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## A case study of ethical bridges: wastewater-based epidemiology in the Rubbertown Air Toxics and Health Assessment (RATHA) project

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**Background:** Wastewater-based epidemiology (WBE) is a valuable tool for assessing community-wide exposure to environmental pollutants. The Rubbertown Air Toxics and Health Assessment (RATHA) project presents a novel approach to integrating community engagement, ethical safeguards, and policy-driven outcomes within a large-scale WBE initiative in Louisville, Kentucky. Particular strengths of this framework include: i) community-engaged development and reporting process, and ii) applicability based on well-established principles of medical and research ethics. This case study is a model to produce actionable public health insights through community-engaged scientific research. **Case:** The RATHA project is a collaboration between local governmental air pollution and public health agencies, community organizations, and academic researchers. It aims to quantify exposure to air toxics through ambient air monitoring and WBE near the Rubbertown area, a predominantly Black fenceline community that faces long-standing environmental health disparities due to industrial emissions. Given the lack of established formal ethical policies for WBE, the research team developed a bioethics-based framework to guide responsible data collection, privacy protection, and equitable benefit-sharing. This framework was then publicly vetted by community organizations. **Conclusions:** This case study underscores both the need for and the feasibility of ethical planning in environmental health research, particularly when using WBE in vulnerable communities. The RATHA project's ethical framework provides a model for realizing scientific innovation through community protection and trust with the intention of influencing policies to protect area residents. This approach helps ensure that outcomes contribute to environmental justice and public health improvements in the areas that need it most.

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### Water impact

The philosophical perspective on wastewater-based epidemiology, which may count as research, intervention, or a blend of both, needs to include both academic and community partners. Our co-created framework for an ethical bridge incorporates ongoing community engagement, strong data governance, and clear communication.

## Background

Wastewater-based epidemiology (WBE) is a valuable tool for assessing community-wide exposure to air pollution.<sup>1,2</sup> WBE allows for large-scale, community-level exposure assessment without direct individual contact by sampling sewer locations representing hundreds to thousands of individuals, followed by targeted laboratory analysis. Depending on the objectives of the sampling team and

community partners, WBE may be considered research, intervention, or a combination of both. National surveys have indicated high levels of support for WBE.<sup>3,4</sup> However, ethical frameworks for implementing WBE in vulnerable communities remain underdeveloped. Existing protocols for wastewater-based testing and surveillance<sup>5,6</sup> are compatible with a top-down, researcher- or government-driven assessment process that may not meet the standards expected by community members or by community-engaged scholars and practitioners. WBE thus presents unique ethical considerations, particularly regarding data privacy, community engagement, risks of distinctive population-level harm, and interpretation of findings.

The U.S. Department of Health and Human Services defines human subjects in research as follows (45 CFR 46.102):<sup>7</sup>

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*Human subject means a living individual about whom an investigator (whether professional or student) conducting research:*

*(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or*

*(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.*

Based on this definition, WBE does not qualify as human subjects research. However, the fact that WBE may use, study, analyze, or generate information about identifiable subpopulations, including those that may be stigmatized or vulnerable relative to the broader population, means that WBE carries risks that are analogous to those confronting human subjects research. Further, technological progress in genetics may allow for the identification of individuals through analysis of stored samples in the future. The absence of accepted ethical standards around WBE can result in conflicts of interest and inconsistencies in the treatment of investigated communities as researchers are currently responsible for establishing their own ethical guidelines.

A 2023 review<sup>5</sup> generated a structured ethical protocol for WBE research. The protocol encompasses 37 questions broadly reflecting concerns about i) community engagement, ii) equality, iii) the establishment of new precedents, and iv) data integrity. The protocol can be administered by independent auditors not connected to the research under scrutiny. In addition to finding major gaps in research involving stakeholder participation during the development and deployment of studies, the authors note issues in data and sample management and, the need to simplify the questionnaire. The World Health Organization<sup>6</sup> developed a 17-principle guide to help government agencies conduct ethical public health surveillance, addressing key considerations such as a) the common good, b) respect for persons, c) equity, and d) good governance. Good governance is aimed at governments, while equity imposes participatory duties on members of surveilled populations. This approach is inappropriate for community-based research and interventions outside the context of emergencies such as an emergent disease outbreak. Further, both the research-based protocol<sup>5</sup> and the intervention-focused WHO guidelines<sup>6</sup> are couched in terms of securing benefits while minimizing risks or harms. Ethics is thus presented as a set of constraints on behavior. Community-engaged initiatives, those in which community members are involved in all stages of the research process, understand ethics not merely as a constraint, but as integral to goal-setting. In this perspective, without community input and interaction, it is impossible to set, specify, or sustain goals. Thus, although these frameworks provide a useful starting point, they require revision and specification for routine or research-based surveillance in community-engaged WBE initiatives.

To date, no case studies have documented genuinely community-engaged ethics review. Community-engaged research is, from the outset, a collaboration between community members, local government agents, and academic

researchers to develop mutually agreed-upon and publicly assessable ethical frameworks for conducting WBE research in disadvantaged communities.<sup>8–10</sup> This case study aims to introduce an ethical template developed in Louisville, Kentucky, which may serve as a model for similar community-engaged WBE initiatives, to benefit the community by promoting ethical conduct.

## Case presentation

Rubbertown is an industrial corridor that borders several human settlements in western Louisville, Kentucky. A historical lack of environmental protections has resulted in the release of pollutants into the air, water, and soil in this region.<sup>11,12</sup> Predominantly home to Black residents, the community faces significant disenfranchisement and health disparities. Exposure to pollutants from Rubbertown are linked to increased risk of cancer, heart disease, and stroke,<sup>11–13</sup> as well as an average life expectancy of 65 years compared to 80 years in eastern parts of Louisville.<sup>13</sup> Due to ongoing environmental health issues and past extractive projects,<sup>14</sup> residents in the area are cautious about new research proposals, anxious to ensure that research contributes to a better understanding of health risks and mitigation strategies without causing harm, reinforcing stigma, or unduly burdening residents' time or resources.

The Rubbertown Air Toxics and Health Assessment (RATHA) project started in 2024 as a collaborative effort between the Louisville Metro-Jefferson County Government's Air Pollution Control District, the Christina Lee Brown Envirome Institute at the University of Louisville, the West Jefferson County Community Task Force, and the Park DuValle Community Health Center (CHC), funded by the U.S. Environmental Protection Agency. The project will reassess ambient air toxics emissions around Rubbertown through air monitoring and assess human exposure to targeted air toxics through urinary metabolites of volatile organic chemical pollution in community wastewater.<sup>1</sup> RATHA can be considered both research and a public health intervention. Its research aim is to validate the Strategic Toxic Air Reduction program's claims of success in improving air quality and reducing exposure to air toxics. Such an assessment is not only a community priority but also elucidates relationships between emissions, exposures, and health. The project is a public health intervention as the collected data and subsequent analysis will form the body of evidence supporting policies that promote clean air and adequate health screening in this historically disadvantaged area.

This project presented a unique ethical challenge. While WBE is not subject to the protections involved in human subjects research, it uses materials that can be linked to identifiable subpopulations, thereby raising analogous ethical concerns and potentially causing consternation among community members. Additionally, the absence of public policy and limited public awareness places the responsibility on research institutions to establish and



enforce their own ethical guidelines, generating a potential conflict of interest and risking inconsistency across studies and institutions. To address the challenge, the project team developed a code of conduct grounded in academic

scholarship and vetted by community organizations. The project team conducted an academic literature review and engaged the community through presentations to develop an ethical bridge that promotes protection, participation, and

**Table 1** Ethical bridge for wastewater-based epidemiology (WBE) research in the Rubbertown Air Toxics and Health Assessment (RATHA) project, Louisville, Kentucky

Ethical consideration	Description	Code of conduct for RATHA project WBE
Institutional Review Board (IRB)	Consult with the IRB to see whether to follow the standard human subjects route, or this code of conduct	<ul style="list-style-type: none"> <li>The University of Louisville IRB reviewed this work and determined that it is not classified as human subjects research. The privacy of individuals represented in the data is protected as no identifiable information will be collected</li> </ul>
<i>Respect for persons and autonomy</i>	Obtain informed, voluntary, and retractable consent of research participants	<ul style="list-style-type: none"> <li>The project will not entail direct contact with individuals (exclusion of household-level sewer data)</li> <li>The project will use only pooled, anonymous, community samples. Addresses of households, within the sampled sewersheds or geographic information system polygon boundaries, will not be shared outside project partners</li> <li>The project will not collect personally identifiable information from individuals in the studied sewersheds, ensuring anonymity</li> <li>Accountable or representative community organizations include WJCCTF (an independent 501(c)(3) focused on environmental justice that holds regular open meetings), and Park Duvalle CHC (a federally funded community health center)</li> <li>Project information will be provided to community organizations and residents through periodic press releases, community meetings, outreach programs, and public opinion surveys</li> <li>If public opinion of WBE shifts, then the research institution must adjust their research practices to accommodate public concerns</li> <li>Any analysis beyond the agreed-upon scope of air toxics research (such as reanalyzing samples for illicit substances or other targets) requires further, explicit, consent</li> </ul>
<i>Beneficence</i>	Maximize benefits	<ul style="list-style-type: none"> <li>The project will maximize public health benefits by providing data vital to improving air quality and health outcomes</li> <li>Findings will be communicated back to the community in accessible (plain language) formats, ensuring shared benefit</li> <li>Findings will be communicated by a community member involved in the research to foster trust and engagement</li> <li>Findings will be presented in peer-reviewed literature to ensure methodological rigor and quality</li> </ul>
<i>Nonmaleficence</i>	Minimize harms	<ul style="list-style-type: none"> <li>Findings will be presented in ways that foster understanding, promote community well-being, and drive positive change</li> <li>Analysis will be limited to public health and air toxics exposure concerns</li> <li>Robust data protection measures will ensure data privacy</li> <li>Samples will not be shared for profit</li> <li>Commitment to transparent and ongoing communication will minimize misunderstandings and proactively address potential concerns or harms</li> </ul>
<i>Justice</i>	Ensure equal and equitable distribution of benefits and burdens	<ul style="list-style-type: none"> <li>All partners acknowledge that Rubbertown area residents receive the benefits and bear the burden of the research</li> <li>Community members can be involved in the research process through community organizations (WJCCTF and Park Duvalle CHC) and community meetings</li> <li>Prior to the start of WBE activities, research design will be presented to the community to share information and hear concerns</li> <li>The University of Louisville will share summary, deidentified, data with community members and organizations that request it</li> <li>Proposed policies and interventions developed from the findings of this project must practically address and mitigate the environmental and health disparities present in this area</li> </ul>

Abbreviations: CHC, Community Health Center; IRB, Institutional Review Board; WBE, wastewater-based epidemiology; WJCCTF, West Jefferson County Community Task Force.



shared benefits for communities involved in wastewater-based air toxics exposure research (Table 1). Such an ethical bridge facilitates communication and trust between researchers, officials, and affected communities. If violations of the ethical principals occur, communication between community members and the research team is emphasized prior to any project halt. This bridge addresses the current gap in ethical protections for WBE initiatives as existing regulations do not fully apply. This approach also ensures that research not only meets scientific and regulatory standards but also aligns with community values and ethical practices. Finally, this framework soothes potential conflicts of interest by providing community members with a structured means to hold researchers accountable.

This framework is grounded in the four principles of biomedical ethics,<sup>15</sup> which themselves derive from the three principles outlined in the Belmont Report, the foundational document of research ethics in the United States.<sup>16</sup> This framework was chosen because of its legitimacy, grounded in longstanding use and vetting by multiple sectors and for its ability to translate individual-level principles into effective community-level analogs. Furthermore, the four-principle framework ensures both ease and broad applicability, reducing the need for a large number of protocols fine-tuned to specific research methodologies. The four principles: respect for autonomy, beneficence, nonmaleficence, and justice, explicitly state ethical expectations, ensuring that research remains focused. Through these four principles, the RATHA project also respects the American Public Health Association (APHA)'s seven core values and implements domains 1–4, 9, and 10 of the APHA Code of Ethics.<sup>17</sup>

## Additional considerations

To further uphold these principles, we offer four additional future recommendations.

### 1. Enhanced community engagement

The project should continue to prioritize enhanced community engagement by involving community members in every research process stage and in the specification of the ethics principles themselves. This includes continuing to host conferences, monthly meetings, radio broadcasts, and podcasts. Such efforts will raise awareness about the project's purpose and safeguards and foster transparency and trust within the community. When researchers and community members know one another and work together, researchers are more motivated to articulate and adhere to the letter and spirit of ethical guidelines.

### 2. Reviews

The project should incorporate regular ethical reviews to ensure its protocols remain aligned with current ethical standards and to address emerging challenges. If additional case studies in this field are released, they should be

reviewed for applicability. Project reviews will provide opportunities to adapt practices in response to community feedback and evolving concerns.

### 3. Data sharing and communication

The project should ensure that information generated through project activities is handled responsibly and the data is not leveraged in ways that could result in financial harm or further stigmatization of area residents. Data produced is owned collectively by the project partners: Louisville Metro-Jefferson County Government and the University of Louisville. Data use and sharing are governed by strict institutional guidelines to protect privacy and confidentiality. The project team should engage in robust conversations with community members and must address questions about data usage. The project team should ensure that wastewater data is safeguarded against misuse by commercial entities, including insurance companies, predatory lenders, and real estate firms, to prevent the exploitation of West Louisville residents. These businesses are excluded from any data transfer agreements. The project team should contextualize wastewater data with other sources, such as industry discharge reports and clinical health data, to provide a comprehensive and equitable foundation for decision-making and advocacy. Further, it is important to consider the audience when sharing data and findings. Messages must be both accessible, made available through a variety of mechanisms, and understandable, written in plain language. Communication mechanisms should include face-to-face and virtual community meetings, as well as physical and electronic documents with concise summaries (e.g., one-page plain language flyers and reports), peer-reviewed articles, and graphics. Finally, inviting a knowledgeable community member who is actively involved in the project to present findings can be instrumental in fostering trust and engagement. This individual should be someone trusted by the community, with a proven track record of subject-specific advocacy. Their collaboration must be structured to ensure that this community member is empowered as a liaison, ensuring that they serve and are publicly known to serve as a genuine representative of the community rather than as a spokesperson for the project.

### 4. Policy development and implementation

The project should ensure that policy development and implementation activities resulting from WBE findings are guided by a collaborative approach that includes policymakers and community members. Additionally, policies should be developed to regulate how WBE data is collected, stored, and used, ensuring it aligns with privacy protections and community expectations.<sup>10</sup> Effective policymaking requires a clear understanding of both the intended outcomes and the potential unintended consequences of proposed policies. Policymakers, community members, and other stakeholders should be equipped with tools, such as if/





then models and ethical frameworks, to evaluate both short- and long-term policy impacts. A thorough assessment of the values guiding policy decisions is essential. Policymakers using WBE data collected from this project should carefully consider whether their approach prioritizes economic development, public health, transparency, or community inclusion. Clearly identifying these values will help align policies with the priorities of the affected communities. To foster meaningful community participation, the project should facilitate opportunities for residents to engage directly with policymakers. Such engagement ensures that policies are informed by the lived experiences of those most affected and allows for the co-development of solutions that address real community needs. However, while research teams and community organizations play a crucial role in advocacy, they should not assume the role of being the sole advocate for the community in environmental mitigation matters. Instead, efforts should be directed toward empowering local residents, strengthening their ability to voice concerns, and supporting sustained, community-led advocacy driving policy change.

## Conclusion

The RATHA project team is committed to upholding the highest ethical standards in WBE application to assess air toxics exposure in West Louisville. Although the University of Louisville's Institutional Review Board has affirmed that this type of work does not constitute human subjects research and poses no risk to personal autonomy, WBE falls into an ethical and regulatory gap that requires an ethical bridge connecting researchers with the community members. The research methodologies employed are designed to safeguard community rights while delivering meaningful benefits to residents. This commitment is demonstrated through the establishment of a publicly vetted code of conduct prior to the initiation of WBE sample collection, the ethical bridge, along with continued efforts to enhance community engagement, implement robust data protection protocols, and ensure the equitable distribution of research findings and benefits. To uphold these principles, the research team has implemented strict data privacy measures, including boundaries in Data Transfer Agreements and ensuring addresses of households within sampled sewersheds or polygon boundaries are not shared. The project is designed to focus solely on assessing exposure to toxic chemicals, thereby minimizing risks of harm and stigmatization. Moreover, the project prioritizes transparency in data sharing, making findings accessible and understandable to all stakeholders. While summary data will be made publicly available at the project conclusion, raw data will be shared exclusively with community groups and collaborators through Data Transfer and Use Agreements. The research team is committed to supporting community members who seek access to the data, facilitating informed participation in the decision-making processes.

WBE initiatives fall into an ethical and regulatory limbo. To address this, the project developed a public

code of conduct to protect identifiable subpopulations and manage potential conflicts of interest when research teams are responsible for self-regulation. The code of conduct established through this project proposes applicable community-level analogues to well-established individual-level guidelines from health care and human subjects research. It thus serves as a foundational framework for fostering ethical collaborations between researchers and communities engaged in WBE studies. By prioritizing transparency, useability, community involvement, and data protection, this approach helps ensure that WBE research is both consensual and beneficial, and its benefits are equitably distributed while minimizing potential harms. Moving forward, this model can inform future WBE and other research initiatives that fall into a similar regulatory gap, guiding ethical research practices in disadvantaged communities to promote public health and environmental justice.

## Data availability

The data supporting this article have been included as part of the manuscript.

## Author contributions

KC, LBA, AG, RHH, AK, TS: literature review, data collection and analysis, and manuscript writing. AK, TS: supervision.

## Conflicts of interest

There are no conflicts of interest to declare.

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