Union (Article 53 of the European Patent Convention), both of which statutorily prohibit the patenting of “inventions liable to contravene public order, morality or public health” (Japanese Patent Law 1959). These limitations are likely to have helped create the biotechnology innovation discrepancies between Europe and Japan and the United States.

There have been numerous inventions in the past decades that have skirted dangerously close to the very wide bounds of patentable subject matter, and contrary to social norms, but nevertheless ended up becoming important new innovations. This was particularly the case in the biotechnology space, where there is also often initial substantial public apprehension—e.g., genetics, synthetic biology, genetically modified organisms, medical technologies, or reproductive technologies.

In contradistinction, recent efforts in introducing social context into the academic, legal, and political debates as to whether genes are patentable subject matter may ultimately

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lead to a change the United States' stance on the patenting of genes (*AMP v. USPTO* 2010) It will be interesting to see how this will affect the related industries if the anti-gene-patent camp ultimately succeeds.

The U.S. Patent System's heretofore methods of disregarding sociopolitical influences should be considered as a potential methodology when evaluating basic science research. Science often outpaces our current ethical and social norms. Examining new science directions within their current social context may create initial visceral reactions, reactions that are likely to become outdated or irrelevant by the time the research comes to fruition.

Moreover, like patent examiners considering the social contexts and social implications of the patents before them, scientists are typically ill-equipped to make judgments as to concerns that arise in light of complex social concerns, even in their area of expertise.

This paper's position is exemplified by the growth of the nascent personal genomics field in light of quickly shifting social contexts.

Personal genomics, particularly, the direct-to-consumer flavor, allows consumers to submit DNA samples (purportedly) of themselves for genetic analysis. Laboratories then analyze the DNA samples and provide feedback as to general or increased risk of diseases or other biological traits. Results from the analyses often read like a confidential medical file, noting possibilities of developing life-changing or debilitating diseases and conditions.

Personal genomics provides data and subjects for further analysis into the human genome via, among other things, genome-wide association studies. Further, the data culled from personal genomics will be useful in the development of personalized medicine, the field that looks to, among other things, prescribe and titrate medicine and medical treatment based on the patient's genetics to optimize medical care and limit adverse reactions to drugs.

With computational and sequencing costs in a freefall, and science and technology quickly advancing, the personal genomics industry has entered the mainstream market somewhat immaturely. Often compared to the Wild West, the sector lacks substantive standards and regulations. But although there are many companies with shady pedigrees, there remain numerous players that are poised to significantly add important genetic data and analyses to science's genomic coffers.

The nature of the industry, particularly its Internet presence and culture of promoting consumers to share test results, would have been anathema to our former understanding of personal and medical privacy. Consumers, most without a clear picture of what the data they have been provided actually means, nevertheless, or perhaps as a direct

result, freely share their risks for adult-onset type II diabetes or wet earwax.

No one could have predicted the substantial shifts in our understanding of privacy and confidentiality brought on, at least partially, by the advent of social networking at the dawn of the genomics age. But as we now share our most banal thoughts, ideas, and experiences with the world—provided that we can communicate it in 140 characters or less—or post embarrassing and compromising photographs on social networking sites or to other cell phones without a second thought, restrictions attached to that nascent field based on then current (now seemingly puritan) understandings of personal privacy might now seem like overreactive impediments to what is likely to be an important field in the further elucidation of human genetics.

The analysis of the social context and implications of such a research path would be similar to a legal journal devoted to the analysis of legal issues arising out of future, heretofore undeveloped technologies: an interesting intellectual endeavor, but a highly impracticable one. By the time that technology is developed, the legal framework will have evolved to an extent that would negate the analysis. Here too, the pace of social change, particularly as it relates to medicine, health, and genomics, is moving at breakneck speed. What is a relevant analysis today during the research's inception is likely irrelevant by the time the issues are applicable. Even morality is relative, tied to the prevailing values in a particular society and differing depending on time and location.

As such, while protocols may be tweaked to ameliorate the public, the wholesale application of concerns arising from the social context (particularly those independent of ethical concern) to the business of science could put a serious dent in the advancement of science. ■

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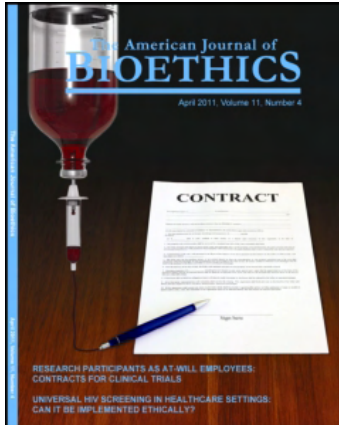
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### Cultural Diversity, Families, and Research Subjects

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# Cultural Diversity, Families, and Research Subjects

Rebecca Bamford, University of Minnesota Rochester

Gordon and colleagues (2011) use a hypothetical case study featuring amyotrophic lateral sclerosis (ALS) patients who are expected to die before anticipated harms from an HIV vaccine research study could occur, in order to illuminate ways in which the social contexts of public opinion, the media, the subjects, and the investigators in biomedical research influence assessment of such research. They contend that the “prevailing paradigm” of assessment of human subjects research is incomplete because such assessment neglects the social context of research actors. By “social context,” Gordon and colleagues mean “the settings in which the actors are situated, including, but not limited to, their social, economic, political, cultural, and technological features.” Attending to the social context will, they argue, promote understanding of choices regarding proposed research.

In light of Resnik’s (2010) reminder of the importance of fostering public trust in human subjects research, Gordon and colleagues’ drawing of attention to the social context of public opinion is especially timely. As Foulkes (2011) notes in her commentary on Gordon and colleagues, given that public opinion impacts significantly upon proposed research and the way in which such research is conducted, Gordon and colleagues’ proposal to increase understanding of the social context may improve the process of community consultation and discussions of ethical issues pertaining to proposed research.

Gordon and colleagues’ engagement with social contexts in order to promote the aims of evaluatory choice, public trust, and protection of human research subjects is laudable. However, in this commentary, I focus upon a gap in their argument: insufficient recognition of the social context of the family. My use of “family” follows the definition in Gallagher and Monroe’s (2006) discussion of psychosocial care of ALS patients, which is that the family is a complex system changing over time with a past and future that exerts pressure on the present, and that all patients have families, whether they are sole survivors, members of large intergenerational groups, or living alone. While Gordon and colleagues correctly point out that no single study can address all social contexts, the social context of the family is directly relevant to their proposal.

It is surprising that Gordon and colleagues chose not to give specific attention to the social context of the family, not least because they comment explicitly and extensively on a relevant case pertaining to the research subject status of families. The case in question is the Victoria Common-

wealth University (VCU) Twins Study controversy, which raised important ethical questions concerning the possible status of family members as research subjects (Botkin 2001). Gordon and colleagues deploy this case to develop their claim that judgments required to analyze their case study must necessarily be influenced by an awareness of media responses to issues that may influence the social contexts of potential research subjects. In discussing this case, their list of relevant social contexts could easily have been extended to include families as important constituents of the communities within which research involving human subjects is concerned. Notice that my point here is concerned with Gordon and colleagues’ discussion of families without recognition of families as a social context, rather than with the influence of the media in creating legacies of anxiety concerning possible unwitting participation in research by family members and investigation of sensitive personal information. With respect to the social context of the media, as Gordon and colleagues point out, the initial complaint about the VCU Twins Study occurred during investigation of VCU by the Office for Protection from Research Risks (OPRR), meaning that it “probably did not influence the decision to suspend research.” Moreover, as Botkin remarks, while the OPRR (which as Gordon and colleagues note is now the Office for Human Research Protections, OHRP) considered the father in the VCU case to be identifiable, it is questionable whether the father could have been identified unless the survey instrument clearly established that the adult daughter in the VCU case was living with her parents.

Insufficient recognition of the social context of the family is particularly noteworthy given that ALS patients are research subjects in the HIV vaccine trial described in the authors’ hypothetical case study. Participation in the study involves the risk that subjects may contract HIV if the vaccine does not induce immunity, and may therefore have to endure ALS treatment and end-of-life care alongside HIV treatment (Foulkes 2011). The families of ALS patients are relevant observers of the case study research involving such patients, and therefore are worthy of consideration as a social context for the purposes of the authors’ argument. Gordon and colleagues appeal to evidence from Rippon and colleagues (2006) showing that 12 out of 40 consecutive patients with ALS showed evidence of cognitive impairment, including 9 (23%) who met the neuropsychological criteria for dementia. As Gordon and colleagues mention, “this finding is relevant to understanding the differences

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between the social contexts of possible subjects who may be considered for AIDS vaccine research studies." If patients are not competent, then families who may be surrogate decision makers are of clear relevance to the case study.

The relevance of the social context of the family also holds when ALS patients are competent. As Gallagher and Monroe (2006) show, ALS has a significant effect upon the relationships between ALS patients' roles and relationships with their families and their friends; good psychosocial care for ALS patients is characterized by the return of a sense of control to patients and their families. In assessing the proposed research, the social context of the family needs to be considered alongside the significant risk in Gordon and colleagues' hypothetical case study. Nolan and colleagues (2008) explore the family experience of decision making in the care context of ALS patients, suggesting that ALS patients often retain decision-making capacity close to death and that competent ALS patients may prefer their families to perform diverse end-of-life decision-making roles. Yet ALS patients and families may not achieve the type of decision making they prefer. According to Nolan and colleagues, ALS patients preferring an individual style of decision making in end-of-life care are more likely to achieve their preference than those who prefer their decision making to be shared with, or deferred to, family. Nolan and colleagues demonstrate the complexity of decision making for ALS patients and their families. The data that they collected indicate that family members experienced "deep distress, exhaustion, and depression" concerning decision making and caregiving at the end of life and that their feelings made it easier for them to defer to the dying patient. Additional factors identified by Nolan and colleagues concerned the use of advance directives that privilege patient autonomy over family-based decision making, family members' concern about being associated with decisions that were not supported by other family members, and family members identifying so closely with patients that decisions were reported as independent patient decisions rather than family decisions. Gordon and colleagues' hypothetical case would benefit from greater consideration of the complexity of family caregiving and decision making at work in the context of ALS patients and families.

Neglect of the social context of the family is also evident when ALS patients' and families' research subject status is considered within and across diverse cultural contexts. While Gordon and colleagues do attend to diversity, e.g. of religious identity, among possible subjects, their hypothetical case study could have given greater attention to cultural diversity in end-of-life decision making among ALS patients and families. Cultural competence is a legal requirement, as well as an ethical obligation (Kagawa-Singer and Blackhall, 2001) and is directly relevant to the ALS case context. For example, in a study examining mental health in ALS patients from Israel, Germany, and the United States, Albert and colleagues (2007) show that ALS patients of sim-

ilar sociodemographic features, diagnosis, disease severity, and proximity to death but of diverse cultures displayed robust differences in indicators of distress as well as in the wish to live. Albert and colleagues' work indicates that cultural factors may affect ALS patients' mental health at the end of life, which would impact upon their research subject roles in Gordon and colleagues' hypothetical case study. More generally, as Koenig and Gates-Williams (1995) have shown, determining whether end-of-life care decisions are made by individuals or by larger social units such as the family forms a meaningful part of engaging with and respecting diverse perspectives.

I agree with Gordon and colleagues that awareness of, and responsiveness to, the social context of actors in biomedical research may help to improve the design of research protocols. Attending to the particular social context of the family should be included in their assessment of how the social context influences assessment of proposed research. ■

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### Social Contexts, Social Media, and Human Subjects Research

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# Social Contexts, Social Media, and Human Subjects Research

Mary Foulkes, George Washington University

The discussion of the influence of social contexts on the ethical considerations of research is an important one, particularly as the conduct of and inference from research is global. Gordon and colleagues (2011) have framed the discussion around a hypothetical case study of a human challenge study of a novel HIV vaccine enrolling participants not expected to live long enough to experience the known risks.

Each of the actors (sponsors, investigators, institutional review board [IRB] members, etc.) involved in research were addressed in turn; however, their responsiveness to the social contexts was not addressed. The response to avoid a particular social context or a particular risk is one that research funding agencies, sponsors, investigators, and IRBs have often taken. With an increasing emphasis on rapid research results in both the private and public sectors (Patlak 2010; Nass, Moses, and Mendelsohn 2011), barriers and delays may be perceived as something to avoid rather than opportunities for collaboration and progress. There are opportunity costs to all the actors when the decision is made not to participate in the research; e.g., a junior investigator may base his/her decision to participate in a study based on his/her tenure-track clock rather than on any other considerations. It would be instructive to expand the case study to consider the ways in which “the social worlds in which actors interact can themselves change quickly” and the responsiveness to those changes. The pace of research and the pace of the news cycle are escalating.

Each of the actors brings his or her own estimates of risks and his or her own desired outcomes. The conflict comes when these are different for each. Gordon and colleagues indicated that the most significant risk in their hypothetical case study is that the vaccine may not induce immunity, which is the most significant risk for the sponsors and future vaccine recipients, and may be the most significant risk for the investigators. The most important risk to the challenge study participants is that they could become infected with HIV, develop serious complications, and then suffer interactions between treatments for HIV, its complications, and their preexisting amyotrophic lateral sclerosis (ALS). Despite the sponsor’s offer to pay all costs of treatment, the participant cannot anticipate the consequences. Proceeding with the hypothetical case study does not indicate how to resolve the conflicts in perceived risks and desired outcomes.

Public opinion impacts proposed research and its conduct. This has been considered in the requirement for “com-

munity consultation” prior to research studies involving waiver of informed consent (21 CFR 50.24 [Food and Drug Administration (FDA) 1996] and 45 CFR 46). Community consultation refers to providing the opportunity for discussions with, and soliciting opinions from, both the communities in which the study will take place and those from which the study subjects will be drawn (FDA 2006). Despite more than a decade of experience, very little had been learned from the process of community consultation (Biros 2011), and increasing the understanding of the social context and enhancing the discussions of ethical considerations, as Gordon and colleagues have done, could improve that process.

One of the changes in the social contexts is that transparency in human subjects research has been increasing, with registration of trials (e.g., [clinicaltrials.gov](http://clinicaltrials.gov)), with education on disease status and prognosis (e.g., the evolution of HIV status from its initial stigma), and with the wide dissemination of research results (e.g., press releases, multiple media reports, international conferences, and scientific literature on recent Phase III HIV vaccine trials; Francis et al. 2003). The impact of the media on the public perception can be expanded to include the impact of social media. Just as social media have been used to gather crowds for a specific event, they are being used to screen and enroll research subjects (Love/Avon 2008). Social media has impact on public opinion and thus public health, as has been seen in the rapid spread of information and misinformation on a link between vaccines and autism. The social media dissemination has been much wider and faster than that of either the traditional media or the scientific literature. Any public discussion of research ethics should take advantage of social media.

In the case study presented, “the stakes are high and the issues are emotionally and ethically charged.” This is exactly the type of research that requires a public discussion and often some public education. The research may be ahead of an evolution in the social context, or may lag behind it. Consider the current debate over enrolling pregnant women in clinical research addressing issues that impact their health. A National Academies report on HIV prevention trials suggests that “although the current policy of excluding pregnant women from biomedical HIV prevention and other trials stems from an historically protectionist orientation adopted by regulators, the principles of research ethics neither mandate nor preclude use of the product by

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pregnant women” (Lagakos and Gable 2008). This is an example of policy lagging behind the perception of autonomy and self-determination applying to pregnant women as to anyone else. The hypothetical case study presented may have been considered with a wider inclusion of patients with concomitant factors or diseases such as ALS, rather than an exclusion of all patients with concomitant diseases save the targeted group of ALS patients.

Development of a “science of community engagement” is a very positive and timely suggestion. This would offer a forum for the discussions of the evolution of social context, the integration of multiple social contexts in global research efforts, and the increased transparency of the research enterprise. The development of a new area of science is a major interdisciplinary undertaking, linking science, technology, and society, which will require some natural home, program planning and evaluation, and initiatives funding. This proposed “science of community engagement” could be modeled after the National Science Foundation’s focus on the Science of Science and Innovation Policy, which developed in response to a call in 2005 from Dr. John Marburger, the U.S. President’s Science Advisor, for a “social science of science policy” (Valdez and Lane 2008). Given the pace of research and of networking, and the globalization of research conduct, dissemination, and application, the development of the “science of community engagement” is already overdue.

In order to provide the reader with the full context within which the hypothetical case study was presented, some indication of alternate studies should be provided. Rather than conduct human challenge studies, animals have been challenged (Abel et al. 2003), or HIV vaccine development trials have been conducted in areas of the world with endemic HIV infection. Phase II and Phase IIB HIV vaccine studies (WHO/UNAIDS/IAVI Expert Group Consultation 2007) have rigorously explored routes of administration, dosage, timing, boosts, antibody titers, adverse events, and characteristics of mucosal immunity.

To substantially impact the research process, the range of potential protocol designs should be discussed, the rapidly evolving social contexts more completely explored, the responsiveness and range of available responses addressed, and the potential for public engagement and using social media fully utilized. ■

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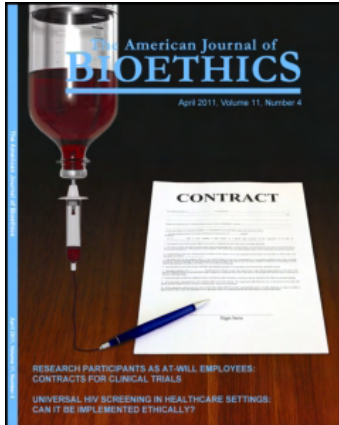
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### Research Impacting Social Contexts: The Moral Import of Community-Based Participatory Research

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# Research Impacting Social Contexts: The Moral Import of Community-Based Participatory Research

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The social context of research matters, though Gordon and colleagues have failed to connect all the dots. In “Social Contexts Influence Ethical Considerations of Research” Gordon and colleagues (2011) contend that a “valid ethical analysis of research involving human subjects must pay attention to the complexities of the social context in which it takes place” (24). Furthermore, they suggest that the current paradigm for institutional review board (IRB) evaluation fails to attend to the “social contexts of all who are involved” (24). They suggest four domains relevant to social context which warrant ethical analysis in research: public opinion, the media, the subjects, and the investigators. We argue further that the social context of research matters because the decision to conduct, sponsor, or participate (as a research subject) in research has moral meaning; moreover, an analysis of social context through a narrow view of the investigator and subjects might not adequately assess what we see as the “social impact” of research, as evaluated by members of the community being studied. In its commitment to involve members of the target population in all stages of research, community-based participatory research (CBPR) offers a broader lens for such an analysis. Thus, the social impact of research provides a more compelling focus for ethical evaluation than the social contexts per se and constitutes what we consider the moral import of CBPR.

## **ACTION RESEARCH: ASSESSING SOCIAL IMPACT BEYOND SOCIAL CONTEXT**

To grasp what we mean by evaluating social impact, it would be helpful to begin with a more thorough analysis of Gordon and colleagues’ construct of social context. The social context analysis described by Gordon and colleagues appears rooted in assuring that protocols pass public relations litmus tests, suggested by Gordon and colleagues’ deference to the media and public opinion. For instance, when the authors suggest a social context analysis, they describe a role for institutional evaluators that, at worst, offers an evaluation of the potential negative public relations impact of research and, at best, represents an assessment of society’s tacit approval of the research.

In contrast to traditional ethical evaluative models that are concerned primarily with the potential harm caused by research, either to human subjects or to the image of the

institution, participatory action research models, such as CBPR, seek to evaluate protocols not only on the traditional core values of autonomy, beneficence/non-maleficence, and justice, but also on the social impact of protocols based on community members’ evaluation of their merits.

## **THE CHALLENGES OF EVALUATING SOCIAL CONTEXT OR SOCIAL IMPACT AT THE INSTITUTIONAL LEVEL**

Whether we commit to a social context analysis or a broader social impact analysis as we have suggested, we must then ask ourselves whether the traditional IRB system is in a position to adequately do either. Consideration of the social contexts and impact of research appears to be at odds with the fundamental premise of the scientific method, which may be the dominant perspective informing IRB evaluations. A basic tenet of the scientific method is that external variables can ultimately be assessed or controlled to discover relationships and effectively measure interventions. This paradigm holds that researchers are capable of assessing external variables well enough to craft protocols that internally validate experimental results or statistically establish correlations.

When we shift our assessment to include the variables the authors identify as relevant to social contexts and impacts, we operate under a similar assumption that we, as researchers and institutional IRBs, are capable of adequately evaluating these domains. The authors’ proposed expanded evaluation (to include social contexts) does not fundamentally shift the paradigmatic lens through which this assessment is to be conducted. However, it may be presumptuous to assert that we as researchers or IRB members define these constructs in the same fashion as the communities in which we execute our protocols. We contend that adequately assessing either social context or impact takes researchers and IRBs into areas beyond their areas of expertise.

Typically, researchers and IRB members represent relatively homogeneous populations. It is difficult to argue that both IRB members and researchers are not also privileged members of society. IRBs are typically populated by individuals with advanced degrees who are well compensated financially in relation to the average citizen; the divide between researchers and IRBs and research subject is even more stark when the subject is drawn from an at-risk

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population such as those in poverty. Furthermore, the social context and impact of research as evaluated by researchers and IRB members involve considerations that differ from the interests of subject populations, such as promotion and tenure, the maintenance of federal funding, and protection from legal liability. Our insulated position in society certainly affects our ability to adequately gauge the social context of public opinion and the media's reaction to our work, and may lead us to overestimate its beneficial social impact. To be sure, these considerations are relevant, and IRBs represent a convenient body already constituted and attuned to the ethical analysis of research; however, it is worth considering whether another model might more effectively and substantively engage these issues with moral clarity.

### COMMUNITY-BASED PARTICIPATORY RESEARCH: A MECHANISM FOR EVALUATION OF SOCIAL CONTEXTS AND IMPACT

Alternatively, the methodological commitment of community-based participatory research (CBPR) provides an opportunity, and the perspective necessary, to conduct the ethical assessment of both social context and impact. More importantly, in light of its characteristic action research orientation, CBPR presumes to create a social impact on its target population based on evaluations influenced by members of that target population, highlighting the moral significance of the methodology.

A fundamental tenet of CBPR is the recognition of community as a unit of identity and the need for collaborative, equitable involvement of community members in all phases of the research (Israel et al. 1998). Furthermore, CBPR recognizes that the characteristics that establish study populations are often the same characteristics that establish the population as a community. Putting these tenets into practice, the consequence is that individuals of the study pop-

ulation, i.e., those who traditionally would be considered "subjects," are equally involved in problem definition/issue selection, research design, data collection, interpretation of the results, and determining how the results should be disseminated. Put simply, members of the sample population serve as "co-investigators," adding their own perspective to the discussion of social context and impact as protocols are developed. Having members of the sample population involved at all stages will provide better insight into the social context and impact of a particular protocol.

In conclusion, given the complexities of evaluating social context and impact of research and the limitations that accompany the perspectives of researchers and IRB members, an alternative approach with a broader perspective is required. In particular, substantive consideration of social context and impact goes beyond considerations of human subjects' protections and the management of public relations concerns. We believe the methodologic commitment of CBPR represents a better way to evaluate social contexts and impact through its commitment to involve the target community in all phases of the research process. This perspective for assessing the social impact of research is critically important for CBPR, in which one of the intended outcomes of its action agenda specifically is to create a social impact. Hence, the moral import we ascribe to CBPR. ■

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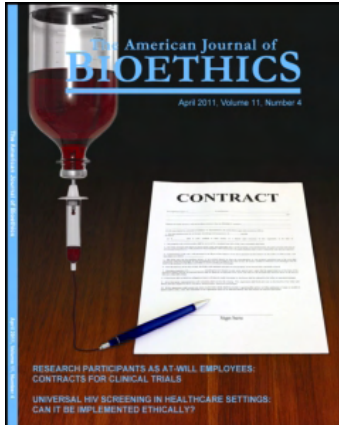
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### Response to Open Peer Commentaries on “Social Contexts Influence Ethical Considerations of Research”

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# Response to Open Peer Commentaries on “Social Contexts Influence Ethical Considerations of Research”

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We greatly appreciate the comments made by each of the commentators on our paper. Taken together, they illustrate the importance of recognizing the changeability, variability and complexity of social contexts. Bamford (2011) directs our attention to the families of research subjects. Munoz and Fox (2011) recommend social impact studies of community based participatory research and the impact of IRBs on the doing of such research. Foulkes (2011) urges our consideration of social media while Greenbaum and Gerstein (2011) propose that we concentrate on US patent law and the business of science. The references used by the commentators and ourselves also vary. Not all commentators took account of the need for an HIV/AIDS vaccine as we did.

Were there just one social context to consider, all of us would have directed our attention to that social context. But we did not. Social contexts are indeed many and diverse. The *American Journal of Bioethics* editorial and review process has, in a certain sense, situated us all. We were obliged to abide by the number of words we could use if we wanted our words to appear in these pages. Our paper was not intended to be, nor could it have been, a comprehensive account of the multiplicity of social contexts. We are very pleased that our necessarily limited publication stimulated the commentators to enrich the discussion of social contexts.

Bamford's thoughtful response provides an expansion of our examples of social contexts. She highlights the importance of varying social contexts of families of persons with ALS who chose to become subjects in a study in which they will be inoculated with the AIDS virus. We agree.

Foulkes elaborates on our statement that “how the social worlds in which actors interact can themselves change quickly” (35). Foulkes points to the importance of rapidly changing social contexts, the impact of the research pro-

cess, the range of potential protocol designs, the range of available responses addressed, and the potential for public engagement by use of social media. We agree.

Munoz and Fox draw attention to the need to study the impacts of community based participant research (CBPR). Given the postulate that members of the sample population who participate in CBPR should be “co-investigators,” there are indeed important moral and research questions that require attention. Munoz and Fox also frame social contexts as illustrated in their discussion of IRB members. Whether or not CBPR is in fact morally superior to other scientific methods has yet to be determined. Doing social impact research based on the assumption that it is superior reflects the social contexts of those who believe in it, nothing more and nothing less. Munoz and Fox underscore implicitly the utility of our discussion of framing social contexts, even though they weave together different facets than those we chose. We did not, however, write our paper to help others “manage public relations concerns” if they were to do an AIDS vaccine study in which the subjects are people with ALS. Munoz and Fox's proposed social impact study provides us with yet another useful example of the necessity of considering the changing social contexts in which research takes place.

We did not intend to assign responsibility to the IRB for social context review. Indeed, we did not assign it to anybody. Our mission was to identify a subject that is worthy of our attention. We think all actors in the field of scientific research should be aware of it and that their behavior should be guided by this awareness. But it is premature to assign responsibility for social context review to any particular agency and, in particular, not to the already overburdened IRB (Fost and Levine 2007). Moreover, we agree with Munoz

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and Fox that the IRB is not designed to shoulder this added responsibility.

Greenbaum and Gerstein directly challenge our argument that attentiveness to social contexts contributes to the processes of design and conduct of research involving humans as subjects. The authors do not appear to disagree with the idea that considerations of the social contexts of research are important but argue that they should be relevant to scientists only when they communicate with the public about the value of their work. They should—categorically—not be used in making decisions about which scientific research to pursue among competing alternatives.

The authors argue that U.S. dominance of biotechnology development is, in large part, due to the fact that research is limited only by the patentability of the fruits of the research. Science they argue should not be limited by contemporary thinking about social contexts as those views are bound to be changed and that what we may think now is bound to appear outdated and flawed in the future. The same can be said of science. Science produces knowledge which changes as new scientific theories and findings replace previously taken-for-granted scientific theories and findings. Changeability is a salient feature of the social contexts of science itself.

The argument that scientific research should have no limitations save for patentability is flawed not only because it eliminates human constraints but also because science, itself, is not free from social contexts; some of these are created by those who fund research and determine whether particular scientific discoveries are patentable. It appears that the authors are willing to abandon decades of commitment to the Belmont standards. Would this again lead to abuses such as those that led to the creation of those and other ethical standards? What about the roles of social actors such as university colleagues, IRB members and research subjects? Are they mere instruments lacking any social context? Human beings, including scientists, create cultures and social organizations—social contexts which are not dispensable. Human beings interact with each other in ways that are shaped by their social contexts. While Greenbaum and Gerstein thrive in a social context that supports their scientific research, that context itself is changing (Wilson 2011).

Patent law is not immutable. Standards for issuing patents in the field of biotechnology specifically are subject to change because of policy-making by the executive branch and law-making by the legislative and judicial branches. Depending on the decision-maker, reasons for law or policy changes may be explicit or implicit. Decisions are sometimes very fact-specific. The legislative branch does not necessarily give reasons. Courts give reasons; however, judicial decisions sometimes take years in the making, while patent law cases move like glaciers through the federal system. All these factors suggest skepticism about relying on patentabil-

ity as the ultimate basis for determinations about what scientific research will be done in what period of time, in what place and in what manner.

Greenbaum and Gerstein's commentary itself demonstrates how social contexts shape our scientific research endeavors and perspectives. As is true for all of us, their considerations reflect their own social contexts situated professionally as they are in the domains of biotechnology and US patent law. However, not all scientists are engaged in research designed to produce products that are patentable and those who are do not all live in the US. The business of science is not threatened by recognition of the fact that all scientists, including social and behavioral scientists do what they do in various social contexts. The opposite is true. The consideration of social contexts in the plural enhances both the scientific and ethical character of research programs. It may also help ensure that the national and international research enterprises do not come to a grinding halt because of a lack of attention paid by scientists to ethical, political and social considerations and realities.

In conclusion, we knew that our paper had not exhausted all there is to be done, seen and studied in the area of social contexts and their relevance to human subjects research. Although some commentaries could be construed to suggest that we failed in our efforts, by not noticing certain important social contexts, we do not agree. We consider this exchange successful in that it clearly demonstrated that social contexts do indeed influence ethical considerations of research. We hope that our paper, enriched as it was by the commentators' contributions, will continue to stimulate research on and analyses of this topic. ■

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