Ethical Considerations in Operations Research

Operations Research Mini-Course

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Issues for Discussion

- Defining research vs. non-research
- Ethics issues in “non-research” activities
- Appropriate review processes and mechanisms

Defining Research vs Non-research

- Generalizibility is key defining characteristic of resarch (not methods)
- Routine program evaluation is not research
- Non-research is publishable
- Need rules, algorithms to help define

Need code of ethics for both

Belmont Ethical Principles (for research)

- Respect for persons – maximize autonomy, protect privacy
- Beneficence – weighing of cost-benefit
- Justice – benefits and burdens shared equally

Research vs Non-Research

CDC Definition

“Research means a systematic investigation,

including research development, testing and evaluation,

designed to develop or contribute to generalizable knowledge.”

UW website

University of Washington
School of Public Health
and Community Medicine

Draft Guidelines

Distinguishing Research from Non-Research Public Health Practice

14 November 2003

Draft prepared by Paula E. Brentlinger, MD, MPH, Mary Anne Mercer, DrPH and David L. Eaton, Ph.D.

Note to the Reader: We welcome comments on this document. Comments may be directed by e-mail to: P. Brentlinger (brentp2@u.washington.edu) and/or M. Mercer (mamercer@u.washington.edu).

Introduction:

Both United States Federal regulations and international codes of ethics require that any research that involves human subjects must be reviewed and approved by properly-constituted ethics committees (e.g., Institutional Review Boards, IRBs), to ensure that research subjects, especially members of historically vulnerable groups, may be properly informed of and protected from research risks.[1 2] At the University of Washington, the Human Subjects Division (HSD) is charged with the responsibility of ensuring that research conducted by the University's faculty, staff, and students that utilizes human subjects is carried out in full conformity with the law and with medical and public health ethics.

Distinguishing Research from Non-Research Public Health Practice - Draft Guidelines

(Adapted from P. Brentlinger, M. Mercer, D. Eaton 2003)

1. What is the aim of the project?
2. Does the activity fit into categories of public health practice?
3. Involvement of vulnerable populations
4. Risks to participants

Declaring projects to be non-research

1. What is the aim of the project?

- Is the primary aim to “develop or contribute to generalizable knowledge,” or to answer or generate a research question?

If yes – research.

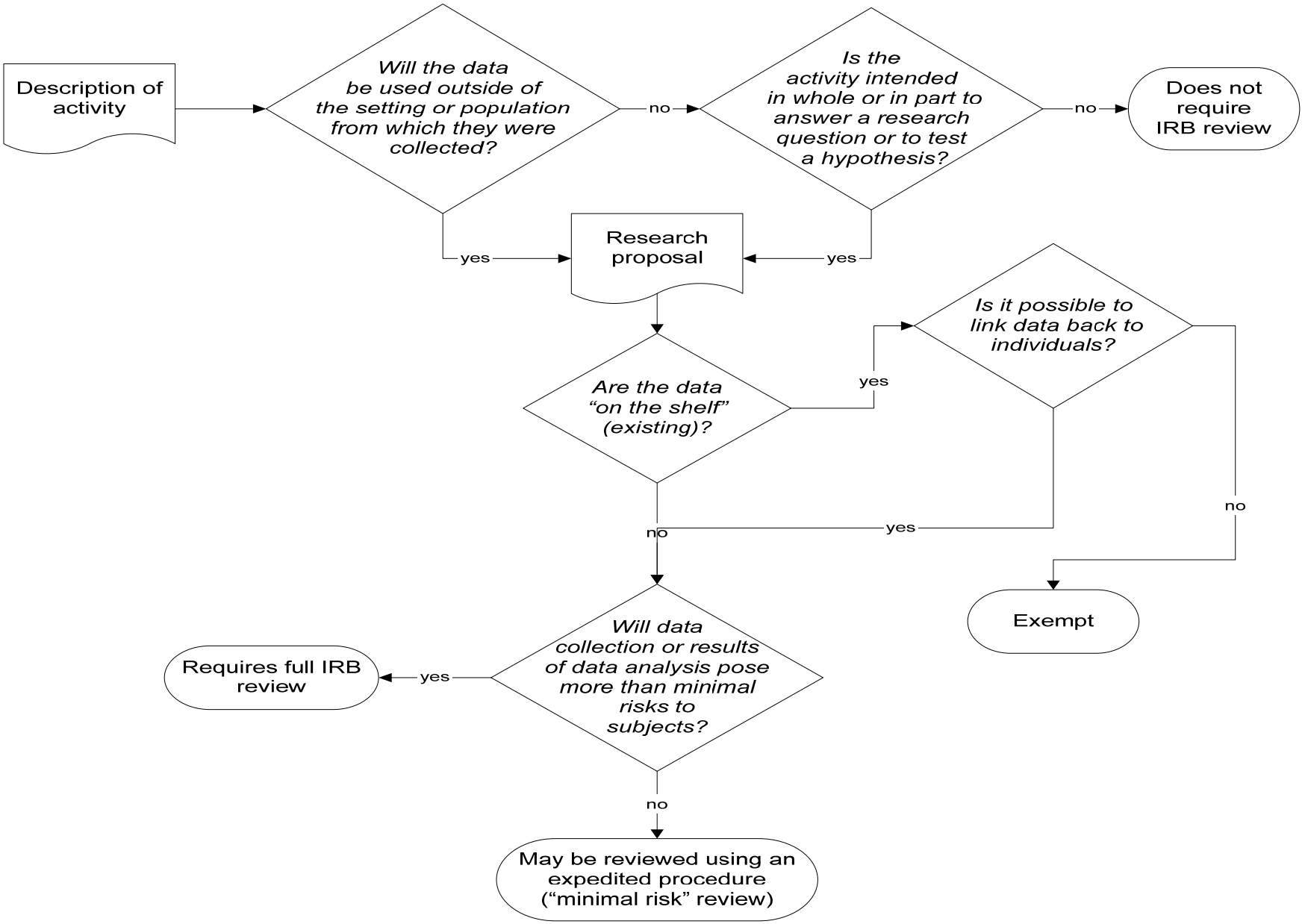
- Is the primary aim to “identify and control a health problem with potential benefits for the project participants or their communities”?

If yes, more likely to be non-research.

- Would the project be conducted exactly as proposed if there would be no academic recognition for then project, including publication in a peer-reviewed journal or presentation at academic meetings?

If yes, more likely to be non-research.

Distinguishing QA/QI from Research



2. Categories of practice with research overlap

There are research non-research attributes of:

- Surveillance
- Program and other evaluation
- Emergency response
- Policy analysis
- Quality assurance/Improvement

Example: Program Evaluation

Non-research attributes

- Assesses success of an established program, and use findings as feedback to that program
- Program to be assessed is not new, and is known to be effective in its setting or similar settings
- Pre-intervention evaluation provides information on how to modify a proven-effective intervention

Research attributes:

- Tests new, previously untested intervention.
- Extends findings to dissimilar settings or populations.
- Designed as systematic comparison using experimental-type design (e.g. RCT of two different interventions.)

3. Vulnerable populations

- If study participants are members of vulnerable populations, additional protections and review are advisable
- IRB is not necessarily required.
- Vulnerable populations include, but are not limited to, the following:
  - Children
  - Pregnant women
  - Fetuses
  - Prisoners or detainees
  - Persons who are not legally competent
  - Refugees or displaced persons
  - Residents of war and conflict zones
  - HIV+ persons

4. Risks to participants

If participation in the project may place participants at risk of harm, additional review is advisable, but IRB is not necessarily required

Potential risks include

- physical harm
- psychological harm (including to professional, financial, social standing, emloyability, reputation)

Examples of Risks

- ANC HIV surveillance (unlinked) for country HIV estimates
- Operational interventions to improve antenatal syphilis, HIV testing – evaluation results may pose risk to positive women when they disclose to partners
- HH surveys, exit surveys and confidentiality
- Tuskegee syphilis study was originally public health system follow-up

Ethics issues in “non-research” activities

- Applying professional ethics codes, guidelines, and principles (e.g. APHA, AMA, CDC, WHO) without IRB oversight
- Internal ethics oversight processes
- Potential informed consent requirements
- Documentation of ethics compliance
- Whistle-blowing protection

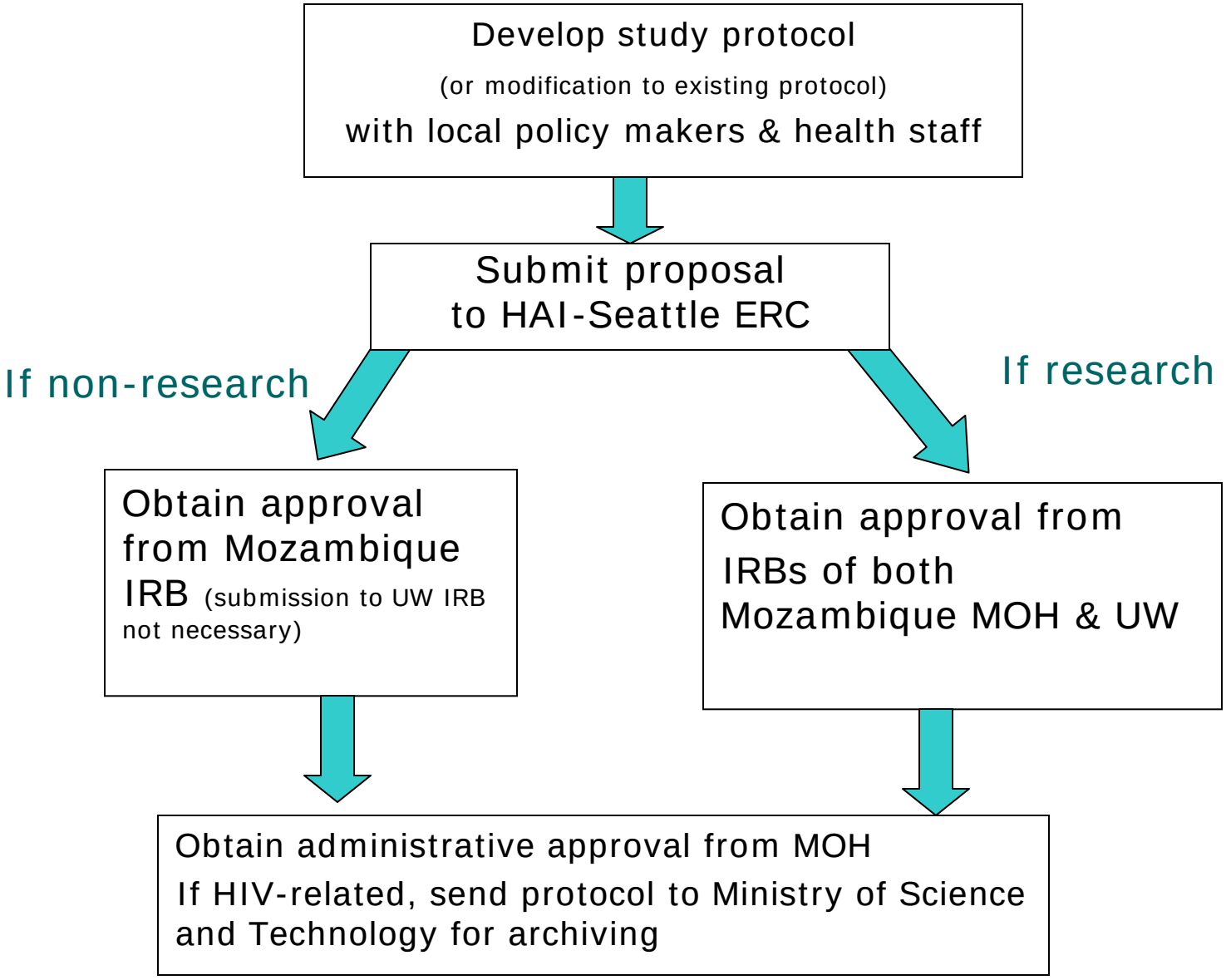
Review processes and mechanisms

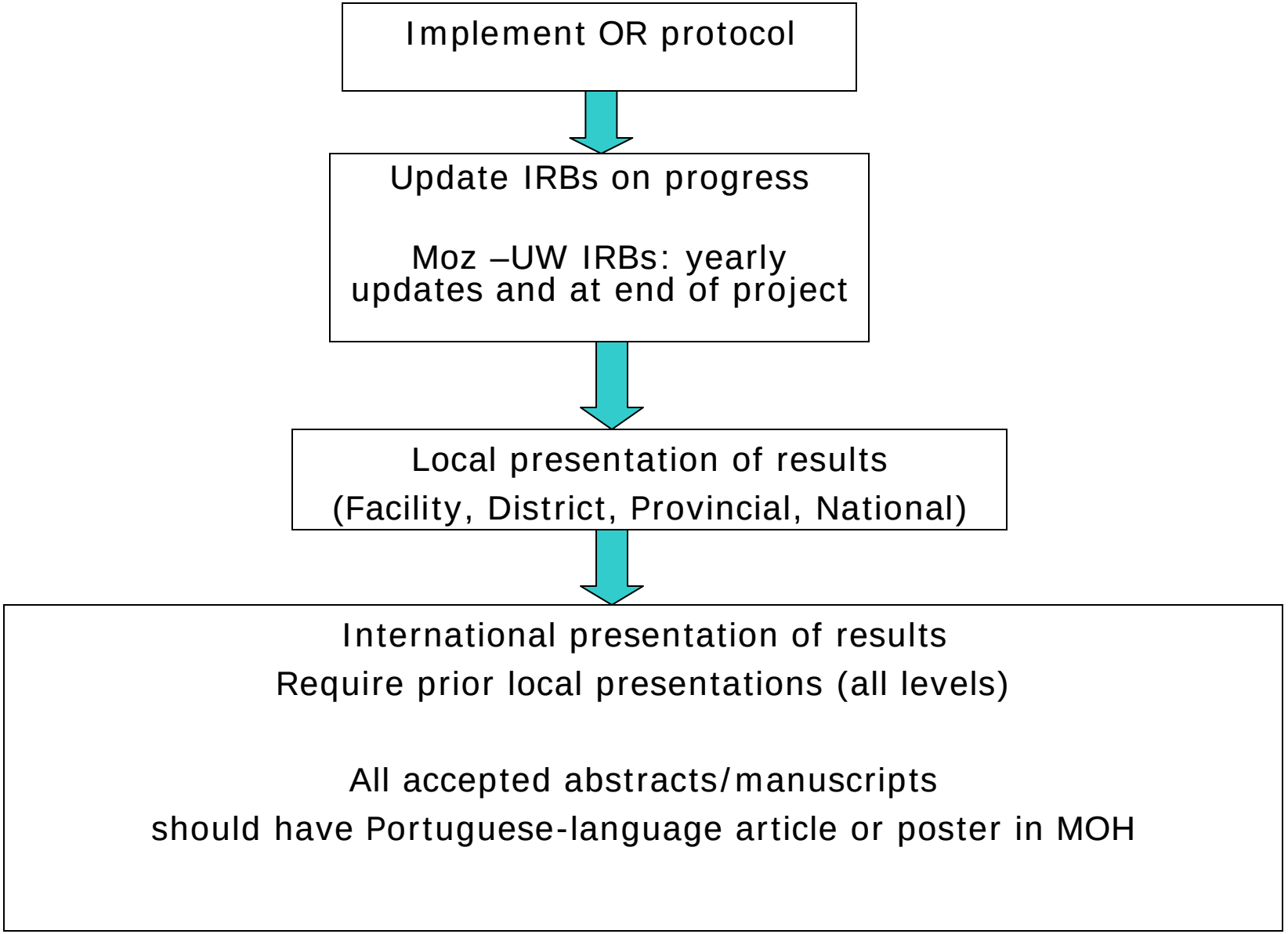
- Initial review process to determine research vs. non-research
- OR staff training in ethics review criteria
- External expert advice
- Database review and approval
- National IRB considerations
- Publication
- Documenting review decisions

Health Alliance International (NGO) Approach

Ethical Review Committee

- Membership: investigators and staff
- Reviews all data gathering activities
- Distinguishes research from non-research
- Research sent to UW IRB
- ERC addresses ethical concerns of non-research activities
- Appeal process available


Develop study protocol
(or modification to existing protocol)
with local policy makers & health staff
Submit proposal
to HAI-Seattle ERC
If non-research
If research
Obtain approval
from Mozambique
IRB (submission to UW IRB
not necessary)
Obtain approval from
IRBs of both
Mozambique MOH & UW
Obtain administrative approval from MOH
If HIV-related, send protocol to Ministry of Science
and Technology for archiving


Implement OR protocol
Update IRBs on progress
Moz –UW IRBs: yearly updates and at end of project
Local presentation of results
(Facility, District, Provincial, National)
International presentation of results
Require prior local presentations (all levels)
All accepted abstracts/manuscripts
should have Portuguese-language article or poster in MOH

Ethics Review Committee Application, Health Alliance International

Instructions: Please fill out the form below and return it to the ERC coordinator Ben Stubbs, at bstubbs@u.washington.edu. If filling out the form on a computer, double click on check boxes and select "checked" to indicate your response.

Title of project:
Date of submission to ERC:
Principal investigator:
Co-investigators:
Key Ministry of Health participants (name/department):
Proposal
Main objectives/aims of project:
Brief description of intervention and/or data collection *Design:*

Research vs. Non-research (please refer to "Distinguishing Research from Non-Research Public Health Practice" when filling out this section, available at http://sphcm.washington.edu/research/human_subjects_guidelines.pdf):

PART 1: Intent of activity				
1. Is the primary aim of the project to "develop or contribute to generalizable knowledge" or to answer a research question, or to generate a hypothesis or research question?		Yes		No
2. Is the primary aim of the project to "identify and control a health problem with potential benefits for the project participants or their communities?		Yes		No
3. Would your project be conducted exactly as proposed if you knew that you would never receive any form of academic recognition for the project, including publication of the results in a peer-reviewed journal or presentation of the project at an academic meeting?		Yes		No

PART 2: Category of activity				
1. What category of public health practice does your proposed activity fall?				
2. Does your project have any component or attribute listed in the "research attributes" in Table 2 of Distinguishing Research from Non-Research Public Health Practice (http://sphcm.washington.edu/research/human_subjects_guidelines.pdf)?		Yes		No
If "yes", describe:				

PART 3: Vulnerable Populations				
Does your project involved members of vulnerable populations?		Yes		No

PART 4: Risk to Participants				
Does the activity involve a risk to participants?		Yes		No
If "yes, describe:				

Presentation of Study Results
Ethics Review Committee, Health Alliance International

Title of presentation/poster/article:

Authors:

Please indicate below where the study results will be presented.

Type	Title of Event or Journal	Presenters	Accepted?	Event Date	Form
☐ Conference ☐ Journal ☐ Presentation			☐ Not yet submitted ☐ Yes ☐ Pending		☐ Oral ☐ Poster ☐ Publication

Is this presentation associated with an ongoing or completed study or OR protocol? ☐ Yes ☐ No

If yes, what is the name of the study or OR protocol?

Have you presented these data before in a different venue? ☐ Yes ☐ No

If yes, was the previous presentation reviewed by the ERC?

☐ Yes → ERC Number _____/_____

☐ No → Please Explain:

Have programmatic changes been implemented as a result of this study? ☐ Yes ☐ No

If yes, please describe:

Summary

Please paste a copy of the corresponding abstract below. If there is not an abstract, please summarize the findings you will present:

Presentation of Study Results
Ethics Review Committee, Health Alliance International

ERC Decision (for use by ERC committee members only)		ERC Number:
Title of study from which data were derived:		
Principal investigator for study:		Funding Source:
Final decision		Approved
		Not Approved
		Other (specify):

Recommended Action
None
Local presentation needed
Documentation of local approval needed
Other (specify):

Decision date	
Signature	Signature date

Thank you!

Some useful websites on ethics

- **Guidelines for Defining Public Health Research and Public Health Non-Research** http://www.cdc.gov/od/ads/opspoll1.htm
- **Distinguishing Research from Non-Research Public Health Practice** http://sphcm.washington.edu/research/human_subjects_guidelines.pdf
- **Protection of Human Subjects - Code of Federal Regulations, Department of Health and Human Services, National Institutes of Health** http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm.
- **Ethical Principles for Medical Research involving Human Subjects, Declaration of Helsinki, World Medical Association** http://www.dvincitbt.com/ohsrsite/guidelines/helsinki.html.