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 the ethical standards of both countries are met, and to avoid exploitation given potential 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: To what extent is the ideal of seeking ethics approval in both host and sponsoring countries met by an international non-governmental organization (NGO) conducting research in developing countries? When this principle cannot be met, what are the main reasons?

Methods: To determine whether dual approval was sought and achieved, we analysed all applications submitted to the NGO’s independent ethics review committee (ERC) in 2012 and 2013. The ERC represents a sponsoring country committee, and its approval is conditional upon approval of a national/local committee in the host country.

Results: Of the 50 applications submitted to the ERC, 37 also sought ethics approval from a national/local committee in a total of 18 host countries. In a single case, the decision of the two committees conflicted, and the ERC deferred to the host country decision. For 13 protocols, host country review was not sought for these reasons: prior experience submitting to the national committee had been slow (n=4); NGO researchers were concerned about submitting to a national committee, as their services could be considered controversial with repercussions for programs and staff (n=4); the protocol was a global template (n=2); no ethics committee exists in the host country (n=1); a national committee confirmed exemption (n=1); and oversight (n=1).

Directions for Future Study: The ideal of securing host and sponsoring country approval is attainable, with few compelling reasons why it cannot be achieved. In practice, delays can be a disincentive for researchers to seek both reviews, particularly in the fast-paced environment of a service-delivery NGO. Future study can explore and test alternatives to “dual approval” that uphold the ethical standards of both countries, e.g., when there are social/legal concerns about the research for host committees that are not shared by the sponsoring country’s ERC, the latter’s approval may no longer be conditional upon the former’s. Also, host country approval may be sufficient when the sponsoring country is confident the ethical standards of the host committee match its own.