Research as Development
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Published by Cornell University Press

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Research as Development: Biomedical Research, Ethics, and Collaboration in Sri Lanka.

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In this book, we set out to describe ethnographically the entanglement of biomedical research with a variety of development objectives in contemporary Sri Lanka. This entanglement has been seen to unfold at a variety of relational scales, ranging from the personal through the institutional and into national and international arenas. The practices through which we explored the dynamics of biomedical research and development were those of clinical trials, collaboration, and bioethics. Methodological engagement with these practices has drawn attention to the manner of their assimilation into the Sri Lankan setting. By way of conclusion, we offer some further reflections on the relationships between these practices and the implications that this study has for biomedical research as development in other parts of the global south.
Bioethics and Clinical Trials

Bioethics is a distinctive and important thread woven into the global reach of biomedical experimentation involving humans, and it is no less so in the account we have given here. The lexicon of bioethics has been built around foundational concepts such as autonomy, dignity, respect, voluntarism, beneficence, and justice (Anderson and Steneck 2011; De Vries, Rott, and Paruchuri 2011), and these terms feature in the cogitations surrounding engagement with clinical trials in Sri Lanka that we have developed here. As Renée Fox argued long ago, this lexicon gives bioethics a distinct orientation and accords “paramount status to the value complex of individualism, underscoring the principles of individual rights, autonomy, self-determination, and their legal expression in the jurisprudential notion of privacy” (1990, 206). The development of this perspective reached a kind of florescence in the approach referred to as “principlism.” Using the four cardinal points of justice, beneficence, non-maleficence, and autonomy, it was believed that bioethicists could navigate their way through the kinds of problems that progress in bio-medicine were increasingly throwing up (Beauchamp and Childress 1989). This formulation—“the Georgetown mantra,” as it became known—has been used widely. Indeed, one of the reasons we refer to it here, thirty years after it was brought into existence, is that it was still in use for teaching medical ethics in Sri Lanka at the time of our fieldwork.

In the clinical trials assemblage, the conceptual architecture that has been drawn on has as its central tenets informed consent (what it is, how it might be meaningfully elicited, and how it might best be rendered “informed”); subject protection (how the aspirations of trialists might be balanced against the acceptable risks to participants); and questions of benefit (how much, to whom, and to what ends). In taking on the responsibility of performing a trial, conformity to the latest standards and directives is crucial. Moreover, these standards and directives are shaped by the deliberations of those who make up the ranks of bioethicists—philosophers, lawyers, doctors, and social scientists working in collaboration with government and industry regulators. As most of these individuals tend to be drawn from countries in the global north, the conceptual underpinnings of bioethics are mostly consistent with those in play in those parts of the world. Clinical trial regulatory tools, such as the International Conference on Harmonization Good Clini-
cal Practice Guidelines (ICH-GCP), thus operate with considerable hegemonic force. This force is most readily apparent across sites in the global south where the conceptual and material infrastructures are least developed.

The guidelines lay out “a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health” (Dixon 1998). Yet bringing together a genealogy of universal human rights with commercial pharmaceutical research interests has raised suspicions about the role of ethical oversight in research (Abraham 2007; Abraham and Reed 2002). Is the work of oversight the handmaiden rather than the governor of trial activity? And does it perform a role that is essentially procedural, bureaucratic, and rule observing (Stark 2011)? Is there a space in which bioethics might operate that is not already hedged about with these parameters?

As the field of expertise that sets out to understand the relationship between Western biomedical knowledge and human value systems, bioethics covers a very wide terrain. However, given its particular genealogy, it is hardly surprising that bioethics brings about particular problems when it travels beyond the human value system out of which it emerged. As we have demonstrated, the standardized, technical specifications underpinning the safe and ethical conduct of a trial are one thing, but just how these articulate with the domain of ethics as constituted in the local setting is quite another. Echoing Arthur Kleinman, we see people’s moral realities as being shaped by local experience whereas bioethics is “translocal”—that is, it is “a view from nowhere” rather than a view from somewhere (Kleinman 1995, 2006; also see Muller 1994). As Jessica Muller once put it, “rationalistic thinking and a deductive utilitarian orientation to problem solving provide an illusion of objectivity and logic. Informed by the legacy of Cartesian duality, the analytical style of bioethics contributes to a distancing of moral discourse from the complicated settings and interactions within which moral dilemmas are culturally constructed, negotiated and lived” (1994, 52). In contexts of poverty and underdevelopment, this point is of even greater consequence as it sits within the broader issues of injustice and abuses of power. Indeed, the conceptual infrastructure of bioethics that underpins the governance and regulation of clinical trials can operate as a device to convert collective local
concerns into ones that are individualized, procedural, and uncontentious. As we argue in the final section of this chapter, bioethics appears to be operating rather like Ferguson’s notion of an anti-politics machine, in that it serves to draw parameters around what is and is not of actionable concern when operating in a low-income setting (Ferguson 1994). Before exploring this point further, however, we must square a particular circle.

The quest for standardization, consistency, and universality in the use and meaning of terms and concepts is integral to the quest for a global bioethics. Yet the aspiration for a singularity of sorts must always confront a plurality of local visions. Attempts to square this particular circle have resulted in some acrimonious but nonetheless healthy debate around the status of local voices and sensitivities in the global bioethics assemblage (Bracanovic 2013, in response to Chattopadhyay and De Vries 2008; Chattopadhyay and De Vries 2013; Ten Have and Gordijn 2011). One obvious conclusion to be drawn from these debates is that at the point of confluence between the global and local, there is work to be done regarding the management of “engaged universals” (Tsing 2004). Our contention here is that there ought to be better opportunities for voices from the global south to shape the terms of north–south engagements where biomedical research is concerned.

In our account, we have tried to provide examples of how researchers in Sri Lanka became part of the global bioethics and clinical trials assemblages and did so by appropriating and reappropriating its ideas and practices in the day-to-day work of installing ethics committees, providing ethics training, building clinical trials capacity, and introducing novel transactions such as informed consent procedures to be used in trials. These appropriations show that there is indeed a relationship between Kleinman’s “nowhere” and our “somewhere,” and furthermore that the distinction may, in any case, be of limited utility. The somewhere of an international clinical trial is, we would argue, increasingly evident in the “nowhere” of bioethics, as the plain facts of cultural diversity, ethnic pluralism, and structural inequality begin to reshape an apparently fixed and hegemonic conceptual architecture—or what we referred to in chapter 6 as science in mode $\text{2}^n$. To appreciate the importance of this point fully, we need to look more closely at the fabric of social and cultural interactions that make up the day-to-day running of a trial—the sociality of experimentation.
Clinical Trials and Collaboration

The chemist and philosopher Michael Polanyi went to great lengths in his explication of “personal knowledge” to argue that the making and validation of knowledge cannot be understood as wholly distinct from the emotional and spiritual interiors of those whose task it is to create and validate such knowledge (Polanyi 1958). In turn, these interiors are shaped by the relationships that make up the social worlds in and out of which scientific practice evolves. Rather like Latour’s critique of the pure emergence of facts (1982, 1993), Polanyi’s treatise was a wide-ranging critique of what he saw as a “naïve objectivism” that underpins the view that the only valid scientific knowledge is that which emerges out of methods that are demonstrably impersonal, explicit, and easily captured in textual representation. What Polanyi was seeking to highlight was not only the importance of the tacit and inarticulate dimensions of how we come to know but also the role of relationships, mutuality, and trust in scientific pursuit. All this he gathered together under the heading of “conviviality,” drawing attention to the continued embeddedness of these vectors in scientific practice and what he referred to as “the civic coefficients of our intellectual passions” (Polanyi 1958, 217).

For Polanyi, there was an important relationship between knowledge and organization; moreover, this relationship was one that should be cultivated and preserved as the wellspring of creativity. Within this view, diversity and locality are necessarily integral to the scientific practice of individual scientists. This is as true for multisite trials in Sri Lanka today as it was in the projects that Polanyi described. What we have tried to describe here are the nexuses that connect the “black box” of research activity (Hess 2001) with the wider social and political settings in which it is situated. Biomedical research, particularly where multisite clinical trials are concerned, is carried out in diverse spaces and places, by people from a variety of social and cultural backgrounds. This variability adds a crucial element to Polanyi’s postulation concerning power and structural injustice in scientific knowledge production. Key to this move for us has been a focus on collaboration across multiple lines of difference.

Throughout this work, we have treated collaboration as an emic concept, a term deployed widely to capture rhetorically the kind of relationships to which people aspire when they work together on joint research projects. We
have paid attention not just to the senior researchers and why they collaborate (Parker and Kingori 2016) but also to the junior and midlevel researchers so that we can map out what they gain from being part of global research networks. In the context of cross-cultural collaborations, we extend Strathern’s notion that collaboration is not merely a *practice* but also operates as a *value* (Strathern 2011). As we argued in chapter 4, it is also a value that carries with it *potentiality*, in that it is at once strategic, forward-looking, and aspirational. Crucially, the move brings into focus the way that trialists, both Sri Lankan and expatriate, are able to use, often in ingenious ways, the human, intellectual, and material resources that are to hand to realize the *potentiality* of collaboration. For these reasons, collaboration resonates strongly with the idea of development. In making a switch from the external form of clinical trials to their internal relations, we have been able to bring into focus the way that social and political values are reconfigured in the face of expert systems that originate in faraway places.

This view of collaboration foregrounds local researchers as active and creative participants in the exchange that is taking place. They are not simply on the receiving end in a hub-and-spoke model of biomedical research activity. Nor are they caught in a double-bind of gratitude and resentment—that is, reliant on and thankful for the attentions of the global north (for example, when in receipt of funding, infrastructure, personnel, or expert knowledge), yet resentful that this is always on and in another’s terms. In fact, there is no simple submission to the rationality of the randomized controlled trial (RCT) at all; crucially, we see evidence of conflict and creativity when it comes to making things work. The Sri Lankan collaborators we have introduced in this book were thus not mere recipients of external research activity and the development possibilities it might bring. The versions of the development processes they articulated to us revealed attempts to actively shape the process to fit local circumstances. As part of this engagement, there are efforts to remoralize the relationship with distant counterparts, and there is no simple, passive acceptance of the material and intellectual assistance on offer. For their part, the Western researchers seek to gain competence in the norms and values of far-flung worlds, but the reverse move is equally important. Efforts to acquire what might be thought of as conceptual and collaborative fluency are in evidence when dealing with outside partners in the conduct of international trials.
With this countermove, novel and emergent geographies of international collaboration merge with old ones, bringing new configurations to scientific and technological sociality. Drawing ethnographic attention to the “doing” rather than the “being done to” takes us onto the next conceptual conjunction and a final reflection on the scope of bioethics.

Collaboration and Bioethics

In his critique of development, James Ferguson offered the notion of the “anti-politics machine” (Ferguson 1994). This image was meant to capture the ways in which development strategies, typically of the hub-and-spoke variety, proceed by suspending, obscuring, or defining as outside their scope the political concerns that are in fact central to those that the aid effort is intended to help. In the wake of development efforts, the effect of the machine is to extend bureaucratic state power in line with external interests. Essential to the anti-politics machine, Ferguson argued, is the “less-developed country” as a foundational construction. We would suggest that in the account we have developed here there are some useful parallels to be drawn with the way in which bioethics operates within the context of biomedical research collaborations.

There is a similar definition of focus in which international interests are cast as inherently benevolent—but in ways that leave the broader political context of trialing and experimentation outside its scope. Regulatory frameworks, such as those available in the form of ICH-GCP guidelines, need to be in place for “ethical” research to happen. However, bioethics as it operates through a variety of practices and discourses is in its own way an anti-politics machine, recasting and thereby containing political questions as ethical ones. Likewise, there is, somewhere in the background, the construction of the “less-ethical country,” one that needs to be educated and brought into line with regard to the practice of bioethics, which continually emerges as a deficient capacity. There is, in short, an incommensurability between the reach of bioethics as this is actualized as part of the assemblage of the multi-site clinical trial on the one hand and, on the other, the landscape of political interests and concerns as they existed in Sri Lanka at the time of our research. In the changing relationship between markets, development, and
new scientific knowledge in the global south, what is encompassed and acted upon in the name of morality, humanism, justice, and, the case in point here, bioethics does not map straightforwardly onto local specificities. The exchanges documented in chapter 8 revealed the practical and conceptual messiness of managing this incommensurability. They illuminated different articulations of power and the points of friction that arise when these are brought together.

This move takes us away from the hub-and-spoke model of how ideas and practices are diffused globally, and we step into the more complex and conflicted flow of concepts and resources that are needed to make a trial happen outside the global north. In this flow are mixed desires that may not sit comfortably together; the protection of local populations may be one group’s primary objective whereas the facilitation of clinical trials may be another’s. As we saw in chapter 8, the normative systems governing research ethics are ambivalent and contested, and they play into wider conflicts in which the notion of ethics might be used strategically to bring about desired ends outside of the trial per se. Such systems operate rather like the semiotician’s floating signifier—that is, they convey a greater sense of their concreteness than the things that they reference and are therefore capable of carrying multiple contradictions.

Of relevance to the kind of analysis we have been trying to develop within this book, these contradictions do not only figure in the discourses of our interlocutors. We ourselves have struggled with questions of what makes trial activity ethical or unethical. We did not work in these trials in any sense as normative bioethicists, and neither did we set out to answer this question in quite the way a bioethicist would, but we also acknowledge that there are no “moral exteriorities” in a study such as this (Biruk 2017; Fassin 2008). The collaborative ethnography we have undertaken situates us within the communities we studied, so our end point cannot be any simple meta-wisdom distilled from the field of conflicts and contradictions in which we found ourselves. An ethnographic attention to detail begins to highlight how, within such a complex assemblage, our engagement made different significations become visible. By focusing on the way two different kinds of trials were set up and run—one for a joint pain treatment and the other for an antidote to paraquat—we go beyond scientific questions and the normative ethics that govern them.

Our approach brings into view a wider field of ethical concerns such as the role of funders, access to medicines, choices of collaborative partners, en-
gagement with local regulatory infrastructures, and levels of health care provision locally. In this framing, ethics is emergent rather than given, a matter of politics rather than rule-based governance, and a feature of structural inequality rather than cultural diversity. Whereas bioethics might operate as an anti-politics machine, the practice of collaboration appears to work in the opposite direction by rendering the parameters of bioethics potent, porous, and open to revision and reinterpretation. One of our main contributions to ongoing discussions regarding the place of biomedical research within global projects of progress, modernization, and development has thus been to place those directly involved with effecting change back at the center of the analysis. Whereas the machine metaphor is apt to marginalize the movers and shakers in the clinical trials assemblage, we have tried to give them voice and to understand their motivations.

It has been our intention to describe from the ground up the rhetorics that are involved in getting one version of what is the ethical way to proceed to predominate over another. Reintroducing the actors who are often invisible—and drawing attention to the wrinkles and creases that are rendered flat, featureless, and peripheral in the global gaze of bioethics—is an important step because it takes us beyond the formality of ethical guidelines and their role in regulating research practice (described earlier) and into the tacit, day-to-day social relations that enable research processes to proceed in the first place (also as described earlier). In contemplating the relationship between collaboration and bioethics, we are thus extending ideas of what bioethics “does” to encompass a situated research ethics with collaboration at its core. This tactic looks beyond the normative framework of international collaborative research and reveals new and unexpected ways in which research operates as a form of development praxis that can transfigure relationships, values, and ethics into something that they were not in the past. Change is incremental and disparate in its consequences rather than revolutionary and causally linear.

In our attempts to characterize these processes, we have considered unintended consequences as well as intended ones. An image that has helped in this is that of the rhizome (cf. Choy et al. 2009). Unlike other images, this one suggests unpredictable and irregular formations rather than predetermined structures of growth and development. In this instance, local stipulations (made by the ethics committee) combined with the changing fortunes and strategic interests of the multinational company behind the Joint Pain
Trial meant that the excursion into clinical trials as a commercial venture never materialized. Lanka Trials failed to take off as a vehicle for global clinical trials. The expected narrative was one of success guaranteed by the backing of powerful multinational pharmaceutical interests rather than one of failure. Equally, the Paraquat Poisoning Trial did not show efficacy in reducing mortality and might also have been thought to be a failure. That said, it is commonplace for trials to fail, and this does not mean they were done badly or were in some sense “wrong.” As Ferguson commented when speaking of development, “what may be the most important about a development project is not so much what it does do but what it fails to do; it may be that its real importance in the end lies in the ‘side effects’” (Ferguson 1994, 254).

Both trials failed to bring positive results in the pharmaceutical sense, but the more important point that we want to make is that changes in the sector of clinical research did occur, albeit not in the ways envisaged! In both instances, considerable capacity was built in terms of training, infrastructure, and the conceptual knowledge needed to conduct a multisite RCT. To return to the cargo-cult analogy presented in chapter 6, the landing strip was carefully built by the local researchers even if the cargo never came. In each of the trials we followed, potentiality was never actualized in the ways that were predicted. Yet they were, in many respects, very successful failures. In terms of first-order development, they built human resources locally, inducted new recruits into the research assemblage, and created visibility for Sri Lankan researchers as motivated and capable of doing such research. It also embedded researchers from outside Sri Lanka into the local networks in new ways—as is evident, for example, in the evolution of the South Asian Clinical Toxicology Research Collaboration (SACTRC) beyond the period followed in this study. The Paraquat Poisoning Trial might not have shown efficacy in reducing mortality, but participants in the study did do better than those who were not involved due to the closer care that they received; the study also trained several junior researchers, who became doctors who understood poisoning patients a little better; and the results persuaded agricultural policy makers to remove paraquat from the market. In second-order terms, the trials introduced and embedded conceptual shifts in practice and policy in relation to local thinking about the nature of human subject research, as discussed in chapter 5.

From the perspective of research on clinical trials and collaboration, these are developments that took place over a considerable period of time. A shal-
low reading of clinical trials activity takes a view that sees researchers merely slicing into networks of connection for the duration of one trial. In so doing, such studies fail to account for how change takes place and why, and how there might be outcomes that cannot be second-guessed. The approach we have taken here reveals that “capacity” is not simply absent, as in the hub-and-spoke model, but present in multiple forms, which lead to development outcomes that are diverse and often unintended. After the trials have left town, many things are not quite as they were before.