

Complaints Procedures for Collaborative Research in Resource-poor Settings



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A Report for TRUST working towards Equitable Research Partnerships

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Executive Summary

The routine use of accessible complaints procedures in research forms part of the overarching strategy for reducing ethics dumping¹ that has been developed by the EU-funded project TRUST.² An effective complaints procedure offers a channel for raising concerns, both during and after a research study, and should help to ensure compliance with research ethics requirements. This report highlights the need for effective, user-friendly complaints procedures which are flexible and culturally sensitive across different forms of research in low and middle-income countries (LMICs).

In the context of research in LMICs, meaningful access to a complaints procedure is currently a complex matter. There are many factors that impact upon the ease of use of complaints mechanisms and peoples' willingness to raise their concerns. For example, a complaints procedure which requires high literacy levels, high assertion levels and access to a computer / internet connection may be totally inaccessible to those who need it. Additionally, many other factors such as age, gender, cultural norms and perceived power imbalances are known to affect usability. To be effective, complaints procedures need to be easy to implement and tailored to suit the particular context and circumstances in each project. Local relevance is vital.

For this report, members of the TRUST team draw upon their experiences of working with vulnerable communities in LMICs to address practical, ethical and legal considerations for dealing with complaints. Four core values have been adopted by the TRUST project as the foundation for ethical collaborative research: respect, care, fairness and honesty. In keeping with this ethos, rather than establishing a formalised 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.



¹ This occurs when researchers from High Income Countries (HICs) undertake activities in Low- and Middle-Income Countries (LMICs) that would not be permitted in their country of origin, resulting in the exploitation of humans, animals and / or environments.

² The TRUST Project strategy involves implementation of the *Global Code of Conduct for Research in Resource-Poor Settings* www.globalcodeofconduct.org; the *Fair Research Contracting Tool* <http://www.cohred.org/frc/> and a mechanism for enhancing compliance with research ethics requirements. See more: www.TRUST-project.eu

The importance of complaints and feedback procedures for collaborative research in resource-poor settings

Complaints procedures play an important role in research, helping to ensure that experience and practice are aligned 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 participants³ in an ongoing manner, beyond the ethical approval process; they offer a mechanism for correcting mistakes and for protecting people, animals and the environment from abuse and mistreatment. Significantly, complaints mechanisms offer a means of revealing lapses and failures in ethical conduct, thereby providing opportunities for enhancing ethical compliance in research.



Researchers, research organisations 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 result in emotional and / or physical harm. While most RECs will specify the need for an identified contact in case of queries or complaints, this commonly takes the form of simple contact details on a participant information sheet, often via an email address. Where further information is available, this frequently stipulates that all complaints must be made in writing. In spite of their importance, accessible and user-friendly complaints procedures are not the norm across all forms of research.

Accessible and user-friendly complaints procedures are not the norm in all forms of research.

For collaborative research that is 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 unknown or unfamiliar to the high-income country (HIC) researchers. Hence, effort is required to understand local needs and preferences so that a complaints mechanism can be implemented that is both user-friendly and fit for purpose.

³ 'Participation' is used here in its broadest sense to include human research participants, as well as experimental research animals, local communities, environments and researchers.

Factors affecting accessibility

We know from studies in the field of dispute resolution that people can feel reluctant to make complaints and that this can be related to a variety of complex factors. In 2009 the Health Professions Council (HPC) in the UK published a comprehensive scoping review of existing complaints mechanisms for complaints about health professionals⁴. In this report, the HPC describe 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 summarise here the factors that are relevant to research in LMICs.

Readiness to complain in any environment can be associated with gender, ethnicity, age, education, income, accessibility of information and the perceived ‘seriousness’ of the problem.⁵ 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 is highlighted as a barrier to making a complaint,⁶ especially where there is ‘information illiteracy’; some people possess the relevant skills and confidence to seek out information, but many do not. When working 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 whom they must direct their complaint can be a factor.⁷ This relationship can either encourage or discourage people from trusting 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 the only access to healthcare 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 complaine. ⁸ 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 be fearful of loss. Research has shown that some people even reconstruct negative experiences in a positive light in order to maintain relationships.⁹

⁴ Health and Care Professions Council (2009) *Scoping report on existing research on complaints mechanisms*. Available from: <http://www.hpc-uk.org/publications/research/index.asp?id=208>

⁵ Pleasence P, Buck A, Balmer N, O’Grady A, Genn H, Smith M (2006) *Causes of action: civil law and social justice*. London: The Stationery Office.

⁶ 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) pp. 589–607.

⁷ Cowan D, Halliday S (2003) *The Appeal of Internal Review: Law, Administrative Justice and the (non-) emergence of disputes*. Oxford: Hart publishing. pp204–206.

⁸ Health and Care Professions Council (2009) *Scoping report on existing research on complaints mechanisms*. Available from: <http://www.hpc-uk.org/publications/research/index.asp?id=208>

⁹ Edwards C, Staniszweska 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)p.159.

In addition to the above, participatory engagement activities in the TRUST project¹⁰ have revealed the following factors that could also act as barriers for research participants to make complaints about research activities in LMICs:

- *Fear of damage or stigmatisation from loss of confidentiality or anonymity.* For example, in Kenya, 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 / 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 lack of understanding of reasonable rights in terms of informed consent and of 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 / internet connections.

Factors affecting accessibility of complaints procedures



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 which is considered inappropriate
- Problems regarding the organisation of the study (for example, the competence of the researchers and their ability to perform duties)

¹⁰ <http://trust-project.eu/>

- The (mis)handling of personal or sensitive information
- Concerns about any unethical behaviour / practices by the research team

The scope of a complaints procedure will also depend upon the intended users. Many complaints procedures are purely intended for use by participants in a research study. However, for collaborative ventures in LMICs, there may be a wide range of potential users, because HIC-LMIC collaborative research is especially prone to ‘ethics dumping’¹¹ with the potential for damage to entire communities.

The box below provides examples of the potential range of users of complaints procedures for different types of research studies.

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 organisations	Local research organisations	Local animal research centres	

While a complaints procedure can have broad scope, it is vital that there is clarity about its purpose, and who can use it, as well as 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.

A values-based approach to developing a complaints procedure

The mere presence of a complaints procedure is not enough to ensure that complaints are voiced; procedures are only helpful if people feel that they can actually use them. A complaints procedure must be offered that gives genuine access to all research participants and local partners. This is unlikely to be the case with an email address on an information sheet. Furthermore, a complaints procedure that works perfectly well in one location and for one purpose, cannot simply be transposed to an alternative situation without due consideration of its applicability. Local relevance and accessibility are vital keys in the design of an effective complaints procedure. Values inspire, motivate and engage people to discharge obligations

Local relevance is key in the design of an effective complaints procedure.

¹¹ Ethics dumping or the application of double standards in research involves the export of unethical practices to LMICs. Read cases of ethics dumping here: <http://www.springer.com/gb/book/9783319647302>

or duties, and the TRUST project has adopted four core values as the foundation for ethical collaborative research.¹² TRUST’s work has shown that certain values are shared by communities around the world,¹³ and through global engagement activities these values have been identified as: fairness, respect, care and honesty. These four values underpin ethical practice in HIC-LMIC collaborative research and hence are recommended as the basis for the development of complaints procedures to be used in such circumstances.

Fairness	Respect
<ul style="list-style-type: none"> • Responses to complaints should be timely • All complaints should be taken seriously and investigated fully • Records of complaints and responses should be maintained to enable reporting and monitoring of complaints • The nature and types of redress should be acceptable to the local community • The lodging of an honest complaint should be encouraged, and even facilitated, in order to overcome power imbalances 	<ul style="list-style-type: none"> • The procedure for complaints should be respectful of local needs and preferences • Appropriate levels of confidentiality and privacy should be maintained throughout the procedure (This includes all documentation, investigations, discussions and hearings) • Researchers and / or appropriate staff should be fully equipped and trained for implementation of the complaints procedure.
Honesty	Care
<ul style="list-style-type: none"> • The purpose and limitations of the complaints procedure should be clearly communicated to all involved in the research • The process for making a complaint should be clearly communicated to all involved in the research • The process for making a complaint should be as simple and straightforward as possible 	<ul style="list-style-type: none"> • The local community should be involved at an early stage in the development of the complaints procedure • Advice should be taken from the local community about the accessibility and usability of the complaints procedure. This may mean offering a variety of methods for information sharing and complaint acceptance – verbal, written, or through trusted spokespersons and community groups etc.

¹² <http://trust-project.eu/wp-content/uploads/2016/12/TRUST-Deliverable-Generic-Risks-Final-copy.pdf>

¹³ This is in contrast to applied ethical principles that appear to have greater affinity with some cultures than others. For a definition of the four TRUST values see: <http://trust-project.eu/wp-content/uploads/2016/12/TRUST-Deliverable-Generic-Risks-Final-copy.pdf>

Methods for dealing with complaints

When a complaint is made about an aspect of a research study there are different ways in which this can be dealt with, depending upon the nature of the complaint. For example, traditional methods may include a study-specific dispute resolution scheme, a dispute resolution process organised by the research institution (often through the REC), compensation for injury, and litigation.¹⁴ Alternatively, there is growing interest and uptake across a number of fields in the use of an approach named *Alternative Dispute Resolution* (ADR). Below, we summarise briefly the more traditional approaches for dealing with complaints before explaining the ADR approach in more depth.



Internal resolution through study-specific resolution schemes

Internal mechanisms for resolving grievances can be very effective, allowing grievances to be heard at a level close to where the problem arose in a supportive and collaborative environment. They can also enable teams to learn quickly from their mistakes and adjust practice as needed.¹⁵

Attempting to resolve problems can be stressful, particularly for the complainant, and can lead to 'unintended consequences' and other forms of failure in resolving the issues. For these reasons informal methods of raising and dealing with an issue at an early stage should be encouraged prior to implementing more formal procedures.



Informal methods may include an attempt at friendly and open engagement with the complainant, including discussions or fact-finding by an appointed person to encourage informal resolution of the issue before it escalates. In this pre-formal phase, complainants may be accompanied in the discussions by a family member, or trusted leader / representative, in the interests of listening and really understanding the source of discomfort. The better the understanding, the easier it will be to de-escalate and resolve the issue. 'Unintended consequences' of not following this process might include the escalation of a small dispute into a major issue (often

Informal methods of raising and dealing with an issue, at an early stage, should be encouraged prior to the more formal procedures.

¹⁴ Underhill K (2014) Legal and Ethical Values in the Resolution of Research-Related Disputes: How Can IRBs Respond to Participant Complaints? *J Empir Res Hum Res Ethics*, 9(1):71–82

¹⁵ Gulland J (2009) Independence in complaints procedures: lessons from community care. *Journal of Social Welfare & Family Law*, 31(1):59-72.

because of poor handling of the initial stages), or the spreading of misperceptions in the community, leading to potential undermining of the research relationships.

Institutional resolution through ethics committees

Ethics committees often require that complaints are directed back to the committee itself.¹⁶ Informed consent templates from the World Health Organization appear to presuppose that ethics committees are available for complaints,¹⁷ with effective and accessible grievance procedures. However, despite the widespread assumption that ethics committees are available to receive grievances, little is known about how they might manage these issues. What can be assumed, with relative confidence, is that there is vast room for improvement in this important area.¹⁸



It may not be comfortable for an institution to open its procedures and actions for scrutiny, but doing so is an important step towards increasing institutional confidence and maturity. A transparent and accessible grievance procedure should thus be actively encouraged for institutions and their RECs.

Seeing litigation through courts as a last resort

Compensation for a wronged individual is often the outcome of a successful grievance, which in serious cases, takes the form of litigation aimed at restoring justice. An approach through law courts for claiming damages in respect of an individual or collective injury¹⁹ is generally regarded as the most severe and least desirable form of resolving disputes. This approach should only be necessary as a 'last resort', when all other alternatives have failed.



A balanced grievance procedure makes clear that all parties have the inherent right to resort to the courts in the event that an attempt to resolve a dispute with other means is unsuccessful. However, litigation is an extreme option; it is expensive, unwieldy, and destructive of the kind of collaborative relationships to which successful research partnerships aspire. Furthermore, litigation may not be effective for the resolution of research-related conflicts, which may involve disparities in knowledge, resources, and unequal access to the legal system. Neither is it an appropriate mechanism for redressing

Litigation should only be used when all alternatives have failed, and as a 'last resort'.

¹⁶ Klitzman R (2011) Views and experiences of IRBs concerning research integrity. *J Law Med Ethics*, 39:513.

¹⁷ World Health Organization (2013) *Informed consent for clinical studies* [template]. Available at: http://www.who.int/entity/rpc/research_ethics/InformedConsent-clinicalstudies.doc

¹⁸ Underhill K (2014) Legal and ethical values in the resolution of research-related disputes: How can IRBs respond to participant complaints? *J Empir Res Hum Res Ethics*, 9(1):71–82

¹⁹ We are not dealing here with judicial reviews for cases unrelated to injury.

some categories of participant complaints, such as cultural insensitivities, which are difficult to assess or quantify using conventional legal methods. Alternatives to litigation are far less costly and more accessible, especially for grievances that may not be cognizable to the legal system, or for injuries that fall outside the remit of insurance programs.

Where a wronged individual is part of a community, it is often appropriate to call in representatives of the collective body, for example leaders of the community, as part of attempts to explore the nature of the problem, and appropriate measures that might satisfy the reasonable requirements of the grievant. This suggests that, for most people and in most cases, a collective as well as collaborative approach to solving problems would be more appropriate than litigation.

Alternative methods: Alternative dispute resolution

Current measures for dealing with complaints about research are limited in all countries, but especially so in LMICs. There is also a deficit of insurance programs to compensate participants who sustain research-related injuries, and litigation remains expensive and comparatively inaccessible.

Indeed, the more vulnerable the community from which participants are recruited, the more likely it is that legal remedies will be inaccessible to that community.

ALTERNATIVE DISPUTE
RESOLUTION



These deficiencies highlight the need for alternative processes for resolving complaints. In the last decade, many advances have been made in the field of Alternative Dispute Resolution (ADR), where creative approaches are sought that resolve issues whilst retaining positive relationships. ADR provides systems and builds skills that are ideally suited for achieving the outcomes desired by RECs and funders alike, namely successful research and resolution of any disputes.

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ADR has become increasingly accepted in many countries as a core subject requirement for legal practitioners, and is commonly included as a standard requirement in legislation where conflicts are customary. For example, the International Arbitration Act 15 of 2017 is based upon the model law drafted by the UN Commission on International Trade Law,²⁰ and provides for all assenting countries to

incorporate the provisions of ADR into domestic law.²¹ ADR is therefore broadly accepted as being the most effective manner to resolve disputes, whether international or local, and is likely to become part of domestic legal systems worldwide.

For example, in South Africa there is a strong trend towards making mediation compulsory in more and more types of disputes, including criminal law, because of its accessibility, speed of resolution and also inherent fairness.²²

²⁰ UNCITRAL (United Nations Commission on International Trade Law). Available at: https://www.uncitral.org/pdf/english/texts/arbitration/ml-arb/07-86998_Ebook.pdf

²¹ www.polity.org.za/article/international-arbitration-act-15-of-2017-2018-01-09

In Europe, an EU Directive on consumer Alternative Dispute Resolution²³ came into force in July 2015. The ADR Directive does not make the use of ADR mandatory, and does not require the national government to force businesses or consumers to use ADR, but governments must ensure that ADR is available if both parties agree to use it.²⁴

Consequently, ADR schemes are becoming extremely common in many areas of trade, services, transport, workplace disputes etc.,²⁵ as well as in other areas in which an organisation might develop some form of contractual interaction with members of the public.

ADR procedures can take a number of different forms, ranging from basic mediation by an acceptable third party, through independent professional adjudication²⁶ as described below, to arbitration.

Mediation

The simplest level of ADR involves the intervention of a neutral third party with a mandate to mediate between the parties. This involves an active process designed to find common ground between the parties and encourage both to compromise in the interests of a mutually agreed and lasting solution to the issue in question. In such cases, the neutral party or mediator has no authority to make a judgement, and neither party is bound by the final position, unless they legally signify their agreement to it.



Adjudication

In situations where there is an imbalance of power (e.g. between industry and worker, company and customer, service provider and service user or indeed researcher and research participant), and where mediation is either not attempted or has been attempted without success, the ADR process may proceed by involving an independent impartial adjudicator with relevant expertise. Here, the terms of reference provide that the adjudicator's final judgement is binding on the company, industry or service provider, but not on the complainant, who retains the right to pursue a legal resolution in a court of law.

Arbitration

Arbitration is a form of adjudication, where the parties agree to jointly appoint an impartial third party or arbitrator to



²² Brand J (2017) *Mandatory mediation. Are there constitutional implications?* <http://www.conflictdynamics.co.za/Files/127/Mandatory-mediation-in-South-implications-MEDIATION-WEEK-PRESENTATION-.pdf>

²³ Directive 2013/11/EU

²⁴ *Implementing the Alternative Dispute Resolution Directive and Online Dispute Resolution Regulation* (2014) UK Department for Business, Innovation and Skills: London.

²⁵ Stipanowich TJ (2004) ADR and the "Vanishing Trial": The growth and impact of "Alternative Dispute Resolution". *Journal of Empirical Legal Studies*, 1: 843-912

²⁶ Gill C, Williams J, Brennan C, Hirst C (2014) *Models of Alternative Dispute Resolution (ADR)*, A report for the Legal Ombudsman. Available at: <http://www.legalombudsman.org.uk/downloads/documents/research/Models-Alternative-Dispute-Resolution-Report-141031.pdf>

make a decision to resolve the situation, and to be bound by that decision.

While the EU ADR Directive does not make any reference to research activities or research participants, it could be argued that where there is an agreement between researcher and participant in which the participant (or their community) receives some form of benefit or payment for participation, then this might fall under the Directive. However, to date there is no evidence of ADR being used for resolution of complaints from research participants. The use of ADR has been postulated for clinical trials,²⁷ but would fall outside the scope of the current Directive, which does not cover health issues. But regardless of the scope of the EU Directive, there is no reason why an ADR entity should not be set up to address complaints relating to research.

Although some LMICs may not yet have trained ADR practitioners, one can assume that this situation will improve with time. Where ADR practitioners are not yet available, a simpler form of dispute resolution can still take place under the framework of a complaints procedure. For example, the REC could secure the intervention of a third party who is acceptable to all parties, or one or more internationally recognised ADR bodies such as already exist in different commercial and societal spheres.²⁸

There is no evidence of ADR being used for resolution of complaints from research participants, in any field of research aside from some proposals for it to be used in clinical trials.

The presence of an established ADR procedure could be particularly valuable in relation to the various actors associated with research conducted in LMICs in the following ways:

For funders, the ability to refer research participant complainants to an ADR process would provide funders with increased confidence that the projects they fund are carried out in accordance with what has been agreed with the researchers. A body such as the EU has the capacity, resources and access to the appropriate and independent expertise needed for establishing its own ADR body for all areas of research. It could, for example, easily be established as an extension of the current Ethics Review process for Framework research projects. However, multiple funders, both large and small, including national governments, might prefer to set up and fund specific joint ADR entities for dealing with particular areas of research.

For research institutions and their RECs, as already mentioned, serious complaints against researchers can be referred back to the REC that has granted ethics approval for the study. However, it may be that the REC does not have the specific expertise needed to assess complaints fairly. This may be particularly problematic when issues are related to local culture and traditions. In such cases, the possibility of referring the complaint to an ADR process that is able to access the relevant expertise, and also liaise with the ethics committee, could be beneficial, as well as fairer for the complainant.

²⁷ Ministry of Justice (2017) *Pre-action protocol for the resolution of clinical disputes*. Available at:

https://www.justice.gov.uk/courts/procedure-rules/civil/protocol/prot_rcd

²⁸ <https://www.cedr.com/consumer/> and <https://www.aviationadr.org.uk/>

For independent and commercial research entities, independent ADR bodies have been established and funded by industry and commercial organisations in relation to other aspects of their activities, so it should be a relatively simple exercise to establish similar independent bodies to address complaints from participants in organisational research activities.

For participants / complainants, the most important benefit of an ADR approach in LMICs is that facilitation, mediation, adjudication, or indeed arbitration by an independent third party, minimises the power imbalance that might otherwise occur between the research team and participants / communities. The complainant should feel free to bring their case, at no cost to themselves, with the assurance that their situation will be understood, and their traditional and cultural circumstances will be taken into account.

While the potential advantages and benefits of using an ADR approach are clear, the success and integrity of ADR is dependent upon the availability of people with the relevant expertise to act as facilitator / mediator / adjudicator / arbitrator. Such individuals should have both training and experience at the appropriate level of the ADR process, ensuring that they acquire a deep appreciation of the societal, cultural and political environment in which the research and the issue in question has taken place. In addition, practitioners would need expertise in gathering relevant information and evidence from all the involved actors, including research institutions, funders, RECs, researchers, participants and trusted spokespersons, as well as any relevant legislation.

Establishing an effective complaints procedure

Although it is perfectly feasible to develop a model complaints procedure template based on the principles already discussed, any complaints procedure for a particular research study involving LMIC populations, especially vulnerable groups or communities, must first consider the circumstances, situation and culture of that community and the individuals to be recruited to the study. A critical step in this process is engagement with the community who will be involved with or affected by the research.²⁹ In many cases, unless the researchers are already very familiar with that community, this is often not extensive prior to the start of the study. Therefore, any complaints procedure must have sufficient inbuilt flexibility to ensure its suitability to the population who will participate and to avoid any problematic imbalances of power during the very early stages of engagement.

A trusted spokesperson to serve as local advocate

A crucial component in the initial stage of research is the early identification and recognition of one or more members of the local community who can take on the role of trusted spokespersons, or are simply “confidants” for the participant community. An assessment

²⁹ For reference, please see our report: *Research with, not about communities*. Available at: <http://trust-project.eu/deliverables/deliverables-and-tools/>

should be made of the integrity and bona fides of such intermediaries, who should make their interest and involvement in the community clear. These individuals need to carry the trust and confidence of research participants and be people that participants feel able to readily approach to share any concerns or complaints. Trusted spokespersons also need to be sufficiently articulate and confident to represent any such complaints to the research team and, where necessary, to speak on behalf of the individual or individuals concerned. They should also know that they have the trust and confidence of the research team; this may even enable them, in some cases, to take on the role of mediator and possibly contribute to arbitration where knowledge of local culture and practices is relevant to the complaint, particularly if the issue is likely to be resolvable at the local level.

Strategies for different types of complaints

For effective complaints procedures, researchers' activities must include the development and implementation of strategies for at least the following four scenarios:

- Straightforward complaints
- More complex or significant complaints
- Complaints affecting many participants or the whole community
- Very serious complaints which may have legal implications

Straightforward complaints or concerns

Example:

A participant is asked questions about their family history and feels unhappy and / or uncomfortable because they believe they are being expected to reveal sensitive personal information about another member of their family.

This will typically involve a single complainant whose concern may be relatively minor, and might well be based upon a misunderstanding that can be clarified or resolved easily.

Straightforward complaints are most easily and best resolved in a face-to-face meeting between the relevant member of the research team and the individual participant and / or their trusted spokesperson. A clear conclusion to the complaint must be agreed, together with any action that needs to be taken. If a face-to-face resolution is not possible or is not desired by the complainant, then the trusted spokesperson can operate as an intermediary by seeking an agreed resolution through oral or written communication with the researchers.

More complex or significant complaints

Example:

The research team have failed to adhere to the original research protocol or to ethical standards and have, without reference to or without the consent of the community and / or individual participants, introduced new experimental studies where risks to participant safety have not been adequately assessed.

Once a complaint affecting many participants or the whole community has come to light, the trusted spokesperson, or indeed local community leaders representing the whole community, should have a clear understanding of how to take such an issue up with the research team. These leaders or spokespersons should have clear and ready access to the leader of the research team.

Depending on the nature of the complaint, a first meeting between key researchers, original complainant(s), trusted spokesperson(s) and other community leaders would normally be the initial response in order to see whether a rapid solution might be possible, even if this requires changes to the research protocol (in which case, studies would have to be halted until appropriate and / or until amended ethical clearance was obtained).

Unless a resolution that satisfied the complainant community could be achieved through this mechanism, referral to ADR would be the logical next step. In such cases, the associated research institution, the relevant REC and indeed the funder of the research should also be directly informed. The result of the ADR would be binding on the research team, its institution and funder, but not on the complainants, who would still have the right to pursue a judicial option.

Complaints affecting many participants or the whole community

Example:

Researchers are collecting and exporting samples of local resources without reference to the local community, or where an existing benefit-sharing agreement is not being honoured.

These would typically involve more than one complainant, and / or the alleged wrongdoing may be of a serious nature (potentially illegal) and damaging to a community as a whole

More complex or significant complaints of this kind should ideally involve the trusted spokesperson. A face-to-face meeting between the original complainant(s) and researcher

could be a useful first step, which may need to be followed up by a written response. However, it must be recognised that the nature of some complaints, particularly when they are serious or have the potential to affect many individuals, can make a face-to-face meeting difficult or impossible. The trusted spokesperson, acting as an intermediary, might be an alternative first step. For complaints that result in disagreement or lack of satisfaction for participants, the use of an ADR procedure may be the most effective way forward.

Very serious complaints which may have legal implications

Example:

Examples here might include complaints made by participant individuals or the local community as a whole, about activities by members of the research team which could relate to areas such as breach of contract, falsification of results, misappropriation of IPR or traditional knowledge, or indeed include activities such as theft, exploitation, serious sexual misconduct, bribery or covert activities, which could very well be illegal, either in the country in which the research is carried out or in the researchers' own country.

A complaint of this nature would be regarded as “material” in that it might have the potential to affect the entire research project. In addition, depending on the nature of the complaint, it will be important to take into account both the cultural context and political contexts in which it occurs. If such a complaint is made, it will also be essential for researchers to be completely honest, open and transparent, and immediately communicate the situation to their institution and funder.

Very serious complaints which may have legal implications are, by their nature, highly sensitive and are unlikely to be suitable for initial face-to-face meetings with individual members of a vulnerable community. Indeed, they might even be outside of the scope for referral to an ADR process. In such cases, not only should the associated research institution, the relevant REC and the funder of the research be directly informed, but they should already have in place robust Standard Operating Procedures (SOPs) for dealing with complaints of this nature. Researchers in the field should be fully aware of these procedures and adhere to them strictly. This includes, where appropriate and necessary, informing the local authorities in the countries concerned.

However the matter proceeds, it will be essential for all actors associated with the research project to take robust steps to ensure that members of the vulnerable community concerned are safeguarded, cared for and empowered to present their complaint to the relevant parties and to receive a meaningful and fair response.

Conclusion

Considering the amount of research that involves human participants or that impacts upon entire communities, it is of serious concern that there is little guidance for the establishment of effective complaints procedures in research. This is of particular concern when working with research participants or communities who are vulnerable in some way as there are often a number of difficult and challenging obstacles that need to be overcome. This is a matter that needs to be addressed urgently in relation to vulnerable populations, particularly those in LMICs.

In such situations, it is important to try and avoid complex and overly burdensome strategies which can all too easily become legalistic and formalised. 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 when working with 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 for establishing an effective strategy should not act as an excuse for researchers to adopt an over-simplified 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 co-create effective strategies that take into account the circumstances, situation and culture of that community and the individuals to be recruited to the study. There is no 'one size fits all' solution, and any complaints procedure must have sufficient inbuilt flexibility to ensure its suitability to the population who will be affected.

While it is not possible for us to specify a particular 'model' complaints procedure, we have suggested some approaches that may be suitable for different levels and types of complaints. Most importantly, we have suggested that taking a values approach to the establishment of a complaints procedure can help to ensure ethical practice in HIC-LMIC collaborative research.

The values described in the TRUST *Global Code of Conduct for Research in Resource-Poor Settings* (Fairness, Respect, Care and Honesty) can provide the basis of any complaints procedure, rather than a formalised set of "rules". 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, applying and improving on these in real situations. The individuals and communities involved should feel respected, cared for, fully informed, treated fairly and empowered.

Ethics by Design

Through adoption of the four values, researchers become "ethics minded" across the whole range of potential research activities / situations, rather than simply seeking to apply a set of prescribed rules in a formulaic fashion.

At the same time, more formalised principles can provide a backstop if the situation proves to be particularly serious. Establishment of internationally acceptable ADR procedures for research activities could well be just the backstop that is needed.