

## ENGAGING RACIAL AND ETHNIC GROUPS IN THE REGULATION OF RESEARCH: LESSONS FROM RESEARCH IN EMERGENCY SETTINGS

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### I. INTRODUCTION

Consider a scenario in which a researcher accesses a large repository of genetic sequences and sets out to look for a gene suspected to predispose carriers to alcoholism. The data has been stripped of all personal identifiers; however, it retains information about participants' racial and ethnic affiliations. After analyzing the sequences, the researcher publishes an article comparing the prevalence of the "alcoholism" gene in "blacks" to "whites." The debate is soon picked up by the media, accompanied by some rather sensationalist headings. African American leaders are disturbed by the publication and worry that the results will lead to hikes in group members' insurance premiums.

The ready availability of gene sequence repositories—set to be increased even further by a policy under development by the National Institutes of Health (NIH)—makes such scenarios evermore commonplace.<sup>1</sup> The NIH policy would impose expansive data-

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\* The author thanks Benjamin Berkman for his guidance in developing this paper. This article was prepared as a component of the author's Doctor of Juridical Science (SJD) at Georgetown University Law Center.

<sup>1</sup> NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., NOT-HG-10-006, NOTICE ON DEVELOPMENT OF DATA SHARING POLICY FOR SEQUENCE AND RELATED GENOMIC DATA

sharing obligations on researchers who generate genomic sequence data with NIH support.<sup>2</sup> Should it follow the policy relating to information generated from genome-wide association studies (GWAS), all personal information will be stripped from the data prior to its inclusion in the database.<sup>3</sup> However, racial and ethnic categorizations of participants—collected almost ubiquitously in population genetic studies—likely will be retained and may be made available to researchers, subject to the approval of a Data Access Committee comprised of “senior Federal employees.”<sup>4</sup> Little imagination is required to predict the potential for conflict with members of minority racial and ethnic groups.

The specter of widespread availability of genetic information linked to socially identifiable groups reinvigorates decades-long debates about the need to protect socially identifiable groups from research-related harms. In this paper, I summarize the arguments that have been put forward to date for instituting such protections, and go on to argue why engaging with minority racial and ethnic groups prior to research commencing will be integral to achieving any such goal. As yet, however, theoretical and practical hurdles have hindered attempts to implement any such requirements for groups other than highly structured indigenous communities. To move beyond this seeming impasse, I look to reported experiences with the community engagement requirements that have been introduced in the context of research in emergency settings (RES). The parallels between community engagement strategies in RES and research involving racial and ethnic groups have not yet been considered in the published literature.

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(Oct. 19, 2009), <http://grants.nih.gov/grants/guide/notice-files/NOT-HG-10-006.html>.

<sup>2</sup> *Id.*

<sup>3</sup> NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., NOT-OD-07-088, POLICY FOR SHARING OF DATA OBTAINED IN NIH SUPPORTED OR CONDUCTED GENOME-WIDE ASSOCIATION STUDIES (GWAS) (Aug. 28, 2007), <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html>.

<sup>4</sup> NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., *Genome-Wide Association Studies (GWAS)*, [http://gwas.nih.gov/04po2\\_1DAC.html](http://gwas.nih.gov/04po2_1DAC.html) (last visited Sept. 5, 2011).

## II. RECOGNIZING THE POTENTIAL FOR RESEARCH TO HARM GROUPS

Policies governing the conduct of research traditionally have focused on protecting individuals.<sup>5</sup> In the U.S., the key framework in this regard is the *Belmont Report*, in which the principles of respect for persons, beneficence and justice form the foundations of the requirements for human subject protection.<sup>6</sup> These principles were highly influential in the formulation of “the Common Rule,” compliance with which is mandated for all medical research involving humans conducted in U.S. public facilities that receive funding from the NIH and certain other federal agencies.<sup>7</sup>

Over the past two decades scholars have criticized the individualistic nature of the Common Rule and most other national and international research ethics guidelines, asserting that certain research projects may harm groups above and beyond any harm they may cause to individual group members.<sup>8</sup> Larry Gostin made an early call for extending research protections to communities, providing the example of the practice of reporting HIV data broken down by race and ethnicity.<sup>9</sup> Since the data is de-identified, it raises no privacy or confidentiality concerns for the individuals affected.<sup>10</sup> However, he noted that “the method of reporting emphasizes the disproportionate impact on African Americans and Hispanics,”

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<sup>5</sup> NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (Apr. 18, 1979), <http://ohsr.od.nih.gov/guidelines/belmont.html>.

<sup>6</sup> *Id.*

<sup>7</sup> 45 C.F.R. § 46.101 (2010); Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,003 (June 18, 1991) (to be codified at 45 C.F.R. pt. 46).

<sup>8</sup> See Neal Dickert & Jeremy Sugarman, *Ethical Goals of Community Consultation in Research*, 95 AM. J. PUB. HEALTH 1123 (2005) (discussing the history of advocacy for protecting groups through research ethics guidelines).

<sup>9</sup> Larry Gostin, *Ethical Principles for the Conduct of Human Subject Research: Population-Based Research and Ethics*, 19 J. L. MED. & HEALTH CARE 191, 197 (1991).

<sup>10</sup> *Id.* at 197.

which potentially impacts on those populations' dignity and self-esteem.<sup>11</sup>

In the years since Gostin's article was published, the risk of research causing harm to groups has featured prominently in public attention:

Havasupai genetic samples: In a story which has now become well known, members of the Native American Havasupai tribe gave DNA samples to university researchers with the aim of finding genetic clues to the tribe's high rate of diabetes.<sup>12</sup> The researchers were unable to ascertain a genetic link to the rate of diabetes; however, they proceeded to use the samples to study matters including mental illness and the tribe's geographical origins.<sup>13</sup> A member of the tribal council was especially upset that the researchers never asked the tribe's permission for the later studies.<sup>14</sup>

Ashkenazi Jewish genetic research: In the late 1990s, leaders of the U.S. Ashkenazi Jewish community raised concerns about the prevalence of research reporting a higher frequency of certain genetic mutations in Ashkenazi Jews than other populations.<sup>15</sup> Community leaders suggested that the research may lead to discrimination against, and stigmatization of, its members.<sup>16</sup>

BiDil: In 2005, the Food and Drug Administration (FDA) approved a heart failure drug, BiDil, for use in self-identified African Americans, making it the first ever racially specific treatment.<sup>17</sup> Although many representatives of the African American community supported the FDA's approval, others raised concerns about its potential to "biologize" social categories of race and detract attention

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<sup>11</sup> *Id.*

<sup>12</sup> Amy Harmon, *Indian Tribe Wins Fight to Limit Research of its DNA*, N.Y. TIMES, Apr. 21, 2010, available at <http://www.nytimes.com/2010/04/22/us/22dna.html>.

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

<sup>15</sup> Sally Lehrman, *Jewish Leaders Seek Genetic Guidelines*, 389 NATURE 322 (1997).

<sup>16</sup> *Id.*

<sup>17</sup> Robert M. Sade, *What's Right (and Wrong) with Racially Stratified Research and Therapies*, 99 J. NAT'L MED. ASS'N 693, 693 (2007).

from the social determinants of health disparities.<sup>18</sup>

While research projects evidently have the potential to harm racial and ethnic groups and group members, most national and international research ethics guidelines do not require institutional review boards (IRBs)—the principal bodies tasked with overseeing the ethical acceptability of research—to assess such harms as a component of ethics review.<sup>19</sup> Indeed, IRBs operate under the specific mandate of considering harms to individual research subjects.<sup>20</sup> A much-discussed option for reform is expanding research ethics guidelines to guard against such harm, for example, through a new “respect for communities” principle.<sup>21</sup> Other arguments include advising IRBs to interpret current ethical guidelines in a manner that accounts for the ways in which research affects communities or to apply a strict scrutiny standard to research that uses race as a biological category.<sup>22</sup> For reasons set out below, engaging racial and ethnic groups in the regulatory process will be integral for any such reforms to be efficacious.

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<sup>18</sup> Dorothy E. Roberts, *Is Race-Based Medicine Good for Us?: African American Approaches to Race, Biomedicine, and Equality*, 36 J. L. MED. & ETHICS 537, 538, 540–41 (2008).

<sup>19</sup> NAT’L INSTS. OF HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS AT THE NATIONAL INSTITUTES OF HEALTH 10–11 (5<sup>th</sup> prtg. 2004), available at <http://ohsr.od.nih.gov/guidelines/GrayBooklet82404.pdf>; Ernest D. Prentice & Bruce G. Gordon, *Institutional Review Board Assessment of Risks and Benefits Associated with Research*, in II ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS L-1, L-4 to L-5 (Nat’l Bioethics Advisory Comm’n, 2001).

<sup>20</sup> See, e.g., NAT’L INSTS. OF HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 19, at 8–9.

<sup>21</sup> Charles Weijer, *Protecting Communities in Research: Philosophical and Pragmatic Challenges*, 8 CAMBRIDGE Q. HEALTHCARE ETHICS 501, 505–06, 510 (1999).

<sup>22</sup> Sandra Crouse Quinn, *Protecting Human Subjects: The Role of Community Advisory Boards*, 94 AM. J. PUB. HEALTH 918, 921 (2004); Roberts, *supra* note 18, at 538; Osagie K. Obasogie, *Beyond Best Practices: Strict Scrutiny as a Regulatory Model for Race-Specific Medicines*, 36 J. L. MED. & ETHICS 491, 494–96 (2008).

### III. COMMUNITY ENGAGEMENT REQUIREMENTS

#### A. Rationale for Engaging Communities in Research Regulation

In recent years, community engagement requirements have received increasing favor across a broad range of science policy—including environmental policy, nanotechnology and other emerging technologies.<sup>23</sup> Community engagement serves a number of goals likely to be relevant to the regulation of research involving racial and ethnic groups.<sup>24</sup> Some of the more salient include: the better identification of benefits and harms that may accrue to groups that are the subject of research; respecting members' relationships with the group; and ensuring the political legitimacy of a research project.<sup>25</sup>

*1. Identifying group harms and benefits:* Typically, IRBs and investigators are not well equipped to identify and accord weight to specific group harms and benefits. Joan McGregor advises, for example, that “[c]ulturally specific risks can seem trivial or not *real* risks to outsiders,” which is well illustrated by one of the professor’s named in the Havasupai lawsuit, who characterized the community’s complaints as “hysterical.”<sup>26</sup> McGregor’s argument is consistent with the claim made by Sara Goering and her colleagues that the institutional framework for research fails “to understand and appreciate the impact . . . [of] a history of discrimination and trauma . . . .”<sup>27</sup> Engaging with groups in the regulation of research that affects them is likely to improve the capacity of researchers and IRBs to understand the specific kinds of risks and benefits that are important to the group and group members, and to tailor studies

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<sup>23</sup> See Gene Rowe & Lynn Frewer, *A Typology of Public Engagement Mechanisms*, 30 SCI. TECH. & HUM. VALUES 251 (2005) (discussing public engagement mechanisms); Renee Kyle & Susan Dodds, *Avoiding Empty Rhetoric: Engaging Publics in Debates about Nanotechnologies*, 15 SCI. & ENG'G ETHICS 81, 83–85 (2009).

<sup>24</sup> Rowe & Frewer, *supra* note 23, at 284.

<sup>25</sup> *Id.* at 283.

<sup>26</sup> Joan L. McGregor, *Population Genomics and Research Ethics with Socially Identifiable Groups*, 35 J. L. MED. ETHICS 356, 364 (2007).

<sup>27</sup> Sara Goering et al., *Transforming Genetic Research Practices with Marginalized Communities: A Case for Responsive Justice*, HASTINGS CTR. REP., Mar.–Apr. 2008, at 44.

accordingly.<sup>28</sup>

2. Respect for relationships: Many individuals care deeply about their group affiliations and accord moral weight to decisions made by a collective body, whether it be a tribal council, religious organization or an extended family. In their pivotal text, *Principles of Biomedical Ethics*, Childress and Beauchamp support the concept of “relational autonomy,” noting that an individual may exercise his or her autonomy by choosing to accept an institution, tradition or community as a means of providing direction.<sup>29</sup> One way to satisfy the principle of respect for persons would be to give weight to these relationships through ethics review.<sup>30</sup> Merely changing principles or regulations may be insufficient to achieve this goal.<sup>31</sup>

3. Ensuring political legitimacy: Community involvement can be an important means of conferring political legitimacy on a project.<sup>32</sup> Echoing the sentiment expressed by John Stuart Mill, seemingly marginal ideas may have truth or partial truth and, even if they are false, an argument will usually be strengthened through the process of having to justify it in the face of dissenting views.<sup>33</sup> The Institute of Medicine has built on this idea, noting that:

Not every group with a position on a particular controversial issue can be equally satisfied by a body’s report, but its recommendations will nevertheless be perceived as authoritative to the extent that all sides have been heard and, ideally, represented in the body’s deliberations. Conversely, groups whose voices have been excluded from the process will tend to view the results as a mere power play and, thus, as lacking legitimacy.<sup>34</sup>

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<sup>28</sup> Lisa Eckenwiler, *Moral Reasoning and the Review of Research Involving Human Subjects*, 11 KENNEDY INST. ETHICS J. 37, 47-50, 52-54 (2001); Daniel Hausman, *Group Risks, Risks to Groups, and Group Engagement in Genetics Research*, 17 KENNEDY INST. ETHICS J. 351, 368 (2007); Dickert & Sugarman, *supra* note 8, at 1125.

<sup>29</sup> TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 60, 61 (5th ed. 2001).

<sup>30</sup> Hausman, *supra* note 28, at 364.

<sup>31</sup> Quinn, *supra* note 22, at 918.

<sup>32</sup> Dickert & Sugarman, *supra* note 8, at 1125.

<sup>33</sup> JOHN STUART MILL, *ON LIBERTY* (Edward Alexander ed., Broadview Press 1999) (1859).

<sup>34</sup> COMM. ON THE SOC. & ETHICAL IMPACTS OF DEVS. IN BIOMEDICINE, INST. OF MED., SOCIETY’S

Political legitimacy has particular importance given the historical injustices perpetrated by the medical research community against some minority groups—most notably, against African Americans in the Tuskegee syphilis study.<sup>35</sup> Despite a generation having passed since termination of the Tuskegee study, research continues to report lingering distrust of medical research in African American communities.<sup>36</sup> A lack of trust also has been reported between research institutions and members of the American Muslim community.<sup>37</sup>

It appears that engaging communities in the regulation of research could improve both the quality and legitimacy of research involving racial and ethnic groups. However, implementing specific community engagement requirements often has proved challenging. Other than the RES example, the most successful implementation of community engagement requirements has been in the context of highly structured indigenous groups. In comparison, policies that have sought to extend blanket protections to groups more generally—such as other racial, ethnic, or disease groups—tend to have languished. The following section of this paper sets out this background before going on to discuss how some commentators have explained this patchy success.

## **B. A Growing International Consensus for Engaging Indigenous Groups**

To date, the greatest success in implementing requirements to engage communities in research has been in the context of indigenous communities, where there is a growing international

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CHOICES: SOCIAL AND ETHICAL DECISION MAKING IN BIOMEDICINE 160 (Ruth Ellen Bulger et al. eds., 1995).

<sup>35</sup> See generally SUSAN REVERBY, EXAMINING TUSKEGEE: THE INFAMOUS SYPHILIS STUDY AND ITS LEGACY (2009) (chronicling the history of the Tuskegee study).

<sup>36</sup> See, e.g., Kumaravel Rajakumar et al., *Racial Differences in Parents' Distrust of Medicine and Research*, 163 ARCHIVES PEDIATRICS & ADOLESCENT MED. 108 (2009).

<sup>37</sup> Khaled Bouri, *Towards Designing Health Education and Communication Campaign for the American Muslim Community about Genetic Medicine and its Impact on Health and Society* (Aug. 29, 2008) (unpublished source).



consensus regarding best-practice policy.<sup>38</sup>

National and international guidelines have been issued requiring researchers to obtain approval from indigenous groups before commencing certain research projects.<sup>39</sup> In Australia, for example, researchers must comply with the National Health and Medical Research Council's "*Values and Ethics: Guidelines for Ethical Conduct and Aboriginal and Torres Strait Islander Health Research*," and, in certain circumstances, must obtain community consent.<sup>40</sup> In 2007, the Canadian Institutes of Health Research published what has been described as "the most comprehensive contribution on this issue to date."<sup>41</sup> Developed in close consultation with Canadian indigenous communities, the guidelines advise that indigenous communities should be given the opportunity to participate in research approval and data interpretation, and to decide how its participation should be acknowledged in reports and publications.<sup>42</sup>

In the U.S., Native Americans have exercised their tribal sovereignty to control research conducted with tribal members.<sup>43</sup> The Navajo Nation was the first tribe to establish its own IRB, claiming extensive powers to review research proposals, review manuscripts before publication, and negotiate study methodologies and research approaches.<sup>44</sup> Notably, in 2002, the Navajo Nation Council passed a moratorium on all genetic and genomic research until it had the

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<sup>38</sup> For a summary of these principles, see, e.g., Bette Jacobs et al., *Bridging the Divide Between Genomic Science and Indigenous Peoples*, 38 J. L. MED. & ETHICS 684, 686-88 (2010).

<sup>39</sup> *Id.* at 686, 687 fig.1.

<sup>40</sup> NAT'L HEALTH & MED. RESEARCH COUNCIL ET. AL, AUSTRALIAN GOV'T, NAT'L STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH 69-71 (2003); see also NAT'L HEALTH & MED. RESEARCH COUNCIL, AUSTRALIAN GOV'T, VALUES AND ETHICS GUIDELINES FOR ETHICAL CONDUCT AND ABORIGINAL AND TORRES STRAIT ISLANDER HEALTH RESEARCH (2003).

<sup>41</sup> Jacobs et al., *supra* note 38, at 686-88.

<sup>42</sup> *Id.* at 688; see also CAN. INSTS. OF HEALTH RESEARCH, NATURAL SCIS. AND ENG'G RESEARCH COUNCIL OF CAN. & SOC. SCIS. AND HUMANITIES RESEARCH COUNCIL OF CAN., TRI-COUNCIL POLICY STATEMENT: ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS, 105 (Dec. 2010) (setting out the relevant research guidelines in chapter 9).

<sup>43</sup> See, e.g., Doug Brugge & Mariam Missaghian, *Protecting the Navajo People Through Tribal Regulation of Research*, 12 SCI. & ENG'G ETHICS 491, 491 (2006).

<sup>44</sup> *Id.* at 491, 499 tb1.1.

opportunity to amend its Human Research Code.<sup>45</sup> Research codes now have been implemented by the Ho-Chunk Nation, the Hopi Tribe, and the Pascua Yaqui Tribe.<sup>46</sup>

As explored below, however, systematic implementation of community engagement requirements in other racial and ethnic group has proved a far greater challenge.

### C. Engaging Non-Indigenous Racial and Ethnic Groups

Although many researchers in recent years have gone to great lengths to engage with the groups that they seek to research—in particular, through community-based participatory research—attempts to incorporate community engagement into formal regulatory requirements often have been unsuccessful.<sup>47</sup>

As early as 1996, a “draft of the [then] new Canadian research guidelines,” the Tri-Council Policy Statement, sought to apply “guidelines for the protection of aboriginal communities in biomedical research to a wide variety of other communities . . .”<sup>48</sup> The effort was quickly curtailed as the incongruities of applying many of the specific protections became apparent.<sup>49</sup> In 1999, the U.S. National Bioethics Advisory Commission recommended that persons conducting research on human biological materials should plan their research so as to minimize harms to groups and “should consult, when appropriate, representatives of the relevant groups regarding

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<sup>45</sup> Jacobs et al., *supra* note 38, at 685. The Navajo Nation Human Research Code is codified at 13 N.N.C. § 3253.

<sup>46</sup> See Native Peoples Technical Assistance Office, Univ. of Ariz., *Tribal Codes/Protocols Pertaining to Research*, NATIVE PEOPLES TECHNICAL ASSISTANCE OFFICE, <http://www.nptao.arizona.edu/research/tribalCodes.cfm> (last visited Apr. 8, 2011).

<sup>47</sup> Community-based participatory research has been described as “a collaborative research approach that is designed to ensure and establish structures for participation by communities affected by the issue being studied, representatives of organizations, and researchers in all aspects of the research process to improve health and well-being through taking action, including social change.” MEERA VISWANATHAN ET AL., *COMMUNITY-BASED PARTICIPATORY RESEARCH: ASSESSING THE EVIDENCE* 1, 3 (2004).

<sup>48</sup> C. Weijer & E.J. Emanuel, *Protecting Communities in Biomedical Research*, 289 SCI. 1142, 1142 (2000).

<sup>49</sup> *Id.*

study design.”<sup>50</sup> This recommendation has not been implemented. One of the few U.S. examples of a broadly applicable policy to take into account group harms comes from the specific context of GWAS.<sup>51</sup> For these, the NIH requires institutions to certify that an IRB or Privacy Board has considered the risks of submitting datasets into the data-sharing repository, including any social stigma that might affect the identifiable groups.<sup>52</sup> However, implementation of this policy has raised some concerns, including its seeming conflict with the Common Rule proscription on IRBs considering possible long-term implications of research.<sup>53</sup>

International research ethics guidelines suggest researchers should engage with communities that may be harmed by projects—particularly when conducting research in developing countries.<sup>54</sup> The extent to which such guidelines apply more broadly—for example, to domestic research involving racial and ethnic groups—is unclear.

Philosophers have criticized as unreflective attempts to expand community engagement requirements developed in the context of indigenous communities. To explain the flaws of extending protections in this way, Daniel Hausman distinguishes between two types of groups, which experience harm differently.<sup>55</sup> First, he considers “structured” groups, which have “definite structures, leadership, causal capacities, and interests that are distinct from and

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<sup>50</sup> NAT’L BIOETHICS ADVISORY COMM’N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 73 (1999).

<sup>51</sup> See NAT’L INSTS. OF HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 3.

<sup>52</sup> *Id.*

<sup>53</sup> See *supra* text accompanying note 8.

<sup>54</sup> See, e.g., COUNCIL FOR INT’L ORGS. OF MED. SCIS., 1991 INTERNATIONAL GUIDELINES FOR ETHICAL REVIEW OF EPIDEMIOLOGICAL STUDIES (1991) (“When investigators work with communities, they will consider communal rights and protection as they would individual rights and protection.”) The guidelines go on to note that “[r]epresentatives of a community or group may sometimes be in a position to participate in designing the study and in its ethical assessment.” *Id.*; see also UNITED NATIONS EDUC., SCIENTIFIC, & CULTURAL ORG., UNIVERSAL DECLARATION ON BIOETHICS AND HUMAN RIGHTS, in RECORDS OF THE GENERAL CONFERENCE: RESOLUTIONS 74, 74-80 (2005), available at <http://unesdoc.unesco.org/images/0014/001428/142825e.pdf>.

<sup>55</sup> Daniel Hausman, *Protecting Groups from Genetic Research*, 22 *BIOETHICS* 157, 159 (2008).

not reducible to the interests of their members.”<sup>56</sup> This would include, for example, most indigenous groups.<sup>57</sup> Because the group’s interests are distinguishable from those of its members, research harms may include changing the beliefs and actions of group members—for example, as may occur through publication of research that challenges traditional narratives regarding group origins.<sup>58</sup> In comparison, *unstructured groups* have no identity beyond that of their members.<sup>59</sup> Harms suffered by individuals due to their group membership typically arise by changing the beliefs and, accordingly, the actions of non-group members—for example, stereotyping.<sup>60</sup> Hausman provides African Americans and Ashkenazi Jews as examples of unstructured groups.<sup>61</sup> Other authors have formulated similar distinctions, albeit on the basis of somewhat different reasoning.<sup>62</sup>

Evidently, therefore, a philosophical and practical disconnect exists between models for engaging structured as compared with unstructured community groups. Accordingly, if policy makers are to require engagement of the broad spectrum of racial and ethnic groups that might incur research harms, successful implementation demands looking beyond the indigenous context. As yet, however, the only clear U.S. analogue from which comparisons may be drawn is the community consultation and public disclosure requirements for obtaining a waiver of consent for RES. The following section of this paper summarizes researcher experiences with implementing these requirements, before extrapolating possible lessons for community engagement requirements in the context of racial and ethnic groups.

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<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.* at 159–60.

<sup>59</sup> *Id.* at 159.

<sup>60</sup> *Id.* at 161.

<sup>61</sup> *Id.* at 159 & n.5.

<sup>62</sup> See, e.g., Weijer & Emanuel, *supra* note 48.

#### IV. WAIVER OF CONSENT FOR RESEARCH IN EMERGENCY SETTINGS

##### A. Background

Pursuant to 21 CFR § 50.24, researchers may seek a waiver of the requirement to obtain the informed consent of study participants for certain research conducted in emergency settings (RES).<sup>63</sup> Most relevantly for the purpose of this paper, before approving a waiver of consent in emergency settings, an IRB must find and document additional protections of the rights and welfare of subjects, including, at a minimum, *community consultation* and *public disclosure*.<sup>64</sup>

In its guidance on these waiver requirements, the FDA explains that community consultation “means providing the opportunity for discussions with, and soliciting opinions from, the community in which the study will take place and the community from which the study subjects will be drawn.”<sup>65</sup> Before deciding whether to approve a research proposal, an IRB must consider such discussions and “assess the adequacy of the consultation process.”<sup>66</sup> In comparison, public disclosure is described as a one-way transfer of information to potentially affected communities, including sufficient information to allow communities to be aware of the plans for the research, and its risks and expected benefits.<sup>67</sup> Public disclosure also requires researchers to report study results to the community within a

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<sup>63</sup> This provision applies to all research regulated by the Food and Drug Administration (FDA). Similar requirements may apply to non-FDA regulated research based on a waiver of applicability of sections of the DHHS regulations at 45 C.F.R. pt. 46; DEP’T OF HEALTH & HUMAN SERVS., OPRR REPORTS: INFORMED CONSENT REQUIREMENTS IN EMERGENCY RESEARCH (Oct. 31, 1996), <http://www.hhs.gov/ohrp/policy/hsdc97-01.html>.

<sup>64</sup> *Id.*

<sup>65</sup> FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS, CLINICAL INVESTIGATORS, AND SPONSORS EXCEPTION FROM INFORMED CONSENT REQUIREMENTS FOR EMERGENCY RESEARCH at 25(March 2011), *available at* <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM249673.pdf>.

<sup>66</sup> *Id.* at 32.

<sup>67</sup> *Id.* at 35.

reasonable period of time after completion of the investigation.<sup>68</sup> The sponsor must also submit to the FDA information made publicly available pursuant to these provisions, which the FDA then publishes on its electronic docket system.<sup>69</sup>

## B. Implementation Experience

Investigators have identified community consultation as the most difficult aspect of initiating research under the waiver of consent provisions for RES.<sup>70</sup> IRB members also have expressed discomfort with reviewing these requirements.<sup>71</sup> As Johns Hopkins bioethicists Neal Dickert and Jeremy Sugarman summarize:

It can be difficult to identify, educate, and recruit relevant stakeholders for consultations, and little is known about how to involve them properly in decision making or how to weigh differing levels of approval or dissent. . . . Several studies apparently have not been conducted because of the perceived financial, temporal, and logistical burdens of compliance with the community consultation requirement. . . . Furthermore, some of the most important populations to involve may be groups of potential participants who are marginalized, disenfranchised, and poorly represented; yet these populations may be the most difficult to reach and involve.<sup>72</sup>

The PolyHeme study illustrates the many practical, ethical, and political challenges of conducting community consultations in accordance with the waiver of consent for RES.<sup>73</sup> This study formed part of a longstanding search for an effective and efficient blood substitute to resuscitate trauma patients.<sup>74</sup> Phase III trials of the proposed substitute (PolyHeme) were approved for trauma centers

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<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at 38.

<sup>70</sup> Katie B. McClure et al., *A Qualitative Study of Institutional Review Board Members' Experience Reviewing Research Proposals Using Emergency Exception from Informed Consent*, 33 J. MED. ETHICS 289, 291 (2007).

<sup>71</sup> *Id.*

<sup>72</sup> Neal W. Dickert & Jeremy Sugarman, *Getting the Ethics Right Regarding Research in the Emergency Setting: Lessons from the PolyHeme Study*, 17 KENNEDY INST. ETHICS J. 153, 160 (2007) (internal citations omitted).

<sup>73</sup> See generally *id.*

<sup>74</sup> *Id.* at 155.

across the United States.<sup>75</sup> Pursuant to the waiver of consent requirements, the study sponsor organized a range of community consultation activities, including four information sessions, a slot on a Rotary Club's meeting agenda, two sessions at a shopping mall and one at a 4th of July baseball game.<sup>76</sup> These incurred significant expense, including personnel time, travel expenses, food, venue rental, printing and postage, media placements, website design and administration, transcription and translation services.<sup>77</sup>

Despite these efforts, the study generated strong public outcry – not the least because of perceived shortfalls in community consultation.<sup>78</sup> Critics raised particular concerns about insufficient consultation with the region's African American community: reportedly, researchers asked to speak to the congregations of two black churches in Durham, North Carolina, but the request was refused.<sup>79</sup> This lack of engagement was especially unfortunate given the particular sensitivity of the PolyHeme study for many African Americans founded on historical denials of admission and treatment of African Americans to hospitals, including racially founded denials of blood transfusions.<sup>80</sup>

Other RES studies also have reported a poor correlation between the expense of community consultation and public disclosure activities and gains in community buy-in to the study.<sup>81</sup>

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<sup>75</sup> Northfield Labs., Inc., *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research*, Document No. EC62, at 1 (Nov. 22, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC62-Attach-1.pdf>.

<sup>76</sup> Karla F.C. Holloway, *Accidental Communities: Race, Emergency Medicine, and the Problem of Polyheme*, 6 AM. J. BIOETHICS 7, 14 (2006).

<sup>77</sup> Northfield Labs., Inc., *supra* note 75, at 2.

<sup>78</sup> Significant concerns also were raised about the protocol design. Holloway, *supra* note 76, at 14–15.

<sup>79</sup> *Id.* at 14.

<sup>80</sup> *See id.* at 15.

<sup>81</sup> *See* Jill M. Baren & Michelle H. Biros, *The Research on Community Consultation: An Annotated Bibliography*, 14 ACAD. EMERGENCY MED. 346, 348 (2007).

### **C. Policy Proposals in the Context of Research in Emergency Settings**

Ongoing concerns about the community consultation and public disclosure requirements for RES were foregrounded in October 2006 when the FDA conducted a public hearing on its draft guidance statement on research into the treatment of life-threatening emergency conditions—a policy document drafted to clarify ongoing uncertainties about the manner in which researchers and sponsors could meet the waiver of consent requirements. Ambiguities include, for example, which communities researchers needed to consult, who counts as a community representative, how much consultation is “enough,” and the purpose served by consultation.<sup>82</sup>

In submissions to the FDA and related publications, researchers suggested a number of ways in which implementation of the community consultation and public disclosure requirements could be improved. In large part, these can be characterized as follows: (1) basing the requisite level of community consultation on study risks; (2) providing greater expertise to IRBs and other review bodies; and (3) expanding the public availability of information about ongoing studies and the community consultation and public disclosure strategies that researchers employed. As explored in detail later in this paper, each of these proposals has relevance to potential future community engagement requirements in the context of research targeting racial and ethnic groups.

#### ***1. Basing Community Engagement Requirements on Study Risks***

Under the original requirements, every study that sought a waiver of informed consent under the RES provisions had to satisfy common standards for community consultation and public disclosure. Many researchers advocated amending the requirements

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<sup>82</sup> See, e.g., American College of Emergency Physicians, *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research*, Document No. C5, at 1 (Sept. 20, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06d-0331-c000005-vol2.pdf>.



to base the required level of community consultation and public disclosure on the incremental risks associated with study interventions<sup>83</sup>—an approach that since has been incorporated into FDA’s non-binding guidance on the waiver.<sup>84</sup> The American Heart Association Emergency Cardiovascular Care Committee proposed, for example, that in the case of low-incremental-risk studies, review or feedback from an appropriate committee or representative group could constitute adequate community consultation.<sup>85</sup> In comparison, it suggested that high-incremental-risk studies may warrant consultation strategies such as public forums, telephone hotlines, and other means of soliciting feedback.<sup>86</sup> Paul Pepe has advocated a similar approach, suggesting that widespread community consultation is likely to be unwarranted for RES studies that seek to compare two well-accepted, longstanding standards of care. However, it should be undertaken if a study seeks to assess a relatively new device.<sup>87</sup>

Associated with linking the requisite level of community engagement to study risks is the need for clarity about the types of risks that community consultation is designed to avert. Relevantly, in their joint submission to the FDA public hearing, Robert Silbergleit, on behalf of the NIH/National Institute of Neurological Diseases and Stroke Neurological Emergencies Treatment Trials Investigators, advised against using community consultation as an opportunity to

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<sup>83</sup> See, e.g., NIH/NHLBI Resuscitation Outcomes Consortium, *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research*, Document No. EC24, at 3 (Sept. 19, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC24-Attach-1.pdf>.

<sup>84</sup> See FOOD & DRUG ADMIN., U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 65, at 7–8.

<sup>85</sup> Henry Halperin et al., *Recommendations for Implementation of Community Consultation and Public Disclosure Under the Food and Drug Administration’s “Exception From Informed Consent Requirements for Emergency Research”*: A Special Report From the American Heart Association Emergency Cardiovascular Care Committee and Council on Cardiopulmonary, Perioperative and Critical Care: Endorsed by the American College of Emergency Physicians and the Society for Academic Emergency Medicine, 116 CIRCULATION 1855, 1859 (2007).

<sup>86</sup> *Id.* at 1860 & tbl.3.

<sup>87</sup> Paul E. Pepe, *Food and Drug Administration Public Hearing on the Conduct of Emergency Clinical Research: Testimony of Dr. Pepe—Defending the Rights of All Individuals to Have Access to Potential Life-saving Therapies and Resuscitation Studies*, 14 ACAD. EMERGENCY MEDICINE e51 (2007).

gather “any and all” feedback.<sup>88</sup> Rather, consultation should be directed toward highlighting community narratives of which the investigators are unaware or to which they have attached insufficient weight.<sup>89</sup> The joint submission noted that this kind of information is difficult for investigators and regulators to obtain by means other than consultation.<sup>90</sup>

## 2. *Providing Expertise to IRBs and Other Review Bodies*

Researchers have given considerable attention to the need to assist IRBs tasked with reviewing community engagement requirements,<sup>91</sup> including through the creation of a national panel of experts tasked with reviewing some or all such proposals and advising local IRBs on their acceptability.<sup>92</sup> In his submission to the FDA public hearing, for example, Robert Nelson suggested that studies that seek an exemption from informed consent could be discussed before an FDA Advisory Committee or an NIH Council, which should also consider the appropriate processes for community consultations.<sup>93</sup> He suggested that such a process would promote a

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<sup>88</sup> Robert Silbergleit, *Response to Food and Drug Administration Draft Guidance Statement on Research into the Treatment of Life-threatening Emergency Conditions Using Exception from Informed Consent: Testimony of the Neurological Emergencies Treatment Trials*, 14 ACAD. EMERGENCY MED. e63, e64–e65 (2007).

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> See, e.g., Jeffrey L. Saver, *Food and Drug Administration Public Hearing on the Conduct of Emergency Clinical Research: Testimony of the American Stroke Association*, 14 ACAD. EMERGENCY MED. e57, e57 (2007).

<sup>92</sup> See, e.g., Public Responsibility in Medicine and Research, *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research*, Document No. EC71, at 2–3 (Nov. 27, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC71-Attach-1.pdf>; see Myron Weisfeldt, *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research*, Document No. C2 (Sept. 14, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06d-0331-c000002-01-vol1.pdf>; see also, NIH/NHLBI Resuscitation Outcomes Consortium, *supra* note 83, at 2 (considering that not all proposals should have to be reviewed by a central IRB because of the potential for undue delay).

<sup>93</sup> Robert M. Nelson, *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency*

public tradition of the regulations' interpretation and application.<sup>94</sup> Martha Farmer, a medical ethicist who also submitted to the FDA hearing, proposed the establishment of an independent central IRB with members who are knowledgeable in the emergency research provisions.<sup>95</sup> Farmer argued that this central board's deliberations might be a more valid strategy for seeking input than community consultation with individuals who have no vested interest in the trial.<sup>96</sup>

In its 2011 guidance document on the exception from informed consent requirements for RES, the FDA expressly recognizes the potential for IRBs to expand their memberships by adding members who are "representative of the community," or to use community members as consultants to the IRB.<sup>97</sup>

### 3. Making Information Publicly Available

As noted above, sponsors relying on the waiver of consent provisions must provide the FDA with information released pursuant to the public disclosure requirement.<sup>98</sup> There is no equivalent requirement to submit information about community consultation, nor is the FDA under an obligation to disseminate the information it receives pursuant to this requirement to researchers or the broader public.<sup>99</sup> Researchers have supported more extensive dissemination of such information.

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Research, Document No. EC26 (Sept. 19, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC26-Attach-1.pdf>.

<sup>94</sup> *Id.*

<sup>95</sup> Martha Farmer, *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research*, Document No. EC60, at 2 (Nov. 21, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/1.htm>.

<sup>96</sup> *Id.* at 7; see also Silbergleit, *supra* note 88, at e65 (advising that "[c]entralized review of the key provisions of a proposed trial by a board capable of developing and maintaining" the relevant expertise would improve the quality of review).

<sup>97</sup> FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 65, at 19.

<sup>98</sup> See *id.* at 4-5.

<sup>99</sup> Baren & Biros, *supra* note 81, at 349.

Jill Baren and Michelle Biros, for example, recommend that all community consultation activities should be included in the FDA docket, and the methodologies used by researchers for such consultations be made available on the national clinical trials register.<sup>100</sup> Several submissions to the FDA public hearing also suggested publicly disseminating the issues that IRBs raised when reviewing the adequacy of community consultation strategies.<sup>101</sup>

Justifications for increasing the amount of publicly available information are twofold. First, interested members of the community should have easy access to information about research that may affect them directly or indirectly. In his submission to the FDA public hearing, for example, Dutton expressed the view that—while community consultation often does not reach the necessary target audience—interested persons should have an easy means to learn more.<sup>102</sup> Secondly, building up a body of precedent could promote better and more transparent decision making by researchers and IRBs.<sup>103</sup>

## V. TRANSLATING RESEARCH IN EMERGENCY SETTINGS TO RACIAL AND ETHNIC GROUPS

This brings us to the pivotal question for this paper: what, if any, broader lessons can we draw from the experience of community consultation and public disclosure requirements in the RES setting? The final part of this paper considers the extent to which the reforms researchers and others have suggested for RES can be applied to research that targets racial and ethnic groups—namely: (1) ensuring proportionality between community engagement requirements and

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<sup>100</sup> *Id.* at 352.

<sup>101</sup> *See, e.g.,* American College of Emergency Physicians, *supra* note 82, at 2; Northfield Laboratories Inc., *supra* note 75, at 4–5.

<sup>102</sup> Richard Dutton, R. Adams Cowley Shock Trauma Center, *Docket No. 2006D-0331: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research*, Document No. EC5 (Sept. 8, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC5.htm>; *see also* Nelson, *supra* note 93.

<sup>103</sup> *See* Nelson, *supra* note 93.

study risks; (2) building relevant expertise among those responsible for regulating research; and (3) increasing the amount of publicly available information about research involving relevant groups. I argue that these strategies are important for the development of constructive and cost-effective policies to engage racial and ethnic groups in research regulation.

However, there are several limitations to what this study can achieve. First, and perhaps most importantly, it does not provide policy makers with a complete framework for implementing community engagement requirements. Significant practical and conceptual difficulties remain as regards, for example, how researchers should deal with negative feedback (i.e., the line between community consultation and community consent) and potential intra-community disagreements. These issues warrant ongoing consideration by philosophers, researchers, community advocates, and others.

Secondly, the rationale for engaging communities in the context of RES differs in some respects from that of research involving racial and ethnic groups. The reason for engaging racial and ethnic groups in research regulation often relates to the need to protect the group, or persons who identify with the group, from harms that result from individual group member participation.<sup>104</sup> In the context of a study on breast cancer predisposition genes in Ashkenazi Jews, for example, individual participants may benefit from information the study obtains about their relative risk of developing cancer.<sup>105</sup> However—should the broader public correlate the study's very existence with increased cancer susceptibility among Ashkenazi Jews generally—other group members may face harms such as stigmatization.<sup>106</sup> In comparison, waiving the requirement for informed consent in RES only poses risks and benefits to those individuals who are recruited into the study: there is no need to balance benefits to individuals against harms to other group

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<sup>104</sup> See, e.g., Dickert, *supra* note 8, at 1125.

<sup>105</sup> See Wadman, *supra* note 71, at 851; see also Kelly-Anne Phillips et al., *Perceptions of Ashkenazi Jewish Breast Cancer Patients on Genetic Testing for Mutations in BRCA1 and BRCA2*. 57 *CLINICAL GENETICS* 376, 379 (2000).

<sup>106</sup> See Lehrman, *supra* note 15, at 322.

members. Another point of difference arises as regards community consultation's potential justification as a strategy for guarding against the recruitment of unwilling research subjects in RES—that is, as a form of “consent by proxy.”<sup>107</sup> No such argument applies in the context of engaging racial and ethnic groups, research on whom will still demand individual informed consent.

On the other hand, however, there are considerable similarities underlying the rationales for community engagement requirements in these two contexts. These include the use of cultural narratives to maximize the benefit and minimize the harm to participants, and the need to promote a study's political legitimacy.<sup>108</sup> There also is a close correlation between policy proposals advocated for RES and theoretical models put forward for research targeting racial and ethnic groups. These similarities will be explored further below.

#### **A. Basing Community Engagement Requirements on Study Risks**

One of the clearest issues to emerge in RES is the high cost of community engagement. Several researchers have drawn links between the financial, time, and other costs of undertaking community engagement and a paucity of research into particular conditions.<sup>109</sup> These disincentives are a cause for concern as regards research that targets racial and ethnic groups. Geneticists continue to lament the under-representation of non-Caucasian—in particular, African—populations in most genetic research.<sup>110</sup> If and when

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<sup>107</sup> This appears to underlie the criticism of the PolyHeme study that Iowa Senator Charles Grassley communicated to the Secretary of the Department of Health and Human Services. Neal W. Dickert & Jeremy Sugarman, *Getting the Ethics Right Regarding Research in the Emergency Setting: Lessons from the PolyHeme Study*, 17 KENNEDY INST. OF ETHICS J. 153, 153–54 (2007) (reportedly condemning the study for “mak[ing] the inhabitants of 32 communities in 18 states, and anyone living or traveling [sic] near these communities, potential ‘guinea pigs’ without their consent and, absent consent, without full awareness of the risks and benefits of the blood substitute.”).

<sup>108</sup> See *infra* pp. 28–30.

<sup>109</sup> See generally Giorgio Sirugo et al., *Genetic Studies of African Populations: An Overview on Disease Susceptibility and Response to Vaccines and Therapeutics*, 123 HUM. GENETICS 557 (2008).

<sup>110</sup> See, e.g., *id.* at 583; Sarah K. Tate & David B. Goldstein, *Will Tomorrow's Medicines Work for Everyone?*, 36 NATURE GENETICS S34, S34 (Supp. 2004).

genetics become relevant to the diagnosis and treatment of common disease, incomplete information about genetic traits in certain populations may preclude them from sharing in the advances in health outcomes.<sup>111</sup> Accordingly, there is a strong argument for limiting the scope of research to which the community engagement requirements apply.

As noted above, in RES, the main strategy that has been advocated to limit the burden of community engagement requirements is to apply them only to studies that exceed a certain risk threshold.<sup>112</sup> For RES, risk typically relates to the *physical* risks manifest in the research protocol—for example, the extent of previous experience with investigational treatments. However, very different risks of harm apply in the context of much research that targets racial and ethnic groups, such as population genetic research, which involves less tangible risks. This raises questions about the practicalities of implementing a risk threshold in such research.

The challenge of implementing a generally applicable risk threshold is most acute in the context of structured (typically indigenous) groups: those groups that are capable of suffering harm independently to any harm suffered by group members.<sup>113</sup> Such harms include disrupting (harms that result from the research process regardless of its findings) and undermining (harms that result from research findings, for example, refuting group beliefs concerning the group's origins).<sup>114</sup> Specialized knowledge is needed to identify the likelihood and seriousness of both of these types of harm.<sup>115</sup> This suggests the need for persons knowledgeable about the particular community—typically community members themselves—to perform any threshold risk calculus.<sup>116</sup>

In many ways, this reflects the position many indigenous groups have adopted already. For example, in New South Wales, Australia,

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<sup>111</sup> Tate, *supra* note 110, at S34.

<sup>112</sup> Halperin et al., *supra* note 85, at 1858.

<sup>113</sup> See Hausman, *supra* note 55, at 159; Hausman, *supra* note 28, at 363, 367.

<sup>114</sup> Hausman, *supra* note 55, at 160.

<sup>115</sup> See Hausman, *supra* note 55, at 161, 165; Hausman, *supra* note 28, at 364–65.

<sup>116</sup> See *id.* at 363–65.

policy guidelines require research projects to be approved by a specially constituted Aboriginal research ethics committee if any of the following apply: the research explicitly focuses on the experience of Aboriginal people; data collection is explicitly directed at Aboriginal peoples; the results will examine Aboriginal peoples as a group; or the information has an impact on one or more Aboriginal communities.<sup>117</sup> Community advisory boards established by some Native American communities take a similarly broad approach to the research projects that are subject to review.<sup>118</sup>

In comparison, harms relevant to unstructured groups—which cannot independently suffer harm—accrue to individuals by virtue of their group membership. Key research-related risks are stigmatization (when individuals suffer harm because of other group members' participation in research, regardless of its findings) and stereotyping (when group members are harmed by research findings—for example, because of an increase in insurance premiums for group members).<sup>119</sup> Because stigmatization and stereotyping harm group members by affecting the beliefs and actions of non-group members, identification of such risks does not require specialized knowledge.<sup>120</sup> Accordingly, development of generally applicable policies specifying the riskiness of particular types of studies should be possible. In the context of pharmacogenetic research, for example, Weijer and Miller have suggested that the “potential for significant impact”—and, accordingly, the need for community engagement—arises when study subjects are enrolled

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<sup>117</sup> Aboriginal Health & Med. Research Council of N.S.W., AH&MRC Guidelines for Research into Aboriginal Health at 6 (Sept. 24, 2011), [http://www.ahmrc.org.au/index.php?option=com\\_docman&task=cat\\_view&gid=22&Itemid=45](http://www.ahmrc.org.au/index.php?option=com_docman&task=cat_view&gid=22&Itemid=45). Similar requirements apply in other Australian states and territories. *See, e.g.*, DEP'T OF HEALTH, GOV'T OF W. AUSTRALIA, WESTERN AUSTRALIAN ABORIGINAL HEALTH INFORMATION AND ETHICS COMMITTEE (WAAHIEC) GUIDELINES: ETHICAL CONSIDERATIONS FOR HEALTH-RELATED RESEARCH INVOLVING ABORIGINAL PEOPLE at 1, [http://www.aboriginal.health.wa.gov.au/docs/WAAHIEC\\_Guidelines.pdf](http://www.aboriginal.health.wa.gov.au/docs/WAAHIEC_Guidelines.pdf) (last visited Nov. 11, 2011).

<sup>118</sup> *See* Native Peoples Technical Assistance Office, Univ. of Ariz., *supra* note 46, at 2 (providing access to pertinent tribal research codes).

<sup>119</sup> Hausman, *supra* note 55, at 160.

<sup>120</sup> *Id.* at 161.



because of their membership in a racial or ethnic group and the study results may have “direct and immediate impact” on the group’s interests.<sup>121</sup> In comparison, they consider the risk of harm from research that uses racial and ethnic variation as a secondary research objective to be too peripheral to justify a consultation requirement.<sup>122</sup> At least theoretically, policies of this ilk could be formulated for other kinds of research involving racial and ethnic groups.

Developing and applying any such policies would require considerable cultural sensitivity. To satisfy the requirements of respect for persons and political legitimacy, communities must “buy in” to the risk thresholds and the manner in which they are applied. Accordingly, any policies that require the application of risk thresholds for community engagement should be developed through an extensive consultation process. Moreover, to apply the risk thresholds, IRBs must have the capacity to recognize and weigh the risk of community harms. Building such capacity is the focus of the following section of this paper.

## **B. Expanding the Expertise of IRBs**

The capacity of IRBs to assess the adequacy of community engagement strategies often has been raised as a concern in the context of RES.<sup>123</sup> During the FDA public hearing, for example, researchers advised that IRBs’ lack of confidence with interpreting the waiver was leading to undue delays and an inconsistent application of the rules.<sup>124</sup> These concerns are equally pertinent in the context of research targeting racial and ethnic groups.<sup>125</sup> This raises

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<sup>121</sup> Charles Weijer & Paul B. Miller, *Protecting Communities in Pharmacogenetic and Pharmacogenomic Research*, 4 PHARMACOGENOMICS J. 9, 14 (2004).

<sup>122</sup> *Id.*

<sup>123</sup> See, e.g., Martha C. Farmer, *Docket No. 2006D-0331: Conduct of Emergency Clinical Research; Public Hearing*, Document No. EC60 1, 11-12 (Nov. 21, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC60-Attach-1.pdf>.

<sup>124</sup> FOOD & DRUG ADMIN., *Public Hearing on Emergency Research and Human Subject Protections, Challenges and Solutions* (Oct. 11, 2006), <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06d-0331-tr00001-vol4.pdf>.

<sup>125</sup> See generally Daniel Hausman, *Third-Party Risks in Research: Should IRBs Address Them?*, 29 IRB: ETHICS & HUM. RES. 1 (2007) (discussing drawbacks of broadening the scope of IRB protection to include third parties).

the question of how, if at all, community engagement strategies can be incorporated within the framework for the regulation of research. Options include establishing new IRBs with specific expertise in group harms, expanding the membership requirements of all IRBs to increase the likelihood of such risks being recognized, or setting up a federal panel of experts on group harms to which IRBs would have access. These options are considered below.

### **1. Group-Specific IRBs**

The most radical option for ensuring the competence of reviewing IRBs would be to create new boards with specific expertise, which would review research protocols in lieu of, or in addition to, local IRBs. Several such boards already have been established to review proposed research involving Native American tribes and other indigenous populations. Many community groups also have established independently processes for reviewing research projects, including for projects involving minority racial and ethnic groups.<sup>126</sup> However, a requirement for review by a group-specific IRB has significant drawbacks. In particular—to the extent that the review operates in addition to, rather than instead of, local IRB review—it may add considerable administrative burden.

Any such board's legitimacy also depends on the degree to which it is representative, and perceived to be representative, of group members' views. In the Australian context, for example, Christine Adams has raised concerns that "protocols are inclined to oversimplify the nature of power relationships, representing 'the community' as a socially cohesive group of Indigenous people and homogenising intra-community power relations and interests."<sup>127</sup> Presumably, this would present an even greater concern should specialist IRBs be established for racial and ethnic groups with even more dispersed values. Consider, for example, the challenges of constituting an IRB that sought to represent the diverse interests of

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<sup>126</sup> Nancy Shore et al., *Understanding Community-Based Processes for Research Ethics Review: A National Study*, 101 AM. J. PUB. HEALTH S359, S359 (Supp. 2010), available at <http://ajph.aphapublications.org/doi/pdf/10.2105/AJPH.2010.194340>.

<sup>127</sup> Christine Adams, *Ethics, Power and Politics in Aboriginal Health Research*, 3 ASIA PAC. J. ANTHROPOLOGY 44, 44 (2002).

African American Muslims, Arabic Muslims and others in the American Muslim community.

For these reasons, requirements for research to be approved by group-specific IRBs are likely to be desirable only for highly cohesive communities. Notably, these are the same groups for which assessment of research risks typically warrants specialized knowledge, heightening the potential benefits of specific review mechanisms. While researchers may decide to foster closer partnerships with other racial and ethnic groups, including through the establishment of community advisory boards, this should not be legally mandated. However, considering the growing prominence of research protocols that expressly consider racial and ethnic groups, other strategies will be needed to ensure that risks and benefits to community members are considered adequately prior to research commencing. Two of these are considered below: namely, expanding the core membership requirements for IRBs and establishing a panel of experts.

## *2. Expanding IRB Membership Requirements*

Pursuant to the Common Rule, IRBs must be “sufficiently qualified through the experience and expertise of [their] members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for [their] advice and counsel in safeguarding the rights and welfare of human subjects.”<sup>128</sup> The primary concerns are that at least one member must be in a nonscientific discipline and at least one member must not be “otherwise affiliated with the institution.”<sup>129</sup> Finally, IRBs that commonly review research involving vulnerable subjects must consider inclusion of persons who are “knowledgeable about and experienced in working with [them].”<sup>130</sup>

Many nonscientific and nonaffiliated IRB members have characterized their role as representing or giving a voice to the

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<sup>128</sup> 45 C.F.R. § 46.107(a) (2010).

<sup>129</sup> *Id.* at § 46.107(c)-(d).

<sup>130</sup> *Id.* at § 46.107(a).

community of human subjects.<sup>131</sup> Feasibly, this could extend to representing the groups from which the human subjects are drawn.<sup>132</sup> Relying on nonaffiliated and nonscientific members in this way, however, has certain limitations. Empirical studies have shown nonaffiliated and nonscientific members to be predominantly white, educated, and professional—a cohort which has questionable capacity to recognize, and be perceived as recognizing, the concerns of minority racial and ethnic groups.<sup>133</sup> Moreover, there is evidence to suggest that nonscientific and nonaffiliated members may feel disrespected by, or lack influence as compared with, scientific members.<sup>134</sup>

In efforts to deal with similar problems, some countries have put in place more specific requirements for nonscientific expertise. Most pertinently, the Australian *National Statement on Ethical Conduct in Human Research* requires that at least one member perform a “pastoral care role in a community, for example, [as] an Aboriginal elder [or] a minister of religion.”<sup>135</sup> In both Canada and Australia, at least one member must be knowledgeable in ethical decision-making.<sup>136</sup> Other countries also have introduced requirements for a more equal balance among IRB members<sup>137</sup>—a move that also has been advocated by numerous commentators in the U.S.<sup>138</sup>

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<sup>131</sup> Sohini Sengupta & Bernard Lo, *The Roles and Experiences of Nonaffiliated and Non-Scientist Members of Institutional Review Boards*, 78 ACAD. MED. 212, 215 (2003).

<sup>132</sup> See *id.* at 216.

<sup>133</sup> See, e.g., Emily E. Anderson, *A Qualitative Study of Non-Affiliated, Non-Scientist Institutional Review Board Members*, 13 ACCOUNTABILITY RES. 135, 151 (2006).

<sup>134</sup> *Id.* at 138, 148; Sengupta & Lo, *supra* note 131, at 214–15, 217.

<sup>135</sup> AUSTRAL. GOV'T NAT'L HEALTH & MED. RESEARCH COUNCIL, NATIONAL STATEMENT ON ETHICAL CONDUCT IN HUMAN RESEARCH § 5.1.30(d) (2007).

<sup>136</sup> CAN. INST. OF HEALTH RESEARCH, NATURAL SCI. AND ENG'G RESEARCH COUNCIL OF CAN., SOCIAL SCI. AND HUMANITIES RESEARCH COUNCIL OF CAN., *supra* note 42, at 70–71; AUSTRAL. GOV'T NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 135, at § 5.1.32.

<sup>137</sup> See Denise Avarad et al., *Research Ethics Boards and Challenges for Public Participation*, 17 HEALTH L. REV. 66, 67 (2009). The U.K. and Denmark recommend one-third and one-half of ethics committee members respectively to be from the community. *Id.*

<sup>138</sup> See, e.g., Eckenwiler, *supra* note 28, at 52–54; Sengupta & Lo, *supra* note 131, at 217; NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, INSTITUTIONAL REVIEW BOARD: REPORT AND RECOMMENDATIONS at 14 (1978) (recommending

To what extent could reforms along these lines assist with recognition of potential group harms in the IRB review process? Analogously to the Australian guidelines, for example, IRBs that review projects that target racial and ethnic groups could be required to include a member knowledgeable in minority group issues.<sup>139</sup> Review of research involving prisoners—for which at least one IRB member must be a prisoner or prisoner representative—provides a precedent in the U.S. for such an approach.<sup>140</sup> However, a generic community representative may not be (or be perceived by community members to be) an adequate substitute for a member who has specialized community knowledge. This limits this reform's potential to both promote political legitimacy and elicit cultural narratives that may maximize benefits and minimize harms to groups and group members.<sup>141</sup> Moreover, unless drafted carefully, such a requirement also could be challenged as imposing an unconstitutional racial or ethnic quota.<sup>142</sup>

Instead, IRBs may derive greater benefit from a requirement that one or more members be knowledgeable in ethical decision making, which presumably would foster a greater awareness of potential group harms. Expanding IRB membership in this way could work especially well in concert with the establishment of a panel of community experts, discussed below.<sup>143</sup> Namely, once a member knowledgeable in ethics alerted an IRB to potential group harms, the IRB could seek input from an expert panel member with particular knowledge of the relevant group and take this advice into account in deciding whether to approve the research.

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that no more than two-thirds of IRB members should be scientists).

<sup>139</sup> See AUSTL. GOV'T NAT'L HEALTH & MED. RESEARCH COUNCIL, *supra* note 135, at §§ 5.1.30(f), 5.1.33.

<sup>140</sup> See 45 C.F.R. § 46.304(b) (requiring IRBs where prisoners are involved to have at least one prisoner or prisoner representative as a member).

<sup>141</sup> See generally, *supra* Section II.A (regarding the establishment of legitimacy through community involvement).

<sup>142</sup> See, e.g., *Regents of the University of California v. Bakke*, 438 U.S. 265, 315–20 (1978) (holding that a university may not use a quota system for its admissions process); *Grutter v. Bollinger*, 539 U.S. 306, 334 (2003) (applying the *Bakke* majority test).

<sup>143</sup> See *infra* Section V.B.3.

Finally, to promote implementation of these reforms, the NIH and/or relevant community organizations should provide IRB members with training and development on the risk of group harm and its relationship with Common Rule requirements. Recent empirical evidence has indicated significant uncertainty in this regard.<sup>144</sup> As a matter of general good practice and compliance with the Common Rule, IRBs should continue to seek racial and ethnic diversity in their membership.<sup>145</sup>

### 3. *Establishing a Panel of Experts*

As foreshadowed above, another strategy for increasing the expertise available to IRBs as regards risks to racial and ethnic groups would be to task the NIH or some other federal body with establishing a panel of experts who could provide advice to IRBs on a protocol-by-protocol basis. IRBs could make use of relevant experts in the same way that many currently seek scientific expert reviewers.<sup>146</sup> Should an IRB receive an application to review a project involving a particular racial or ethnic group—for example, a genetic study proposed to be undertaken only with African Americans—the IRB would have the discretion to seek advice from one or more members of the expert panel who had relevant knowledge.

An expert panel of this nature should have limited cost implications for the establishing body. Since input from panel members would be sought as a component of a single IRB review, the additional burden on researchers would be minimized as compared with, for example, *de novo* review by a specialist IRB. Further, the panel would provide access to a far more extensive range of expertise than could be accommodated through IRB membership, eliciting feedback more closely attuned to the particular cultural narratives raised by a project. If a reviewer expressed specific concerns about

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<sup>144</sup> Bethany G. Deeds et al., *An HIV Prevention Protocol Reviewed at 15 National Sites: How do Ethics Committees Protect Communities?*, 3 J. EMPIRICAL RESEARCH ON HUM. RES. ETHICS 77, 80, 82–84 (2008).

<sup>145</sup> See 45 C.F.R. § 46.107(a) (2010).

<sup>146</sup> See, e.g., Douglas J. Crawford-Brown, *Truth and Meaning in the Determination of Radiogenic Risk*, 5 IRB: ETHICS & HUM. RES. 1, 3 (1983) (describing a particularly complex scenario in which an IRB turns to a scientific expert).

the project, the IRB would decide whether the research should be approved and, if so, under what conditions. Hypothetically, for example, a researcher investigating a cohort of American Muslims for genes suspected to be relevant to a propensity toward violence could be asked to hold focus group discussions with imams and other community leaders regarding culturally sensitive ways of recruiting participants and reporting study results. This may be considerably more manageable than an open-ended requirement to consult with community leaders about the project more generally. Finally, centralizing the knowledge base through the availability of an expert panel also is consistent with moves to streamline the review of multi-site research.<sup>147</sup>

### C. Making Information Publicly Available

Researchers seeking to use the waiver of consent provisions for RES have advocated a greater public availability of information about the waiver and its use, including through expanding the information disseminated on the national clinical trials register.<sup>148</sup> One benefit of this would be to build a body of precedent to enhance decision-making by researchers, IRBs and others.<sup>149</sup> This objective has underpinned most RES proposals in this regard.<sup>150</sup> A less frequently discussed benefit is the prospect that improving the information environment will allow interested group members to learn about research projects that may affect them and petition an approving IRB or some other regulatory authority for change. This could considerably enhance the scope for community advocacy as regards sensitive research projects.

In the context of population genetics research, Hausman has advocated public facilitation of community advocacy pathways on

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<sup>147</sup> See Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,521-22 (proposed July 26, 2011).

<sup>148</sup> See generally Baren & Biros, *supra* note 81.

<sup>149</sup> See *id.* at 351-52.

<sup>150</sup> See, e.g., *id.*

the basis of the “principle of voice.”<sup>151</sup> He explains that:

Genetics researchers who are publicly funded and are thus implementing public plans have an obligation to inform the groups that they wish to study so that members are able to make their voices heard both to their political representatives and to the researchers. In just the same way that members of a community have a right to be informed of the details of plans to locate electrical transmission lines and to offer their advice, to make their complaints, and to attempt to modify the plans, so should members of an indigenous group, whether or not they will participate individually as research subjects, have the right to be informed of the details of proposed genetics research, to offer their advice, to make their complaints, and to attempt to modify the research protocol.<sup>152</sup>

Community advocates have had some success in amending research protocols that treat differently certain races or ethnicities. In 2005, for example, Schering-Plough initiated a phase 2 hepatitis C study that expressly excluded African Americans from the pool of eligible subjects.<sup>153</sup> Company representatives reportedly justified the exclusion based on the need for “genetic homogeneity” in the trial population, advising that this was the most efficient way to conduct the study.<sup>154</sup> Following advocacy efforts from groups such as the Hepatitis C Advocacy Coalition and the Treatment Action Group, Schering-Plough announced it would add a small number of African Americans to a new high-dose treatment arm.<sup>155</sup>

Of the reforms set out in this paper, increasing the public availability of information appears the least costly in regards to financial and time burdens for researchers, sponsors and IRBs. This bodes well for its future uptake. However, successful implementation requires considerable policy development, and choosing a vehicle for dissemination remains a crucial question. In RES, the national clinical

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<sup>151</sup> Hausman, *supra* note 28, at 360–61.

<sup>152</sup> Hausman, *supra* note 55, at 163.

<sup>153</sup> Hepatitis C Harm Reduction Project, *Exclusion of African Americans from Schering Hepatitis C Protease Inhibitor Study* (April 21, 2006), [http://hepcproject.typepad.com/hep\\_c\\_project/2006/04/exclusion\\_of\\_af.html](http://hepcproject.typepad.com/hep_c_project/2006/04/exclusion_of_af.html).

<sup>154</sup> Community HIV/AIDS Mobilization Project & Hepatitis C Action & Advocacy Coalition, *Backgrounder: African Americans Banned from Early Hepatitis C Clinical Trial*, <http://www.champnetwork.org/media/Schering-Backgrounder.pdf>.

<sup>155</sup> See Hepatitis C Harm Reduction Project, *supra* note 153.



trials register is commonly suggested as a suitable site;<sup>156</sup> however, this does not readily translate to the context of research involving racial and ethnic groups, much of which is non-clinical, and hence not within the scope of the national clinical trial register.<sup>157</sup> Since there is no clear precursor for disseminating the information, the NIH or the OHRP may need to establish a new site. Finally, electronic dissemination may not be optimal for some minority racial and ethnic groups—for example, Amish populations, in which computers can be seen as posing a threat to community integrity.<sup>158</sup> Further research is warranted on strategies for disseminating information on research involving racial and ethnic groups, including the types of information that should be included and suitable methods of dissemination.

## VI. CONCLUSION

As population genetics and associated pharmacogenomic research continues to proliferate, there is a high premium on the development of strategies to protect racial and ethnic groups from potential research harms. Commentators continue to debate the relative merits of an explicit “respect for communities” principle as compared with more incremental steps; however, engaging affected racial and ethnic groups in the regulatory process will be an essential part of either of these approaches. Nevertheless, the implementation of community engagement requirements raises a vast array of practical difficulties. To date, success largely has been confined to highly-structured indigenous groups, using models which do not translate clearly to more dispersed groups such as African Americans and Ashkenazi Jews. Accordingly, we must seek guidance from elsewhere. The closest analogue in this respect is community

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<sup>156</sup> See Baren & Biros, *supra* note 81, at 352.

<sup>157</sup> See NAT'L INSTS. OF HEALTH, ABOUT CLINICALTRIALS.GOV, <http://clinicaltrials.gov/ct2/info/about> (last visited Nov. 12, 2011) (describing the ClinicalTrials.gov site as an information database for clinical trials).

<sup>158</sup> Erick Wesner, *Do the Amish Use Computers and the Internet?*, AMISHAMERICA.COM, <http://amishamerica.com/do-the-amish-use-computers-and-the-internet/> (last visited Nov. 11, 2011).

engagement requirements in the context of RES.

A decade's experience with the community consultation and public engagement requirements that operate as preconditions to an IRB approving a waiver of informed consent for RES has generated a number of policy proposals. This notably includes basing the requisite level of community engagement on the incremental risk associated with the study, implementing strategies to provide a greater level of expertise to IRBs tasked with reviewing the acceptability of community engagement, and generally increasing the amount of information publicly available about relevant studies. Each of these proposals has potential application to the implementation of community engagement requirements for racial and ethnic groups. Although pressing philosophical, legal, and policy issues remain, the strategies set out in this paper can move us a step closer to a feasible implementation of requirements to engage racial and ethnic groups in the regulation of research that affects them.