Chapter 8
Good Practice to Counter Ethics Dumping

Abstract An ethics code is not enough to avoid ethics dumping. Ethics codes can inspire, guide and raise awareness of ethical issues, but they cannot, on their own, guarantee ethical outcomes; this requires a multifaceted approach. For research in resource-poor settings, engagement is crucial. Such engagement has been built into the Global Code of Conduct for Research in Resource-Poor Settings as a requirement, but how can it be put into practice? An approach for ethical community engagement is presented in this chapter, which also includes suggestions for an accessible complaints mechanism. At the institutional level, we tackle the question of concluding fair research contracts when access to legal advice is limited. Throughout, at a broader level, we show how the four values of fairness, respect, care and honesty can be used to help guide decision-making and the practical application of the code.

Keywords Community engagement · Complaints procedure · Research contracts · Values compass

Introduction

The Global Code of Conduct for Research in Resource-Poor Settings (GCC) is not enough to prevent ethics dumping. While codes are necessary, they are not sufficient in themselves to ensure good governance (Webley and Werner 2008). For codes to be effective, researchers must know how to use them appropriately (Giorgini et al. 2015), and codes can be totally ineffective when badly implemented (Bowman 2000). The use of codes, especially new ones, invariably raises challenges of interpretation and implementation.

The way that the GCC has been developed helps to minimize potential challenges. For instance, implementation problems are lessened when the needs, values

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1 The export of unethical research from a high-income setting to a resource-poor setting with weaker compliance structures or legal governance mechanisms.
and interests of all stakeholders, particularly those who are likely to be subject to the codes (Lawton 2004), are taken into account during development. This helps ensure that the code is aligned with real needs and has practical value. Hence the bottom-up approach that was taken during development, which has facilitated an “insider” perspective, should help to increase effectiveness and counter the view that ethics codes are no more than a bureaucratic tool imposed from above. Additionally, the GCC does not replicate existing codes, nor does it seek to replace them. Rather, the GCC can be viewed as complementary to other codes, and this helps to avoid the confusion that can arise when codes seem contradictory.

However, even the most conscientiously developed codes are open to differences in interpretation, and researchers need an ethical foundation for making decisions about application in particular situations (Eriksson et al. 2008). Furthermore, codes must form part of a wider framework that also includes mechanisms for compliance, accountability and addressing legal concerns.

This chapter seeks to address these issues with practical guidance for implementation. We show how the four values of fairness, respect, care and honesty can serve as an ethical foundation for decision-making. Specifically, we highlight the importance of ethical techniques for engagement with local communities and a complaints procedure which is accessible to highly vulnerable populations, and finally we summarize a resource built in parallel to the code: a fair research contracting tool.

### The Values as an Ethical Foundation

The four values constitute the foundation for ethical research collaborations and can be applied in virtually any situation to guide decision-making. When researchers keep the values at the heart of their activities, they can recognize and respond to ethical challenges more effectively. This requires reflexivity on the part of the researchers such that they consciously and regularly “stand back” from their activities to ask whether their activities are aligned with the values. At any stage researchers must ask themselves: Am I behaving with fairness, respect, care and honesty? We call this practical application of the values the “values compass” (see Fig. 8.1).

The compass can be used continually as a tool for ethical reflection, but is particularly helpful at key stages of the research process when important decisions are made.

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2 As noted earlier, “stakeholders” is an increasingly contested term, as it may imply that all parties hold an equal stake. Some prefer the term “actors”, yet this brings its own complexities. While acknowledging the debate, we use the well-established term “stakeholders” throughout.

3 “Reflexivity” can be thought of as a researcher’s ongoing critical reflection upon his or her own biases and assumptions and how these impact upon their relationship to the research, the course of the research and knowledge production.
In the following sections we show how the practical application of the values can help guide two important activities in collaborative research: community engagement and the development of an accessible complaints procedure.

**Ethical Engagement with Communities**

The term “community” is contentious and contextual, and can be difficult to define (Day 2006). For the purposes of this chapter, we use an early definition from the World Health Organization which describes a community as:

A specific group of people, often living in a defined geographical area, who share a common culture, values and norms, are arranged in a social structure according to relationships which the community has developed over a period of time. Members of a community gain their personal and social identity by sharing common beliefs, values and norms which have been developed by the community in the past and may be modified in the future (WHO 1998: 5)

As we can infer from this definition, there are many different types of communities and also communities within communities. For example, indigenous communities, having a historical continuity with preinvasion and precolonial societies that developed on their territories, may consider themselves distinct from other sectors of the societies that now prevail on those territories, or parts of them. They generally form nondominant sectors of society and can be intent on preserving, developing and transmitting to future generations their ancestral territories and their ethnic identity, as the basis of their continued existence as peoples, in accordance with their own cultural patterns, social institutions and legal systems (Martínez Cobo
They often have particular relationships with advocacy groups who work to protect or represent their interests.\(^4\)

The concept of communities within communities also includes groups of people who are vulnerable because of a range of physical (disabilities, for example) or cultural (religion, for example) characteristics. For instance, sex workers, injecting drug users and men who have sex with men are often marginalized within their own broader communities.\(^5\) People from such groups are frequently sought for international research and yet the community at large or the community leaders are often unable to provide the input needed to ensure ethical management of research projects. Communities and their leaders may be unaware of the specific circumstances of these people and their lives, and they may even be openly hostile. We therefore need mechanisms for ensuring that the voice of marginalized and vulnerable populations is heard, and that their interests in research are represented.

In the 1990s, community engagement assumed prominence as the new guiding light of public health efforts; research and health-improvement programmes that involved communities had better results than programmes led by government alone (NIH 2011). At the same time, the limitations of existing guidelines for the protection of communities in genetic research was becoming increasingly apparent (Weijer et al. 1999). The benefits of community engagement in all types of research are now widely acknowledged, and numerous publications describe many potential benefits such as:

- increasing community understanding and acceptance of the studies
- enhancing researchers’ ability to understand and address community priorities
- improving logistics and the running of studies
- strengthening the quality of the information collected
- ensuring culturally sensitive communications and research approaches
- enhancing opportunities for capacity building (Hebert et al. 2009; Cook 2008; Bassler et al. 2008; Dunn 2011).

Community engagement is an ethical imperative (a “must”) for researchers operating globally. Research participants, their local communities and research partners in international locations should be equal stakeholders in the pursuit of research-related gains (Anderson et al. 2012). Ahmed and Palermo (2010) provide a salient definition of community engagement in research as

a process of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus.

To be effective in international research, community engagement requires the development of partnerships with “local” stakeholders (for example, national,

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\(^4\) Advocacy groups (also known as pressure groups, lobby groups, campaign groups, interest groups or special interest groups) use various forms of advocacy in order to influence public opinion and/ or policy.

\(^5\) Here “broader community” can refer to a village, town, ethnic group etc.
regional or advocacy groups), involving them in assessing local challenges and research priorities, determining the value of research, planning, conducting and overseeing research, and integrating the results with local needs where relevant (Jones and Wells 2007). Moreover, it requires members of the research team to become part of the community, and members of the community to become part of the research team to create bespoke working environments before, during and after the research.

Many models have been proposed for effective community engagement in research, and many written guides already exist. Rather than add an invention of our own to the numerous existing models, we show here how reference to the four values of fairness, respect, care and honesty can highlight the primary ethical considerations for organizations or researchers engaging with communities over the course of a research project. After all, as Dunn (2011: 5) points out, “Engagement is not a benchmark for ethics. Ethics does not stop when community engagement takes place. Engagement itself has ethical implications.”

Our guidance for community engagement is intended to be useful; we show how application of the values compass at key stages of the research process can invoke particular questions for contemplation. There may be other relevant questions, depending upon the circumstances, but these questions are a useful starting point.

The key stages we consider are:

1. Setting the research aims and/or developing the research question
2. Designing the study
3. Implementing the study
4. The results phase
5. Evaluating the study

**Setting the Research Aims and/or Developing the Research Question**

During the initial phase, when researchers are formulating their research aims or a research question, the values compass can be applied to help ensure that ethical considerations are attended to during their community engagement. Table 8.1 enumerates checklist questions for contemplation at the very outset.

One of the first tasks is to establish community preferences and protocols for engagement, even before discussions about the research are started. This may require a local spokesperson or other trusted intermediary to be identified.

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6Examples are community-based participatory research, empowerment evaluation, community action research and participatory rapid appraisal.
Table 8.1 Questions for reflection when setting research aims

| Fairness | Honesty |
|----------|---------|
| How are the community being meaningfully involved in discussions about the aims of the research including why it is needed and who will benefit? | Have all background details been shared and discussed with the community, including the funding situation and the intentions of the researchers? |
| | What procedures will be used for two-way, open communication? |
| | What procedures are in place to ensure, without being patronizing, that research issues are understood? |
| | What promises are being made to the community, and can they definitely be fulfilled? |

| Respect | Care |
|---------|------|
| How are community preferences for engagement strategies being discussed and acted upon? | How are local needs and the potential for capacity building being taken into account in developing the aims of the study? |
| Are the relevant community spokespersons or representatives being consulted? | Is due attention being paid to the impact of the study and the study team upon the participants, their families, the local community and the environment? |
| Is permission from community elders/leaders or representatives needed for this consultation? | |
| How are the research team familiarizing themselves with local culture – including organizational structures, history, traditions, relationship with the environment and sensitivities? | |

Designing the Study

The community, as well as local researchers, need to be included in the research design process, both effectively and transparently. Table 8.2 sets out some of the many factors to consider.

It is imperative that researchers consider the practical implications for the persons, communities and environments involved, as well as the scientific integrity of the research design.

Implementing the Study

Ethical research is conducted with communities rather than about communities. To ensure that this is how it actually happens, effective engagement is vital throughout the implementation of the project. Table 8.3 suggests questions to consider during the implementation phase.
Where possible, members of the local community should be actively involved in undertaking the research. This may be in simple, practical operational or administrative capacities, but where appropriately qualified or experienced candidates are available, and/or where necessary training can be provided, this involvement should also include more complex tasks, with support from experienced researchers.

### Table 8.2  Questions for reflection when designing a study

| Fairness                                                                 | Honesty                                                                 |
|-------------------------------------------------------------------------|------------------------------------------------------------------------|
| How are the community involved in the planning and design of the study? | How is full transparency in all aspects of the engagement and planning being ensured? |
| Are the potential benefits and harms for the participants and the community being discussed fully? | Are procedures for open, two-way communication in place? |
| Have the most relevant types of benefits for the participants and communities been discussed and agreed? | Have all details that might impact upon individuals or the community been disclosed? |
| In health research, has post-study access to successfully tested treatments or interventions been agreed? | Have requirements for an accessible and user-friendly complaints mechanism been discussed and agreed? |
| Where relevant, have means for recognizing and protecting traditional knowledge been agreed? | What promises are being made to the local community in the design of the study and are they likely to be fulfilled? |

| Respect                                                                 | Care                                                                 |
|------------------------------------------------------------------------|----------------------------------------------------------------------|
| Are the research team complying with local/community ethics codes? | How are local needs being taken into account in the design of the study? |
| How is community knowledge being respected and integrated into the design? | Is due attention being paid to the impact of the study and the study team upon the participants, their families, the local community and the environment? |
| Are the relevant members of the community, as identified by the community itself, involved in the design? | What measures have been taken to ensure understanding (such as translators and the use of clear, non-technical language) |
| How is community culture and tradition being respected in the design of the study? | Have the resource implications of this design for the local community been identified? |
| Have the relevant persons in the community given permission/approval for the study design? | What measures are in place to ensure that the research is high quality and worthwhile so that the efforts of the community are not wasted? |
Table 8.3 Questions for reflection during implementation

| Fairness                                                                 | Honesty                                                                 |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------|
| How are the local community engaged in the ongoing implementation of the research? | How are lines of communication functioning? Is there clear and transparent, two-way communication between the research team and the local community? |
| Are local researchers and other members of the community taking active roles in the implementation? | How are the community being informed about developments or any changes that occur during the research process? |
| Have measures for ensuring ethical compliance been discussed with the community and put in place? | How is the complaints system functioning? Does it need to be amended in any way? |

| Respect                                                                 | Care                                                                 |
|-------------------------------------------------------------------------|---------------------------------------------------------------------|
| Are researchers taking steps to ensure all activities are respectful of local culture and traditions? | Have the researchers taken the time and necessary steps to ensure that the implications of the study have been fully understood by participants and the community? |
| Has both individual and community consent, assent or approval (where appropriate) been granted? | Are researchers paying due attention to the impact of the study and the study team upon the participants, their families, the local community and the environment? |
| What measures are in place to respect rights to privacy, anonymity and confidentiality? | Is the community being properly resourced for participation? |
| Are the participants and community fully aware of their right to withhold personal/sensitive information and to refuse engagement/participation? | |

**The Results Phase**

During this phase, results are analysed and disseminated through publications as well as being fed back to the community. Table 8.4 formulates some helpful questions to ask during the results phase.

Findings can be enriched when members of the community have been consulted and engaged during the analysis process and the interpretation of results. For some studies, sharing results with the research participants or the community can elucidate aspects that were previously obscure to the researchers (for example, an understanding of why or how something happens).

**Evaluating the Study**

Though the publication of research results and feedback to the community represent, in a sense, the end of the research cycle, the process of further research involving the same or other communities can be greatly helped by an evaluation of the
study and, in particular in the context of this report, of the community involvement elements. Table 8.5 lists important questions for the evaluation phase.

When researchers apply the values of fairness, respect, care and honesty over the course of a research project, this creates a relationship of trust with the community. Our main advice for ethical community engagement is to build long-term, mutually beneficial relationships based on the four values, applied before, during and after research studies.

In addition, for a relationship of trust to develop between researchers and local communities, it is important to have a well-functioning complaints procedure.

### Developing an Accessible Complaints Procedure

The routine use of accessible complaints procedures in research forms part of the overarching strategy for reducing ethics dumping, because such procedures can help to ensure that experience and practice correspond with expectations. An effective complaints procedure can give voice to those who participate in research, offering a channel for raising concerns that might otherwise remain unheard, both during and after a study. Complaints procedures can contribute to the safeguarding of

| Table 8.4 Questions for reflection during analysis of results |
|---------------------------------------------------------------|
| **Fairness**                                               | **Honesty**                                    |
| How are members of the local community involved in analysis and interpretation of the results? | Have promises that were made about access to the results been fulfilled? |
| What measures are in place to ensure access to findings that might be beneficial to the community? | Have all findings been disclosed in an honest manner? |
| Are appropriate steps being taken to recognize and protect traditional knowledge contributions? | |
| **Respect**                                               | **Care**                                     |
| Have the community been given an opportunity to review the results and implications of the study prior to publication? | What measures are in place to ensure that the findings and implications of the study are accessible to and fully understood by participants and the community? |
| Have the community’s knowledge and contribution been fully acknowledged in the results? | |
| Have community culture and tradition been taken into consideration in the interpretation of the results? | |
| Have rights to privacy, anonymity and confidentiality in reporting been respected? | |
Table 8.5 Questions for reflection during the evaluation of a study

| Fairness                                                                 | Honesty                                                                 |
|--------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Have the agreed benefits for participation been realized?                | Have all promises to the community been fulfilled?                        |
| In health research, is the agreed post-study access to successfully tested treatments or interventions being made available? | How have complaints been managed? Are there lessons to be learned and shared? |
| How have the community been involved in the evaluation of the research findings? | Have implications that might impact upon individuals or the community, including potential harms and benefits, been disclosed? |
| How have the community been involved in the evaluation of the research process? |                                                                            |
| Do the community believe that they have benefitted from the research?    |                                                                            |

| Respect                                                                 | Care                                                                 |
|--------------------------------------------------------------------------|------------------------------------------------------------------------|
| Are there mechanisms in place to feedback news about broader impacts of the research? | Do the community believe that researchers paid due attention to the impact of the study and the study team upon the participants, their families, the local community and the environment? |
| Has the contribution of members of the local community been fully credited? | Was the resulting project of high quality and worthwhile so that the efforts of the community were not wasted? |
| Have the community’s knowledge and its value to the research been fully credited? |                                                                            |
| Do the community believe that local culture and tradition have been respected? |                                                                            |

Researchers, research organizations and research ethics committees (RECs) can go to great lengths to ensure that research protocols are scientifically rigorous and that research is conducted in accordance with the relevant ethical principles. However, even when the greatest care is taken, unexpected events can occur and participation can lead to emotional and/or physical harm. While most RECs will specify the need for an identified contact person in case of queries or complaints, this commonly takes the form of basic contact details on a participant information sheet, often in the form of an email address. Where further information is given, it

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7 “Participation” is referred to here in its broadest sense to include experimental research animals and environments, as well as human research participants, local communities and researchers.
frequently stipulates that all complaints must be made in writing. The requirement to complain in writing via email might preclude complaints from the most vulnerable research participants.

For collaborative research undertaken in resource-poor settings, especially low and middle-income countries (LMICs), the accessibility of a complaints procedure may be affected by many factors that are unfamiliar to researchers from a high-income country (HIC). A concerted effort is therefore required to understand local needs and preferences so that a complaints mechanism can be implemented that is both user-friendly and fit for purpose.

**Factors Affecting Accessibility**

It is known from studies in the field of dispute resolution that people often feel reluctant to make complaints and that this can be related to a variety of complex factors. In 2009 the Health Professions Council in the UK published a
comprehensive scoping review of existing mechanisms for complaints about health professionals (HPC 2009). In this report, the HPC describes a range of factors that can act as barriers to making a specific complaint. As there are no equivalent publications about complaints procedures in LMICs, we summarize here the factors that are relevant to research in LMICs.

Readiness to complain in any environment can be influenced by gender, ethnicity, age, education, income, accessibility of information and the perceived “seriousness” of the problem (Pleasence et al. 2006). Specifically, ethnic minority communities are less likely to use systems that they perceive as being culturally insensitive and are more fearful of the consequences of taking action when they feel those systems have failed them.

Difficulties with access to information are highlighted as a barrier to making a complaint (Henwood et al. 2003), especially where there is “information illiteracy”; some people possess the relevant skills and confidence to seek out information, but many do not. In situations where levels of education and literacy are not high, this is likely to be exacerbated.

The relationship between the person who brings the complaint and the bureaucracies to which they must direct their complaint can be a factor (Cowan and Halliday 2003). This relationship can either encourage or discourage a potential complainant's trust in complaints mechanisms. The power imbalance between parties in such relationships can be substantial. For example, when working with impoverished communities, HIC researchers should be aware that participation in a clinical study may provide a participant’s only access to health care or other much-needed benefits. Fear of retribution is often cited as a barrier to making a complaint, particularly in circumstances where the complainant has an ongoing relationship with the complainee (HPC 2009). In situations where there is a power imbalance, people may not have the confidence to complain; they may be reluctant to seem ungrateful, not wish to be seen as a complainer, or fear loss. Research has shown that some people even reconstruct negative experiences in a positive light in order to maintain relationships (Edwards et al. 2004).

In addition to the above, participatory engagement activities in the TRUST project (Chapter 6) have revealed the following factors that could also act as barriers to research participants making complaints about research activities in LMICs:

- **Fear of damage or stigmatization from loss of confidentiality or anonymity.** In Kenya, for example, where sex work is illegal, sex workers may be reluctant to make any formal complaints.
- **Cultural norms that preclude complaining.** In some cultures, it is not acceptable to make complaints, especially to or about visitors and/or those in authority. Complaining may be perceived as disrespectful, ungrateful or inappropriate.
- **Illiteracy of research participants and communication (language) difficulties,** leading to a lack of understanding of reasonable rights relating to informed consent and to reasonable expectations of the research.
• Inability to access the means by which to file a complaint: for example, if only an email address is provided as a contact and one has no access to computers or internet connections.

The Scope of a Complaints Procedure

A comprehensive complaints procedure can have a broad scope; it can be used to complain about any activities that are associated with a research study. These may include, for example:

• any perceived deviation from the information provided
• any deviation from agreed processes
• treatment by members of the research team that is considered inappropriate
• problems with the organization of the study (for example, the competence of the researchers and their ability to perform duties)
• the (mis)handling of personal or sensitive information
• concerns about any unethical behaviour or practices by the research team

The scope of a complaints procedure will also depend upon the intended users. Many complaints procedures are intended for use purely by participants in a research study. However, in collaborative ventures in LMICs, there may be a wide range of potential users, because HIC-LMIC collaborative research is especially prone to ethics dumping, with the potential for damage to entire communities.

Table 8.6 gives examples of the potential range of users of complaints procedures for different types of research studies.

While a complaints procedure can have broad scope, it is vital that there be clarity about its purpose and who can use it, as well as about what can and cannot be dealt with through this mechanism. A lack of common understanding of any procedure’s purpose can be a source of great dissatisfaction and cause wider distrust in the process.

Table 8.6 Potential users of complaints procedures in different types of research

| Social science       | Clinical trials      | Animal experimentation | Agricultural research |
|----------------------|----------------------|------------------------|-----------------------|
| Research participants| Research participants| Local community        | Local farmers         |
| Local community      | Local community      | Local researchers      | Broader local community |
| Local researchers    | Local researchers    | Local animal handlers  | Local researchers     |
| Local research       | Local research       | Local animal research centres |
A Values-Based Approach to Developing a Complaints Procedure

A complaints procedure that works perfectly well in one location and for one purpose cannot simply be transposed to a different situation without due consideration of its applicability. Local relevance and accessibility are vital keys in the design of an effective complaints procedure. Rather than a formally laid-down set of “rules” for complaints procedures, a strategic values-based approach needs to be implemented to deal with different levels and types of complaints, so that individuals and communities feel respected, cared for, fairly treated, fully informed and empowered. The four values can provide a framework for the development of an appropriate procedure, as shown in Table 8.7.

Any complaints procedure for a research study involving LMIC populations, especially vulnerable groups or communities, must first consider the circumstances, situation and culture of such communities and the individuals to be recruited to the study. A critical step in this process is engagement with the community that will be

| Fairness | Respect |
|----------|---------|
| Responses to complaints should be timely | The procedure for complaints should be respectful of local needs and preferences |
| All complaints should be taken seriously and investigated fully | Appropriate levels of confidentiality and privacy should be maintained throughout the procedure (including for all documentation, investigations, discussions and hearings) |
| Records of complaints and responses should be maintained to enable reporting and monitoring of complaints | Researchers and/or appropriate staff should be fully equipped and trained for implementation of the complaints procedure. |
| The nature and types of redress should be acceptable to the local community | |
| The lodging of honest complaints should be encouraged, and even facilitated, in order to overcome power imbalances. | |

| Honesty | Care |
|---------|------|
| The purpose and limitations of the complaints procedure should be clearly communicated to all involved in the research | The local community should be involved at an early stage in the development of the complaints procedure |
| The process for making a complaint should be clearly communicated to all involved in the research | Advice should be taken from the local community about the accessibility and viability of the complaints procedure. This may mean offering a range of methods for information sharing and complaint acceptance – verbal, written, and through trusted spokespersons and community groups etc. |
| This process should be as simple and straightforward as possible | |

Table 8.7 Values-based considerations for the development of a complaints procedure
involved with or affected by the research so that they can help guide the development of appropriate procedures.

Additionally, strategies\(^8\) will need to be developed for dealing with different types of complaints. It is important to try to avoid complex and overly burdensome strategies which all too easily become legalistic and formalized. In practice this can mean that nothing is set up at all, or that what is established becomes little more than an ineffective bureaucratic exercise. While more formal approaches and structures may work in “Western” settings, these are unlikely to be effective in the kinds of vulnerable communities where care is needed to safeguard and empower; they may even have the opposite effect, and discourage any engagement at all on complaints issues.

Equally, the challenges in establishing an effective strategy should not act as an excuse for researchers to adopt an oversimplified model (such as a contact name on the information sheet) that is of little or no benefit to anyone. For each unique situation, researchers should work with communities to cocreate effective strategies that take into account the circumstances, situation and culture of that community and the individuals to be recruited to the study.

While it is not possible for us to specify a single “model” complaints procedure, we have shown how the values can provide the basis of any complaints procedure. With these values embedded in the thinking of the research community, they can then seek to work with whatever procedures and structures are available, adapting, improving and tailoring them for application in the real world. The individuals and groups involved should feel respected, cared for, fully informed, treated fairly and empowered.

Most protective mechanisms, including complaints procedures, are strengthened when supported by legal systems, but participants, communities, researchers and institutions in LMICs often have no or very limited access to legal advice or protection. The next section introduces an online toolkit that will be helpful in such situations.

**A Fair Research Contracting Tool**

The need for fair research contracts is best illustrated by the situation in international collaborative health research. Research undertaken in LMICs can lead to significant benefits flowing into HICs. In 2009, Glickman et al. undertook a systematic review to examine what had led to a “dramatic shift in the location of clinical trials” and concluded that important factors were:

- shortened timelines for clinical testing due to a larger pool of research participants

\(^8\)These might include internal resolution through study-specific schemes; internal resolution through research ethics committees; litigation through the courts; or alternative dispute resolution mechanisms such as mediation, adjudication and arbitration.
• lower regulatory barriers for research in LMICs
• international harmonization of intellectual property rights protection

To take full advantage of the benefits of conducting medical research in LMICs, research institutions in HICs have invested substantially in building legal and contracting expertise for the benefit of their own institutions and stakeholders. Such expertise may not be as easily available in LMIC institutions. As a result, the benefits of research collaborations remain heavily skewed towards the beneficiaries based in HICs (Sack et al. 2009).

In 2011 the Council on Health Research for Development (COHRED) committed itself to launching its Fair Research Contracting (FRC) initiative to support LMIC partners when negotiating equitable research partnerships. FRC aimed to identify best practices for the research contracting process that would be useful in the following three scenarios:

• where there is no lawyer
• where there may be lay personnel who could be trained
• where there is a lawyer or legal expertise

A basic framework was subsequently developed by COHRED and partners to assist LMIC collaborators in making contractual demands on HIC collaborators without requiring large legal teams of their own. This focused on the fair distribution of post-research benefits, intellectual property rights, data and data ownerships, specimen ownership and usage, technology transfer and institutional capacity building as key outcomes of the FRC process. Between 2015 and 2018, and as part of the TRUST project, the existing FRC framework was enhanced and expanded to provide an online toolkit relevant for all types of research.

The FRC online toolkit\(^9\) now provides information, tips and case studies in six key areas:

• Negotiation strategies: for understanding the various aspects of negotiations, whether a research partner is at a basic starting point or an advanced level in the development of contract negotiations
• Research contracting: for a basic understanding of contracts and contracting so that a research partner can better manage responsibilities, opportunities and risks that impact the research partnership
• Research data: providing the essential principles concerning rights and responsibilities, including accountability and access to data in collaborative research
• Intellectual property: providing an introduction to some of the key general principles that require consideration before participation in collaborative research agreements
• Research costing: providing research partners with a basic understanding of cost considerations when developing a full cost research budget proposal

\(^9\)The entire online toolkit is available at http://frcweb.cohred.org/
• Technology transfer and capacity: concerning the flow of knowledge, experience and materials from one partner to another, and the ability of people and organizations to manage their affairs and reach objectives successfully.

The development of this resource means that vulnerable groups, such as communities or researchers without legal support, have access to resources that can help develop a good understanding of research contracting for equitable research partnerships and avoid exploitation in research.

Conclusion

According to Eriksson et al. (2008), a serious flaw in most new ethics guidelines is that they are produced with the pretension that there are no other guidelines in existence, and it would be much better if they just stated what they added to existing guidelines. Such is the case with the GCC, which focuses solely on factors that are specific to collaborative research ventures in resource-poor (primarily LMIC) settings. The GCC is succinct and written in plain language; it is meant to be equally accessible to researchers in HICs and to their intended partners in LMICs. In these respects, the GCC is very straightforward, but its simplicity will inevitably generate questions about how it should be implemented.

For example, article 13 of the GCC states that a clear procedure for feedback, complaints or allegations of misconduct must be offered that gives genuine and appropriate access to all research participants and local partners to express any concerns they may have with the research process. Aside from the injunction that the procedure must be agreed with local partners at the outset of the research, there is no guidance on what this procedure should look like. This “thin approach” was used for a reason: no complaints mechanism will fit all situations. Hence, the emphasis is on the process, namely to agree with local partners on an approach. Codes are not enough in themselves to ensure ethical conduct; they need buy-in from all those involved, and such buy-in needs to be generated through effective engagement mechanisms.

Researchers should therefore see community engagement as the gateway to effective implementation of the GCC. For example, when considering the local relevance of the proposed research (article 1), who better to ask than members of the local community? When wondering how best to seek informed consent, who better to ask than members of the local community? Consultation with the community offers the most direct route to addressing questions about implementation and to realizing the essence of the GCC: a global collaborative effort to eradicate ethics dumping.
References

Ahmed SM, Palermo AGS (2010) Community engagement in research: frameworks for education and peer review. American Journal of Public Health 100(8):1380–1387. https://doi.org/10.2105/AJPH.2009.178137

Anderson EE, Solomon S, Heitman E, DuBois JM, Fisher CB, Kost RG, Ross LF (2012) Research ethics education for community-engaged research: a review and research agenda. Journal of Empirical Research on Human Research Ethics 7(2):322–319

Bassler A, Brasier K, Fogel N, Taverno R (2008) Developing effective citizen engagement: a how-to guide for community leaders. Center for Rural Pennsylvania, Harrisburg PA. http://www.rural.palegislature.us/effective_citizen_engagement.pdf

Bowman JS (2000) Towards a professional ethos: from regulatory to reflective codes. International Review of Administrative Sciences 66:673–687

Cook WK (2008) Integrating research and action: a systematic review of community-based participatory research to address health disparities in environmental and occupational health in the United States. Journal of Epidemiology and Community Health 62(8):668–676. https://doi.org/10.1136/jech.2007.067645

Cowan D, Halliday S (2003) The appeal of internal review: law, administrative justice and the (non-) emergence of disputes. Hart, Oxford

Day G (2006) Community and everyday life. Routledge, London

Dunn A (2011) Community engagement: under the microscope. Wellcome Trust, London

Edwards C, Staniszewska S, Crichton N (2004) Investigation of the ways in which patients’ reports of their satisfaction with healthcare are constructed. Sociology of Health and Illness 26(2):159

Eriksson S, Höglund AT, Helgesson G (2008) Do ethical guidelines give guidance? A critical examination of eight ethics regulations. Cambridge Quarterly of Healthcare Ethics 17(1):15–29

Giorgini V, Mecca JT, Gibson C, Medeiros K, Mumford MD, Connelly S, Devenport LD (2015) Researcher perceptions of ethical guidelines and codes of conduct. Accountability in Research 22(3):123–138

Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, Schulman KA (2009) Ethical and scientific implications of the globalization of clinical research. New England Journal of Medicine 360:816–823. https://doi.org/10.1056/NEJMsb0803929

Hebert JR, Brandt HM, Armstead CA, Adams SA, Steck SE (2009) Interdisciplinary, translational, and community-based participatory research: finding a common language to improve cancer research. Cancer Epidemiology, Biomarkers & Prevention 18(4):1213–1217. https://doi.org/10.1158/1055-9965.EPI-08-1166

Henwood F, Wyatt S, Hart A, Smith, J (2003) Ignorance is bliss sometimes: constraints on the emergence of the “informed patient” in the changing landscapes of health information. Sociology of Health and Illness 25(6):589–607

HPC (2009) Scoping report on existing research on complaints mechanisms. Health Professions Council. https://www.hcpc-uk.org/resources/reports/2009/scoping-report-on-existing-research-on-complaints-mechanisms/

Jones L, Wells K (2007) Strategies for academic and clinician engagement in community-participatory partnered research. Journal of the American Medical Association 297(4):407–410

Lawton A (2004) Developing and implementing codes of ethics. Viešoji politika ir administrawimas 7:94–101

Martínez Cobo M (2014) Study on the problem of discrimination against indigenous populations. United Nations Department of Economic and Social Affairs. https://www.un.org/development/desa/indigenouspeoples/publications/2014/09/martinez-cobo-study/

NIH (2011) Principles of community engagement. Washington, DC: CTSA Community Engagement Key Function Committee Task Force on the Principles of Community Engagement, National Institutes of Health. https://www.atihr.cdc.gov/communityengagement/pdf/PCE_Report_508_FINAL.pdf
References

Pleasence P, Buck A, Balmer N, O’Grady A, Genn H, Smith M (2006) Causes of action: civil law and social justice. The Stationery Office, Norwich
Sack DA, Brooks V, Behan M, Cravioto A, Kennedy A, IJsselmuiden C, Sewankambo N (2009) Improving international research contracting. WHO Bulletin 87:487–488
Webley S, Werner A (2008) Corporate codes of ethics: necessary but not sufficient. Business Ethics: A European Review 17(4):405–415
Weijer C, Goldsand G, Emanuel EJ (1999) Protecting communities in research: current guidelines and limits of extrapolation. Nature Genetics 23(3):275
WHO (1998) Health promotion glossary. World Health Organization, Geneva. http://www.who.int/healthpromotion/about/HPR%20Glossary%201998.pdf, page 5.

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