ETHICS CASE

Expanding Ethics Review Processes to Include Community-Level Protections: A Case Study from Flint, Michigan

Commentary by Kent D. Key, MPH, PhD

Abstract

As the Flint community endeavors to recover and move forward in the aftermath of the Flint water crisis, distrust of scientific and governmental authorities must be overcome. Future community engagement in research will require community-level protections ensuring that no further harm is done to the community. A community ethics review explores risks and benefits and complements institutional review board (IRB) review. Using the case of Flint, I describe how community-level ethical protections can reestablish a community's trust. All IRBs reviewing protocols that include risk to communities and not merely individual participants should consider how community members are engaged in the proposed research and identify and respond to questions and domains of concern from community members.

Case

All researchers who use federal funding to do their work, including those interested in investigating effects of lead water contamination on health in the aftermath of the Flint water crisis, are required to have their protocols reviewed by an institutional review board (IRB) to motivate compliance with federal human subject research regulations. A team of researchers from University X has proposed a protocol that involves investigating acute changes in kidney function, new onset of high blood pressure and gout, and each of these conditions' relationship with changes in Flint water composition. They hope to arrange for community members' blood tests, urine tests, blood pressure measurements, and joint aspiration and fluid analysis. Furthermore, they hope to enter community members' homes to sample and test their tap water for lead, phosphates, and trihalomethanes. The protocol is being reviewed by an IRB from University X. Some members of the Flint community have raised strong opposition to this research, citing no reasonable basis for trusting the researchers or their institutions to do the research ethically or to justly share the risks and benefits of their work with the community.

Commentary

The community of Flint, Michigan, suffered a manmade public health crisis based on the decision of a governor-appointed emergency manager (EM) to change Flint's water

source from Lake Huron to the Flint River, which began in April 2014 [1]. However, the root of the Flint water crisis (FWC) began in March 2011, when the Michigan state government passed the Local Government and School District Fiscal Accountability Act [2]. This law allowed state-appointed EMs to replace community-elected representatives in executive and legislative branches of city government. EMs were charged with protecting the health, safety, and welfare of citizens with a focus on fiscal "belt-tightening" [3]. Community members in Flint and other parts of Michigan organized and protested this law, which resulted in the law being overturned in November 2012 [4]. Months later, the state government passed a very similar law, the Local Financial Stability and Choice Act [5]. Two critical components of the law were met with opposition from the Flint community: (1) the implementation of the EM, which undermined the local community's democratic processes [6]; and (2) the switch to the Flint River as an intermediate water source, which was made from a fiscal perspective with no consideration of health risks to residents. Although required by law in water systems serving more than 50,000 residents [7], anticorrosive chemicals were not added to the water supply due to cost (less than $150 a day) [8]. These decisions resulted in damage to public health from elevated lead levels and *Legionella* in Flint's water as well as over $100 million in Flint water infrastructure damage [9]. Because the government, at all levels, failed to protect the Flint community [1], the residents were harmed [1], and their trust in government and other institutions eroded [10].

Purpose and Ethical Principles of Institutional Review Boards
The 1979 Belmont Report, written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, established three ethical principles to protect research subjects and provide a framework of accountability and responsibility for researchers: (1) respect for autonomy, (2) beneficence and nonmaleficence, and (3) justice [11-14]. These principles provided new levels of protection for research participants following the outrage of the Tuskegee syphilis study [11]. This was a first step in the evolution of ethical protections in human subject research.

The [institutional review board](#) (IRB) process was established to protect research participants [14]. IRBs typically deliberate about whether risks are reasonable and whether participants, especially those from vulnerable populations, are adequately informed to consent to participate and are aware of the benefits and risks of participating [12, 14]. IRBs are often housed within academic institutions or community institutions, such as hospitals [15], but some IRBs are corporate entities. In either case, community considerations are often missing from IRB deliberations [16, 17], although IRBs are federally required to have community members and consider community concerns, according to Title 21 of the Code of Federal Regulations (CFR) [18]. Some IRBs do not fully assess community protections, consent, risks, or benefits, restricting their

main focus to individual protections [16], and thus failing to incorporate another important ethical principle, respect for communities [19].

To understand why Flint residents in the case scenario did not trust researchers, it is worth examining how the ethical principles guiding IRBs and the Belmont Report were violated in the Flint water crisis.

- *Respect for autonomy*. Community members' autonomy and the democratic processes in place to support it were undermined by the governor-appointed EM and the EM's decision to switch the water source [10] and the state's decision not to add anticorrosion chemicals [8].
- *Beneficence*. The EM model was designed to maximize fiscal savings in selected communities experiencing financial hardship, but it provided no consideration for maximizing the health of the community residents.
- *Nonmaleficence*. The harm experienced by the Flint community manifested in various forms: biological, psychological, environmental, financial, social, and cultural.
- *Justice*. Undercurrents of racism and socioeconomic classism led to the FWC. Results of the Michigan Civil Rights Commission's report highlighted environmental racism as a contributor to the FWC [10], legitimizing some Flint residents' claims that the crisis occurred because Flint was a predominantly black city and inciting the "Flint Lives Matter" movement, derived from the ongoing Black Lives Matter movement.

Community engagement would allow members of the community to take on the responsibility of distributing risks and benefits that they identify. This process could address, and possibly alleviate, distrust and restore key relationships between the community and research institutions by giving the community a sense of co-ownership and co-leadership.

Evolution of Community Ethics Reviews
The First Community Consultation on the Responsible Collection and Use of Samples for Genetic Research of the National Institute of General Medical Sciences took place in 2000. This consultation yielded ten recommendations, three of which included: (1) defining community in appropriate meaningful ways, (2) obtaining broad community input in all phases of the research, and (3) establishing appropriate review mechanisms and procedures [20]. Although these recommendations helped move the needle in a positive direction for community-engaged research, other problems remained. Over the past decade, there have been a growing number of concerns regarding the inconsistency of community representation on IRBs [21, 22]. Community-based researchers have expressed deep concerns about the ethics of community partnership and engagement processes, social justice, and the need to expand the boundaries of ethical reviews to include community-level considerations [21]. In addition, some university IRBs have struggled to recognize the role of community partners since it was not customary to

view community partners as equals with academic researchers, which has created challenges in obtaining IRB approval [23]. Community-based research shifts the traditional power dynamic, raising questions of equity, co-ownership of data, and mutual benefit. Shore et al.'s [16] study of community-engaged researchers' experiences with IRBs revealed that there is a need to expand the ethical analysis to include community-level considerations, which they posit is often missing in the IRB process.

Community-based participatory research (CBPR) practitioners have argued that the Belmont principles must be reconceptualized in order to address community-level considerations in ethical reviews [13, 19, 20, 24]. The community-level ethical principles (see table 1) of veracity, sustainability, nonmaleficence, and justice are meant to expand the frame and ethical lens of the traditional Belmont principles. As community engaged research has evolved, it has become evident that efforts to incorporate diverse community stakeholders in the research process have progressed from "subject"-focused-only engagement to include a "community-partnered" focus.

Table 1. Comparison of internal review boards and community ethics review boards [14]

Internal review board	Community ethics review board
Ethical principles	
Respect for autonomy	Veracity
• Right to know, informed consent	• Respect for dignity and recognition of worth within community frame • "Right to know" expanded to "right to know and understand," transparency
Beneficence	Sustainability
• Maximize benefit	• Maximize benefit not only for the group but also for the individual and over time, for generations to come • Research efforts sustain the broader ecologic and local community to which individuals are connected
Nonmaleficence	Nonmaleficence
• Do not harm the subject	• Do not harm the community
Justice for study subjects	Justice for the community
• Fair distribution of costs and benefits to research subjects	• Fair distribution of costs and benefits to the community
Other key differences	
Narrow focus on individual research subjects	Broader focus on the community regardless of participation in research
Institutional lens	Community lens
Individual autonomy	Community autonomy
Individual benefit	Community benefit

Expanding the Boundaries of Ethical Reviews in Flint

In 2009, the author, who is the executive deputy director of the Community Based Organization Partners (CBOP), founded the CBOP Community Ethics Review Board (CERB) in Flint to establish a community-level ethical protection entity led by local residents [25]. Members of the CERB are community members with years of experience in research and in serving on regional and national ethics review committees. They

review proposed studies and work with researchers to ensure compliance with human research protections outlined in the CFR and to ensure community protections and mutual benefit. The CERB partners with two local universities to continue ongoing research ethics training for its members, who are required to obtain CFR human subjects protections training certificates from one of the two universities. In a community experiencing psychological stress and mistrust from failures of government at all levels [26], in spring 2016 the CERB also partnered with the Healthy Flint Research Coordinating Center as the vetting arm for research in Flint. The CERB process is a win-win for both the community and researchers. CERB services include: (1) community ethics reviews and critiques of proposals; (2) identifying and assisting in developing a community advisory board for research projects, if needed; (3) identifying community partners, research participants, and community research sites; (4) suggesting strategies for community engagement; (5) vetting research ideas; and (6) issuing letters of support for particular projects.

Case Analysis
As illustrated by the case scenario that opened this essay, an overarching concern for researchers is residents' lack of trust in research and government institutions. The proposed research in this case includes blood draws and other biospecimen extractions, in addition to physical space intrusion through home visits. To an already overburdened, stressed, and distressed community, community-specific questions need to be addressed, including: What are the community-level protections? What are the community-level benefits and risks? What are best methods of community engagement to obtain community-level buy-in? It is critical to approach this study with the aforementioned considerations in order to respond to distrust and to reach a level of effective community participation. Given that in this case the research protocol has been reviewed only by a university IRB and has had some opposition from the community, it will be necessary for a respected community entity to review and possibly endorse this research project to ensure the protocol's compliance with community interests, priorities, and ethical standards. Hence researchers in this ethics case should engage with the CERB. Upon completing the CERB's review process, a letter of support or endorsement could be granted confirming that the research has been reviewed and deemed appropriate by community members. Considering the current climate of mistrust and the historical mistrust of communities of color toward research [27], the local IRB in this case study should recognize and respond to ethical concerns, such as community protections, and partner with the CERB. This approach would expand the lens of the ethics review that researchers would receive.

National Implications
Nationally, the ethics review process should not protect institutional power at the expense of community [23], but instead reconstruct its review domains to include questions that assess community-level protections, risks, benefits, and issues of social

justice. This reorientation would ensure that IRB research protocols explicitly address community-level considerations. Specific questions to assess studies' risk of community-level harms—biological, psychological, environmental, and socio-cultural—are ideal. Questions could include, but are not limited to: Are the risks and benefits from this study different for the individual participant than the collective community? If so, how are they different? Is there a fair distribution of these risks and benefits on a community level? Additional questions should focus on the consent process. IRBs should ask researchers how they are verifying that participants understand all the risks and benefits before giving consent. The concept of the "right to know" should be expanded to include the "right to understand." Is there a level of "community understanding" regarding the study? Is there acceptable or sufficient transparency with community members? Will this study protect the dignity of the community?

There are three recommended strategies to assist IRBs in including community-level ethical protections: (1) IRBs should partner with local CERBs to conduct a joint-review process; (2) IRBs should include community members from local CERBs; and (3) IRBs should reroute researchers to local CERBs for protocol review prior to the IRB review and consider the results of the CERB review in their deliberations. Furthermore, risks and benefits of research should be justly distributed by engaging the community in the process of identifying and assessing those risks and benefits.

Conclusion
In conclusion, research is a critical component in the growth and evolution of knowledge aimed at making the lives of people healthier and better. Research institutions are working to develop more effective approaches to engage communities in their studies, which require a reconstructed frame for assessing ethical protections. IRB review processes would be enhanced by incorporating community ethics reviews to ensure community-level protections and to maximize the impact of engaging communities in research across the disciplines. Flint is an excellent example of how city residents came together to develop and set in place a mechanism for the community to access proposed research to ensure protection of the community.

References
1. Flint Water Advisory Task Force. *Flint Water Advisory Task Force: Final Report.* Lansing, MI: State of Michigan. https://www.michigan.gov/documents/snyder/FWATF_FINAL_REPORT_21March2016_517805_7.pdf. Accessed March 1, 2016.
2. Local Government and School District Fiscal Accountability Act, HR 4214, 96th Leg, Reg Sess (Mich 2011). https://www.legislature.mi.gov/documents/2011-2012/publicact/htm/2011-PA-0004.htm. Accessed August 15, 2017.

3. Miller DS, Wesley N. Toxic disasters, biopolitics, and corrosive communities: guiding principles in the quest for healing in Flint, Michigan. *Environ Justice.* 2016;9(3):69-75.

4. Longley K. Flint emergency: timeline of state takeover. *MLive.* December 1, 2012. http://www.mlive.com/news/flint/index.ssf/2012/12/flint_emergency_timeline_of_st_1.html. Accessed April 15, 2016

5. Local Financial Stability and Choice Act, H 865, 96 Leg, Reg Sess (Mich 2012). 865. https://www.legislature.mi.gov/documents/2011-2012/publicact/pdf/2012-PA-0436.pdf. Accessed August 29, 2017.

6. Butler LJ, Scammell MK, Benson EB. The Flint, Michigan, water crisis: a case study in regulatory failure and environmental injustice. *Environ Justice.* 2016;9(4):93-97.

7. Maximum contaminant level goals and national primary drinking water regulations for lead and copper; final rule. *Fed Regist.* 1991;56(110):26460-26564.

8. Kaffer N. Why didn't Flint treat its water? An answer, at last. *Detroit Free Press.* March 30, 2016. http://www.freep.com/story/opinion/2016/03/30/flint-water-crisis/82421546/. Accessed August 15, 2017.

9. Burke MN. EPA gives Flint $100M to help repair pipes. *Detroit News.* March 17, 2017. http://www.detroitnews.com/story/news/michigan/flint-water-crisis/2017/03/17/flint/99301466/. Accessed August 15, 2017.

10. Michigan Civil Rights Commission. *The Flint Water Crisis: Systemic Racism through the Lens of Flint.* Lansing, MI: Michigan Civil Rights Commission; February 17, 2017. http://www.michigan.gov/documents/mdcr/VFlintCrisisRep-F-Edited3-13-17_554317_7.pdf. Accessed February 17, 2017.

11. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: ethical principles and guidelines for the protection of human subjects of research. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html. Published April 18, 1979. Accessed August 15, 2017.

12. Bromley E, Mikesell L, Jones F, Khodyakov D. From subject to participant: ethics and the evolving role of community in health research. *Am J Public Health.* 2015;105(5):900-908.

13. Mikesell L, Bromley E, Khodyakov D. Ethical community-engaged research: a literature review. *Am J Public Health.* 2013;103(12):e7-e14.

14. Gilbert SG. Supplementing the traditional institutional review board with an environmental health and community review board. *Environ Health Perspect.* 2006;114(10):1626-1629.

15. Stoecker R. Challenging institutional barriers to community-based research. *Action Res.* 2008;6(1):49-67.

16. Shore N, Brazauskas R, Drew E, et al. Understanding community-based processes for research ethics review: a national study. *Am J Public Health.* 2011;101(suppl 1):S359-S364.

17. Flicker S, Travers R, Guta A, McDonald S, Meagher A. Ethical dilemmas in community-based participatory research: recommendations for institutional review boards. *J Urban Health*. 2007;84(4):478-493.
18. IRB membership, 21 CFR sec 56.107 (2017). https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.107. Accessed August 15, 2017.
19. McGrath MM, Fullilove RE, Kaufman MR, Wallace R, Fullilove MT. The limits of collaboration: a qualitative study of community ethical review of environmental health research. *Am J Public Health*. 2009;99(8):1510-1514.
20. Quinn SC. Ethics in public health research: protecting human subjects: the role of community advisory boards. *Am J Public Health*. 2004;94(6):918-922.
21. Grignon J, Wong KA, Seifer SD. Ensuring community-level protections: proceedings of the 2007 Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research. Community-Campus Partnerships for Health; 2008. https://ccph.memberclicks.net/assets/Documents/FocusAreas/finalresearchethicscallseriesreport.pdf. Accessed July 10, 2017.
22. De Vries R, Forsberg CP. Who decides? A look at ethics committee membership. *HEC Forum*. 2002;14(3):252-258.
23. Malone RE, Yerger VB, McGruder C, Froelicher E. "It's like Tuskegee in reverse": a case study of ethical tensions in institutional review board review of community-based participatory research. *Am J Public Health*. 2006;96(11):1914-1919.
24. Martin del Campo F, Casado J, Spencer P, Strelnick H. The Development of the Bronx Community Research Review Board: a pilot feasibility project for a model of community consultation. *Prog Community Health Partnersh*. 2013;7(3):341-352.
25. Community Based Organization Partners. Community ethics review board. http://cbop-national.org/index.php/community-ethics-review-board. Accessed August 15, 2017.
26. Gostin LO. Lead in the water: a tale of social and environmental injustice. *JAMA*. 2016;315(19):2053-2054.
27. Cobie-Smith G, Thomas SB, St. George DM. Distrust, race, and research. *Arch Intern Med*. 2002;162(21):2458-2463.

Kent D. Key, MPH, PhD, is the director of the Office of Community Scholars and Partnerships at the Michigan State University College of Human Medicine in Flint, Michigan. He is also the chair of the Community Based Public Health Caucus of the American Public Health Association and a 2017 Robert Wood Johnson Foundation Fellow for the Culture of Health Leader Program. His research interests include both racial and ethnic health disparities research, workforce development, and community-engaged research.

Related in the *AMA Journal of Ethics*

[Communicating Results of Community-Based Participatory Research](), February 2011
[The History and Role of Institutional Review Boards](), April 2009
[Identifying the Challenges in Community-Based Participatory Research Collaboration](), February 2011
[Improving Institutional Review of Community-Based Participatory Research Applications](), February 2011
[The National Clinician Scholars Program: Teaching Transformational Leadership and Promoting Health Justice Through Community-Engaged Research Ethics](), December 2015
[Physician, Researcher, Neighbor—Conflicting Roles in Community-Based Participatory Research](), February 2011
[Setting the Agenda for Community-Based Participatory Research](), February 2011

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

The viewpoints expressed in this article are those of the author(s) and do not necessarily reflect the views and policies of the AMA.