WAIANAE COAST COMPREHENSIVE HEALTH CENTER

Conference Call Series on Institutional Review Boards and Ethical Issues in Research
Co-sponsored by Community-Campus Partnerships for Health & Tuskegee University National Center for Bioethics in Research and Health Care

May 24, 2007
COMMUNITY-BASED; COMMUNITY DRIVEN

• Research Committee
• IRB
RESEARCH COMMITTEE

• Ensure approved proposals are sensitive and relevant to community
• Ensures scientific merit
• Review prior to proposal submission
• Focus on integrity in research
RESEARCH GOALS

• Sensitive to culture
• Involves community leaders/residents in planning, implementation & protection
• Creates a sense of ownership
• Provides job opportunities
• Generates meaningful data
• Establishes cooperative working relationship between community and research agency

KEY COMPONENTS

• Benefit to community
• Cost to community
• Collaboration
• Resources provided
• Resources required
• Congruence w/ mission
• Community-based strategies
REVIEW PROCESS

- REQUEST TO CONDUCT RESEARCH FORM
- SOURCE/FUNDING AMOUNT AVAILABLE:
- FUNDING AVAILABLE TO WCCHC:
- COST TO WCCHC/NON-FUNDED ITEMS:
- FUNDING PERIOD:
- LETTER OF INTENT DEADLINE/PROPOSAL DEADLINE:
- PROPOSED ACTIVITY/CONCEPT:
- WCCHC INVESTIGATORS/STAFFING AND THEIR ROLE:
- EXTERNAL STAFFING/ROLE:
- COLLABORATIVE ARRANGEMENTS:
- HOW DOES ACTIVITY FIT INTO GOALS OF WCCHC:
- WHAT WOULD THE BENEFITS TO THE COMMUNITY:
- HOW WILL THE COMMUNITY BE INVOLVED IN PLANNING AND/OR IMPLEMENTATION:
- ETHICAL ISSUES/HIPAA/IPATIENT SAFEGUARDS:
- CURRENT STAGE OF DEVELOPMENT:
- AMOUNT/TYE OF IN-KIND CONTRIBUTION BEING SOUGHT FROM WCCHC:
BENEFIT TO COMMUNITY

• Effect positive health, socio-economic, and environmental outcomes
• Evidence-based approaches
• Respect the values and mores of the community
• Data owned by community
INSTITUTIONAL REVIEW BOARD

• Established to protect the special features of the community
• Ensures that the community has a voice
COMMUNITY VS “GOLD STANDARD”

- Researchers question the need to obtain community IRB approval when they’ve already received university/hospital approval
INFORMED CONSENT

• Participant FULLY understands purpose, benefits, risks
• Researcher FULLY understands
• Consent process observable in community
REVIEW BOARD

• Multidisciplinary Research Committee
• Collaborative partner representatives
• Other disciplines at Center
• Cultural/community (non-voting) members
IRB PROCESS

WCCHC Research Committee and IRB Process

Proposal comes to Committee Chair.

Proposal comes to Research Committee.

Interested and meets core criteria?

YES

Inform researcher, proposal comes back to IRB, if funded.

Proposal funded?

YES

Committee Chair to Determine if proposal is expedited, exempt, or full review.

_EXPEDITED:

Review by 3 members within 4 weeks.

Requires majority (2 out of 3 reviewing members) for decision.

Approve, Reject, Approve with Revisions?

YES

Approve: Coordinate with Dept Head/Provider, comments to researcher, research may proceed.

NO

Reject: Comments to researcher, research cannot proceed.

Members present including 1 non-scientific for decision.

_EXEMPT:

Researcher can proceed as outlined in letter from WCCHC.

Full Review:

Reviewed by 3 primary reviewers within 8 weeks.

Requires 2/3 of voting members present including 1 non-scientific for decision.

Approve with Revisions, conditionally approve, etc. Comments to researcher, primary reviewers to review revisions.

NO

Inform researcher, revise if applicable.
RESOURCES

• [www.wcche.com](http://www.wcche.com) (research & IRB policies/procedures)

• Oneha MF; Beckham S. Re-examining community based research protocols. Pacific Public Health 2.11:1;2004.