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The Presidential Commission for the Study of Bioethical Issues (PCSBI) recently introduced "[t]he principle of democratic deliberation" (2010; 2012) as part of its reports on the ethics of synthetic biology and of human subjects research. The PCSBI noted that democratic deliberation is "a less familiar principle in bioethics than the principles of beneficence and justice" (2010, 30); indeed no other prominent list of bioethical principles lists anything similar (Veatch 2007). Though new to lists of bioethical principles, democratic deliberation has been employed elsewhere in practical ethics (Gutmann and Thompson 2004, 18–19, 31, 33).

This chapter explains democratic deliberation and considers its implications for ethical review of human subjects research. It argues that democratic deliberation favors the inclusion of research participants' perspectives in ethical review as well as the ethical review of "public benefits" research.

10.1 Democratic Deliberation Explained

Democratic deliberation involves a public exchange of ideas within and across groups of ordinary citizens, experts, and political representatives. Participants should aim to engage actively with one another, and to offer reasons that are acceptable and intelligible to their interlocutors. Decisions should be revisable as new information and new perspectives come into view (DHHS 2010).

The PCSBI emphasized the deliberative character of its own procedures, in particular when engaging with religious and moral concerns about the synthetic biology innovations it was then evaluating (2010, 139). These examples of public involvement far exceed the current requirement in human subjects research that an Institutional Review Board (IRB) include a nonscientific and a lay member (Fost and Levine 2007).

Incorporating democratic deliberation into decision-making can render the resulting decisions both more respectful and more accurate. First, by involving all parties in the decision-making process, democratic deliberation can ensure that the process's outcomes, whatever they are, express participants' values. Amy Gutmann, the PCSBI's current chair, has argued that even when some lose out in democrative deliberation, the outcome is not *imposed* on them, but instead results from something they *authorized* (Gutmann and Thompson 2004, 21–23). Such authorization can differentiate a just from an unjust outcome, even when the content of the two outcomes is identical.

Other legal and political contexts feature democratic deliberation. For example, recent innovations in restorative justice emphasize deliberative engagement between criminals and victims, which makes it possible for both to see the legal resolution as just (Parkinson and Roche 2004, 510). Within the civil law, deliberative engagement helps ensure that contentious processes—such as divorce proceedings and family disputes—respect both prevailing and defeated participants (Menkel-Meadow 2004, 361).

Deliberation can enhance accuracy as well as respectfulness. Each participant in deliberation brings a distinctive positional perspective; an ordinary citizen may have less technical knowledge than an expert but more knowledge about how people are employing technology (Anderson 2003, 57). A well-structured deliberative body can, ideally, know more than even its most knowledgeable individuals, rather than simply knowing as much as its average participant (Gutmann and Thompson 2004, 12).

10.2 Participatory Inclusion: Involving Research Participants in Ethical Review

As we consider how to revise existing human subjects research regulations, consider that a revised Common Rule might incorporate democratic deliberation by drawing on the experience of research participants themselves when reviewing human subjects research proposals. The current regime charges IRBs with protecting research participants, but assigns no member the task of *representing* research participants. While IRBs must "[safeguard] the rights and welfare of human subjects" (45 CFR 44.107(a) (2011)), they are neither required to engage deliberatively with research participants nor to provide a voice for participants in the ethical review process. The lay member on the IRB is

not required to learn about, or advocate for, research participants' concerns.

In contrast, professional ethics and policy review boards outside research ethics frequently represent the clients, governments, and professionals they regulate or protect (Porter 1987). These boards exemplify the participatory inclusion of laypeople (Johnson 2009; Agarwal 2008). Numerous legal provisions ensure the participatory inclusion of clients on a variety of committees in the health care context, as shown in table 10.1.

10.2.1 Participatory Inclusion as Democratic Deliberation

How do participatory inclusion statutes advance democratic deliberation? Review boards that are not directly democratic (e.g., the National Park Service's board of directors) often are thought of as democratic because a democratically elected official (the US president) appoints an officer (the secretary of the interior) who in turn appoints the board. In contrast, participatory inclusion aims at more direct legitimacy, by mandating that the board reflect the perspectives of a variety of interests.

Does having a representative group member on an advisory board suffice to drive that group toward democratic deliberation? I'll consider three potential objections: (1) that representing research participants on boards doesn't help protect them and can even hurt their interests, (2) that research participants' interests are best served by a notice-and-comment or survey process rather than a representative member on a board, and (3) that democratic deliberation should have no special solicitude for research participants.

Does Participatory Inclusion Protect Participants?

Rand Rosenblatt worries that a participant representative on an advisory board might provide a veneer of approval without substantively influencing the board's decisions (Rosenblatt 1978). Concerns that procedural protections such as rights of voice and representation are inferior to substantive protections have arisen elsewhere in criminal and civil law (Cassell 2011; MacCoun 2005), and in the development of community advisory boards for clinical research (NIAID 2009). This concern would counsel against representing participants on boards and in favor of instead writing strong participant protections into research regulations. Such a suggestion would parallel the more general argument that an advisory committee can deliberate effectively regardless of its composition, and that considering a committee's output is enough to assess its deliberative efficacy (Walters 2012, 681). But for deliberation to be effective,

Table 10.1

Participants included	*Advisory board*	*Jurisdiction*	*Source*
Benefit recipients	*Social Security*	*Federal*	*42 USCA 907a(a)(2)(C)*
Clients (encouraged)	*Adult day care*	*TN*	*Tenn. Code Ann. 71-2-410*
Consumers	*Health care appeals*	*MA*	*Mass. Gen. Laws Ann. 6 166*
Consumers (2)	*Human subjects research*	*NH*	*N.H. Rev. Stat. Ann. 171-A:19-a(V)*
Consumers (2)	*Health care associated infections*	*CT*	*Conn. Gen. Stat. Ann. 19a-490n(b)*
Consumer member of state board of health	*Electronic health information*	*IA*	*Ia. Code. Ann. 135.156(2)(a)*
Current or former users (>=50%)	*In-home supportive services*	*CA*	*Cal. Welf. & Inst. Code 12301.3*
Deaf (>50%)	*Schools for the deaf*	*KY*	*Ky. Rev. Stat. 167.037(2)*
Disabled and advocates (>50%)	*Rehabilitation technology*	*Federal*	*29 USCA 764 (D)(ii)*
Hearing aid users	*Hearing aid fitters' licensure*	*RI*	*R.I. Admin. Code 31-5-3.9.2*
Mentally ill offenders; relatives	*Mentally ill offender task force*	*CO; AZ*	*Colo. Rev. Stat. Ann. 18.1-9.104(1)(c)(XIV)(A-C)*
Professional clients	*Physicians and pharmacists' licensure*	*SD*	*S.D. Stat. Ann. 36-4-2.1, 36-11-4.1*
Recipients; donors; public	*Cord blood stem cell banks*	*IL; MI*	*20 Ill. Comp. Stat. 2310/2310-577(d); Mich. Comp. Laws. Ann. 333.2682(4)*
Representatives of elderly, needy, or underprivileged	*County boards of health*	*GA*	*Ga. Code Ann. 31-3-2(a)(6)*
Sufferers; family	*Mental illness advocacy*	*Federal*	*42 CFR 51.22(b)(2)*
Sufferers; parents and family	*Developmental disability*	*LA*	*La. Rev. Stat. Ann. 28-451.3(D)(2)*
User advocates	*Protection and advocacy service*	*IN*	*Ind. Code 12-28-1-6(a)*

the deliberative body must "represent a personal, educational, and cultural variety of life experiences" (Estlund 1997, 191). Including research participants in deliberation can help to advance this goal.

Despite his initial worries, Rosenblatt ultimately endorses involving participants in the deliberative process, arguing that doing so can both produce empowering outcomes and itself be empowering:

> [I]t is important to remember that the value of consumer participation and agency explanation does not lie solely in the opportunity to secure a different outcome. What Professor Tribe has termed "the right to be heard from, and the right to be told why . . . express the elementary idea that to be a person, rather than a thing, is at least to be consulted about what is done with one." Expressed in political terms, this root concept of human dignity highlights the need for a reconstruction of the democratic process, in which consultation over fundamental human needs is not made meaningless by a labyrinthine bureaucracy. By offering unorganized interests the right to participate in programs for their own benefit, the traditions of structural due process also help to encourage its exercise and thereby help to strengthen democratic capacity. (1978, 264)

In the Medicaid context, Rosenblatt therefore endorses "medical care advisory committees," which "include Medicaid recipients and other consumers (as well as providers) in the policy-making process" by giving them "adequate opportunity for meaningful participation in policy development and program administration" (1978, 264).

Survey Representation versus Personal Representation

Including participants' perspectives might be achievable without including participants directly in ethical review: for instance, participants' perspectives could be solicited via a notice-and-comment process analogous to the requirement that administrative agencies solicit and respond to public comments when they engage in rulemaking (Cuellar 2005, 421). For instance, ethics review committees might be required to survey research participants and consider the results when deciding whether to renew or approve protocols.

Representation via surveys, however, may fail to provide participants sufficient voice. To see why, imagine that instead of adding new senators when admitting a new state, new states were instead represented in the Senate through surveys: whenever a bill is proposed in the Senate, new states would be surveyed and the existing senators would be required to attend to the survey results. The new states might complain that (1) senators will not be held accountable for attending to the survey results and (2) minor decision-making will either require a surfeit of referenda or exclusion of those represented by surveys. Similarly a survey of research

participants might not be taken seriously by a review board and would be unable to anticipate specific issues that arise in ethical review. In contrast, a participant representative would be on equal footing with other board members and well placed to investigate and deliberate about major and minor issues as they arise. Finally, participatory inclusion approaches do not rule out the use of surveys: the representative, for instance, could survey other participants as part of her review process.

Why Represent Research Participants At All?

What is the normative argument for setting aside special seats for participants? After all, IRB-reviewed research is supported by tax revenue, and benefits many individuals in society who do not participate in research, yet there is no movement to represent these beneficiaries on IRBs.

That participatory inclusion requirements are widespread on boards analogous to ethics review bodies, as table 10.1 indicates, already offers intuitive support for the claim that setting aside seats for participants is justified. But discussions of consociational democracy can provide an additional, more theoretically developed basis for including participants in the ethical review of research. Andreas Føllesdal describes a consociational system as follows:

> [C]onsociational democracy . . . . is a non-territorial form of federalism, characterized by cooperation among elites of different segments of a society, often split along religious or ethnic lines. It entails government by grand coalitions, granting autonomy to groups with veto rights over matters important to them. (1998, 202)

Like consociationalism, participant representation constitutes "non-territorial federalism": research participants should be represented in decisions that affect them, even if we do not grant them "veto rights" as the consocialist might (Cuellar 2005, 417). Joshua Cohen and Joel Rogers have similarly suggested that we open up more arenas in democracies for decision-making by bodies of representatives of particular interest groups (1992).

10.2.2 Participatory Inclusion in the Human Subjects Research Context

Many participatory inclusion provisions include clients. Others include people whom institutions evaluate or regulate. Participants are both objects of evaluation and clients: as such, participatory inclusion seems no less appropriate in a research context than in either of the two it melds.

How might research participants' perspectives be better integrated into the ethics review process via participatory inclusion? Laurie Flynn and Ronald Honberg suggest that IRBs reviewing mental health research

should "require the inclusion of individuals who have personally experienced severe mental illnesses as consumers or family members," because "consumers and family members, by virtue of their personal experiences, are more likely to focus on those aspects of research designs which may impact (positively or negatively) on the well-being of vulnerable research subjects" (1999, 188). Flynn and Honberg, however, mandate the inclusion of *patients*, rather than *research subjects*. Although research subjects *resemble* patients, subjects and patients are importantly different: for instance, some subjects are healthy volunteers (Keane 2008, 352), and the common good can justify risks to consenting subjects that could not be justified for ordinary patients (Katz 1993, 17).

Additional regulations on IRB composition along the lines Flynn and Honberg suggest, however, may exacerbate concerns that IRBs are overbureaucratized (Fost and Levine 2007, 2196). Regulations on composition that prevent IRBs from achieving a quorum could produce "substitution effects," such as pressures to strip jurisdiction from IRBs, that vitiate their direct effects.

Concerns about overbureaucratization might counsel permitting and encouraging, but not requiring, that research participants be represented in ethical review. This parallels the approach ultimately taken in staffing the boards of the PPACA's health insurance "exchanges." Public comment suggested that board members should have various specific forms of expertise and background. DHHS responded by requiring that "at least one member of the Exchange's board must include one voting member who is a consumer representative," but stopped short of mandating more specific expertise (77 Fed. Reg. 18,301, 18,310).

Representation by advocates rather than fellow participants is also possible, and might help alleviate overbureaucratization concerns by widening the pool of potential representatives or allowing current nonscientific IRB members to serve as advocates. Some nonscientific or unaffiliated members required by current IRB regulations see their roles as including "[r]epresenting . . . human subjects' interests"; "[r]eviewing the research from the point of view of a potential subject"; "[a]cting as the ally or the peer of the research subject," and "[a]cting as a patient advocate and surrogate subject" (Porter 1997, 2 tbl. 1). Nonvoting observers or advisors who explicitly represent research participants' perspectives might augment the phenomenon Porter identifies: Sirotin et al. suggest that "[p]rofessionals who work extensively with prospective research populations could help articulate those perspectives and should be encouraged to formally explore those perspectives, perhaps through focus

groups and interviews," and that "IRBs might also work with research subject advocates, who work closely with research participants and seek to represent their perspectives" (2010, 15). Advocates might have expertise that makes them better able to protect participants' interests, may not be vulnerable to conflicts of interest, or might have broader expertise in the conduct of research than individual participants might. These arguments could be counterbalanced, however, by symbolic and practical advantages of having the representative come from the group being represented (Minow 1991, 278–79).

Those revising research ethics regulations should consider more explicitly including research participants' perspectives in review (45 CFR 46.107(f)), which provides that the IRB may "invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB," and may already allow the inclusion of participants. The current wording frames the invitees as technical experts, which might seem to exclude participants. But this provision might be understood, or even reworded, to recognize the experiential expertise of research participants—a form of special knowledge that they acquire through experiencing a medical condition and participating in the research enterprise from the participant perspective (Bal, Bijker, and Hendriks 2004, 1340), just as it has been understood to include expert bioethicists (DeRenzo and Wichman 1990, 6). While the current provisions make these experts nonvoting members, the rules could be revised to grant research participant members a voice as voters.

Meanwhile, although 45 CFR 46.111(b) directs the IRB to specially scrutinize the substance of research on vulnerable subjects, it could also justify modifying the review procedure, and thus present an avenue for participant inclusion. Where research proposes to involve vulnerable populations, protecting their interests may counsel democratically including them or their representatives in the deliberations leading up to research approval. The numerous participatory inclusion requirements in statutes regulating mental health, elder care, and disability issues outside of research (reviewed in table 10.1) lend support to such an approach. Indeed IRBs reviewing research on prisoners already are required to include a "prisoner or prisoner representative" under 45 CFR 46.304.

10.3 The Need for Ethical Review of Public Benefits Research

Democratic deliberation also has implications for the exemption of public benefits research—experimental research on the efficacy of

programs like Medicare and Medicaid—from IRB review under 45 CFR 46.101(b)(5). The ANPRM suggests expanding the exemption. But deliberative democratic concerns counsel against such expansions. Public benefit research has the potential to force beneficiaries of public programs like Medicaid—who are often socially and economically vulnerable—into research whose intended aims may be contrary to participants' interests. In contrast, ethical review of public benefits research requires those attempting to revise public benefit programs to get the consent of current beneficiaries, which requires that researchers explain the proposed changes and provide an account of why research is justified.

10.3.1 The Public Benefit Exemption

The history of the public benefit exemption suggests that it was initially understood as a procedural change, rather than an exemption from ethical review entirely. Amici curiae in two appellate cases, *C.K. v. New Jersey Dep't of Health & Human Servs.*, 92 F.3d 171 (3d Cir. 1996), and *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994), argued that the public benefits research exemption displaced public benefits research review from IRB oversight, but not from oversight altogether.

Initially, IRBs reviewed public benefits research just as they reviewed other human subjects research, and this practice was upheld in *Crane v. Matthews,* 417 F. Supp. 532 (ND Ga. 1976). *Crane* prompted the public benefits exemption, which removed public benefits research from IRBs' jurisdiction. However, the Ninth Circuit in *Beno* recognized that public benefit research exempt from IRB review is still subject to "an examination of the proposed project's potential danger to participants' physical, mental and emotional well-being," *Beno*, 30 F.3d at 1070. The Third Circuit agreed, stating that "the 'additional layer of review' from which DHHS exempted public benefits experiments was the regulatory requirement of IRB review, not the statutory requirement of review for danger" (*C.K.*, 92 F.3d at 190).

Some have argued for expanding the exemption beyond research on the benefit levels of federal programs like Medicare and Medicaid, thus exempting a wide swath of research on public benefits. Law professor Elmer Abbo argues that quality-improvement research should be exempt from ethical review (Abbo 2007, 579), as does a Hastings Center working group (Baily et al. 2006, S33). The Secretary's Advisory Committee on Human Research Protections (SACHRP) believes "institutions should be able to apply the exemption to public programs supported by state

agencies" as well as to federal programs (Office for Human Research Protections 2008).

These arguments have been accompanied by some de facto expansion of the exemption. The DHHS secretary has exempted randomized trials on the quality of care among Medicare beneficiaries (Peikes et al. 2009). Research on the allocation rules for transplantable organs (Egan et al. 2006), and on HIV epidemiology in at-risk communities (Merion et al. 2005), has also been exempted. Most strikingly, research on the prevalence of preterm birth and infant death among participants in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) was held exempt. This research involved looking through and analyzing infant death certificates, matching the names on the death certificates to the names of children whose mothers received WIC prenatally, and comparing the death rates of African-American infants and white infants whose mothers were on WIC (Khanani et al. 2010). One can certainly imagine the mothers—had they been asked—refusing permission to have the death certificates coded in this way and matched, as they were, with factors like race and whether the mother smoked tobacco during pregnancy.

10.3.2 Fair Benefits and Public Benefits

Some have already endorsed the ethical review of public benefits research, though without explicitly invoking concerns about democratic deliberation (Harvard Law Review 1995; Rosenbaum 1992, 123–26). Democratic deliberation, I will argue, further favors the ethical review of public benefits research.

Existing advocates have focused on the threat that public benefits research poses to participants' *medical well-being*—that is, the threat that research harms participants. This concern seems to fit into the branch of research ethics that addresses risk–benefit balancing. There is an additional concern, however, that *Beno* and the federal regulations also seem to recognize: the danger that research will use subjects against their will for the benefit of others. This fits more clearly into the branches of research ethics that address informed consent and respect for participants.

In particular, public benefits research potentially stands in tension with the *Belmont Report*'s dictum that research "should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research" (National Commission 1979, 10). This "fair benefits" requirement is echoed in other statements of clinical research ethics, such as CIOMS's requirement that research be "responsive to the

health needs and the priorities of the population or community in which it is to be carried out" (2002). Public benefits research frequently involves taking resources away from poor and disadvantaged beneficiaries to see whether these beneficiaries are able to maintain a tolerable standard of living after losing benefits. Therefore the fair benefits requirement may limit public benefits research on economically disadvantaged subjects, particularly when conducted for the benefit of more advantaged individuals who want to minimize the tax burden of supporting entitlement programs rather than for the benefit of other disadvantaged individuals.

Jan Blustein demonstrates this ethical tension in discussing the ethics of the National Job Corps Study, a program evaluation that would fall under the current public benefits exception (Blustein 2005, 824). The study randomized some Job Corps applicants into a control group that did not get to participate in Job Corps (a program that offers educational and vocational training to young adults between 16 and 24 years of age). The study was ostensibly justified on the basis that "random assignment was necessary because it was the only way to provide Congress and the public with credible evidence about the success of the program" (Burghardt et al. 1997). However, participants complained about being treated as guinea pigs and about the study serving the interests of wealthier individuals, but not their own interests (Blustein 2005, 834). As Blustein suggests:

> Research is prima facie unjust if some groups disproportionately bear the burdens and others reap the benefits. Yet over the past 30 years, evaluations have been conducted almost exclusively on public programs that benefit low-income and vulnerable populations. Middle-class benefits like Medicare, the home mortgage deduction, and the college Work-Study programs have been largely untouched. To the extent that participants in social program evaluations assume risk or miss out on desired services, this disparity would seem to raise questions of justice. (2005, 838)

In a context—that of federal and state entitlement programs—where there is already a "democracy deficit" and where deliberative involvement with current recipients of entitlements is limited, expanding the public benefits research exemption risks allowing research that fails to adequately represent the interests of participants, and so violates the principle of democratic deliberation.

10.4 Conclusion

How would incorporating a democratic deliberation principle change the ethics of human subjects research? I have argued that it would

recommend greater inclusion of participants in the review process, and would counsel against exempting public benefits research from ethical review. This would not give deliberation unlimited scope. Legal institutions, for instance, often are initially constructed through intensive deliberation but later governed by systems of rules that grow out of that initial deliberation (Dryzek 2000, 14). Likewise deliberation might be more important in initial review or the drafting of regulations than in day-to-day enforcement.

Nonetheless, the principle of democratic deliberation supports efforts to make the ethical review of research more publicly accessible. The PCSBI continued to embrace a principle of democratic deliberation in its recent work on human subjects research ethics (2012). The proposals I suggest give this principle content.

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References

Abbo, Elmer D. 2007. Promoting free speech in clinical quality improvement research. *Northwestern University Law Review* 101: 575–92.

Agarwal, Bina. 2008. Toward participatory inclusion: A gender analysis of community forestry in South Asia. In Jorrit de Jong and Gowher Rizvi, eds., *The State of Access*. Washington, DC: Brookings Institution Press, 37–70.

Anderson, Elizabeth. 2003. Sen, ethics, and democracy. *Feminist Economics* 9 (2–3): 239–61.

Baily, Mary Ann, Melissa Bottrell, Joanne Lynn, and Bruce Jennings. 2006. The ethics of using QI methods to improve health care quality and safety. *Hastings Center Report* 36 (4): S1–39.

Bal, Roland, Wiebe Bijker, and Ruud Hendriks. 2004. Democratisation of scientific advice. *British Medical Journal* 29: 1339–41.

Beno v. Shalala, 30 F.3d 1057 (9th Cir. 1994).

Blustein, Jan. 2005. Toward a more public discussion of the ethics of federal social program evaluation. *Journal of Policy Analysis and Management* 24 (4): 824–46.

Burghardt, John, Sheena McConnell, Alicia Meckstroth, and Peter Schochet. 1997. *Implementing Random Assignment: Lessons from the National Job Corps Study*. Princeton: Mathematica Policy Research.

Cassell, Paul G. 2011. Freeing the guilty without protecting the innocent: Some skeptical observations on proposed new "innocence" procedures. *New York Law School Law Review* 56: 1063–96.

C.K. v. New Jersey Dep't of Health & Human Servs., 92 F.3d 171 (3d Cir. 1996).

Cohen, Joshua, and Joel Rogers. 1992. Secondary associations and democratic governance. *Politics and Society* 20 (4): 391–472.

Council for International Organizations of Medical Sciences (CIOMS). 2002. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: WHO.

Crane v. Matthews, 417 F. Supp. 532 (N.D. Ga. 1976).

Cuellar, Mariano-Florentino. 2005. Rethinking regulatory democracy. *Administrative Law Review* 57 (2): 411–500.

Deeds, Bethany Griffin, Marne Castillo, Zephyr Beason, Shayna D. Cunningham, Jonathan M. Ellen, and Ligia Peralta. 2008. An HIV prevention protocol reviewed at 15 national sites: How do ethics committees protect communities? *Journal of Empirical Research on Human Research Ethics* 3 (2): 77–86.

Department of Health and Human Services. Presidential Commission for the Study of Bioethical Issues. 2010. *New Directions: The Ethics of Synthetic Biology and Emerging Technologies*.

Department of Health and Human Services. 2012. *Moral Science: Protecting Participants in Human Subjects Research*. Washington, DC: GPO.

DeRenzo, Evan, and Alison Wichman. 1990. A pilot project: Bioethics consultants as non-voting members of IRBs at the National Institutes of Health. *IRB: Ethics and Human Research* 12: 6–8.

Dryzek, John. 2000. *Deliberative Democracy and Beyond: Liberals, Critics, Contestations*. Oxford: Oxford University Press.

Egan, T. M., S. Murray, R. T. Bustami, et al. 2006. Development of the new lung allocation system in the United States. *American Journal of Transplantation* 6 (5): 1212–27.

Estlund, David. 1997. Beyond fairness and deliberation: The epistemic dimension of democratic authority. In James Bohman and William Rehg, eds., *Deliberative Democracy: Essays on Reason and Politics*. Cambridge: MIT Press, 173–204.

Flynn, Laurie, and Ronald Honberg. 1999. Achieving proper balance in research with decisionally-incapacitated subjects: NAMI's perspectives on the working group's proposal. *Journal of Health Care Law and Policy* 1: 174–92.

Føllesdal, Andreas. 1998. Subsidiarity. *Journal of Political Philosophy* 6 (2): 231–59.

Fost, Norman, and Robert J. Levine. 2007. The dysregulation of human subjects research. *Journal of the American Medical Association* 298 (18): 2196–98.

Gutmann, Amy, and Dennis Thompson. 2004. *Why Deliberative Democracy?* Princeton: Princeton University Press.

Harvard Law Review. 1995. Administrative law—waivers—Ninth Circuit holds statutory waivers for welfare experiments subject to judicial review. — *Beno v. Shalala*, 30 F.3d 1057 (9th Cir. 1994). *Harvard Law Review* 108: 1208–13.

Johnson, Genevieve Fuji. 2009. Deliberative democratic practices in Canada: An analysis of institutional empowerment in three cases. *Canadian Journal of Political Science* 42 (3): 679–703.

Katz, Jay. 1993. Human experimentation and human rights. *Saint Louis University Law Journal* 38: 7–54.

Keane, Moira A. 2008. Institutional review board approaches to the incidental findings problem. *Journal of Law, Medicine and Ethics* 36: 352–55.

Khanani, Intisar, Jon Elam, Rick Hearn, Camille Jones, and Noble Maseru. 2010. The impact of prenatal WIC participation on infant mortality and racial disparities. *American Journal of Public Health* 100 (1): S204–209.

MacCoun, Robert. 2005. Voice, control, and belonging: The double-edged sword of procedural fairness. *Annual Review of Law and Social Science* 1: 171–201.

Menkel-Meadow, Carrie. 2004. The lawyer's role(s) in deliberative democracy. *Nevada Law Journal* 5 (2): 347–69.

Merion, Robert M., Valarie B. Ashby, Robert A. Wolfe, et al. 2005. Deceased-donor characteristics and the survival benefit of kidney transplantation. *Journal of the American Medical Association* 294 (21): 2726–33.

Minow, Martha. 1991. From class actions to Miss Saigon: The concept of representation in the law. *Cleveland State Law Review* 39 (3): 269–300.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. 1979. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. Washington, DC: GPO.

National Institute of Allergy and Infectious Diseases (NIAID). Division of AIDS. 2009. Recommendations for community involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS clinical trials research. http://www.hvtn.org/community/CAB_Recommendations_Certified.pdf.

Office for Human Research Protections. Secretary's Advisory Committee on Human Research Protections. 2008. SACHRP letter to DHHS Secretary. http://www.hhs.gov/ohrp/sachrp/sachrpletter091808.html.

Parkinson, John, and Declan Roche. 2004. Restorative justice: Deliberative democracy in action? *Australian Journal of Political Science* 39 (3): 505–10.

Peikes, Deborah, Arnold Chen, Jennifer Schore, and Randall Brown. 2009. Effects of care coordination on hospitalization, quality of care, and health care expenditures among Medicare beneficiaries: 15 Randomized trials. *Journal of the American Medical Association* 301 (6): 603–18.

Porter, Joan P. 1987. How unaffiliated/nonscientist members of institutional review boards see their roles. *IRB: Ethics and Human Research* 9 (6): 1–6.

Rosenbaum, Sara. 1992. Mothers and children last: The Oregon Medicaid experiment. *American Journal of Law and Medicine* 18 (1–2): 97–126.

Rosenblatt, Rand. 1978. Health care reform and administrative law: A structural approach. *Yale Law Journal* 88 (2): 243–336.

Sirotin, Nicole, Leslie E. Wolf, Lance M. Pollack, Joseph A. Catania, M. Margaret Dolcini, and Bernard Lo. 2010. IRBs and ethically challenging protocols: Views of IRB chairs about useful resources. *IRB: Ethics and Human Research* 32 (5): 10–19.

Veatch, Robert. 2007. How many principles for bioethics? In Richard E. Ashcroft, Angus Dawson, and Heather Draper, eds., *Principles of Health Care Ethics*. London: Wiley, 43–50.

Walters, Daniel. 2012. The justiciability of fair balance under the Federal Advisory Committee Act: Toward a deliberative process approach. *Michigan Law Review* 110: 677–708.