Improving international research contracting

David A Sack,[a] Vanessa Brooks,[a] Michael Behan,[a] Alejandro Cravioto,[a] Andrew Kennedy,[b] Carel IJsselmuiden[b] & Nelson Sewankambo[c]

Funding for global health research has increased dramatically over the last 10 years[1] and low- and middle-income countries (LMICs) are playing an increasing role in this research.[2] There has been a corresponding increase in complexity of the legal arrangements accompanying such funding without a corresponding increase in the legal resources and capacities of research institutions in LMICs. This can lead to an unequal power relationship between the institution and the funder (in this context often a donor agency, research council, multilateral agency, foundation, public–private partnership, private company or a research institution from a high-income country) – a relationship that should be mutually beneficial. While for the scientist and the funder, the major focus of the contract is the research protocol, the legal aspects are equally important for a successful partnership.

The International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B), experienced the increasing complexity in these agreements and decided to review past draft contracts and the negotiations that were needed to reach equitable agreements. It was noted that contracts were often sent to the Centre with the expectation that they would be signed with no revision. Fortunately, the ICDDR,B has legal staff to negotiate equitable clauses but such a resource is not available to many research institutions in LMICs.

During the review, the following issues of greatest concern were identified. Exclusive data ownership was often claimed by the funder even though data were collected by the institution. This was especially a problem with multisite studies where only the funder had access to the complete data set. Though they may have unique scientific merit, multisite studies could be disempowering to local institutes since the local investigators had little independence and were simply collecting data as prescribed by the funder. The funder sometimes claimed specimen ownership even though it had no way to actually store or use the specimens, and it sometimes restricted the use of the samples in other approved research activities. Exclusive ownership of intellectual property rights was often claimed by the funder and, in one case, was even claimed for intellectual property developed during a training programme conducted by the institution. Some draft contracts restricted the right to publish data and even contained language that would allow the funder to change the report before publication. Contracts often describe ways of settling disputes, however, it may be difficult to identify a neutral body for dispute settlement. Most draft contracts have indemnification clauses but many of those reviewed were one-sided or, at best, potentially confusing to an institution without adequate legal staffing and some included requirements for types of insurance not available in the country. The wide variety of contract formats developed by each funder further complicated the process for institutions in LMICs.

These findings were presented to the WHO Advisory Committee on Health Research, where leading researchers from other institutes in LMICs confirmed that they faced similar problems in contract negotiations.

The issue of inequitable international research partnerships is not new[3] and it is not limited to the health sector.[4] To address this problem, guidelines on good practice have been developed,[5,6] but implementation appears limited and the problems of inequitable research partnerships persist.[7–10] Effective implementation strategies are the key to ensuring that guidelines change practice and achieve the planned impact.[11] Agreed standards and norms for research contracting provide a framework around which guidelines for equitable partnerships can be put into practice. They have the potential to empower both research institutions and the research governance bodies responsible for ensuring that research in LMICs addresses the needs of local populations.

To expand this review and ensure its relevance to research funders, research institutions and governments in LMICs, the International Collaboration on Equitable Research Contracts has been established to conduct a global assessment of research contracting. It will identify those issues that can be effectively addressed by developing and disseminating model contracts in which the rights, responsibilities and requirements of all partners are recognized and addressed in a transparent fashion, and it will analyse the factors influencing the negotiating positions of the different parties. This evidence will inform the development of practical tools that all can use to achieve more equitable results, e.g. template contracts and principles to guide the contract negotiation process.

As long as standards and norms remain undefined in this legal environment, contractual matters will consume excessive energy, detract from the real work of health research professionals and set up collaborating institutions as potential adversaries rather than partners with a common research agenda. Uneven playing fields do not allow research institutions and governments of LMICs to build the competencies needed to become self-sufficient in concluding equitable research contracts. ■

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[a] International Centre for Diarrhoeal Disease Research, Bangladesh, Dhaka, Bangladesh.
[b] Council on Health Research for Development, 1-5 Route des Morillons, 1211 Geneva, Switzerland.
[c] Faculty of Medicine, Makerere University, Kampala, Uganda.
Correspondence to Andrew Kennedy (e-mail: kennedy@cohred.org).

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