Shared Authority and Responsibilities

Don E. Workman, PhD
Northwestern University

National Conference on Alternative IRB Models:
Optimizing Human Subject Protection
November 20, 2006
Northwestern University
Human Subject Protection Program

Northwestern University
IRB Panel A
Northwestern University Human Subject Protection Program

Northwestern Memorial Hospital

Northwestern Medical Faculty Foundation

Northwestern University

IRB Panel A
Northwestern University Human Subject Protection Program

Northwestern Memorial Hospital
Northwestern Medical Faculty Foundation
Rehabilitation Institute of Chicago

Northwestern University
IRB Panel A
Northwestern University
Human Subject Protection Program

Northwestern Memorial Hospital
Northwestern Medical Faculty Foundation
Rehabilitation Institute of Chicago

Jesse Brown VA Medical Center

IRB Panel A
Northwestern University
Human Subject Protection Program

Northwestern Memorial Hospital
Northwestern Medical Faculty Foundation
Rehabilitation Institute of Chicago

Jesse Brown VA Medical Center

University of Illinois at Chicago

Northwestern University
IRB Panel A

UIC IRB #1
Northwestern University
Human Subject Protection Program

Northwestern Memorial Hospital
Northwestern Medical Faculty Foundation
Rehabilitation Institute of Chicago
Northwestern Memorial Hospital
Children’s Memorial Hospital
Evanston Northwestern Hospital
Jesse Brown VA Medical Center
University of Illinois at Chicago
UIC IRB #1
CMH IRB
ENH IRB

Northwestern University
How Can Shared Authority and Responsibility be Managed Best?

- Shared authority and responsibility will be better managed when a human subject protection program has already developed its organizational responsibilities along the lines of AHRPP's five domains.
- The FWA and sample IRB Authorization Agreement may be overly simple documents.
- FWA institutions would benefit from having access to other sample agreements or additional guidance on topics and mechanisms for delineating shared responsibilities.
How Can Shared Authority and Responsibility be Managed Best?

- Alternative models for IRB review and oversight offer different and possibly better business process models.
- We need to empirically evaluate alternative models to determine effectiveness.
When are alternative forms of review most appropriate?

- Alternative IRB models may be a useful way for managing institutional conflicts-of-interest.
- Alternative models become more appropriate as the number of institutions engaged in the research increases.
- Alternative models may also become more appropriate when the type of research under review is specialized.
When are alternative forms of review most appropriate?

- §46.107 IRB membership (a) The IRB shall be sufficiently qualified... to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

- If the use of alternative forms of IRB review and oversight promote greater respect in the research community (see above), then they are most appropriate.