Upholding the ideal of ‘dual approval’ for externally-sponsored research: A reality check

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Background

- For research that is ‘externally sponsored’ — carried out in one country (the ‘host’) and funded by sponsors from another (the ‘sponsoring’ country) — international guidelines advise that independent ethics committees in both countries approve the research to ensure that standards of both countries are met, and to avoid exploitation that may result from imbalances of power and resources.
- There is little documentation to show how well this principle is upheld in practice and the challenges of doing so.

Research Questions

We sought to answer:
- To what extent is the ideal of seeking ethics approval in both host and sponsoring country met?
- What are the main challenges to fulfilling this principle, from the host and sponsoring country perspective?
- How can this principle work most productively in practice?

Methods

We conducted a case study of two ethics review committees – a national-level IRB representing a ‘host’ country committee (in Kenya) and the IRB of an international NGO, representing a ‘sponsoring’ country committee (United Kingdom), with these steps:
1. To determine whether dual approval was sought and attained, we tracked all applications submitted to the committees in 2012 and 2013.
2. For protocols in which dual approval was not sought or attained, or created challenges, reasons were identified through analysis of documentation or communication with the research applicants and IRB administrators or Chairpersons.

Results

- Dual approval was attained for all protocols reviewed by the host country committee and most (40/45) of those reviewed by the sponsoring country committee.
- Dual approval was not sought by the NGO researchers in 5 cases, for reasons listed in the table.
- Attaining dual approval often created long delays (e.g., months between each committee’s approval, longer if revisions were required by one or both committees) and unexpected costs.

The main challenges of attaining dual approval

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<th>Challenge</th>
<th>Cases</th>
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<td>No coordination or communication between committees</td>
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<td>Conflicting decisions by different committees</td>
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<td>Changes required by one committee after approval received by the other can create further rounds of review, submission of amendments, and delay research. In some cases this led to cancellation of funding and/or the research.</td>
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<td>Differences in timing of approval dates between committees leads to different dates of annual review and continuing approval (with knock-on effects for employment).</td>
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<td>Some national/local committees are reluctant to review social science or operations research, and written evidence of exemption can be difficult to attain.</td>
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<td>Multi-country studies are hard to synchronise given different review timelines in each country.</td>
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Reasons why dual approval was not sought in 5 cases

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<th>Reason</th>
<th>Cases</th>
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<td>Concerns by the NGO about national committees’ objections to the research topic (e.g., sexual practices which may be illegal in the host context)</td>
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<td>NGO researchers had negative past experiences with national committees in two host countries (e.g., very slow or non-responsive)</td>
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<td>No local ethics committee exists in the host country</td>
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Reflections

The ideal of securing both host and sponsoring country approval for externally-sponsored research is largely attainable. Experiences of these committees show it can almost always be achieved, particularly when it is required by both host and sponsoring country IRBs. In practice, however, lack of coordination and communication between committees can create delays and costs for researchers, jeopardising research.

Challenges were minimised when:
- NGO researchers planned early, budgeted for dual review, and shared review comments and decisions with each committee involved.
- The local ethics committee benefited from long-standing collaborations with partners to coordinate reviews.
- The national committee was the ethics committee of record/note, i.e., other approvals were secured prior to submitting to the host country committee.

Future Study

1) What works to enhance communication between IRBs, to coordinate timing and identify complementary roles?
2) What are alternatives to the parallel process of dual approval, to minimise duplication and delays? For example:
- Reliance agreements whereby sponsoring country IRBs agree to a single review by the national IRB.
- For multi-country studies, site-specific addendums can be submitted to the national IRBs, enabling the research to begin simultaneously across sites.