



# Yakima Valley Farm Workers Clinic

## “Research Participation” Procedure

Corporate-wide Procedure

Supersedes: 6/25/02

Approved by Executive Committee

Effective Date: 1/1/03

**SUBJECT:** *Research Participation Procedure*

### **ADMINISTRATIVE**

**APPROVAL:** Executive Committee

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**Date:** 1/1/03

**Supersedes:** 6/25/02

**I. Purpose:** This procedure has been developed so that YVFWC may critically evaluate our agency’s involvement in potential research projects. Our intent is to ensure that

- 1) the rights of our patients/clients, their records and our staff are protected,
- 2) proposed research projects are coordinated with other clinic projects,
- 3) research findings are incorporated into organizational planning; and
- 4) the resources of YVFWC continue to be directed toward high quality patient care and identified clinical priorities, and
- 5) YVFWC involvement in research meets all applicable laws and statutes.

Additionally, YVFWC has interest in partnering with research institutions in a collaborative, proactive manner to help solve those health issues that are most pressing for the population we serve. In addition to the specific criteria identified in this Procedure, YVFWC also asks any potential research partner to commit to working according to the “Principles of Community-Based Research” endorsed by the University of Washington Health Sciences Deans, 1996 (Attachment A).

### **II. Definitions:**

**Clinic Sponsor** - The identified YVFWC health professional, program director or department supervisor who is the primary agency contact for the proposed research project. The Clinic Sponsor accepts professional responsibility for hosting the outside researcher.

**Principal Investigator** – A research professional or student leading the conduct of research under this policy. A PI may be either a YVFWC employee or an outside researcher.

**Research Review Subcommittee** – A subcommittee of the Executive Committee, appointed to provide initial review and provisional approval for research projects submitted to the



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organization. The Research Review Subcommittee consists of the Corporate Medical Director, Corporate Dental Director, Director of Program Operations, Director of Planning & Development, and one member who is not affiliated with YVFWC. The Research Review Subcommittee will be trained in research review ethics and procedures, and knowledgeable of applicable laws and statutes. The Research Review Subcommittee will also function as the YVFWC Privacy Board described in HIPAA Privacy Regulation 164.512, paragraph (i)(1)(i)(B).

**Research** – Any systematic investigation, including research development (pilot testing), testing and evaluation, designed to develop or contribute to generalizable knowledge beyond YVFWC’s practice setting. Generalizable knowledge refers to any systematically gathered data that is intended for dissemination beyond the institutional setting, and which might reasonably be generalized beyond the research sample. Generalizable research knowledge is often (although not always) research funded by an outside entity, and may be expected by the researcher to result in professional publication or presentation at a professional or student research conference. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered “research” for other purposes.

**Program Evaluation** - Program evaluation research for internal agency use only does not usually need review under this procedure, unless gathering of the data involves more than minimal risk for subjects or their data.

**Student Research Practica:** Student Research Practica (usually in the form of course-related research projects and/or directed studies) are designed to provide students an opportunity to practice various research methods. Typically such projects are quite limited in scope, do not lead to generalizable knowledge and are not undertaken with that goal in mind. Often employees of YVFWC who are also students currently enrolled in a degree program request to use YVFWC records or staff to perform their “student research practica”. This procedure includes provision for Student Research Practica by employees to be approved at the Program Director/Clinic Administrator level.

**Protected Health Information:** Protected Health Information, under the August 2002 revisions of the HIPAA Privacy Rule, is individually identifiable health information. *Identifiable* refers not only to data that is explicitly linked to a particular individual (that's *identified* information). It also includes health information with data items which reasonably could be expected to allow individual identification.

Health Information is any information, whether oral or recorded in any form or medium that:



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- Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

### III. Procedure:

Prior to any formal review of any research project the project should be reviewed, understood thoroughly and endorsed by the Clinic Sponsor and the appropriate Clinical Director (Corporate Medical or Dental Director), Operations Director or Director of Program Operations.

1. Clinic Sponsor will prepare a proposal, not to exceed 4 pages, that addresses the elements described in the Research Involvement Application Elements (Attachment B).
2. Upon receipt of a completed Application Elements from proposed researcher, the Clinic Sponsor will initiate an ad-hoc committee to provide initial review and approval of the research project. Note that the ad-hoc committee does not need to meet in person if review and feedback may be obtained by email or telephone. The ad-hoc committee will consist, at minimum, of the following members:
  - For *clinically related* research projects: The Corporate Medical Director, or Dental Director (depending on which department impacted), Director of Operations, Clinic Medical Director and Director of Planning & Development.
  - For *program specific* research projects: The Director of Program Operations, Program Director and Director of Planning & Development.
  - For *management* research projects: The Finance Director or Director of Operations (depending on which department impacted) and the Director of Planning & Development.
  - The ad-hoc committee will also include supervisors from other departments expected to be impacted by the proposed research including Finance, IS and Quality Assurance as warranted by the scope of the project.



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3. Following initial review and concurrence by the ad-hoc committee, the Clinic Sponsor will submit the project to the Research Review Subcommittee for review and possible recommendation for approval.
4. Decision makers at all levels will consider the following criteria in deciding whether to authorize YVFWC involvement in the proposed research project:
  - alignment of project with YVFWC mission and priorities
  - potential benefit to YVFWC patients/clients and system of care balanced against YVFWC resources required, and
  - additional information provided in written application
5. The Director of Planning & Development will notify the Principal Investigator and Clinic Sponsor of the Research Review Subcommittee's decision. Expectations for reporting and project tracking will also be included in the notification.
6. The YVFWC Planning & Development Department will track all approved research projects, receive the final reports and provide regular updates to the Executive Committee.
7. Upon receipt of the final report, the Clinic Sponsor will present research results to the YVFWC Executive Committee and other corporate oversight committees as appropriate. The purpose of reporting results is to ensure that research results may be incorporated into organizational planning processes.

### **IV. Student Research Practica:**

All of the following circumstances must exist in order for a research project to be considered Student Research Practica exempt from Executive Committee review and approval:

- The Student proposing the research is an employee of YVFWC in good standing, and is enrolled in a degree program related to the intended area of research,
- The project is not intended to result in generalizable knowledge, including professional publication or presentation at a professional or student research conference,
- The student signs a statement affirming that they will not publish or present the data or results of the research practica unless full review and approval is obtained by YVFWC's Executive Committee (see Attachment C),
- The project does not put subjects or their data at more than minimal risk, and



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- Data is recorded anonymously with no names, social security numbers or any other codes that can be linked to a list of names.

If the proposed Student Research Practica meets all of these circumstances, Steps 1-2 of this procedure, with final approval by the appropriate Program Director/Clinic Administrator, constitute sufficient review and approval. In these cases, the approving Program Director/Clinic Administrator will retain a file on the student project, including written application and written approval by the Program Director/Clinic Administrator, and will provide a copy of these documents to the YVFWC Planning & Development Director.

It should be noted that Student Research Practica DO need Research Review Subcommittee review and approval according to this procedure if such student research results in generalizable knowledge including professional publication, presentation at professional or student research conferences. Student Research Practica will also be subject to Research Review Subcommittee review and approval according to this procedure if the subjects or their data are put at more than minimal risk, or if the student in question is not a YVFWC employee.

### **V. Education and Training in the Protection of Human Subjects**

Members of the Research Review Subcommittee, Program Directors, Clinic Administrators, and investigators who are subject to Executive Committee review, will complete education and training in the protection of human research subjects.

### **VI. Investigator Responsibility**

Investigators who conduct research under this procedure have the following responsibilities. Failure to fulfill these responsibilities may result in suspension or termination of approval to conduct research with YVFWC.

1. Investigators acknowledge and accept their responsibilities for protecting the rights and welfare of human research subjects and for complying with all the provisions of this procedure.
2. No protected health information is to be removed from YVFWC by the researcher in the course of review (HIPAA).
3. Investigators will initiate study activities only after written study approval from the YVFWC Executive Committee (or Program Director/Clinic Administrator in the case of eligible Student Research Practica) has been received.



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4. Investigators will promptly report proposed changes in previously approved research activities to the YVFWC Executive Committee (or Program Director/Clinic Administrator in the case of eligible Student Research Practica). The proposed changes

will not be initiated without review and written approval from the appropriate approving authority.

### **ATTACHMENTS**

**Attachment A: Principles of Community-Based Research endorsed by the  
University of Washington Health Sciences Deans, 1996**

**Attachment B: YVFWC Research Application Elements**