E&HR

Institutional Review Board Use of Outside Experts: *What Do We Know?*

KIMBERLEY SERPICO, VASILIKI RAHIMZADEH, EMILY E. ANDERSON, LUKE GELINAS, AND HOLLY FERNANDEZ LYNCH

Appendix A.
Summary of U.S. Landmark Standards Specifically Addressing the Extent to Which IRBs Are Permitted to Utilize Outside Experts

Year	Description	Text concerning outside expertise
1966	U.S. Surgeon General published *Directives on Human Experimentation Policy Statement*. The statement serves as the genesis of independent human subjects research review and origin of Institutional Review Boards (IRBs).	"Assignment of Responsibility…The grantee institution may utilize staff, consultants, or both to carry out the review. Any group responsible for review should possess not only specific scientific competence to comprehend the scientific content of the investigations reviewed, but also other competencies pertinent to the judgments that need to be made" (p. 351).
1974	Regulations for the Protection of Human Subjects of Biomedical and Behavioral Research [45 CFR 46] is established.	"§46.107 IRB membership…(f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB" (p. 109).
1981	U.S. Food & Drug Administration (FDA) regulations revised to be congruent with 45 CFR 46, to the extent permitted by law, establishing IRB membership regulations.	"§56.107 IRB membership… (f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB" (p. 298).

Appendix B.
Summary of International Landmark Standards Specifically Addressing the Extent to Which Ethics Committees/IRBs Are Permitted to Utilize Outside Experts

Year	Description	Text concerning outside expertise
1996	International Conference on Harmonisation published *Guideline E6: Good Clinical Practice, Consolidated Guideline*, setting forth international standards in human subject protection assurances.	"3.2 Composition, Functions, and Operations…3.2.6 An IRB/IEC may invite nonmembers with expertise in special areas for assistance" (p. 12).
2006	India's Council of Medical Research (ICMR) published a revision to their national guidelines, *Ethical Guidelines for Biomedical Research on Human Participants*, taking into account recent developments in the areas of science and technology.	"Chapter II - Ethical Review Procedures. Composition. If required, subject experts could be invited to offer their views, for instance, a pediatrician for pediatric conditions, a cardiologist for cardiac disorders etc." (p. 10).
2007	Australia's national guidelines, the *National Statement on Ethical Conduct in Human Research 2007*, sets forth the requirements to ensure that human subjects research meets ethical standards and guidelines, as well as the operations of Human Research Ethics Committees (HRECs).	"Chapter 5.1: Institutional Responsibilities, Composition of HRECs - 5.1.33 The institution should ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider. This may necessitate going outside the HREC membership" (p. 87).
2010	The Canadian Interagency Advisory Panel on Research Ethics (PRE) published revisions to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* policy to address the evolving needs of Canada's three federal research agencies in promoting the ethics of research involving humans.	"Chapter 6: Governance Of Research Ethics Review… Ad Hoc Advisors: Article 6.5 The Research Ethics Board (REB) should have provisions for consulting ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. Application: In the event that the REB is reviewing a project that requires particular community or participant representation or specific disciplinary or methodological expertise not available from its members, it should have provisions for consulting ad hoc advisors…Ad hoc advisors are consulted for a specific research ethics review and for the duration of that review. Should this

Year	Description	Text concerning outside expertise
		occur regularly, the membership of the REB should be modified to ensure appropriate expertise on the REB…While ad hoc advisors may complement the REB through their experience, knowledge or expertise, their input is a form of consultation that may or may not be considered in the final decision of an REB. They are not REB members…Ad hoc advisors should not be counted in the quorum for an REB, nor be allowed to vote on REB decisions" (p. 73).
2016	China's National Health and Family Planning Commission published the *Measures for the Ethical Review of Biomedical Research Involving People* to protect the rights and welfare of human subjects and regulate the ethical review of biomedical research.	"Chapter Two: Ethics Committee - Article 9. When necessary, the ethics committee can hire independent consultants. Independent consultants provide advice on specific issues of the project under review and do not participate in voting" (p. 1).