Humanitarian research

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Humanitarian Research

Ethical Considerations in Conducting Research during Global Health Emergencies

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32.1 INTRODUCTION

Global health emergencies (GHEs) are situations of heightened and widespread health crisis that usually require the attention and mobilisation of actors and institutions beyond national borders. Conducting research in such contexts is both ethically imperative and requires particular ethical and regulatory scrutiny. While global health emergency research (GHER) serves a crucial function of learning how to improve care and services for individuals and communities affected by war, natural disasters or epidemics, conducting research in such settings is also challenging at various levels. Logistics are difficult, funding is elusive, risks are elevated and likely to fluctuate, social and institutional structures are particularly strained, infrastructure destroyed. GHER is diverse. It includes biomedical research, such as studies on novel vaccines and treatments, or on appropriate humanitarian and medical responses. Research might also include the development of novel public health interventions, or measures to strength public health infrastructure and capacity building. Social science and humanities research might also be warranted, in order to develop future GHE responses that better support affected individuals and populations. Standard methodologies, including those related to ethical procedures, might be particularly difficult to implement in such contexts.

The ethics of GHER relates to a variety of considerations. First are the ethical and justice-based justifications to conduct research at all in conditions of emergency. Second, the ethics of GHER considers whether research is designed and implemented in an ethically robust manner. Finally, ethical issues also relate to questions arising in the course of carrying out research studies. GHER is characterised by a heterogeneity (of risk, nature, contexts, urgency, scope) which itself gives rise to various kinds of ethical implications:[1] why research is done, who conducts research, where and when it is conducted, what kind of research is done and how. It is therefore difficult to fully capture the range of ethical considerations that arise, let alone provide a one-size-fits-all solution to such questions. Using illustrations drawn from research projects conducted during GHEs, we discuss key ethical and governance concerns arising in GHER – beyond those traditionally associated with biomedical research – and explore the future direction of oversight for GHER. After setting out the complex context of GHER, we illustrate the various ethical issues associated with justifying research, as well as considerations related to

[1] M. Hunt et al., 'Ethical Implications of Diversity in Disaster Research', (2012) *American Journal of Disaster Medicine*, 7(3), 211–221.

context, social value and engagement with the affected communities. Finally, we explore some of the new orientations and lenses in the governance of GHER through recent guidelines and emerging practices.

32.2 THE CONTEXT OF GLOBAL HEALTH EMERGENCY RESEARCH

GHEs are large-scale crises that affect health and that are of global concern (epidemics, pandemics, as well as health-related crises arising from conflicts, natural disasters or forced displacement). They are characterised by various kinds of urgency, driven by the need to rapidly and appropriately respond to the needs of affected populations. However, effective responses, treatments or preventative measures require solid evidence bases, and the establishment of such knowledge is heavily dependent on findings from research (including biomedical research) carried out in contexts of crises.[2] As the Council for International Organizations of Medical Sciences (CIOMS) guidelines point out: 'disasters can be difficult to prevent and the evidence base for effectively preventing or mitigating their public health impact is limited'.[3] Generating relevant knowledge in emergencies is therefore necessary to enhance the care of individuals and communities, for example through treatments, vaccines or improved palliative care. Research can also consolidate preparedness for public health and humanitarian responses (including triage protocols) and contribute to capacity building (for example, by training healthcare professionals) in order to strengthen health systems in the long run. Ethical consideration and regulation must therefore adapt to both immediate and urgent issues, as well as contribute to developing sustainable and long-term processes and practices.

Adding to this is the fact that responses to GHEs involve a variety of actors: humanitarian responders, health professionals, public health officials, researchers, media, state officials, armed forces, national governments and international organisations. Actors conducting both humanitarian work and research can encounter particular ethical challenges, given the very different motivations behind response and research. Such dual roles might, at times, pull in different directions and therefore warrant added ethical scrutiny and awareness, even where such actors might be best placed to deliver both aims, given their presence and knowledge of the context, and especially if they have existing relationships with affected communities.[4] Medical and humanitarian responses to GHEs are difficult contexts for ethical deliberation – for ethics review and those involved in research governance – where various kinds of motivations and values collide, potentially giving rise to conflicting values and aims, or to incompatible lines of accountability[5] (for example, towards humanitarian versus research organisations or towards national authorities versus international organisations).

Given the high level of contextual and temporal complexity, and the heightened vulnerability to harm of those affected by GHEs, there is a broad consensus within the ethics literature that research carried out in such contexts requires both a higher level of justification and careful ongoing ethical scrutiny. Attention to vulnerability is, of course, not new to research ethics.

[2] N. M. Thielman et al., 'Ebola Clinical Trials: Five Lessons Learned and a Way Forward', (2016) *Clinical Trials*, 13(1), 86–86.

[3] Council for International Organizations of Medical Sciences, 'International Ethical Guidelines for Health-related Research Involving Humans', (CIOMS, 2016), Guideline 20.

[4] A. Levine, 'Academics Are from Mars, Humanitarians Are from Venus: Finding Common Ground to Improve Research during Humanitarian Emergencies,' (2016) *Clinical Trials*, 13(1), 79–82.

[5] Nuffield Council on Bioethics, 'Research in Global Health Emergencies: Ethical Issues,' (*Nuffield Council on Bioethics*, 2020).

It has catalysed many developments in the field, such as the establishment of frameworks, principles, and rules aiming to ensure that participants are not at risk of additional harm, and that their interests are not sacrificed to the needs and goals of research. It has also been a struggle in research governance, however, to find appropriate regulatory measures and measures of oversight that are not overly protectionist; ones that do not stereotype and silence individuals and groups but ensure that their interests and well-being are protected. The relationship between research and vulnerability becomes particularly knotty in contexts of emergency. How should we best attend to vulnerability when it is pervasive?[6] On the one hand, all participants are in a heightened context of vulnerability when compared to populations under ordinary circumstances. On the other hand, those individuals who suffer from systematic and structural inequality, disadvantage and marginalisation, will also see their potential vulnerabilities exacerbated in conditions of public health and humanitarian emergencies. The presence of these multiple sources and forms of vulnerability adds to the difficulty in determining whether research and its design are ethically justified.

32.3 JUSTIFYING RESEARCH: WHY, WHERE AND WHEN?

While research is rightly considered an integral part of humanitarian and public health responses to GHEs,[7] and while there may indeed, as the WHO suggests, be an 'ethical obligation to learn as much as possible, as quickly as possible',[8] research must be ethically justified on various fronts. At a minimum, GHER must not impede current humanitarian and public health responses, even as it is deployed with the aim of improving future responses. Nor should it drain existing resource and skills. Additionally, the social value of such research derives from its relevance to the particular context and the crisis at hand.[9] Decisions regarding location, recruitment of participants, as well as study design (including risk–benefit calculations) must ensure that scientific and social value are not compromised[10] in the process. The Working Group on Disaster Research Ethics (WGDRE), formed in response to the 2004 Indian Ocean tsunami, has argued that while ethical research can be conducted in contexts of emergencies, such research must respond to local needs and priorities, in order avoid being opportunistic.[11] Similar considerations were reiterated during the 2014–2016 Ebola outbreak. Concern was expressed that 'some clinical sites could be perversely incentivized to establish research collaborations based on resources promised, political pressure or simply the powers of persuasion of prospective researchers – rather than a careful evaluation of the merits of the science or the potential benefit for patients. Some decision-makers at clinical sites may not have the expertise to evaluate the scientific merits of the research being proposed'.[12] Such observation reflects considerations that have been identified in a range of GHE settings.

The question of social value is not only related to the ultimate or broad aims of research. Specific research questions can only be justified if these cannot be investigated in non-crisis

[6] C. Tansey et al., 'Familiar Ethical Issues Amplified', (2017) *BMC Medical Ethics*, 1891, 1–12.
[7] Thielman et al., 'Ebola Clinical Trials'.
[8] WHO, 'Guidance For Managing Ethical Issues In Infectious Disease Outbreaks', (WHO, 2016), 30.
[9] Ibid.
[10] CIOMS, 'International Ethical Guidelines', Commentary to Guideline 20.
[11] A. Sumathipala et al., 'Ethical Issues in Post-disaster Clinical Interventions and Research: A Developing World Perspective. Key Findings from a Drafting and Consensus Generating Meeting of the Working Group on Disaster Research Ethics (WGDRE) 2007', (2010) *Asian Bioethics Review*, 2(2), 124–142.
[12] Thielman et al. 'Ebola Clinical Trials', 85.

conditions,[13] and as specified above, where the answers to such questions is expected to be of benefit to the community in question – or to relevantly similar communities, be it during the current emergency, or in the future. Relatedly, research should be conducted within settings that are most likely to benefit from the generation of such knowledge, perhaps because they are the site of cyclical disasters or endemic outbreaks that frequently disrupt social structures. Given the heightened precarity of GHE contexts, the risk of exposing study participants to additional harm is particularly salient, and such potential risk must therefore be systematically justified. If considerations of social value are key, these need to extend to priority-setting in GHER. Yet, the funding and development of GHER is not immune to how research priority is set globally. Consequently, this divergence (between the kind of research that is currently being funded and developed, and the research that might be required in specific contexts of crisis) will present particular governance challenges at the local, national, and global levels. Stakeholders from contexts of scarce resources have warned that priority-setting in GHE might mirror broader global research agendas, where the health concerns and needs of low- and middle-income countries (LMICs) are systematically given lower priority.[14] The global research agenda is not generally directed by the specific needs arising from crises (especially crisis in resource-poor contexts), and yet the less well-funded and less resilient health systems of LMICs frequently bear the brunt and severity of crises. The ethical challenges associated with conducting research in contexts of crisis therefore are consistently present at all levels, from the broader global research agenda, to the choice of context and participants, from how research is designed and conducted, to how research data and findings are used and shared.

32.4 JUSTIFYING RESEARCH: WHAT AND HOW?

GHER includes a wide range of activities, from minimally invasive collection of data[15] and systems research aimed at strengthening health infrastructure,[16] to more controversial procedures including testing of experimental therapeutics and vaccines.[17] A common issue of GHER, one that has arisen prominently during recent epidemics and infectious disease outbreaks, is the challenge to long-established standards and trials designs, in particular to what is known as the 'gold standard': randomised, double-blind clinical trials as the standard developmental pathway for new drugs and interventions. The ethical intuitions and debates often pull in different direction. As discussed earlier in the chapter, the justification for conducting research in crises must be ethically robust, as must research design and deployment. Equally, in the context of the COVID-19 pandemic, a strong argument has been made for the need to ensure methodologically rigorous research design and not to accept lower scientific standards as a form of 'pandemic research exceptionalism'.[18] At the time of writing, human challenge trials – the intentional infection of research participants with the virus – proposed as a way to accelerate the development of a vaccine for the novel coronavirus, remain ethically and scientifically controversial. While some commentators have suggested that this may be a rapid and necessary route to

[13] Tansey et al., 'Familiar Ethical Issues'.
[14] Sumathipala et al., 'Ethical Issues'.
[15] Nuffield Council on Bioethics, 'Briefing Note: Zika – Ethical Considerations', (Nuffield Council on Bioethics, 2016).
[16] S. Qari et al., 'Preparedness and Emergency Response Research Centers: Early Returns on Investment in Evidence-based Public Health Systems Research', (2014) *Public Health Reports*, 129(4), 1–4.
[17] A. Rid and F. Miller, 'Ethical Rationale for the Ebola "Ring Vaccination" Trial Design', (2016) *American Journal of Public Health*, 106(3), 432–435.
[18] A. J. London and J. Kimmelman, 'Against Pandemic Research Exceptionalism', (2020) *Science*, 368(6490), 476–477.

vaccine development,[19] others have argued that the criteria for ethical justification of human challenge studies, including social value and fair participation selection, are not likely to be met.[20]

Such tensions are particularly heightened in contexts of high infectious rates, morbidity and mortality. During the 2014–2016 Ebola outbreak in West Africa, several unregistered interventions were approved for use as investigational therapeutics. Importantly, while these were approved for emergency use, they were to be deployed under the MEURI scheme: 'monitored emergency use of unregistered and experimental interventions (MEURI)',[21] that is, through a process where results of an intervention's use are shared with the scientific and medical community, and not under the medical label of 'compassionate use'. This approach allows clinical data to be compiled and thus contributes to the process of generating generalisable evidence. The deployment of experimental drugs was once again considered – alongside the deployment of experimental vaccines – early during the 2018 Ebola outbreak in the Democratic Republic of the Congo.[22] This time, regulatory and ethical frameworks were in place to approve access to five investigational therapeutics under the MEURI scheme,[23] two of which have since shown promise during the clinical trials conducted in 2018. The first Ebola vaccine, approved in 2019, was tested through ring vaccine trials first conducted during the 2014–2016 West African outbreak. Methods and study designs need to be aligned with the needs of the humanitarian response, and yet it is not an easy task to translate the values of humanitarian responses onto research design. How experimental interventions should be deployed under the MEURI scheme was heavily debated and contested by local communities, who saw these interventions as their only and last resort against the epidemic.

While success stories in GHER heavily depend on global cooperation, suitable infrastructure, and often collaboration between the public and private sector, such interventions are unlikely to succeed without the collaboration and engagement of local researchers and communities, and without establishing a relationship based on trust. Engaging with communities and establishing relationships of trust and respect are key to successful research endeavours in all contexts, but are particularly crucial where social structures have broken down and where individuals and communities are at heightened risk of harm. Community engagement, especially for endeavours not directly related to response and medical care, is also particularly challenging to implement. These challenges are most significant in sudden-onset GHE such as earthquakes,[24] if prior relationships do not exist between researchers and the communities. During the 2014–2016 Ebola outbreak, the infection and its spread caused 'panic in the communities by the lack of credible information and playing to people's deepest fears'.[25] Similarly, distrust arose during the subsequent outbreak in eastern DRC, a region already affected by conflict, where low trust in institutions and officials resulted in low acceptance of vaccines and a spread of

[19] E. Zamrozik and M. J. Selgelid, 'Covid-19 Human Challenge Studies: Ethical Issues', (2020) *Lancet Infectious Disease*, www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30438-2/fulltext.

[20] S. Holm, 'Controlled Human Infection with SARS-CoV-2 to Study COVID-19 Vaccine and Treatments: Bioethics in Utopia,' (2020) *Journal of Medical Ethics*, 0, 1–5.

[21] WHO, 'Ethical Issues Related to Study Design for Trials on Therapeutics for Ebola Virus Disease', (WHO, 2014), 2.

[22] E. C. Hayden, 'Experimental Drugs Poised for Use in Ebola Outbreak,' *Nature* (18 May 2018), www.nature.com/articles/d41586-018-05205-x.

[23] WHO, 'Ebola Virus Disease – Democratic Republic of Congo', *WHO* (31 August 2018), www.who.int/csr/don/31-august-2018-ebola-drc/en/.

[24] Tansey et al., 'Familiar Ethical Issues', 24.

[25] A. Saxena and M. Gomes, 'Ethical Challenges to Responding to the Ebola Epidemic: The World Health Organization Experience', (2016) *Clinical Trials*, 13(1), 96–100.

the virus.[26] Similarly, in the aftermath of Hurricane Katrina there was widespread frustration and distrust of the US federal response by those engaged in civil society and community-led responses.[27] However, such contexts have also given rise to new forms solidarity and cooperation. The recent Ebola outbreaks, the aftermath of Katrina, the 2004 Indian Ocean tsunami and the Fukushima disaster have also given rise to unprecedent levels engagement and leadership by members of the affected communities.[28] Given that successful responses to GHEs are heavily dependent on trust as well as on the engagement and ownership of response activities by local communities, there is little doubt that successful endeavours in GHER will also depend on establishing close, trustworthy and respectful collaborations between researchers, responders, local NGOs, civil society and members of the affected population.

32.5 GOVERNANCE AND OVERSIGHT: GUIDELINES AND PRACTICES

The difficulty of conducting GHER is compounded by much complexity at the level of regulation, governance and oversight. Those involved in research in these contexts are working in and around various ethical frameworks including humanitarian ethics, medical ethics, public health ethics and research ethics. Each framework has traditionally been developed with very different actors, values and interests in mind. Navigating these might result in various kinds of conflicts or dissonance, and at the very least make GHER a particularly challenging endeavour. Such concerns are then compounded by regulatory complexity, including existing national laws and guidelines, international regulations and guidance produced by different international bodies (for example, the International Health Regulations 2005 by the WHO and Good Clinical Practice by the National Institute for Health Research in the United Kingdom), all of which are engaged in a context of urgency, shifting timelines and rapidly evolving background conditions. Two recent pieces of guidance are worth highlighting in this context. The first are the revised CIOMS guidelines, published in 2016, which have a newly added entry (Guideline 20) specifically addressing GHER. The CIOMS guidelines recognise that '[d]isasters unfold quickly and study designs need to be chosen so that studies will yield meaningful data in a rapidly evolving situation. Study designs must be feasible in a disaster situation but still appropriate to ensure the study's scientific validity'.[29] While reaffirming the cornerstones of research ethics, Guideline 20 also refers to the need to ensure equitable distribution of risks and benefits; the importance of community engagement; the need for flexibility and expediency in oversight while providing due scrutiny; and the need to ensure the validity of informed consent obtained under conditions of duress. CIOMS also responds to the need for flexible and alternative study designs and suggests that GHER studies should ideally be planned ahead and that generic versions of protocols could be pre-reviewed prior to a disaster occurring.

Although acting at a different governance level to CIOMS, the Nuffield Council on Bioethics has also recently published a report on GHER,[30] engaging with emerging ethical issues and echoing the central questions and values reflected in current discussions and regulatory frameworks. Reflecting on the lessons learned from various GHEs over the last couple of decades, the report encourages the development of an ethical compass for GHER that focuses on respect,

[26] P. Vince et al., 'Institutional Trust and Misinformation in the Response to the 2018–2019 Ebola Outbreak in North Kivu, DR Congo: A Population-based Survey', (2019) *Lancet*, 19(5), 529–356.
[27] Nuffield Council on Bioethics, 'Research in Global Health Emergencies', 41.
[28] Ibid., 32–36.
[29] CIOMS, 'International Ethical Guidelines', Guideline 20.
[30] Nuffield Council on Bioethics, 'Research in Global Health Emergencies'.

reducing suffering, and fairness.[31] The report is notable for recommending that GHER endeavours attend not just to whose needs are being met (that is, questions of social value and responsiveness) but also to who has been involved in defining those needs. In other words, the report reminds us that beyond principles and values guiding study design and implementation, ethical GHER requires attention to a wider ethics ecosystem that includes all stakeholders, and that upholding fairness is not only a feature of recruitment or access to the benefits of research, but must also exist in collaborative practices with local researchers, authorities and communities.

All guidelines and regulations need interpretation on the ground,[32] at various levels of governance, as well as by researcher themselves. The last couple of decades have seen a variety of innovative and adaptive practices being developed for GHER, including the establishment of research ethics committees specifically associated with humanitarian organisations. Similarly, many research ethics committees that are tasked with reviewing GHER protocols have adapted their standard procedures in line with the urgency and developing context of GHEs.[33] Such strategies include convening ad-hoc meetings, prioritising these protocols in the queue for review, waiving deadlines, having advisors pre-review protocols and conducting reviews by teleconference.[34] Another approach can be found in the development of pre-approved, or pre-reviewed protocol templates, which allow research ethics committees to conduct an initial review of proposed research ahead of a crisis occurring, or to review generic policies for the transfer of samples and data. Following their experience in reviewing GHER protocols during the 2014–2016 Ebola outbreak, members of the World Health Organization Ethics Review Committee recommended the formation of a joint research ethics committee for future GHEs.[35] A need for greater involvement and interaction between ethics committees and researchers has been indicated by various commentators, pointing to the need for ethical review to be an ongoing and iterative process. One such model for critical and ongoing engagement, entitled 'real-time responsiveness',[36] proposes a more dynamic approach to ethics oversight for GHER, including more engagement between researchers, research ethics committees, and advisors once the research is underway. An iterative review process has been proposed for research in ordinary contexts[37] but is particularly relevant to GHER, given the urgency and rapidly changing context.

It is important to also consider how to promote and sustain the ethical capacities of researchers in humanitarian settings. Such capacities include the following, which have been linked to ethical humanitarian action:[38] foresighting (the ability to anticipate potential for harms), attentiveness (especially for the social and relational dynamics of particular GHE contexts), and responsiveness to the often-shifting features of a crisis, and their implications for the conduct of the research. These capacities point to the role of virtues, in addition to guidelines and

[31] Ibid., xvi–xvii.
[32] Ibid., 29.
[33] M. Hunt et al., 'The Challenge of Timely, Responsive and Rigorous Ethics Review of Disaster Research: Views of Research Ethics Committee Members', (2016) *PLoS ONE*, 11(6), e0157142.
[34] Ibid.
[35] E. Alirol et al., 'Ethics Review of Studies during Public Health Emergencies – The Experience of the WHO Ethics Review Committee During the Ebola Virus Disease Epidemic', (2017) *BMC Medical Ethics*, 18(1), 8.
[36] L. Eckenwiler et al., 'Real-Time Responsiveness for Ethics Oversight During Disaster Research', (2015) *Bioethics*, 29(9), 653–661.
[37] A. Ganguli-Mitra et al., 'Reconfiguring Social Value in Health Research Through the Lens of Liminality', (2017) *Bioethics*, 31(2), 87–96.
[38] N. Pal et al., 'Ethical Considerations for Closing Humanitarian Projects: A Scoping Review', (2019) *Journal of International Humanitarian Action*, 4(1), 1–9.

principles, in the context of GHER. As highlighted by O'Mathuna, humanitarian research calls for virtuous action on the part of researchers in crisis settings 'to ensure that researchers do what they believe is ethically right and resist what is unethical'.[39] Ethics therefore is not merely a feature of approval or bureaucratic procedure. It must be actively engaged with at various levels and also by all involved, including by researchers themselves.

32.6 NEW ORIENTATIONS AND LENSES

As outlined above, GHEs present a distinctive context for the conduct of research. Tailored ethics guidance for GHER has been developed by various bodies, and it has been acknowledged that GHER can be a challenging fit for standard models to ethics oversight and review. As a result, greater flexibility in review procedures has been endorsed, while emphasising the importance of upholding rigorous appraisal of protocol. Particular attention has been given to the proportionality of ethical scrutiny to the ethical concerns (risk of harm, issues of equity, situations of vulnerability) associated with particular studies. Novel approaches, such as the preparation and pre-review of generic protocols, have also been incorporated into more recent guidance documents (e.g. CIOMS) and implemented by research ethics committees associated with humanitarian organisations.[40] These innovations reflect the importance of temporal sensitivity in GHER and in its review. As well as promoting timely review processes for urgent protocols, scrutiny is also needed to identify research that does not need to be conducted in an acute crisis and whose initiation ought to be delayed.

Discussions about GHER, and on disaster risk reduction more broadly, also point to the importance of preparedness and anticipation. Sudden onset events and crises often require quick response and reaction. Nonetheless, there are many opportunities to lay advance groundwork for research and also for research ethics oversight. In this sense, pre-review of protocols, careful preparation of standard procedures, and even research ethics committees undertaking their own planning procedures for reviewing GHER, are all warranted. It also suggests that while methodological innovation and adaptive designs may be required, methodological standards should be respected in crisis research and can be promoted with more planning and preparation.

32.7 CONCLUSION

Research conducted in GHEs present a particularly difficult context in terms of governance. While each kind of emergency presents its own particular challenge, there are recurring patterns, characterised by urgency in terms of injury and death, extreme temporal constraints, and uncertainty in terms of development and outcome. Research endeavours have to be ushered through a plethora of regulation at various levels, not all of which have been developed with GHER in mind. Several sectors are necessarily involved: humanitarian, medical, public health, and political to name just a few. Conducting research in these contexts is necessary, however, in order to contribute to a robust evidence-base for future emergencies. Ethical considerations are crucial in the implementation and interpretation of guidance, and in rigorously evaluating justification for research. Governance must find a balance between the protection of research

[39] D. O'Mathúna, 'Research Ethics in the Context of Humanitarian Emergencies', (2015) *Journal of Evidence-Based Medicine*, 8(1), 31–35, 31.

[40] D. Schopper et al., 'Innovations in Research Ethics Governance in Humanitarian Settings', (2015) *BMC Medical Ethics*, 16(1), 7–8.

participants, who find themselves in particular circumstances of precarity, and the need for flexibility, preparedness, and responsiveness as emergencies unfold. Novel ethical orientations suggest the need, at times, to rethink established procedures, such as one-off ethics approval, or gold standard clinical trials, as well as to establish novel ethical procedures and practice, such as specially trained ethics committees, and pre-approval of research protocols. However, the ethics of such research also suggest that time, risk and uncertainty should not work against key ethical considerations relating to social value, fairness in recruitment or against meaningful and ongoing engagement with the community in all phases of response and research. A dynamic approach to the governance of GHER will also require supporting the ability of researchers, ethics committees and those governing research to engage with and act according to the ethical values at stake.