How can research ethics committees help to strengthen stakeholder engagement in health research in South Africa? An evaluation of REC documents

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Background. All health researchers in South Africa (SA) are explicitly encouraged by the ethicolegal framework to engage stakeholders meaningfully in their research. Research ethics committees (RECs) have a role to play in shaping researchers' practices in this regard, but very little research has explored how RECs might best achieve this.
Objectives. To explore whether SA REC documents are prompting researchers to plan sound stakeholder engagement in health research.
Methods. We reviewed publicly available documents of RECs registered with the SA National Health Research Ethics Council. Of the 46 registered RECs as of November 2019, the documents of 37 were publicly accessible. These comprised 72 documents (e.g. standard operating procedures and application forms). We coded these according to ethical reasons mentioned for engagement, stakeholders and strategies highlighted for engagement. We used semantic coding, staying close to the actual wording of REC documents. We utilised thematic analysis to identify key themes.
Results. We found that many REC documents encouraged researchers to plan engagement in a way that resonates with ethics guidance (theme 1: 'encouraging sound engagement'). However, we found many wasted opportunities in this regard (theme 2: 'missing opportunities'). For some RECs, there was little harmonisation across their key documents regarding this important issue (theme 3: 'moving towards harmonisation').
Conclusion. In the short term, we recommend that RECs should amend their application forms in particular to better 'trigger' researchers to thoughtfully plan sound stakeholder engagement. In the longer term, we recommend that RECs' documents be better harmonised internally regarding their stance on stakeholder engagement.

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All health researchers in South Africa (SA) are explicitly encouraged by the ethicolegal framework to engage 'stakeholders' in their research. Research ethics committees (RECs) have a role to play in shaping researchers' practices, but very little is known about how RECs in SA might best achieve this. This article hopes to go some way toward filling this gap, by exploring how well REC documents encourage researchers to implement their 'stakeholder engagement' responsibilities.

Stakeholder engagement is increasingly discussed in the research ethics literature

Stakeholder engagement is becoming an increasingly important consideration in health research and research ethics discourse.[1-3] MacQueen[4] has argued that engagement may offset some of the vulnerabilities of participating communities. Slack *et al*.[3] have noted that engagement can mitigate potential harms for participants and communities. Tindana *et al*.[5,6] have underscored the ethical importance of engagement in mitigating ethical complexities in vulnerable communities. Lavery[7] has argued that stakeholder engagement can 'make or break the success of some science'. Several models of engagement have been developed for clinical trials, including, but not limited to, the 'good participatory practice' (GPP) model[8,9] and the community advisory board (CAB) model.[5]

International guidance encourages researchers to engage

Stakeholder engagement has emerged as a central component of ethical health research, according to international ethics guidelines. The Council for International Organisations of Medical Scientists (CIOMS),[10] for example, recognises the importance of engagement in ethical research. CIOMS asserts that researchers should engage stakeholders – those parties who can influence or who are affected by the research – across the lifecycle of health research, for example, community stakeholders who reside locally and represent the interests of participants, but also advocates, policy-makers and media. The World Health Organization (WHO)[11] asserts that researchers

'should actively engage with communities in decision-making about the design and conduct of research'. A leading ethics framework[12] lists 'collaborative partnership' as the first component of ethical health research in low- to middle-income countries (LMICs).[3]

International guidelines suggest that sound stakeholder engagement is ethically grounded ('why'); inclusive of relevant stakeholders ('who'); early and sustained across the lifecycle ('when'); and responsive to context, and dynamic over time ('how').[3] At present, many studies have explored how stakeholder engagement is implemented in research studies.[1,2,5,13,14] This clearly shows that stakeholder engagement has migrated out of the HIV clinical trials arena[9] into health research more generally.[15-17]

National guidance encourages researchers to engage

SA ethics guidance for health research states:

> 'Researchers should engage key role-players at various stages of planning and conducting research to improve the quality and rigour of the research, to increase its acceptability to the key role-players, to harness role-player expertise where possible and to offset power differentials where these exist. Engagement efforts may comprise of various activities, including awareness-raising initiatives for role-players, including but not limited to participating communities.'[18]

SA ethics guidance for clinical trials states:

> 'Protocols for clinical trials to be conducted in community settings must include a clear plan on how the communities will be consulted or involved in the research process, and how they will be kept informed.'[19]

SA regulations for research with human participants state that researchers are obligated to 'consult with representatives from the participating community or other relevant research stakeholders, where appropriate' and 'consult with and notify the affected institutional or governmental authorities where necessary'.[20]

Ethics guidance encourages RECs to review engagement

CIOMS (2016) and the WHO (2011) recommend that RECs everywhere should make stakeholder engagement a component of their ethics review of health research.[3,10,11] SA guidelines state that 'where research is to be conducted in community settings, evidence of consultation and plans for ongoing involvement' of community/stakeholders be included in 'applications for ethics review'.[18]

Objectives

We aimed to explore whether and how documents from SA RECs prompt researchers to plan sound engagement.

Methods

We located 46 RECs registered with the SA National Health Research Ethics Council (NHREC). We identified that 37 RECs had documents locatable by internet search (Table 1). The remaining 9 did not have publicly available documents on their websites. Some institutions had more than one REC, and these RECs often shared documents; however, duplicate documents were only analysed once. REC documents included REC application and renewal forms, REC standard operating procedures (SOPs), REC policy documents, REC checklists and guidelines, codes of research ethics and REC handbooks.

Table 1. REC documents located (*N*=72)

Type of document	*n*
Application forms	25
SOPs and ToRs	23
Renewal forms	10
Research ethics policies	8
Other*	6
Total documents	72

REC = research ethics committee; SOP = standard operating procedure; ToR = terms of reference.
*Other = reviewer guidelines (*n*=3), REC checklist (*n*=2), code of research ethics (*n*=1).

Some RECs have not made all of their documents publicly available.

We coded REC documents using inductive (bottom-up) and deductive (top-down) codes[21] – the latter derived from ethics guidance setting out the 'who', 'what', 'why' and 'when' of engagement.[10] We used thematic analysis[22] to analyse REC documents. First, we read all documents for text related to stakeholder engagement, and more specifically, text related to the following terms: community; stakeholder; gatekeeper; role-player; institution(al) authority; permission; approval; engage(ment); consult(ation); participate/ion/ory; involve(ment), disseminate/ion; and/or recruit(ment). Second, we copied all relevant text into an Excel (Microsoft, USA) document (we avoided coding text related to participants specifically – even though they are defined as key stakeholders, they were not the focus of the study). Third, we coded text guided by our study questions. Finally, we developed a narrative account for each theme.

To increase rigour, the documents were coded by two coders independently, and approximately 25% of codes were audited by a third coder to improve rigour by triangulation.[23,24] Any differences in coding were resolved by discussion and consolidation.[25] We obtained exemption from ethics review for a review of documents in the public domain from the University of KwaZulu-Natal Social Science and Humanities REC (ref. no. HSS/0029/018). We anonymised RECs. While RECs may be identifiable from quoted text, we estimate that risks to RECs from this review are minor, and are outweighed by the potential benefits of knowledge gains.

Results and discussion

Theme 1: Encouraging sound engagement

Many SOPs and policy documents, and a few application forms, encourage researchers to plan engagement in a way that resonates with the ethical rationales valued in ethics guidance. In this way, RECs help researchers to locate engagement in explicit ethical rationales, and appropriately position engagement as a key component of ethical studies.[12]

Firstly, researchers were encouraged to locate engagement of community stakeholders in the reduction of study risks/burdens, power imbalances and possible exploitation:

> 'Collaborative partnerships should allow community members to become genuine, active partners in the research process. This requires sustainable forums for regular communication and

problem-solving. Likewise, in international multicentre research, collaborative partnerships between researchers and sponsors from developed countries and researchers and communities in the host country are likely to reduce exploitation, facilitate the negotiation of fair benefits and show awareness of and respect for cultural differences.' (REC 44, guidelines for ethics review, p3)

This corresponds with guideline rationales:

'Good-quality community engagement helps to ensure that […] power inequities are not allowed to derail the process.'[10]

Engagement aims to minimise any 'negative effects on communities such as stigma or draining of local capacity'.[11]

Secondly, many SOPs and some application forms encouraged researchers to locate engagement of community stakeholders in respect for the rights of community to be involved in decisions that affect them:

'The Committee must ensure that, particularly with regard to research involving communities, those communities' traditions and values are respected, particularly with regard to obtaining consent to participate in the research.' (REC 7, SOP, p12)

Thirdly, a few REC documents located the rationale for engagement of stakeholders in improved recruitment and improved uptake/impact of the research:

'This [recruitment] process should […] be fair and equitable. Include aspects of community entry e.g. advertisements, community advisory boards and the use of gatekeepers and mediators etc.' (REC 30, application form, p13)

'[The process should] involve partners in sharing responsibilities for determining the importance of a health problem, assessing the value of research, planning, conducting and overseeing research, and integrating research into the healthcare system.' (REC 17, SOP, p6)

This resonates with guideline rationales: 'establish community advisory groups […] that may […] give advice on accrual and retention of trial participants',[19] and 'failure to engage the community can […] threaten the recruitment and retention of participants'.[10]

Lastly, a few REC documents encourage researchers to locate engagement of community members in strengthening protections for enrolled participants, such as improved payment methods or consent processes for participants:

'The costs of participation should be established in consultation with community representatives who may be familiar with expenses for, for example, travel, parking, meals or childcare. Investigators are well placed to consult representatives regarding these expenses.' (REC 14, SOP, p48)

'Disclose information in culturally and linguistically appropriate formats. Implement supplementary community and familial consent procedures where culturally appropriate. Obtain consent in culturally and linguistically appropriate formats.' (REC 17, SOP, p7)

This rationale resonates with guidance statements – for example, 'community members should be invited to assist in the development of the informed consent process and documents to ensure that they are understandable and appropriate for potential participants.'[10]

Theme 2: Missing opportunities

We found several 'missed opportunities' to encourage engagement in a way that resonates with ethics guidance.

Omitting explicit reference to 'stakeholders' more broadly

Very few REC documents explicitly referred to 'stakeholders', as set out in the example below:

'Who are the major stakeholders in the research? Describe how those affected by the study can express their views, clarify their needs and contribute to the research.' (REC 5, SOP, p10)

In terms of application forms specifically, very few explicitly used the precise term 'stakeholder' or 'party' or 'role-player'. This is a missed opportunity to encourage researchers to carefully consider all parties who could be affected by (or influence) the study – who have 'a stake' – more broadly than only 'community stakeholders' residing locally around sites.[10] If REC application forms took this stance, it would encourage researchers to realise the kind of engagement envisaged in national ethics guidelines, i.e. 'key role-players', including but 'not limited to, participating communities',[18] and national regulations, i.e. not only representatives of participating communities but 'other relevant stakeholders, where necessary',[20] as well as to acknowledge that many studies may lack a geographical community, but almost all will have affected 'interest groups'.

Focusing on securing permission from institutional gatekeepers

Most application forms (more than half) require researchers to obtain permission from institutional gatekeepers to collect data or to conduct a study. For just under a third of application forms, this was the only form of engagement mentioned:

'Has permission of relevant authorities/gatekeepers been obtained? Yes/no/not applicable. (If YES, state name/s of authority/ies and attach copies of approval letters.' (REC 2, application form, p9)

Securing permission from gatekeepers is a sound strategy to respect the autonomy of institutions and to minimise potential harms to them.[26] It is consistent with Department of Health guidelines, which state: 'Research involving collectivities should include measures to ensure […] permission is sought from appropriate representatives of the collectivity to approach individual participants.'[18] However, it should not represent the sum total of a study's engagement activities, and securing permission from institutional gatekeepers should not be conflated with engagement more broadly.

Not encouraging sustained engagement (throughout the study)

Only about one-third of REC documents explicitly encourage engagement throughout the lifecycle of the study. Also, only about a third of application forms explicitly encourage sustained engagement, as set out in the example below:

'What consultation is planned within the community at the following stages: 1. preparation, 2. implementation of the study

and 3. dissemination of the results thereafter.' (REC 23, application form, p7)

Only one renewal form contained statements that prompted researchers to describe any engagement in the previous year (however, it narrowly focused on 'complaints' from stakeholders).

Only about one-third of REC documents in general, and application forms specifically, prompted researchers to engage at the end of the study in the form of results dissemination. REC documents and application forms could go further to encourage engagement throughout the study lifecycle by explicitly using such words.[10] As a whole, this is a missed opportunity to help researchers to view (and plan) engagement as a sustained responsibility.

Theme 3: Moving towards coherence

In many instances, RECs did not show a harmonised stance on engagement across their own key documents. For example, RECs were often primed by SOPs to review engagement of various stakeholders (i.e. 'inclusive' engagement), but were primed in application forms to review a much narrower range of stakeholders – largely institutional gatekeepers. Below is an example from REC 5:

'Who are the major stakeholders in the research? Describe how those affected by the study can express their views, clarify their needs and contribute to the research.' (REC 5, SOP, p10)

'Which authority will be approached for institutional approval? Note: Institutional approval/permission must be obtained before study commencement and must be obtained from the institution where the research data is being collected […] prior to starting the project.' (REC 5, application form, p8)

In other instances, an REC's SOP prompted the REC to consider various engagement strategies (e.g. negotiating or capacity building), but application forms focused narrowly on securing permission. Below is an example from REC 17:

'[…] develop the capacity for researchers, makers of health policies and the community to become full and equal partners in the research enterprise.' (REC 17, SOP, p6)

'Does permission need to be obtained in terms of the location of the study? If yes, indicate how permission is to be obtained.' (REC 17, application form, p6)

Each REC's documents should promote a coherent view of key ethics concerns.[27,28] Researchers are most likely to read application forms (given their time pressures), so the view promoted in SOPs should ideally be reflected ('trickled down') in application forms without making application forms unwieldy, nor unnecessarily duplicating normative guidance.

Study limitations

We could only access documents from 37 of the 46 RECs registered in SA, as some REC documents were not publicly available, e.g. sometimes websites were restricted, or documents were unposted – which means that the sample may be biased in ways that we cannot determine. We did not contact REC administrators for unavailable documents, because this would have violated our exemption from ethics review. Furthermore, we did not distinguish between social science RECs and biomedical RECs in our analysis. Future research could analyse a larger sample of REC documents, especially to assess coherence of engagement recommendations across multiple documents from a single REC.

Conclusion

We conclude that many REC documents sampled do help researchers to plan engagement in a way that is encouraged by national and international ethics guidance. However, there are many missed opportunities to do this even better. In the short term, RECs should check that their application forms prompt researchers to engage with interest groups likely to influence or be affected by the study, more broadly than merely engaging with institutional gatekeepers. To encourage sustained engagement, application forms should explicitly prompt researchers to plan engagement over the study lifecycle, and not only at recruitment/data collection or results dissemination. Renewal forms should trigger researchers to describe stakeholder engagement activities post approval in the preceding year. In the long term, each REC should ensure that their stance on stakeholder engagement is coherent across all their own documents. In the meantime, researchers should always attempt to describe sound stakeholder engagement for their studies, even where not explicitly prompted by REC documents. Over and above these recommendations, this research will inform the development of a resource for RECs to potentially aid in the ethics review of stakeholder engagement.

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