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## Clark County Public Health

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<b>SUBJECT: Human Subjects/IRB Review</b>	<b>POLICY NO: HAE001</b>
<b>UNIT: Health Assessment and Evaluation</b>	<b>EFFECTIVE DATE: 4/4/07</b>
<b>SIGNATURE OF DEPARTMENT DIRECTOR:</b> 	
<b>SIGNATURE OF HEALTH OFFICER:</b>	
<b>COPIES DISTRIBUTED TO: Program Managers, HAE staff</b>	<b>REVIEW: Annually</b>
<b>REFERENCES: 45 CFR 46</b>	

### POLICY

Clark County Public Health (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. 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 comply with Title 45 Code of Federal Regulations Part 46, 1991 revision (45 CFR 46) in the protection of human subjects.

### DEFINITION OF TERMS

1. Federal Wide Assurance (FWA) – Under a Federal Wide Assurance, institutions engaged in non-exempt human subjects research commit to the Department of Health and Human Services that it will comply with all requirements set forth in 45 CFR part 46 as well as the Terms of Assurance.
2. Human Protections Administrator (HPA)--Individual appointed by the Department Director, and working under the Federal-Wide Assurance (FWA) for the Protection of Human Subjects, as the primary institutional contact person responsible for the administration of the human subjects review program including (1) communication and education, (2) recordkeeping and reporting, and (3) monitoring and oversight.
3. Human Subjects Review Committee (HSRC) – Committee appointed by Department Director to review activities that involve human subjects or client records.
4. Institutional Review Board (IRB) – As per 45 CFR 46, the Institutional Review Board (IRB) is responsible for reviewing any proposed activities related to human research. For purposes of this policy, the Washington State Institutional Review Board serves as the department's primary IRB. Other IRBs listed on the department's FWA may be used for specific research projects.

The remaining definitions for this policy are the same as those used in The CDC Guidelines for Defining Public Health Research and Public Health Non-Research. (1997).

5. Research--As defined in the regulation, 45 CFR 46, research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable

knowledge." Activities conducted with the "intent" of generating generalizable knowledge are considered research.

6. Human Subjects--As defined in the regulation, 45 CFR 46, human subject means "a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information."
7. Surveillance--The ongoing, systematic collection, analysis and interpretation of outcome-specific data for the purpose of timely dissemination of these data to those responsible for preventing and controlling disease or injury (Thacker and Berkelman, 1988).
8. Emergency Response--A public health activity undertaken in an urgent or emergency situation, usually due to an imminent health threat to the population, but may also be due to the public and/or government authorities perceived imminent threat which demands immediate action (Langmuir, 1980).
9. Program 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).

## OVERVIEW

Federal law (45 CFR 46) requires the review of all activities related to human research funded by the US Department of Health and Human Services to determine whether the design qualifies as research. If so, it is then bound by the fundamental ethics of human subjects protections.

Under CCPH's Federal-wide Assurance for the Protection of Human Subjects (FWA00000856), any proposed activities related to human research must be reviewed by an Institutional Review Board (IRB). Because CCPH does not have an IRB, the Washington State IRB will be used as necessary in coordination with CCPH's Human Subjects Review Committee. When appropriate, other IRBs listed on the department's FWA will be used.

## PROCEDURE - GUIDELINES

### Staff will:

- Notify their Supervisor of any new activities or modifications of current activities that involve human subjects or client records (such as surveys, questionnaires, pilot projects, program evaluation).
- Prepare Human Subjects Review Activity Description and Approval Form (see attached form) and submit to Supervisor for written approval.
- Modify project as needed based on review by HPA, HSRC, or the IRB to meet federal and state human subjects protections requirements.
- **Consider 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).**

### Supervisor will:

- Review Activity Description and Approval Form.
- Sign form and submit to CCPH HPA if deemed an appropriate activity.
- Provide each new employee under his/her supervision a copy of the Human Subjects/IRB policy, review during new employee orientation, and document that employee received it and had an opportunity to read it and ask questions.

### Human Protections Administrator will:

- Serve as point-of-contact for HSRC.

- For any new activities or modifications of current activities that involve human subjects or client records (such as surveys, questionnaires, pilot projects, program evaluation), HPA will screen the Activity Description and Approval Form to determine if the proposed project or activity:
  1. Requires Human Subjects Review. If it does not, the HPA will complete the form and return to primary staff contact.
  2. Requires more information before a determination can be made. If it does, the HPA will communicate this to the appropriate Public Health Services Manager.
- Document findings of review to primary staff contact, Supervisor/Public Health Services Manager, and HSRC.
- Convene HSRC at least once per year to review policy/procedures.
- Serve as point of contact for information for all department employees.

Human Subjects Review Committee will:

- Consists of the HPA, Health Officer, and at least three additional members. The HPA and other committee members will be appointed by the Department Director. A quorum will require the HPA, Health Officer and at least one of the three additional members. If consensus cannot be reached, consultation with the Washington State IRB, or other approved IRB, will be required.
- The HSRC will review proposals, as screened by the HPA, for any new activities or modifications of current activities that involve human subjects or client records (such as surveys, questionnaires, pilot projects, program evaluation) and will determine if the project must go through formal Human Subjects Review by an IRB.
- Committee will maintain a working relationship with the department's designated IRB and will assist with the application process as needed.

Department Director will:

- Appoint the HPA.
- Appoint members to the HSRC.
- Fill vacancies in a timely manner.

EMPLOYEE EDUCATION AND TRAINING

1. Each employee will receive a copy of this policy within one month of hire and will have a chance to review it and ask questions of his/her supervisor.
2. This policy will be reviewed annually with all employees as part of the department's annual policy review.
3. Any substantive updates to this policy, as determined by the supervisor of the Health Assessment and Evaluation unit, will be emailed to all employees. Supervisors will be responsible for securing an employee acknowledgement form within one month of the update.
4. All HRSC members will be required to complete on-line training at <http://www1.dshs.wa.gov/rda/hrrs/training/shtm> regarding human subjects protection.

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 Department**  
Human Subjects Review Activity Description and Approval Form

**Staff: Please complete Parts 1 and 2 of this form and submit to your Supervisor.**

**Part 1: Activity Description Summary**

Title	
Date Submitted	
Objectives	
Methods and Procedures	
Significance of this Project	

**Part 2: Primary Staff Contact Information**

Name		Title	
Unit		Extension	
Signature		Date	

**Part 3: Supervisor Approval**

I have reviewed the Activity Description Summary and by my signature below approve and submit for consideration of the Human Subjects Review Committee.

Name		Title	
Unit		Extension	
Signature		Date	

**PART 4: FOR HUMAN SUBJECTS REVIEW COMMITTEE ONLY**

- Proposed project:
- Does not need Human Subjects Review
  - Needs more information to determine if project requires Human Subjects Review
  - Project must go through Human Subjects Review by Washington State IRB

HRSC Member Name			
Signature			
Date		Extension	