



proud past, promising future

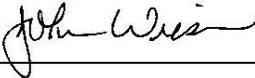
Clark County Public Health

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SUBJECT: Human Subjects/IRB Review	POLICY NO: HAE 001
UNIT: Health Assessment and Evaluation	EFFECTIVE DATE: May 1, 2012
MANAGER: Janis Koch	ORIGINAL DATE: April 4, 2007
SIGNATURE OF DEPARTMENT DIRECTOR: 	
SIGNATURE OF HEALTH OFFICER:	
COPIES DISTRIBUTED TO: Program Managers, HAE staff	REVIEW: Biennially NEXT REVIEW: May 1, 2014
REFERENCES: Code of Federal Regulations – Title 45 CFR Part 46, 2009 Revision; Federalwide Assurance for the Protection of Human Subjects – FWA #00000856 Clark County Public Health; Centers for Disease Control and Prevention <i>Distinguishing between Public Health Research and Public Health Non-Research Policy</i> (2010)	

POLICY

Clark County Public Health (CCPH) will comply with federal law in the ethical collection of data involving and use of human subjects and will seek Institutional Review Board (IRB) approval as needed.

OVERVIEW

CCPH is committed to protecting an individual’s privacy and to prevent any untoward health consequences or breaches of confidentiality as a result of interventions, evaluations or assessment activities (hereafter referred to as activities) implemented by CCPH staff or with CCPH clients. Therefore, it is the policy of CCPH that any new activity or changes in current activities involving human subjects or client records be reviewed by the CCPH Human Subjects Review Committee (HSRC) prior to implementation and at regular intervals as necessary. When an activity is classified as research involving human subjects, CCPH will seek IRB review and comply with Title 45 Code of Federal Regulations Part 46, 2009 revision (45 CFR 46) in the protection of human subjects. Note: the HSRC does not serve as an IRB.

DEFINITION OF TERMS

CCPH	Clark County Public Health
CFR	Code of Federal Regulations
FWA	Federalwide Assurance for the Protection of Human Subjects is where an institution engaged in non-exempt human subjects research commits to the US Department of Health and Human Services that it will comply with all requirements in 45 CFR 46.
HPA	Human Protections Administrator designated on the FWA is the primary institutional contact person for CCPH and responsible for the human subjects review program.
HSRC	Human Subjects Review Committee of Clark County Public Health is tasked with reviewing activities that involve human subjects or client records to identify potential research projects or concerns.

Human Subjects	A living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information (45 CFR 46.102(f)).
IRB	Institutional Review Boards are responsible for reviewing any proposed activities related to human research (45 CFR 46).
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(d)).
WSIRB	Washington State Institutional Review Board in the Washington State Department of Social and Health Service serves as the department's primary IRB. Other IRBs listed on the department's FWA may be used for specific research projects.
Emergency Response	A public health activity undertaken in an urgent or emergency situation, usually because of an identified or suspected imminent health threat to the population, but sometimes because the public and/or government authorities perceive an imminent threat that demands immediate action. The primary purpose of the activity is to document the existence and magnitude of a public health problem in the community and to implement appropriate measures to address the problem (Langmuir, 1980).
Evaluation	The systematic application of scientific and statistical procedures for measuring program conceptualization, design, implementation, and utility; making comparisons based on these measurements; and the use of the resulting information to optimize program outcomes (Rossi and Freeman, 1993; Fink, 1993).
Program Evaluation	An essential organizational activity in public health using a systematic approach to improve and account for public health actions (Centers for Disease Control and Prevention, 1999).
Surveillance	The ongoing systematic collection, analysis and interpretation of health data, essential to the planning, implementation and evaluation of public health practice, closely integrated to the dissemination of these data to those who need to know and linked to prevention and control.

BACKGROUND

Federal law (45 CFR 46) requires the review of all activities related to human subjects research conducted or funded by the US Department of Health and Human Services to determine whether the activity qualifies as research. Research activities are bound by the fundamental ethics of human subjects protections as defined in the regulation. Separate regulations require review for other federal agencies that support human research.

Under CCPH's FWA (FWA00000856), any proposed activities related to human research must be reviewed by an IRB (not only those federally conducted or supported). Because CCPH does not have an internal IRB and cannot make a formal IRB determination, the WSIRB will be used for formal review of projects. When appropriate, other IRBs listed on the department's FWA will

be used. The HSRC will coordinate internally which projects need an IRB review or determination.

ROLES AND RESPONSIBILITIES

A. Human Protections Administrator

- Appointed by the Department Director.
- Designated on the FWA as the primary institutional contact person for CCPH
- Serves as point-of-contact for HSRC and all department employees.
- Convenes HSRC at least once per year to review policy, procedures and training.
- Serves as resource to other committee members.
- Updates FWA as necessary.

B. Human Subjects Review Committee

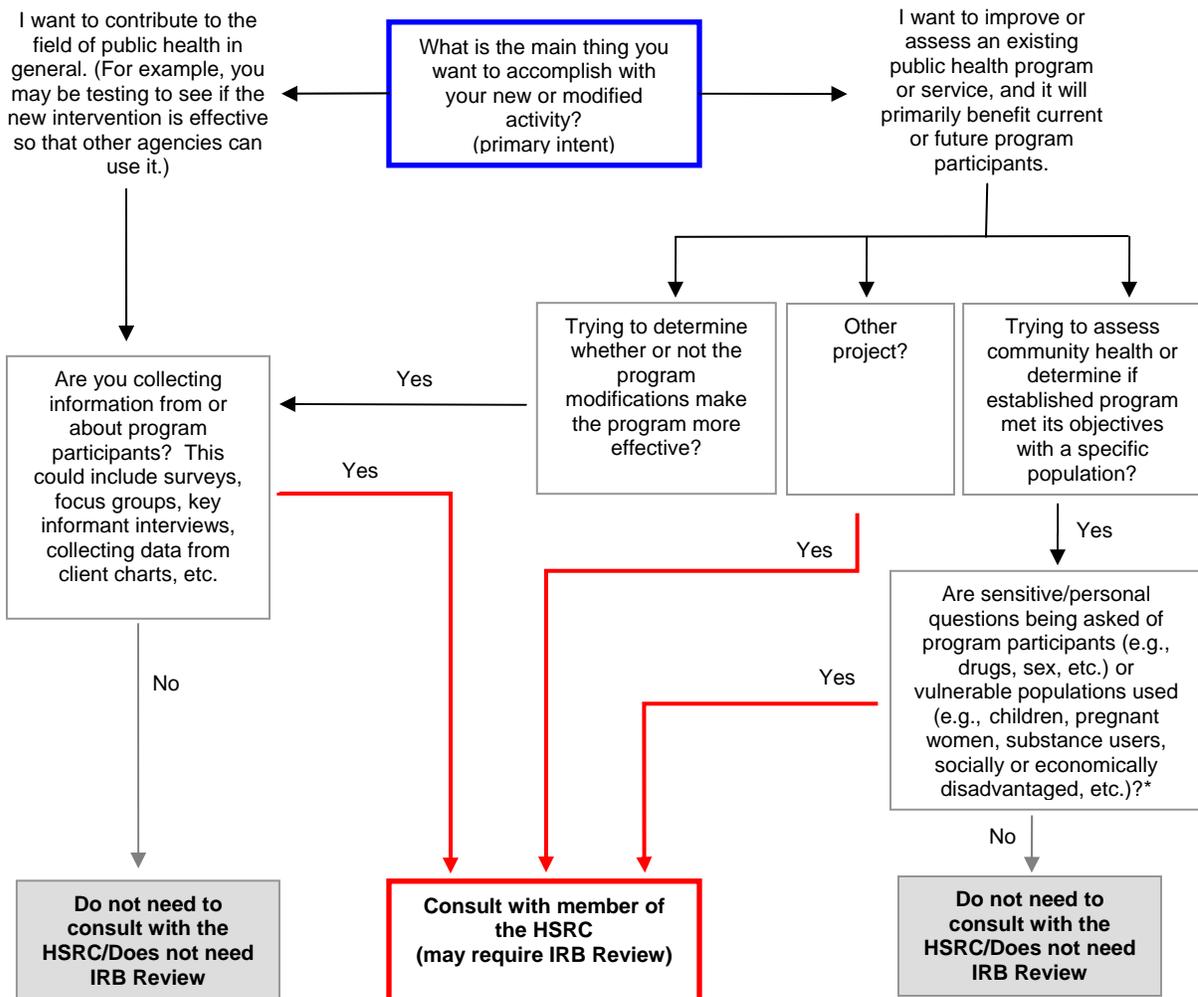
- Consists of the HPA and at least two additional members.
- Maintains a working relationship with the department's designated IRB and assists with the IRB application process as needed.
- Meets at least once per year to review policy, procedure, and training.

C. Department Director

- Appoints the HPA.
- Serves as Signatory Official for modifications or updates to FWA.

PROCEDURE - GUIDELINES

- **Staff conducting work related to human subjects or client records**
 1. Develops project idea including new activities or modifications of current activities that involve human subjects or client records (such as surveys, focus groups, pilot projects, program evaluation). (Note: In general, surveillance and emergency response activities do not require human subjects review.) The following decision tree can be used with the HSRC to determine whether or not the project may need Human Subjects/IRB review.



2. Meets with HRSC member to discuss project and identify necessary steps.
3. Prepares Human Subjects Review Activity Description and Approval Form (see attached form) with assistance from HRSC member.
4. Submits completed form to Manager for written approval.
5. Submits signed form to HRSC for review.
6. Modifies project as needed based on review by HSRC or the IRB to meet federal and state human subjects protections requirements or to strengthen proposed work if applicable.
7. Considers the time required to successfully complete CCPH requirements and/or meet IRB approval (note: if IRB approval is needed, the process may take several months). If IRB review is required, no project work may begin until study approval is extended by the IRB.

- **Managers approving work related to human subjects or client records**
 1. Reviews Human Subjects Review Activity Description and Approval Form.
 2. Signs form for HSRC review.
 3. Ensures each employee under his/her supervision reviews the Human Subjects/IRB policy upon employment and is notified of any substantive updates to policy.
- **HSRC reviewing proposals for work related to human subjects or client records**
 1. HSRC or HSRC member discusses proposed project with staff, identifies necessary steps, and helps prepare the Activity Description and Approval Form.
 2. HSRC or HSRC member reviews Activity Description and Approval Form.
 3. Determines the disposition of project regarding IRB review and records on form.
Disposition categories:
 - Requires IRB/Human Subjects review – facilitate contact with IRB.
 - Does not require IRB/Human Subjects review – no further action required although can make suggestions to strengthen proposed work if applicable.
 - Needs more information to determine if project requires IRB/Human Subjects review – communicate need for more information to staff contact and Manager.
 4. Consults with the WSIRB, or other approved IRB, if a decision on disposition of proposed activity cannot be reached.
 5. Documents findings of review on the Activity Description and Approval Form and sends to primary staff contact, Manager, and HSRC records.

EMPLOYEE EDUCATION AND TRAINING

1. Upon employment, each employee is expected to review the Human Subjects/IRB policy.
2. Employees will be notified to any substantive updates to this policy, as determined by the manager of the Health Assessment and Evaluation unit
3. All HSRC members are required to maintain appropriate training for human subjects protection. Members must complete training outlined in the HSRC Training Plan including on-line training at <http://www.dshs.wa.gov/rda/hrrs/training.shtm> regarding human subjects protection. Training must be completed every three years.

Failure to comply with the policy or procedure could result in disciplinary action up to and including immediate dismissal, consistent with Clark County Personnel Policies and the current labor agreement.

Clark County Public Health
Human Subjects Review Activity Description and Approval Form

Staff: Please complete Parts 1 and 2 of this form and submit to your Manager for approval. Please note the HRSC is available to assist.

Part 1: Activity Description Summary

Title	
Date Submitted	
Objectives What are you doing? What is purpose? Who is involved? How is info used? Who benefits?	
Methods and Procedures How will you do it? What population? Vulnerable pops? How many people? How selected? How recruited? What data and how collected? (e.g. survey, intv, chart review)	

Part 2: Primary Staff Contact Information

Name _____	Title _____
Unit _____	Extension _____
Signature _____	Date _____

Part 3: Manager Approval

I have reviewed the Activity Description Summary and approve it for consideration by the Human Subjects Review Committee.

Name _____	Title _____
Unit _____	Extension _____
Signature _____	Date _____

PART 4: Human Subjects Review Committee Disposition

- Project Disposition: Requires IRB/Human Subjects Review by an IRB
 Does not require IRB/Human Subjects Review
 Needs more information to determine if project requires IRB/Human Subjects Review

HRSC Member Name _____	
Signature _____	
Date _____	Extension _____