

360 Degrees of Human Subjects Protections in Community Engaged Research: A Proposed Taxonomy of Risks and Their Management

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Topic: Ethics and Risk Assessment

Problem/Issue Statement

In the 30 years since the Belmont Report, the role of the community in research has evolved and taken on greater moral significance. In contrast to prior focus on 'bench to bedside' research, investigators now seek to design research such that their findings will be as significant in patients from the real world as they were under highly controlled conditions. Such research is referred to as translational research, and spans a continuum from first clinical application, to real world outcomes. Increasingly translational research is performed with the active engagement of communities as collaborative partners with their own goals, values, beliefs and needs. Novel risks arise when communities become partners in research. Additional considerations, beyond those focused on the rights of the individual, are required to mitigate the potential impact that community partnerships and community-based research may have for those communities that participate.

Description of Program

Methods: A group of community researchers, community representatives, ethicists, and human protections experts was assembled, supported by an NCRR funded Clinical and Translational Science Award Administrative Supplement, to develop a vision and recommendations for "360 Degrees of Human Subjects Protection in Community Engaged Research". Face to face meetings, a series of conference calls and writing workshops were conducted. Through iterative collaboration, a framework for the risks presented by community engaged research was defined, the implications explored, and development of appropriate safeguards discussed.

Results: A new taxonomy for risks in community research was developed, specifying the intersections of those at risk: 1) Individual, 2) Individual by Group association, and 3) Community, —with types of risk: 1) Process Risks to Well-being, 2) Outcome Risks to Well-being, and 3) Risks to Agency. Illustrative examples for each risk were developed and discussed. A human subjects protection (HSP) program for Community Engaged research must address 9 main ethical concerns: 1) minimizing risks; 2) reasonable benefit: risk ratio; 3) fair subject selection; 4) adequate monitoring; 5) ensuring informed consent; 6) ensuring privacy and confidentiality; 7) managing conflicts of interest; 8) addressing vulnerabilities; and 9) proper training in human subjects protections. These functions should be coordinated between the various entities that may serve to protect human subjects including-- the investigator, the Research Ethics Consultation, the Institutional Review Board, the Research Subject Advocate, the Data and Safety Monitoring Plan, and the Community Advisory or Oversight Board. Key questions were developed to



ensure full consideration of each ethical concern by the HSP program, allowing individual sites to determine which entities are responsible for which issues. Some overlap was recommended in order that the process incorporated some checks and balances.

Limitations: The proposed taxonomy and recommendations have not yet been implemented. Next Steps: To develop an implementation plan, and evaluation method for testing the effectiveness of the new taxonomy in anticipating and reducing risks to communities.