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Community Bioethics: Provocations for Institutionalized Ethics from Community-Based Biology

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RESEARCH PAPER

ANDY MURRAY
DAN SANTOS
*Author affiliations can be found in the back matter of this article

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ABSTRACT

In the United States, institutions of scientific and medical ethics developed out of histories that continue to shape their principles and scope of concerns. Many have identified that the movement of practitioners identifying as community-based biologists (or any of several overlapping labels) presents challenges for institutionalized ethics. Community-based biology has been the subject of ethical controversies, but it has also taken proactive measures to establish ethics of its own. We argue that the challenges that community-based biology poses for establishment, institutionalized ethics are just as significant as their challenges to establishment science more generally, and that the two are inextricable. We also assert that these challenges are more profound than either existing literature suggests or that efforts to establish ethics within community-based biology so far are equipped to address. Drawing on our experiences as social scientists working with the Open Insulin Project and community-based biology more broadly, we demonstrate several ways that community-based biology efforts problematize established approaches to institutionalized research ethics. We describe how, at the same time, efforts to institutionalize ethics in community-based biology risk reproducing features of institutionalized ethics seemingly at odds with the critiques community-based biology itself embodies. Through a series of three empirically grounded provocations, we argue that community-based biology should evolve in tandem with a community bioethics that more consciously engages critiques of institutionalized ethics and embraces the diversity and pluralism of community-based biology.

CORRESPONDING AUTHOR:
Andy Murray
Harvard Kennedy School, US
andymurray@hks.harvard.edu

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INTRODUCTION

With the expansion of the biotechnology industry and accompanying refinement and proliferation of bioengineering tools and techniques, hobbyists have taken an increasing interest. These hobbyists, including some formally trained scientists, have organized under a range of loose and overlapping labels: do-it-yourself biology (DIYbio), biohacking, and community bio are among the most popular.[1] Members of these groups have often argued that the increased accessibility of biotechnology has revolutionary potential (e.g., Shukman 2012; Lang 2014; Pontoniere 2022). Some of the most prominent efforts in this space, such as the Open Insulin Project (now the Open Insulin Foundation, openinsulin.org), explicitly aim to challenge the values and exclusionary nature of conventional biotechnology paradigms.

As they have grown and built momentum, these groups have also faced ethical questions that are inevitable in the 21st-century biosciences. Combinations of individual whims, values diverging from the status quo, and a lack of formalization have resulted in controversial experiments (e.g., Baumgaertner 2018; Zhang 2018). Efforts to articulate and institutionalize the ethics and values of community-based biology have evolved as important steps toward formalizing and legitimizing it. This puts community-based biology practitioners in a bit of a predicament: They are compelled to reproduce hallmarks of establishment science, such as institutionalized ethics, while also attempting to challenge some of their underlying values.

We argue that the challenges that community-based biology efforts pose for institutionalized ethics are just as significant as their challenges to institutionalized research, and that they are inextricably intertwined. We also assert that these challenges are more profound than existing literature suggests and than efforts within community-based biology to establish ethics so far have adequately addressed. To make this case, we draw on science and technology studies (STS), as well as our experiences as ethnographic researchers and participant-observers within the Open Insulin Project and the community biology movement more broadly. We approach institutionalized ethics very broadly, capturing different kinds of established institutions and disciplines–including bioethics, which has risen to prominence over the past several decades–with ethical mandates. Grounded as it is within Open Insulin and community bio, our focus is primarily on the United States. We argue that our situated perspective as embedded social scientists allows us to read community-based biology in ways that present provocations for the ongoing efforts to institutionalize ethical approaches that adequately encompass it.

We present three such provocations grounded in our experiences and speaking to broader contemporary ethics debates: over ways of accounting for structural and political-economic determinants of health, over the limitations of individualized ethics and consent, and over the frequent focus on identifying common principles. Drawing on these insights, we suggest that community-based biology should be composed in tandem with what we call community bioethics, and provide some brief suggestions of next steps for developing these ethics. The term community bioethics is not intended as a parallel of bioethics for community-based biology; rather, it is intended broadly to capture the institutionalization of ethics within community-based biology and to emphasize its orientation toward pluralist collectives. At present, the institutionalization of ethics in community-based biology is at a critical juncture: It risks reproducing some of the shortcomings of institutionalized ethics, but as a movement that aspires to wider participation, it also has the potential to establish more inclusive ethics.

ETHICS AND ITS CRITIQUES IN ESTABLISHMENT AND COMMUNITY-BASED SCIENCE

The institutionalization of ethics in science and medicine has a long history, and it is not necessary to recount that history here. However, it is worth briefly describing some prominent ongoing debates in 21st-century ethics to better contextualize how our insights from community-based biology efforts contribute. Because community-based biology is so broad, our insights make contributions to diverse areas of ethics, particularly bioethics and human subjects research ethics. They especially question the typically individualized focus of institutionalized ethics in the United States. These contributions are not new to ethics discourse; bioethics, for example, is a diverse field in which many scholars have made similar observations and arguments. However, we aim to contribute to these existing debates within ethics and between ethics and the social sciences and argue for their salience to the ongoing development of community-based biology and institutionalized ethics alike.

Though ethics have taken shape and been institutionalized differently in different countries (Jasanoff 2005), institutionalized ethics are deeply shaped by their Western origins (Chattopadhyay and De Vries 2008) as well as by bioethics' origins in philosophy and clinical settings (Farmer 2004; Fox and Swazey 2008; Rennie and Mupenda 2008; Brock 2010). Critiques of bioethics–from both within and outside bioethics–have noted that in the United States especially, its framing of ethical questions tends toward an individualist orientation, as well as a focus on utilitarian cost-benefit assessments that revolve around questions of access to healthcare and cutting-edge biomedical technologies (Jasanoff 2005; Turner 2004; Berlinguer 2004; Daniels 2006). Additionally, a focus on articulating universal ethical principles–deemed principlism–has resulted in both a parochialization of ethics and a selective emphasis on those principles–like autonomy–most compatible with institutionalized ethics' individualist orientation (Evans 2000; Rennie and Mupenda 2008; Petersen 2013; Obasogie and Darnovsky 2018). In the process, ethical pluralism and more encompassing interpretations of existing principles, like justice, have been sidelined (Powers and Faden 2006; Daniels 2006; Brock 2010), and broader ethical deliberation has been displaced from the public sphere (Jasanoff 2005).

The pervasive orientation toward individuals has been attributed to roots in the doctor-patient relationship (Brooks 2010) as well as to the ongoing neoliberalization of medicine, which has undermined public health as medicine has become increasingly technologized, personalized, and marketized (Berlinguer 2004; Birch 2008; Clarke et al. 2010). The focus on cutting-edge technologies has also been ascribed to bioethics' need to establish its relevance and to secure funding by emphasizing new and exciting prospects (Turner 2004; Berlinguer 2004; Rennie and Mupenda 2008). The tendency to focus on access to healthcare–and specifically, individuals' rights to access healthcare–has been attributed to the legibility of individual rights within US political discourse generally (Brock 2010). Likewise, critics have attributed principlism to the appeals of calculability and predictability in bureaucratic ethical decision-making (Evans 2000).

To begin to address these critiques, some–again, both within and outside bioethics–have suggested that the discipline could productively engage the social sciences, including sociology, ethnography, and STS (Farmer 2004; Daniels 2006; De Vries et al. 2007; Azétsop and Rennie 2010; Petersen 2013). Specifically, arguments have been forwarded that institutionalized ethics should pay more attention to power and to structural determinants of health and to understand health as more socially situated and less the product of medical and technological intervention (Powers and Faden 2006; Illingworth and Parmet 2009; Brock 2010). Some have argued that ethics could also benefit greatly from contributions from the Global South and the medically marginalized (Farmer 2004; Rennie and Mupenda 2008).

We aim to contribute to these conversations about broadening institutionalized ethics using our perspectives as ethnographers and social scientists working within a specific type of space at the margins of modern biology and medicine: community-based biology. Although our analysis is based in the United States, it speaks to a project (the Open Insulin Project) and movement (the Global Community Bio Summit) that both have global aspirations and hope to speak to marginalization within contemporary science and medicine. In doing so, we also contribute to ongoing conversations about the ethical challenges presented by community-based biology.

Novel forms of community-based research in health and biomedicine present many such challenges. Scholars have identified the need to fill the "ethics gap" brought about by the growth of research outside conventional institutions (Rasmussen 2016; Trejo et al. 2021) and worked to explore how to do so. Stories from several community-based science efforts, including those in health and biomedicine, have demonstrated the sheer number of issues that need to be confronted in practice, highlighted some of the shortcomings of existing approaches in institutional ethics, and noted the difficulties of applying them to community-based science (Rasmussen 2019a). This includes the reality that community-based science contains a diversity of practices and more than one ethos differentiating it from establishment science (Wiggins and Wilbanks 2019; Aungst, Fishman, and McGowan 2017). Often, this differentiation is intentional and explicit (McGowan et al 2017). The diversity within community-based science includes perspectives on ethical oversight itself, and community-based researchers often prefer community-driven and voluntary approaches to externally developed and imposed requirements (Trejo et al. 2021). Collectively, this insightful work affirms the existence and importance of "pluralistic ethics" (Wiggins and Wilbanks 2019, p. 11) and the need to be attentive to the ethics that unconventionally situated researchers bring to the table and how they challenge established institutionalized ethics, both explicitly and implicitly.

Though there is recognition of the unique ethical challenges that community-based biology efforts pose, many efforts focus on a relatively small number of ethical dimensions of community-based science. A focus on sets of issues like biosafety and harm, validation and replication, or authorship and credit (e.g., Wexler and Rasmussen 2020) risks narrowing lines of ethical questioning. Likewise, emphasizing legal regulation (e.g., Zettler, Guerrini, and Sherkow 2019), while doubtless significant, does not fully capture the ethical stakes involved in the proliferation of modes of citizen engagement with the life sciences and medicine. Some analyses advocate adapting or tweaking existing institutional frameworks. For example, Vayena and Tasioulas (2013a) propose that evaluating whether particular participant-led research projects require ethical review is a matter of firstly determining whether a participant is part of a conventional institution (and therefore the project can be reviewed in conventional ways), and if not, whether it involves activities which exceed some threshold of minimal risk. Such approaches are pragmatically useful but limited because they remain dependent on existing institutional standards while dealing with both novel scenarios and critiques of the underlying ethical frameworks. Like the image of the ethics gap, they may suggest the need to merely extend and adapt existing ethics frameworks to suit community-based biology, rather than question some of the built-in assumptions of existing frameworks in light of the challenges and critiques that community-based biology presents.

One notable exception in this space is Rasmussen and colleagues' (2020) call to develop a "trust architecture" to support potentially valuable contributions that non-establishment research could make to health and medicine, including community-based biology. This involves developing structures that avoid importing established ethical norms into such research, and instead "build[s] on work these communities have already been doing" (p. 12). We agree with Rasmussen's argument that "citizen science challenges much more than just our regulation, it also challenges the categories of thought on which those regulations depend" (2019b, p. 19).[2] However, there is a danger that trust architecture will be treated as an instrumental means to secure legitimacy for community-based biology and that the approach does not go far enough–especially in light of recent controversies over public trust in science (e.g., Kennedy, Tyson, and Funk 2022)–in questioning establishment science's own trust architecture.[3]

These communities have indeed been working on ethics. Since its early days, community-based biology has taken steps to create assurances that the work it was doing was both ethical and–especially–safe. Community-based biologists themselves have argued, particularly in response to ethical and safety concerns, that community-based biology has better ethical practices and procedures than establishment science (Trejo et al. 2021). Some observers, too, have taken community-based biologists' efforts as evidence of decentralized and proactive governance often lacking in establishment science and noted that because community-based science takes place in group settings and in laboratories that are transparent, they have built-in safeguards against unethical science (Kuiken 2016). Amateur biologists established cooperative relationships with the Federal Bureau of Investigation (FBI) (Wolinsky 2016), produced voluntary codes of ethics at "congresses" in both the US and Europe (DIYbio 2011; Kuiken 2016), and–more recently–took steps toward establishing an "IRB for biohackers" (Ware 2020, n.p.). Despite the initiative demonstrated by these efforts, their emphases have often been meeting existing legal requirements, legitimating biohacking in the public eye, and facilitating collaboration with institutional science. These efforts have therefore also risked treating ethics both instrumentally and narrowly, reproducing some of the features of status quo ethics and failing to capture the ethical diversity of community-based science.

Within community-based biology, conversations around ethics have also focused on certain principles lending themselves to calculability and predictability. Safety especially–and understandably, due to early community concerns and FBI interest–has become a central concern that also readily lends itself to technical risk analysis rather than a broader mode of ethical deliberation (e.g., Grushkin 2018). Claims that ethical concerns over community-based science are premature or misguided given their limited technical capabilities reinforce the idea that technological capacity should guide determinations of ethical validity. Likewise, belief in the built-in safeguards of community-based science tends toward an idealistic picture of community-based science, and further, is seemingly at odds with how ethical controversies typically play out in establishment science. This understanding favors characterizing unethical science as the work of insufficiently checked rogue individuals; however, it fails to account for either the gaps between the transparency of community-based science in theory versus practice or the ways that establishment science communities often support and endorse activity that is recognized as unethical only in hindsight (see Hurlbut 2020).[4]

Taken together, the critiques of institutionalized ethics and the challenges of developing ethics in community-based biology demonstrate the need for spaces of broader ethical deliberation. Such deliberation should both question the assumptions built into established ethical institutions and frameworks and acknowledge the critiques of established institutions that community-based biology presents. The growth of community-based biology is both a symptom of frustrations with the shortcomings of institutionalized science and an opportunity for redress. Challenging the categories of thought that undergird institutionalized research ethics entails proliferating examples of the mismatches between the values driving community-based science and existing ethical frameworks. Our focus on situated ethics closely tied to both collective discussions around community-based biology and a particular community-based biology project is an attempt to draw out some of these mismatches and thereby explore some strands of ethical pluralism that complicate and problematize narrower and more restrictive ethical conventions.

PROVOCATIONS FOR COMMUNITY BIOETHICS

Our perspective on the ways that community-based science compels us to rethink the place of ethics in science more broadly comes largely from our work with the Open Insulin Project, along with our participation at the Global Community Bio Summit (GCBS, biosummit.org). The Open Insulin Project aims to create an open-source form of insulin, which includes both the insulin itself and the protocol on how to make it. Motivated by the rising prices of insulin in the US and the near monopoly of insulin production, they ultimately want to establish a distributed, democratized community-scale insulin production network. Both authors conducted ethnographic fieldwork with the Open Insulin Project. AM conducted participant-observation and interviews with Open Insulin from 2017 to 2019, during which time he attended meetings for the Project and participated in the broader community-based biology networks of which Open Insulin is part. DS conducted fieldwork from June to December 2019 as part of a larger project on the democratization of biotechnology in community science labs, of which Open Insulin was a case study; this involved attending weekly project meetings, participant observation of lab work, and interviews with project members. Following in-person fieldwork, both authors continued to be involved in the project remotely.

No doubt due to its focus on justice and equal access to an essential medicine, many uphold Open Insulin as a shining example of community-based science's potential to serve the public good (e.g., Talbot 2020; Maloney 2021; Marks 2021; AP, personal communication). Open Insulin's work remains early stage (with clinical trials with human subjects not yet on the horizon). Because it is directed at issues of cost and medical access, the Project invites consideration of institutionalized ethics that it both challenges and stands poised to engage. Without assuming that Open Insulin, or community-based biology, are inherently more ethical than the institutional science to which they present an alternative, we wish to provide some examples of how our work has prompted us to rethink both research ethics as commonly practiced and as they are being implemented in the broader community-based science ecosystem.

In what follows, we detail some of the ways in which our work with Open Insulin and community-based biology have informed our thinking on the ethics of community-based biology and what community bioethics could become. We present empirical moments that we hope serve as provocations that encourage not just a broader and more purposeful rethinking of community bioethics in formation, but also of institutional ethics in light of the ethical challenges that community-based biology helps bring to the surface. In particular, our experiences in community-based biology have drawn attention to: 1) the ethical limitations of a narrow conception of risk that takes systemic vulnerability, particularly within a market-based model, for granted; 2) the shortcomings of a reliance on an individualized approach to the protection of research subjects; and 3) the constraints on ethical deliberation that arise by privileging the identification of ethical principles. Each will be discussed in the sub-sections that follow. Speaking to what we have characterized as a juncture in the institutionalization of community bioethics, in each case, developments within community-based biology exist in tension with institutionalized ethics. That is, these efforts both provide situated empirical critiques of the status quo's shortcomings and show signs of reproducing some of the status quo's critiqued tendencies. To help navigate these tensions, we provide a few modest suggestions for how community bioethics might avoid reproducing these patterns, and in so doing, gesture toward more promising new directions.

INSULIN ACCESS AND THE EXPERIMENTAL SUBJECT

Self-experimentation was one of the early sources of ethical controversy in community-based biology. It was therefore surprising for one of the authors (AM) to learn that self-injection with open-source insulin was not out of the question for Anthony, the Open Insulin Project's founder. He wanted to probe what made a self-injection stunt carried out by Open Insulin different from those ill-fated attempts by biohackers like Josiah Zayner (Lee 2017) and Aaron Traywick (Bromwich 2018). The seeming disjuncture between Open Insulin's ethos and institutionalized ethics around medical experimentation revealed different possible frameworks for thinking about danger and the scale of experiment.

Anthony did have a streak of the libertarian bodily-autonomy politics that often marked his fellow self-identified biohackers, but he and other Open Insulin members were quick to dismiss any comparison between these self-injections, for a simple reason: This was not an experimental treatment, but rather an established and necessary medicine (TT, personal communication). The presence of insulin was testable, so once the Project had cracked its production and purification, injecting the product would be no different than injecting the insulin he was already taking–except that it would have been made in a community lab instead of in the facilities of a pharmaceutical corporation. Indeed, for people lacking access to affordable insulin, who may turn to rationing despite harmful–even fatal–results (Herkert et al. 2019; Lipska 2019), the community-lab insulin could be lifesaving.

Open Insulin members were keenly attuned to the structures of insulin production and provision. They regularly disparaged not only "Big Pharma," but also the Food and Drug Administration (FDA). The former largely referred to the three major pharmaceutical companies that produce the vast majority of the world's insulin supply: Eli Lilly, Sanofi, and Novo Nordisk (Wirtz et al 2016). Open Insulin's members often criticized the insulin market as an oligopoly dominated by this small number of players. Members cited these companies' suspicious tendency over the preceding decade to raise prices stepwise as a group (Robbins 2016; HCCI 2019) and the practices of patent thickets and the incremental improvements in insulin production and formulation that have resulted in the domination of the insulin market by on-patent forms, preventing generic insulins from becoming widely available to patients (Greene and Riggs 2015; I-MAK 2018; Foti 2020). Though getting their insulin to people in the United States would likely require going through FDA one way or another,[5] Anthony and other Project members viewed FDA as part of the oligopolistic control of the insulin market, providing barriers to entry that helped secure Big Pharma's market share, and were reluctant to engage them. They believed that FDA was not fully living up to its mandate to promote public health and protect patients, and saw engagement with it largely as a bureaucratic hurdle.

Open Insulin's wariness of institutionalized regulation and patient protection and the willingness to deviate from established institutional pathways encourages a different way of conceptualizing the relationship between drug producers, regulatory institutions, and patients. This reconceptualization lies at the nexus of these many factors: initial surprise at the prospect of self-experimentation, the confidence with which Open Insulin members dismissed its comparisons to seemingly similar efforts, the deaths of people with type-1 diabetes forced to ration insulin because of lack of affordable access, criticisms of patent system abuse, and FDA's gatekeeping role. In brief, the concept of experimental risk that drives the discourse around self-experimentation is limited and largely blind to the social and economic structures that put American insulin users in a fundamentally precarious position. As a result, it is blind to the dangers that people who cannot afford insulin face in their day-to-day lives. What good is an ethical conceptualization of risk, even at the individual level, that does not account for the ways in which such risks are systematically produced by broader political economies of health and medicine, even prior to a recognizable medical intervention?

Some steps have been taken to increase clinical trial participation among patients of lower socioeconomic status (e.g., Unger et al. 2016), reasoning that they can increase access to treatments that would otherwise be unaffordable for these groups. However, there is little discourse of the broad systemic economic risks shouldered by patients who rely on life-sustaining medications like insulin. Clinical trials of new insulin formulations, for example, do not factor in the risk that many insulin patients will face if a new patented formulation makes it to market and displaces prescriptions for more affordable forms. The bounds of the experiment–and consequently, the experimental human subject–accounted for by institutionalized ethics are too narrow. This creates a system of limited accountability for the development and marketization of new treatments and limited space for the expression of patients' experiences of vulnerability.

However, Open Insulin's turn to community-produced insulin could also reinforce the focus on access to medicine as the chief guarantor of health. Open Insulin is directed toward a problem of access to a drug with stark life-or-death consequences for those who depend on it, as well as the specific American context in which these drugs become unaffordable. Consequently, it–along with other community efforts focused on medicine and biotechnology–risks reproducing the idea that access to medicine and healthcare is the primary determinant of health, when this is not necessarily the case in all contexts.

It would behoove us to rethink the bounds of experiments to encompass the bioeconomic experimentation in which patients have been enrolled without their consent. This is especially true of the era of biocapital (Sunder Rajan 2006) and biomedicalization (Clarke et al 2010). In this era, commercialization has expanded and become increasingly inextricable from the development of science and medicine, without sufficient corresponding expansions of how we account for the evolving role of markets in human-subjects research ethics. Community-based projects like Open Insulin are drawing attention to this type of societal-scale experimentation. Even so, community bioethics would do well to understand the social determinants of health still more broadly, to consider the ways in which many forms of health are not merely questions of access to medicine. Incorporating considerations of multiple types of systemic vulnerability–for example, those that motivate environmental justice efforts–into the fledgling institutions of community bioethics would help them avoid playing into some of the same neoliberalized understandings of health that underpin the contemporary biopharmaceutical industry. Community bioethics could serve as an example for how established institutions like FDA could become more accountable to the patients who rely on them but are losing faith in their ability to protect them.

INSTITUTIONAL REVIEW BOARDS AND LEGAL AND COLLECTIVE RISK

Our work with Open Insulin reveals another facet of the tendency of institutionalized ethics to individualize and narrow questions of risk and also speaks to the principle–and limits–of openness in community-based science. Further, it engages a side of human-subjects research not typically discussed in the context of community-based science: social science research.

As social science researchers working within and studying the Open Insulin Project, we required ethical review from our respective institutions to receive assurances that the risk we posed to our research participants was minimal. The principle of openness, extending to the open-door policy at Counter Culture Labs (CCL), suggested that there were few expectations of privacy or risks of loss of reputation from accidental disclosure. In one institution's ethical review, the research was judged exempt from full review on the grounds that it would not "reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation" (OHRP 2018: n.p.).[6] This exemption was granted in part because CCL and Open Insulin presented themselves as "open" in a broad sense.

However, the unique challenges presented by studying community-based scientists proved difficult for typical approaches carried out by institutional ethical review. Operating under the terms of this exemption, it became clear that the principles and policies of openness were more complex than they initially seemed. It was very easy for us, as social scientists, to enter the lab space and be accepted as members of a community that was, in this sense, open. Despite this, it became clear over the course of fieldwork that not all the activities or spaces of the Project were open in the same sense, and that there were vulnerabilities and risks that necessitated special protections. The IRB noted earlier showed that they were not well-equipped to consider them.

The risks that Open Insulin faced stemmed from its specific strategy of circumventing intellectual property protections for an insulin analog by developing a new process for bioengineering insulin. Because of this strategy, the concern of potential patent infringement became relevant for protecting the project and for considering risks of "criminal or civil liability" (OHRP 2018: n.p.). For example, the IRB was notified of the ambiguous liability around patent infringement and some of the protections that Open Insulin members felt were necessary to ensure that they would not become the target of a lawsuit, forced to wage a court battle they would be hard pressed to afford. Despite the fact that Open Insulin explicitly sought to develop a protocol avoiding existing patent thickets, the legal nature of patent infringement meant that a patent-owning entity could nonetheless take the Project to federal court for infringement–and that infringement or non-infringement remained fundamentally indeterminate in the absence of a ruling. In such processes, ethnographic fieldnotes could be subject to discovery processes, and even collecting or reviewing existing patents in the interest of circumventing them could be presented and interpreted as evidence of infringement. Thus, openness, while often a broadly interpreted principle of community-based science, could also both prove a source of vulnerability and come into conflict with some of Open Insulin's other values.

When notified of these new concerns, this IRB responded by suspending the research and initiating an investigation, the end result of which was that the research could proceed effectively unchanged. The research remained exempt from full review, and the IRB seemed not to know how to handle the questions of ambiguity around either openness or infringement, or how to understand a risk that was posed to the future of a volunteer-based, nonprofit project, but not exactly to its individual members. It also did not know how to assess whether this potential for risk was a "reasonable expectation," in the language of the exemption criteria. In cases like this, the forms of reason and reasonableness that guide community-based projects like Open Insulin push back against the reason that commonly guides conventional research ethics.

The tools in the social science toolkit that point out the social construction of risk and reason (for example, the STS theory of co-production; Jasanoff 2004) have the potential to contribute to community-based projects and to an ethics that is more capable of weighing questions of community values and risks. These developments were among the impetuses for forming the Open Insulin in Society Working Group, a former sub-group within the Open Insulin Project and of which this paper's authors were founding members. This group aspired to reflect on and make legible the place of the social sciences and social science researchers within the project. It crafted and adopted shared ethical practices that went beyond the requirements of our individual IRB protocols and considered the group-level vulnerabilities of Open Insulin.

Though the "IRB for biohackers" signals a positive form of ethical proactivity, if such a community-based IRB is to be established, it should do more than merely reproduce this institutional model or seek to satisfy existing legal requirements. Instead, it should carefully consider how ethics and ethical review can be situated within the specific context of community-based science. In doing so, it can help illuminate and address some of the ethical concerns for which institutionalized ethics has proven inadequate. Grounding ethics within the idea of community wellbeing will expand the concerns guiding the pursuit of ethical research. Ideally, this will encourage reflection on how reasonable expectations of harms are subject to specific constructions of both harm and reason that are in turn subject to dynamics of power and expertise. These expectations, like institutionalized ethics in the US more broadly, are particularly attuned to the individual and thus under-equipped to think about community-level harms. Taking steps to address these shortcomings would help research ethics become more of an ongoing dialogue between community members, research participants, social scientists, and ethicists.

DOCUMENTING ETHICS IN COMMUNITY BIO

Several members of the Open Insulin Project–including this paper's authors –have participated in the Global Community Bio Summit (GCBS). The Summit, an annual conference for those working in community biology labs from around the world, was first held in 2017 at the MIT Media Lab. At the 2018 Summit, a Statement of Shared Purpose was developed that encapsulated the global community's overarching aspirations, and at the 2019 Summit a Community Ethics Document was produced. In this section, we analyze the process of creating the ethics document to highlight constraints on ethical deliberation and pluralist ethics in community-based biology. The ethics activity and its outcomes constitute promising foundations toward more robust community bioethics–if we understand the activity and treat what emerged from it not as ethical consensus, but as impetus for further debate and deliberation.

We focus on how the logic and assumptions that undergirded this ethics activity espouse an approach to governance that limits community bio's capacity to radically rethink ethics in scientific practice. These assumptions include the idea that community bio has latent shared ethics that merely need to be drawn out; that scientists–including community-based scientists–are best positioned to ethically govern themselves; and most pragmatically, that community-based biology has adequate resources at its disposal to devote to ethical deliberation.

The methods of this community ethics activity are detailed elsewhere (Pearlman and Kong, in this special collection), but they are worth recounting briefly. The ethics activity expanded on two activities at the previous year's summit, GCBS 2.0. The first activity was a series of group sessions that collected ideas to edit the "Statement of Shared Purpose" that had been drafted by organizers. The Statement sought to articulate the common aims of those gathered under the community bio banner. Emphasizing convergence rather than disagreement, the statement was ultimately broad enough to accommodate quite disparate values. The second activity involved a series of issues relevant to community bio with potential differences of opinion arranged along spectra. Attendees could write their ideas on sticky notes and place them along a given spectrum. At times, participants could not find appropriate places for their perspectives along the spectra at all and instead chose to place them in the marginal spaces outside them.

The ethics activity's approach at the next summit, GCBS 3.0, built on these activities. In a series of three ethics-focused sessions, Summit attendees shared and explained their ethical convictions. Sticky notes were again used to gather attendees' thoughts on the movement's core ethical principles. After the three separate sessions, the principles on these notes were compiled into a spreadsheet. A smaller group (ranging from 4 to 8 people over six hours) of self-selected attendees–including this paper's authors–then gathered to use the spreadsheet as the basis of the ethics document.

The ethics activity shared some of the same shortcomings as its predecessor. Generating the Statement of Shared Purpose presumed a common purpose, much like the ethics activity sought to identify common ethical principles held by the community. The repeated assertions that participants already shared values and ethics, repeatedly emphasized in the early stages of the Summits, may have even served as a disincentive to participate in these activities directed at articulating them. Limitations to the approach of collecting and then distilling attendees' ethical principles became apparent, as the proliferation of ethics and values, rather than revealing an underlying ethical cohesion, revealed differences that remained irreconcilable.

As a result, the group that gathered to generate an ethics document faced a more demanding task than initially anticipated. Furthermore, the self-selected group was less representative than the Summit itself. Social scientists like ourselves were overrepresented, and the fact that the session ran parallel to sessions focused on community bio in specific regions also contributed to the underrepresentation of global, more diverse perspectives. This small group wielded considerable interpretive influence to distill the participants' perspectives on ethics, and it was partly for these reasons that the group decided that the ethics document should take the form of a list of questions rather than a statement of principles. Principles could not do justice to a group this diverse, and attempting to articulate them, especially so prematurely, would run the risk of narrowing community bioethics and falling into the same tendencies toward principlism as bioethics writ large.

The list of questions presented at the conference's conclusion, while intended as a starting point, remains the effective official document for GCBS (see GCBS 2019). Potential future conference attendees must read through, consider, and agree to the ethics document at the time of application. But the original intent of its formulation as questions that require answers–answers that are important precisely because they are likely to differ across the community bio sphere–seems to have been lost. Instead, there is a danger that the ethics document is being treated as a signifier of ethical consensus.[7] Community bio members can treat the ethics document as a flexible boundary object (Star and Griesemer 1989) that allows their work to continue relatively unaffected by the ethics activities, in an example of cooperation without consensus (Star 1993)–or perhaps, cooperation disguised as consensus.

The activity and the ethics document evince ongoing struggles to define the demos–the who–of community bio, a difficulty that was apparent in previous efforts to develop the Statement of Purpose. The simultaneous desires to pitch a large tent and to find ethical common ground, especially amid controversy, have resulted in articulations that are either broad to the point of near meaninglessness (as in the Statement of Purpose; GCBS 2018) or that remain largely stagnant (as in the Community Ethics Document; GCBS 2019). The large-tent approach stems from community bio's global focus and from its self-fashioning as a diverse and inclusive public. The push for ethical common ground arose not only from controversies that had affected and threatened amateur biotechnology hobbyists and the institutions like the Media Lab that had played a role in convening them (see Tracy and Hsu 2019), but also from desires to set community bio apart from the scientific institutions to which it offers a critique and an alternative. However, attempting to articulate common ethical principles without adequately taking up the question of the *demos* doing the speaking creates substantial difficulties.

Community-based biology has the potential to challenge the arrogation of ethical decision-making to experts. Inherent in this arrogation is the assumption that only those with technical knowledge are equipped to govern science and technology. However, in failing to clarify that it also consists of a specialized community of technical enthusiasts, community bio also asserts a right to speak at least partially grounded in technical knowledge–even if this technical knowledge is not obtained by conventional means or sanctioned by conventional institutions. Indeed, community bio's theory of empowerment lies in increasing access to the information and tools of biology and biotechnology. In doing so, it tends toward reinscribing, albeit in a more inclusive form through its expansion of who may be designated an "expert," the doctrine of expert self-governance.

The impulses toward diversity and inclusion–including the willingness to accept social scientists into the community–are promising, but seeing them through means sustaining important ethical conversations and expanding them well beyond the still-relatively-narrow crowd of community bio enthusiasts, as well as more deeply exploring the kind of publics community bio represents. This will necessitate drawing out the pluralism of values that exists among those gathered under the community bio banner, for example by establishing commitments to answering the questions presented in the Community Ethics Document. It will also require recognizing that even this diverse group represents specific factions interested in both doing science and rethinking the place of science in society, and that technical fluency is not a precondition for participation in remaking the relationship between science and ethics.

CONCLUSION: TOWARD COMMUNITY BIOETHICS

Institutionalized ethics have made important strides in setting standards for scientific research. However, as pushes for more accessible and inclusive life sciences makes clear, these standards have been set in ways that are often exclusionary and that constrain the breadth of possible ethical consideration. The involvement of more people in the sciences helps open the door to broader discussions about the relationships between science and democracy. At the same time, the tendencies to overestimate the breadth of the public of community-based scientists and to over-rely on the frameworks and precedents of institutionalized ethics–including individualist and consumerist orientations, principlism, and expert self-governance–risk limiting the transformative potential of community-based biology when it comes to building broader and more inclusive ethical foundations.

We are therefore less interested in identifying the ethics of community-based bio or even designing or adapting ethics for community-based bio than we are in recreating ethics in light of community-based bio. This is necessarily a broader, even more radical, project than most initiatives, which have relied too heavily on applying, adopting, or adjusting existing institutional ethical approaches to these novel community-based research contexts. It is a project with implications for how science is conducted and how science-society relations are imagined and enacted.

Our empirically informed suggestions are, generally, to incorporate broader systemic understandings of health, experiment, and vulnerability into experimental and human subjects ethics and to foster sustained commitments to ethical deliberation and drawing out the ethical pluralism of community-based biology. While these suggestions are not new, we also demonstrate ways in which the opposite tendencies threaten to take root in the institutionalization of ethics in community-based biology. Within community-based biology, these suggestions advise more critical and less instrumental discussions of research ethics that engage and address the shortcomings of institutionalized ethics. They also advise addressing the value differences that the question-based GCBS ethics document was designed to draw out. Our hope is that by illustrating tensions between ethical critique and the reproduction of institutionalized ethics' narrow framings, our provocations can help community bioethics realize their potential of building a different kind of science, a science that draws the boundaries between research and ethics differently and hopefully, better. Community-based biology stands to be more than merely science done in different places and by different people. In part by taking inclusive ethical deliberation more seriously, it stands to help build sciences that are more democratic, more attuned to the diversity of human belief and values, and ultimately more accountable to the worlds it helps usher into being.

DATA ACCESSIBILITY STATEMENT

To protect the identities of research participants according to the terms of the authors' institutional review board approvals, data used in this research project have not been made publicly available.

NOTES

1 Both within the movement and the literature analyzing it, there have been a range of terms used to describe the identities and activities involved in efforts to engage in science and biotechnology outside of existing institutionalized contexts. No consensus has emerged around a particular term, and so terms are used for a variety of reasons; for example, Guerrini et al. (2019) and Trejo et al. (2020). Lacking a cohesive overall term, we opt for community-based biology here to distinguish talk of the overall group of practices from discussions of specific subsets (e.g., community bio, biohacking).

2 As an example, Rasmussen points out the ways in which community-based biology blurs lines such as those between research and treatment. We argue that owing to developments including personalized medicine, this line is blurring in biomedicine more generally.

3 We would also caution that a focus on public trust may reinscribe the "deficit model" of the public understanding of science (Wynne 1992, 2006).

4 The recent high-profile example of experiments that led to human beings born with heritable genome edits is illustrative (see Regalado 2018). There is evidence that many members of the international scientific community were aware of the experiments but did not raise significant ethical objection; only after news of the experiments broke in 2018 did consensus that the experiments were a serious breach of ethics form (Hurlbut 2020; Cohen 2019). He himself had bioethics training and apparently believed that his work was ethical (see Begley 2018).

5 Open Insulin members hoped to do it by establishing insulin as a biosimilar. A relatively new pathway in the United States, the biosimilar designation is the rough equivalent to generics for larger-molecule biopharmaceuticals that allows for an abbreviated clinical trials process, reducing the cost to bring drugs to market (FDA 2021).

6 This language is from the federal criteria for exemption from IRB review at the time of the exemption decision. This language was later slightly updated in 2018.

7 One of the questions in the ethics document even anticipated these developments: "Is there an active commitment to consider these questions?"

ETHICS AND CONSENT

Research was approved by institutional review boards at the University of California, Santa Cruz (Protocol #HS2679/3527) and Clark University (Protocol #2018-065). The Office of Research Compliance and Administration (ORCA) at UC Santa Cruz deemed this research exempt from full review. After receiving an incident report from AM, the research was again deemed exempt:

> "The Office of Research Compliance Administration has determined that the human subjects research protocol referenced above meets the criteria for exemption described in 45 CFR 46.104 and/or the UCSC Policy on IRB Regulatory Flexibility under the following category(ies): Exempt 2 – Limited Review / Exempt 3X."

In both cases, the IRB determined that the research was exempt from written informed consent procedures. However, the IRB approved a procedure in which all participants in the study received an information sheet and a verbal explanation of the study, its potential risks to participants, and their rights as human research subjects. Following this explanation, all participants provided verbal consent to participate. According to the approval from the IRB at Clark University, informed consent was required and obtained from participants involved in the study (interviews and lab-based participant observation), on the condition that identities would be anonymized in published outputs.

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COMPETING INTERESTS

The authors have no competing interests to declare.

AUTHOR CONTRIBUTIONS

AM took the lead with conceptual framing, empirical data analysis, and writing of the piece, with DS providing support with respect to literature review, data analysis and writing. Both authors contributed to drafting, editing and revisions. Both authors provided final approval of the published version and agree to be named as authors and to be accountable for all parts of the published work.

AUTHOR AFFILIATIONS

Andy Murray orcid.org/0000-0003-0161-5333
Harvard Kennedy School, US
Dan Santos orcid.org/0000-0002-6413-4150
Australian National University, AU

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