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Community confidentiality, consent, and the individual research process: Implications for demographic research

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Abstract. Institutional review boards are increasingly meticulous about informed consent and risks and benefits to study participants. Concurrently, heated debate in a number of fields has advanced the notion of *community* risk and benefit. When research is conducted in communities, and the results may "do harm to" communities socially, economically, or medically, should informed and voluntary consent be obtained from communities as well? We argue that for demographers – by definition interested at the phenomena at the population level – concern for individuals *as a part of communities* is critical to the research process. Questions of community consent, confidentiality, and participation will be pushed to the fore as demography delves into new areas and methods of investigation. This paper provides a brief overview of the historical development of ethics in human subjects research and the subsequent ties to community-level concerns. Drawing on current examples from a variety of settings, we explore definitions of community, the scope and viability of community participation in research, and the implications of these for demographic enquiry. We find that in contrast to substantive debates, little attention has been given to ethical issues in the demographic research *process*. Research accountability to communities, including the documentation of community risks and benefits, and community representation and consultation in the research process are recommended

Keywords: Communities, confidentiality, demographic research, ethics, informed consent

Ethics in research have gained increased attention over the last few years, as the National Institutes of Health (NIH) has halted research in institutions that have not adhered to human subjects research standards. Quite often, the research most at risk of violation – and which draws most institutional and media attention – is medical research. Historic cases involving psychological and medical research tend to fit easily into today's framework of right and wrong: The Tuskagee syphilis research, the holocaust medical experiments, the Milgram study of obedience (Caplan 1992; Jones 1993; Milgram 1974). Most researchers would recoil at the egregious violation of human subjects' rights to informed consent in these instances. Demographic research has had, for the most part, the luxury of receiving exempted or expedited review for approval for human subjects research because such research tends not to involve medical experiments: "do no harm" seemed a fairly straightforward ethical tenet to accommodate in social research. As many social science re-

searchers submitting research proposals now may attest, this luxury is rapidly disappearing. Institutional review boards (IRBs) are increasingly meticulous about informed consent and risks and benefits to the individual, even when investigations are limited to questions and answers, or other non-medical methodologies (Office of Human Research Protections [OHRP, formerly OPRR] 2001).

At the same time, heated debate in a number of fields has advanced the notion of *community* risk and benefit (Weijer 1999). When research is conducted in communities, and the results may implicate, or do harm to, communities socially, economically, or medically, should not informed and voluntary consent be obtained from communities as well? We argue that for demographers – by definition interested in the phenomena at the population level – concern for individuals *as a part of communities* is critical to the research process. Demographic research involving individuals by definition implicates the communities in which those individuals live. The debates raging over community rights in research in other fields may be very pertinent to demographic endeavors. For what kind of research should communities be a viable part of the research process, and to what extent? To what kinds of communities might this apply? Under what circumstances do communities have the right to informed consent? Or do they have a right at all? Demographic research has primarily adhered to the supremacy of individual rights and responsibilities in the research process: Voluntary participation and informed consent of the research participant have been the currency of ethical standards of most social science. Will this continue to be sufficient?

Many demographic research efforts, of course, have included community participation to some extent, sometimes through local advisory boards (Blanchard 1998), through explicit or implicit support via cooperative efforts, or even post-hoc, through dissemination activities. However, the level and type of community involvement in research efforts is changing. In some cases, the role of the community has expanded to include setting the research agenda, approving protocol design, monitoring implementation processes, approving publications and presentations, and requiring ownership of data and results. The extent to which demographic enquiry will be affected is still unknown, but we argue that a proactive assessment of the role of communities in research will be highly beneficial. Questions of community consent, confidentiality and participation will be pushed to the fore as demography delves into new areas of investigation, for example, with the advent of biomarkers in household surveys (Boerma et al. 2001; Finch et al. 2001); with the increased level of intimate detail required for reproductive health research, migration, or family processes; and with advances in analytic methods that produce great detail about communities and the people living within them. Specifically,

we argue that if researchers are able to identify a socially or geographically bound community with which they work, they must be accountable to that community. Specific level or scope of involvement in research by communities may vary tremendously, depending on both the nature of the community and the type of research in question. However, detailing risks and benefits accrued to the community in the individual consent process itself, we argue, is a first step in explicitly linking individual-level and community-level concerns, and thus encouraging such researcher accountability.

This paper seeks to extend the dialogue and delineate questions that may not have entered yet into the research calculus of demographers. As the review climate changes, it is our hope that the questions posed in this manuscript will provide a basis from which to develop a critical ethics of demographic research. We present this discussion as a contribution to a framework by which researchers can work proactively in developing useful research protocols that are accountable for the requirements of the communities in which they work.

A short history of research ethics and the implication for communities

Interest in ethics of research has received spikes of attention over several decades, corresponding to flagrant violation of human rights and protections. The Nuremburg trials brought to the public the extent of abuse and horror involving medical experimentation, usually related to the war effort and the Nazi ideology (e.g., altitude sickness, war-related injuries, sterilization, and efficient means of killing, by Nazi physicians using holocaust camp prisoners) (Faden & Beauchamp 1986). The Nuremburg code came about as a result of the trials, and constituted the first systematic set of principles on conduct in experimentation using human subjects, including informed and voluntary consent, consolidating and enhancing a prior thin layer of protections. Perhaps the study that has most profoundly affected the psyche of ethics in research for U.S. researchers is the Tuskegee experiments. In this study of the U.S. Public Health Service, a group of 399 poor African-American men were recruited to participate in a study on the progression of untreated syphilis. The men were not informed of their participation in the study and were deliberately deceived about the treatments they were receiving. Most disturbingly, treatment was withheld from infected men, even after the development of effective antibiotics. The study continued for 40 years, ceasing activities in 1972, only after widespread media attention (Brandt 1978; Jones 1993). The study and its implications are still under debate (Reverby 2001; Fairchild & Bayer 1999), and as Fairchild and Bayer (1999: 921) point out, “very effective in riveting public attention”.

Other studies have also shaped ethical standards, though perhaps to a lesser extent in the public domain. The Willowbrook study involved research on mentally disabled children who had been deliberately infected with hepatitis so researchers could study a new vaccine; Milgram's experiments on obedience and authority involved deception to subjects and possibly great psychological harm; Humphreys' research on homosexuals was criticized for not obtaining consent from participants, even though the research posed no risk or harm (Faden & Beauchamp 1986). These are only a few cases that have been criticized for ethical lapses. Indeed, King et al. (1999b) make the point that government review has concurred that research still continues to be implemented with uneven adherence to regulations governing research with human subjects. The existing bodies of regulation governing research in human subjects in the U.S. derive mainly from the Common Rule, a set of regulations, consolidated over the past 30 years, that require the establishment of an institutional review board (IRB) for all institutions receiving federal funding to review and approve proposed research. The regulations govern informed consent and protections of privacy and confidentiality for individuals.

Several sources of code on ethical conduct with human subjects, such as the Belmont Report, the Declaration of Helsinki, and the Council for International Organizations of Medical Science (CIOMS) guidelines, exist for both epidemiological and biomedical research. The list of guideline names suggests that work on human subjects protection appears to center on biomedical research. However, the underlying dimensions apply to concerns about community participation in research in general.[1] The Belmont Report, produced in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, was intended to present and inform regulations in the United States, and strengthened the tenets of voluntary and informed consent to individuals. The report's guidelines rested on three principles: respect for persons, beneficence towards subjects, and justice. The first, respect for persons, is concerned with maintaining the rights of humans as autonomous persons, that individuals have a right to privacy, to information about their participation, and to accept or decline the invitation to participate. The second, beneficence, is the one that has received the most attention, especially in the biomedical world, but with particular implications for social science. It states that experimentation should do no harm, and that it should seek to maximize benefits and minimize risks to persons involved in a study. The carrying assumption for social science had been on harm – interpreted as physical harm – and thus perceived as a distal risk for social science research. Interpretations of beneficence since the Belmont Report have included risk from deception, psychological harm, breach of confidentiality, or misrepre-

sentation of research. Justice relates to the fair treatment of persons and the equitable distribution of benefits; it is this principle that guards against biases and prejudices against minority, underprivileged or impaired groups. In its original draft, justice was associated with protections in the recruitment of subjects. Recent writing has interpreted the concept to include empowerment of groups over the research process, including access to long-term benefits (Benetar 2002; King et al. 1999b; Mastroianni & Kahn 2001; Stein 1997).

The World Medical Association's Declaration of Helsinki, the first international code of ethics in biomedical research, was finalized in 1964 and has been redrafted several times since. Moreno (2001) argues that while the Nuremburg Code and the Belmont Report were moves towards limiting the discretion of the investigator and increased protection over the individual participant, the Helsinki Declaration allowed for greater latitude for researchers, especially clinicians. Language in the 1989 version, for example, allowed for instances in which informed consent was not required or in which consent could be obtained from someone other than the participant. The CIOMS guidelines, first published in 1993, were the international codes embodying the Belmont Report. They provided for absolute protections for individuals and specifically addressed research conducted in developing countries. They provide against the exploitation of individuals and communities, and require that research must meet the standards of the sponsoring country and then the standards of the host country.

The CIOMS guidelines, intended in part to elevate interests of developing nations, have resulted in further controversy. They have, for example, included phrasing for the acceptability of epidemiological research to the community where "collective decision-making is customary". While the requirement of meeting sponsoring country standards first means that research banned or unacceptable in developed settings cannot be done elsewhere, it also means that standards set in developing countries may not be taken as seriously (King et al. 1999). Specific controversies emanating from international guidelines, such as the ethics of placebo-control experiments in developing countries, have generated heated debate (Weijers & Anderson 2001). Lurie and Wolfe (1997), for example, have argued that placebos are not ethical for a control group experiment involving AIDS therapies because known effective treatment is available. Supporters of the placebo-control experiments insist that the appropriate comparison is no treatment, since that is what is available in developing nation settings (Varmus & Satcher 1999). Few demographic studies use randomized control designs or are involved with interventions that include life-prolonging medications. However, other controversies, which are pertinent to social science research, have arisen.

The sets of extant guidelines dominating ethical standards for research involving human subjects assert the preeminence of individual autonomy over that of any other entity. In spite of some language that may accept that communities of other cultures have differing means of extending authority or granting permissions, the guidelines call ultimately for individual informed consent. The emphasis on individual rights in research no doubt stems in part from the evolution of discourse on human rights, which tended to reach peaks in tandem with discussions on ethics in human subjects research (Easley et al. 2001). Since their inception, however, some have accused the guidelines of imposing Western moral imperialism by not accommodating cultures in which communal forms of authority exist, or where familial decision-making is preeminent (Christakis 1992; Levine 1991; Khan 1991). Others insist that ethics are not subject to cultural relativism and that the principle of individual autonomy is universal (Macklin 1999; Ijsselmuiden & Faden 1992). As Macklin (1999: 28) asserts, "To argue that different ethical standards are permissible because research in any culture is acceptable, so long as it follows the customs and norms of that culture, is either to sanction violations of human rights in the countries where those violations occur, or else to deny that there are any fundamental human rights. Either view embodies a form of ethical relativism . . . ".

The debate posed as such, universal principles versus Western ethical imperialism, quickly polarizes discussion. Indeed, the Western emphasis on individuals allows each person to assert his or her own authority over participation; for example, the focus assures, in principle, that a woman makes her own decision about study participation without her partner's consent. However, the practical implementation of securing the consent may be quite challenging (see, for example, the discussion by Macklin 1999). She may be unable to consent in the presence of her husband and finds it easier to decline participation. Researchers in this case cannot know if she is declining voluntarily or because she feels she has no other option. Even if researchers were able to arrange the circumstances so that such a woman could confidentiality consent to or decline participation, researchers may be asking for more than her participation, but her cooperation in defying local customs (Blanc 2001). Similarly, a chief or mayor may have sole decision-making power over whether a study could be conducted within the boundaries of his or her jurisdiction, regardless of the presumed autonomy of individuals living there (e.g., Rutenburg et al. 2000). Furthermore, this may not be an imposed decision on the part of the leader, but an expected decision for him or her to take, as understood by the constituency. In such communities, the supremacy of individual assertion of rights may be an inaccessible concept for the prospective participants (see Dickens 1991 and Khan 1991 for an anal-

ogous discussion for epidemiology). Anecdotally, communitarian or familial authority over consent is not uncommon; however, the phenomenon receives little attention in methodological description and virtually none with respect to human subjects rights in research.

Conversely, an unmodified focus on individual rights can destroy collective goals or social entities. Examples abound. Weijer (1999) discusses the example of specific genetic research among the Ashkenazi Jews. While individual consents were obtained for original sample collection and testing related to Tay-Sachs disease, results of these studies revealed this group carried, at a higher rate than in the general population, specific gene mutations linked to some forms of cancer (Lakem et al. 1997; Streuwing et al. 1995). Such reporting then may jeopardize employment or insurance coverage for this group and, in general, stigmatize the group (Stolberg 1998). Norton and Manson (1996) describe the case of a research study conducted among the Inupiat people of Alaska (Foulks 1989). In this case, a press release, provided by the researchers, was published by the *New York Times* and the United Press International wire service with headlines proclaiming "Alcohol Plagues Eskimos". Norton and Manson (1996: 857) describe the results: "These headlines engendered tremendous conflict and controversy among the Inupiat community, the outside investigators, and the local agencies that commissioned the study. Any possible scientific merit of the study was overshadowed by these events. Moreover, the Standard and Poor bond rating of the local community dropped dramatically overnight, precluding their ability to fund a number of important municipal projects, the lack thereof severely curtailed local citizens' quality of life". The incident also severely curtailed research in Alaska Native communities due to suspicion and mistrust on the part of both researchers and Alaska Natives. In India, an NGO produced and distributed a pamphlet based on research within a certain community. While ostensibly developed for HIV education purposes, the contents of the pamphlet included material on incest, causing a furor by residents who felt unjustly maligned and slandered, and subsequently jailed the researchers (Butalia 2000). In a Native American community, the NIH has sponsored diabetes-related research for over thirty years. In this community, the diabetes rate among persons over 55 increased dramatically from 45% in 1965 to over 80% in 1999. Yet, researchers and funders deferred prevention efforts until 1996 (Associated Press 1999). The NIH claims to have made no promises for cures; yet, does not the obligation to act exist given the rise of the disease in this population (Bowekaty & Davis 2003)?

In each of these cases, the consent of individuals was most likely obtained according to international guidelines: Individuals voluntarily provided their consents upon a description of risks and benefits to the individual. However,

the results of research go beyond the individual, implicating the community to which the individual belongs. Each participant agreed to take part in a study that would "do no harm", but the individual may not have been aware of harm (or benefit) that could come to the collective as a result of the research. Indeed, if a consent excludes an explanation of research risks and benefits to communities, have consenting participants been fully apprised of the implications of the research? We argue that in most cases, they have not been. That is, if the researcher intends to focus his or her work on a particular community, there will be risks and benefits to that community *because* of individuals' participation. Each of those individuals should be aware of those risks and benefits, above and beyond those applicable to them as individuals. Neither does community-level compliance necessarily compromise individuals' rights. If, for example, community leaders agree that a study can be conducted among its members, individuals may still be given the right to accept or decline participation, given that they are fully apprised of the risks and benefits to themselves and to the community. In short, even with leadership endorsement, individual members may choose not to accept the risks to themselves or to the community. Community compliance, however, does not guarantee voluntary, individual consent. As noted above, particular circumstances may preclude individual autonomy regardless of community leadership endorsement. The point here, rather, is that within the context of the research process, community confidentiality, community risks and benefits, individual autonomy, and individual risks and benefits are interconnected. Compromised community confidentiality, for example, arguably violates individual confidentiality as well, that is, as members of that community.

The power of communities to determine the course of research – or, conversely, their vulnerability to research agendas – is becoming quickly a prominent feature of ethical consideration in research on human subjects (Mastroianna & Kahn 2001; Benjamin 1999; Estroff 1999; Norton & Manson 1996; Weijer 1999). As evidenced by the foregoing discussion, the preponderance of the debate has been in biomedical and genetic research. The arguments, however, are unlikely to be relevant only to those fields.

Demographic research processes: Why should we worry now?

As debates of informed consent, confidentiality, and community roles in research rage in other fields, demographic enquiry, thus far, has lingered at a distance from the deliberations. In part, this is understandable because of the field's history of data sources and methodologies. Demographic research historically has been concerned with the statistical analyses of secondary data.

Censuses and large ongoing national and international population surveys, often collected for administrative or national monitoring purposes and not specifically designed to address research questions, have been the primary source of data for demography. The secondary nature of the data has not precluded debate or misuse (Seltzer & Anderson 2001). However, from a researcher-user perspective, assurances of informed and voluntary consent for individuals were under the purview of the primary data-collecting organization. Once that data had been collected and released publicly, personal identifiers had been removed and concern for individual protections at the analysis stage were largely unwarranted. Those researchers who collected their own primary data obtained the (often somewhat confused) approval of IRBs, most of which had been setup to review medical research. Since virtually no demographic research protocol included medical experimentation, and hence risk or harm to individuals was thought to be virtually non-existent, IRBs often exempted or expedited reviews if proposals contained, minimally, an informed consent process. Informed consent[2] and voluntary participation for individuals, then, has been an ethical standard of research in the field. Is the continued focus on the individual with respect to consent appropriate for a field substantively concerned with populations living in communities? Gostin (1991: 198) articulates the problem: "Could individuals in a study each give consent to disclosure of information, and yet the study would violate the right of the collective to privacy? The answer is yes if one believes that populations have a right to defend their reputation and dignity as much as individuals do. It is conceivable, even where the information revealed about each member of the group is non-consequential or is not personally identifiable, that the group can be harmed .... The right of populations to have some say in the collection and spread of data that they believe reflect badly on their identity is an important ethical principle".

Demographic enquiry has evolved considerably over the last few decades and has changed the landscape of ethical concern. The multidisciplinary field now encompasses a wide range of methodologies. Some of these bring about greater ambiguity over confidentiality and the informed consent process. Surveys, for example, are commonly carried out in multiple locations with explicit intention for comparisons that may not be welcome. Localized demographic surveys and ethnographic methodologies, including focus groups and in-depth interviews, are commonly designed to collect detailed information on individuals and the communities in which they reside. Advances in analytic techniques such as multi-level analyses or small-area estimation techniques, also have brought about tremendous increases in the kinds of information known about relatively small geographic units (or possibly social units) and the individuals that belong to them. A cursory review of abstracts in

recent Population Association of America meetings provides ample examples of research for each of these categories.

Recent forays combining biological data collection with household surveys also have brought a host of ethical issues. While research teams involved in such projects no doubt have grappled with many ethical issues in implementing such designs, very little has yet been written in the social sciences (Finch et al. 2001; King et al. 1999a). Studies involved in the collection and then testing of biological samples to determine disease, viral load, or other chemical or biological substances must struggle with a host of challenging issues. Many of the ethical challenges remain at the individual level and are akin to the issues of biomedical research. However, many new questions arise at the individual and community level since data from these studies include both biological and behavioral information that can be linked. The combination is a powerful one for analytic purposes (Aral & Peterman 1998; Stephenson et al. 2000), but what then are the obligations of the researchers? For example, if a study of adolescents is designed to collect samples to determine HIV status, are the researchers obligated to give the results of the test to the individual? Many such surveys will include sexual histories, sexual practices, and drug use behaviors. In short, researchers will know who is HIV positive, the likelihood of mode of transmission, and potential partners that may contract the disease, if they have not already. To what extent are researchers obligated to contact partners, both for individual-level medical treatment and for community health concerns?

One may argue that these questions are identical to ones that occur in medical research (see, for example, Blanchard 1999; National Institutes of Health 1999; Council for International Organizations of Medical Sciences 1993). However, there are two critical differences. One, persons selected into the sample are done so randomly; they are not presenting at clinics for the purpose of testing or some other reason, nor are they recruited into studies because they meet certain health criteria. Such randomly selected respondents are likely to be less prepared to receive negative results than patients, and may receive the results in a setting incompatible with appropriate counseling or care. Second, social science surveys are usually conducted in homes. Some studies that include biomarkers have requested participants to be tested in a medical setting (Weinstein & Willis 2001), but many biological markers can now be used in the field, easing costs and logistics. In either case, in a sample survey, this means that within a community some households will be selected for testing, and others will not be. In short, the sampling methodology inherent in household surveys, particularly when coupled with biological testing, may compromise confidentiality.

In summary, changing research methods in the context of shifting ethical considerations may pose new ethical questions for those involved in demographic investigation. In the following section, we review aspects of community relationships that might be especially critical in demographic research.

Community concerns and individual rights in the demographic research process

Demography is concerned with the study of population and population dynamics. Populations, in turn, could be some form of a collective or group, all persons residing in a village, a random sample of a city, or a particular sub-group, such as pregnant teenagers or single fathers. Thus far, we have discussed the implications of community for the process of demographic research without delineating the types of involvement, the large variations in social and political cohesion, or the representation of persons belonging to such groups. In what ways might communities become involved in the research process? How do we define communities for the purposes of research? Should all communities be involved in all research efforts? To address these questions, we first present the specific arguments on community consent and research involvement from various fields and perspective. We then turn to the substance of community participation and the types of settings in which this could transpire.

As Foster et al. point out (1997), individual privacy is assured in research via IRB procedures. However, referring specifically to their field of genetic research, information about common ancestry or geography may implicate others who did not participate in the research or provide informed consent. Indeed, indigenous groups have spoken strongly about research related to the genome project (Macilwain 1996; Dukepoo 1998). Still, IRBs rarely, if ever, require an accounting of community-level implications of research. Foster et al. (1997: 278) delineate their experiences with two Native American groups to illustrate models of community involvement with differing structures of authority and various geographic distributions. These researchers began involvement with the community through a series of community meetings. The specific concerns raised included use of the tribal name in publications, arrangements for participant recruitment, participant incentive, and royalty income from any invention deriving from the research. They assert that risks to identifiable populations should be anticipated through informed consent, and that informed consent is a social act of individual identity: “Thus, for a consent process to effectively inform those who are likely to be affected

by genetic information, it must conform to local social constructions of relatedness".

Critics of a community consent process dismiss such involvement as inappropriate and ineffective (Juengst 1998; Reilly 1998). They question the relevance and meaning of group consent along several dimensions: Communities do not necessarily have a common voice, nor do they necessarily have a structure of authority that could readily assert an entire community's interest. Further, including communities or groups explicitly in this way may conflate social phenomena with biological ones. That is, the disease or genetic code or characteristic of interest will not, in general, be confined to a social grouping. Moreover, community consent quickly loses meaning in geographically dispersed groups or within groups that do not have cohesive social ties. These authors also assert that allowing groups a gatekeeping role in research is likely to increase risk of discrimination by explicitly linking research with a specific group. Indeed, proposing that communities need special protections is, in the first place, paternalistic. Linking a study with a group may unduly promote perceptions of homogeneity within the group, and "special protections" presupposes impairment. Of special concern to these authors is whether community consent should be required or regulated in some way, and if so, whether communities then have the authority to prohibit research.

Consideration of community consent and participation thus is by no means a broadly accepted tenet of ethical standards in human subjects research. However, rapidly accumulating examples indicate that communities are increasingly cognizant of possible deleterious consequences of research. For example, several American Indian and Alaska Native tribes have formed, or are forming, their own research review boards, or have required prior tribal approval of all research efforts. (Local or community review boards are not unique to the tribal groups. The goals of local boards, the process they use, and the implications for research has also received scholarly attention [Blanchard 1999; Wailoo 1999; Burman et al. 2001; Strauss et al. 2001].) Some also require tribal approval of proposals prior to submission to funders, ongoing updates on research currently in progress, review of publications prior to journal submission, and ownership of or negotiated access to all data collected in studies. Indigenous groups abroad, for example in Australia and Canada, have collaborated in recent human subjects ethical guidelines development that now include explicit requirements of consent and protections for collectives (Weijers et al. 1999). Community review of research is not limited to indigenous peoples' groups nor biomedical research (Benjamin 1999; Weijers et al. 1999), nor is it necessarily involved in circumscribing research efforts. Advocacy groups for HIV positive persons, women's health, and other minority groups have lobbied strongly, and effectively, for inclu-

sion in medical research (Mastroianni & Kahn 2001; Moreno 2001). In short, regardless of philosophical underpinnings of a given view of community consent or participation in research, communities are organizing to assure their own interests in research are served. Researchers increasingly will have to address community involvement in the research process.

What are the forms of community participation?

Weijers et al. (1999) reviewed 15 ethical guidelines from the U.S., Canada, and Australia, along with CIOMS guidelines, to assess which ones explicitly addressed research protections for collectives, and what kind of protections were advised. The comprehensive list of items is provided in Table 1. The list divides various points of participation by phases of research, including protocol development; consent process, including consent on protocol changes and option to withdraw from research; research implementation; and final products of the research, including access to or ownership of data, review and approval of publications, and reporting procedures. From our own experience, we have added several other points of the research process that may also be a part of community participation: community data analyses requests, consent process for using data for reasons not originally stated (access to data and samples), and approval process for public presentations for unpublished or published materials (dissemination and publication).

Each item in Table 1 relates to community or collective interests. The list provides a sense of the level of comprehensiveness participation could entail. For example, communities could invoke their own research agendas, or require that a given protocol address issues of priority in a community, or use a methodology more culturally appropriate. The consent process includes not just individual consent, but that of the community, which may include a request to not identify the community in publications. Often research efforts include "capacity building" or technological transfers of some kind (e.g., computers, research skills), less often, communities may require ongoing reports on the research process. The products of research, data, samples, publications and reports may be some of the most controversial aspects of community involvement. Ownership of data, analysis, and results has long been under the de facto aegis of the investigator, with varying levels of institutional de jure ownership. However, from the point of view of some communities, data or samples collected from a community belong to that community; results of analyses using that data should first come under the review of the community from which they are derived. Review of publications outside of the peer review process in journals is a challenging issue in academics (Estroff 1999), as is the monitoring of presentations.

Table 1. Guidelines designed for the protection of aboriginal communities in research

- Community involved in drafting the guidelines
- Consultation in protocol development
  - ◯ Respect for community
  - ◯ Input on protocol
  - ◯ Research useful
  - ◯ Respect for knowledge and experience
- Consent process and informed consent
  - ◯ Non-technical and appropriate disclosure
  - ◯ Face-to-face meetings
  - ◯ Adequate time for review
  - ◯ Consent
  - ◯ Consent required for protocol changes
  - ◯ May withdraw consent
- Involvement in research conduct
  - ◯ Transfer of skills and research expertise
  - ◯ Employment
  - ◯ Reimbursement for research costs
  - ◯ Informed about research process
- Access to data and samples
  - ◯ Consent for further use of samples
  - ◯ Storage of data negotiated
  - ◯ Process for data analysis requests
  - ◯ Consent of use of data other than for reasons specified
- Dissemination and publication
  - ◯ Involvement in manuscript preparations
  - ◯ Draft report for comment
  - ◯ Acknowledgement
  - ◯ Consent to identify
  - ◯ Report compliance with guidelines
  - ◯ Final report
  - ◯ Consent for researcher media interview
  - ◯ Consent for presentation of data
    - ■ Published
    - ■ Unpublished manuscripts

Adapted from: Weijers et al. (1999).

The items on the list are certainly controversial, and in themselves require an immense amount of analyses and debate about their appropriate place in demographic research. That discussion is beyond the scope of this paper. These debates, we hope, will be ongoing and contribute to improvements in research efforts. For now, the items of Table 1 are intended as an assessment tool for researchers – the items are a checklist of types and scope of community participation.

What is a community or membership in it?

Most examples about community participation in research come from research in socially identifiable communities, usually but not always geographically contained. Cohesion within such a group usually provides for structures of authority that can legitimately work for the benefit of the community. Weijer et al. (1999) point out that Irish-Americans, for example, or Ashkenazi Jews do not have a well-defined means of communication or generally accepted political bodies that would make difficult an articulation of community needs, or the approval of community-based research. They propose that requirements of community consent, confidentiality, and other participation in research can only be achieved in socially defined populations that share histories, cultural traditions, and language, and which have legitimate political structures. These authors do not elaborate on the many variations across communities along these dimensions, but do point out that principles of community involvement, such as those specified in Table 1, may not all be applicable to all communities, but many will be, or could be adapted to fit with a specific research context.

Should investigators involved in demographic research worry about community involvement only when communities are socially and politically cohesive? Gostin (1991: 197) discusses the use of terms referring to broader definitions of community: "Consider, for example, the widespread practice in the United States and elsewhere of reporting HIV seroprevalence data broken down by race and ethnicity. Although the data are collected for a valuable purpose and do not identify individuals, the method of reporting emphasizes the disproportionate impact on African Americans and Hispanics. A valid reason may, in fact, exist for so publicly characterizing race and ethnicity as risk markers (but not risk factors) for HIV, rather than using more neutral classifications such as socioeconomic status or geographic area. The practice is so well entrenched, however, that no one asks whether the public health justification is significant enough to outweigh the potential impact on the dignity and self esteem of the populations affected". As noted by Gostin, particular analytic categories may potentially represent populations unfairly. The answer may not be simply to disallow the categorical analyses, but to

address concerns of the population early on in the research process. In short, the benefits of research, what some have equated to the ethical tenet of justice in the Belmont Report, may be the means by which community "dignity and self-esteem" is most appropriately addressed.

Several authors have proffered models in research recognizing community interests (Foster et al. 1997, 1999; Manson et al. forthcoming). Foster et al. (1999), for example, suggest that identifying cultural risks can lay the foundation for the form and structure of appropriate community involvement. In particular, they suggest that in their experience with widely dispersed larger populations, group consent does not need to derive from one recognized body of authority, but is still possible by accessing alternative forms of group authority such as families; only community members are able to identify risks particular to their own group; and community concerns can in fact be incorporated into existing review mechanisms without extending veto power over research. It is worth noting that a number of examples of research with communities involve the methodology of participatory research (Cornwall & Jewkes 1995; Macauley et al. 1998; Lindsey & Stajdahur 1998; Gladwin et al. 2002). Participatory research methodologies may have a number of lessons to offer a development of ethics in community-based research; however, it is a methodology, whereas the issues presently discussed are of ethics, which can be applied to any number of methodologies, including participatory ones. Still, a number of articles have appeared that empirically address community involvement in research efforts (Seeley et al. 1992; Altman 1995; Mitchell et al. 2002).

The extent to which demographic enquiry might be subject to concerns of community reach protections will ultimately depend on the scope and design of a particular project. The inherent emphasis on populations in the field will necessarily require an examination of the relationship between research and community.

Implications, concerns, and conclusions

A number of scholars have asserted that in addition to respect, beneficence and justice, guidelines on ethics in research involving human subjects should include *respect for community* (Weijer 1999: Levine 1982). The additional tenet implies that community concerns are distinguishable from individual ones, and that communities have moral status as collectives. This approach may be a fruitful one for research initiatives in general. A historical emphasis on individual rights may not be misplaced, but must be expanded to include an address of rights of communities from which participants are drawn.

Table 2. Relations with and responsibilities towards research participants (UK based)

Guidelines	Association of Social Anthropologists, Commonwealth	British Society of Criminology	British Educational Research Association	British Association for Applied Linguistics	British Sociological Association	Royal Statistical Society
Protecting research participants and honouring trust	✓	✓	Limited to publications only	✓	✓	Implicit
Anticipating harms	✓	–	–	✓	✓	–
Avoiding undue intrusion	✓	✓	–	✓	✓	–
Negotiating informed consent	✓	✓	✓	✓	✓	✓
Rights to confidentiality and anonymity	✓	✓	✓	✓	✓	✓
Fair return for assistance	✓	–	–	–	–	–
Participants' intellectual property rights	✓	✓	–	–	–	
Recognize constraints of participating organizations	–	✓	–	–	–	–
Community protection and assent	–	–	–	–	–	–

Citations:

1. Association of Social Anthropologists of the Commonwealth. http://www.asa.anthropology.ac.uk/ethics2.html
2. British Society of Criminology. http://www.lboro.ac.uk/departments/ss/bsc/council/CODEETH.HTM
3. British Educational Research Association. http://www.bera.ac.uk/guidelines.html
4. British Association for Applied Linguistics. http://www.baal.org.uk/ethicsug.htm
5. British Sociological Association. http://www.britsoc.org.uk/about/ethic.htm
6. Royal Statistical Society. http://www.rss.org.uk/membership/prof.html

Table 3. Relations with and responsibilities towards research participants (US-based)

Guidelines	Academy of Criminal Justice Sciences	American Association for Public Opinion Research	American Psychological Association	American Anthropological Association	American Sociological Association	American Statistical Association
Protecting research participants and honouring trust	✓	✓	✓	✓	✓	✓
Anticipating harms	Implicit	–	–	–	–	–
Avoiding undue intrusion	✓	–	✓	–	✓	✓
Negotiating informed consent	✓	–	✓	✓	✓	Implicit
Rights to confidentiality and anonymity	✓	✓	Not guaranteed	✓	✓	✓
Fair return for assistance	–	–	✓	–	–	–
Participants' intellectual property rights	–	–	–	–	–	–
Recognize constraints of participating organizations	–	–	–	–	–	–
Community protection and assent	–	–	–	–	–	–

Citations:
1. Academy of Criminal Justice Sciences. http://www.acjs.org/PDF
2. American Association for Public Opinion Research. http://www.aapor.org/ethics/code.html
3. American Psychological Association. http://www.apa.org/ethics/code.html#6.10
4. American Anthropological Association. http://www.aaanet.org/committees/ethics/ethcode.htm
5. American Sociological Association. http://www.asanet.org/ethics.htm
6. American Statistical Association. http://www.amstat.org/profession/ethicalstatistics.html

We argue that implementing "respect for community" as a tenet in ethical research guidelines requires action at several levels. Funding organizations must clarify their expectations of the level of community participation in research. IRBs should require an explication of community involvement in the research process, community-level risks and benefits in protocols, and where appropriate, include such risks and benefits in consenting procedures. Researchers should proactively engage the communities in which they work

in the research process, from inception through publication. Reviewers and journals can require that authors report on the safeguards that researchers took to ensure community protection. Such calls for community consideration at multiple levels will undoubtedly bring about greater regulation and oversight of researchers' work, and a commensurate increased bureaucracy. Researchers also will have to find more time and funding to cover costs of extra efforts to work with communities. None of these suggestions is likely to be sanguinely received. However, we argue that community involvement in research is necessary for studies conducted with groups either geographically or socially bound. The litmus test for community consideration is not whether such groups have viable bodies of representation with which to consult, or even that some regulatory agency or board requires community-level address of research processes. Instead, researchers must be accountable for their study activities within a community: Can a community be named in a given research effort? If this questions elicits a positive response, then the onus is upon the researcher to conduct research in a way that is respectful and accountable to that community. In epidemiology, Levine (1991) had attempted to assemble a list of minimal requirements, including community-based research ethics committees, and a set of review procedures addressing international research. While we endorse his list, we also warn that existence of established review committees is not the requisite for involving communities in research. At a minimum, the researcher has an obligation to specify risks and benefits to that community for all consenting participants. Even this simple step is likely to prompt some meaningful community participation, if only in generating discussions on the effects of a research effort on a community. Indeed, optimally, researchers would engage communities in the research process from inception through publication.

Whether a professional code of ethics, one that might incorporate a principle of respect for community, is necessary for demographers is for debate within the discipline. Currently, the Population Association of America (2002) states that it "does not provide specific ethical standards but expects that its member maintain familiarity with ethical principles . . . ". Demographers hail from a variety of disciplines, many of which already include their own code of ethics (see Tables 2 and 3 for selected list of organizations and dimensions of the respective ethical guidelines). Is the research of demographers sufficiently unique to further consider special ethical reviews or guidelines? Are there research areas or methods unique to demographers that are not included in other disciplinary codes? A cursory overview of guidelines suggests that other disciplines have not, as yet, addressed issues at stake in community research. Is the concern important enough to lobby other professional socie-

ties to address this topic? Where, if any place, should ethical commitment to communities in which demographic researchers work be embodied?

Currently, few fora exist for open and honest dialogue about methodological ethics of demographic research. Journal articles rarely provide space for, or require summations about, ethical considerations in social research. Controversies often remain in the realm of news media or unpublished reports. This paper is intended to bring communities into a broader discussion of ethics in demographic research. We have outlined the arguments indicating that demographers must be accountable for the research process in the communities in which they work, and they should think proactively about the ethical building blocks and consequences for that process. Many of the questions raised in the foregoing review are controversial. Others may not apply across all demographic research initiatives. They all remain only partially addressed; we look forward to further exchange.

Notes

1. Although some efforts have been made to particularize fields with respect to ethical guidelines in research (Homan 1992; Wax & Cassell 1981), we support King's view (1999b: 21) of such an exercise: "distinguishing between biomedical and social science research represents no more than the crudest cut at the issues of concern to most researchers, and misrepresents the importance of evaluation the potential harms, wrongs, benefits, and burdens of all proposed research".
2. Informed consent itself is a charged issue. Some authors, for example, have argued that researchers tend to confuse the administrative form and signature with true informed consent (Macklin 2000; Emmanuel et al. 2000; Gostin 1995). The issue is an important one, and integrally related to the themes in this paper, but beyond the scope of the present review and assessment. See also Yoder and Konate (2002).

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