INSTITUTIONAL REVIEW BOARD REVIEW OF RESEARCH INVOLVING OTHER VULNERABLE POPULATIONS

DESCRIPTION

Some populations who would otherwise be competent to give informed consent for research participation may be vulnerable to coercion or harm because of their circumstances. Examples include, but are not limited to, students or patients of the researcher, employees of the researcher or research site, individuals who are educationally or economically disadvantaged, and individuals who do not speak English or whose cultural background is very different from that in the United States of America. The University of Cincinnati (UC) Institutional Review Board (IRB) shall ensure that appropriate additional protections are provided so the rights and welfare of these populations are maintained.

CIRCUMSTANCES THAT MAY INCREASE POTENTIAL FOR COERCION

- Includes illiterate and limited educational status
- Includes visual impairment
- Includes low socioeconomic status, homelessness or lack of medical insurance
- Includes non-English speaking but literate in their own language
- Includes cross-cultural and international research
- Includes terminal illness

RELATIONSHIPS INVOLVING UNEQUAL SUPERIOR/SUBORDINATE POSITIONS

- Includes students
- Includes employees
- Includes patients
RESPONSIBILITY

The IRB Chair or designee shall determine whether or not individuals who are vulnerable to coercion or harm due to their circumstances or relationships will be recruited as participants in a research study and, if so, shall ensure that review processes described in Human Research Protection Program (HRPP) Policy V.01 Protecting Vulnerable Populations in Human Subject Research are followed.

Human Research Protection (HRP) staff shall ensure that required documentation is maintained in the IRB's study records and meeting minutes.

PROCESS

CONSIDERATIONS

1. Does the scientific or scholarly design of the study require inclusion of the vulnerable population? Can a different population be used?

2. What is the likelihood and magnitude of the potential coercion or harm?

3. Is it likely that a participant’s circumstances or relationships may change during the course of the research such that potential for coercion becomes more likely?

4. Will the vulnerable population receive direct benefit from participating in the research?

5. Are the population-specific risks reasonable in relation to the anticipated benefits?

6. Are protections adequate to avoid coercion during recruitment, consenting and participation of this vulnerable population?

7. Are participants able to give documented consent? Is it necessary for the IRB to waive documentation of consent to reduce potential for coercion or harm?

8. Are these vulnerable participants able to withdraw from the study without penalty, undue influence to remain in the study, or loss of benefits they would otherwise have?
REQUIREMENTS OF IRB REVIEW

Investigators may not recruit their own employees, students, or other subordinates as participants in research studies unless the IRB determines that the investigator has included sufficient safeguards in the protocol to protect subjects from being coerced to participate, whether the coercion is intended or not.

The IRB shall ensure that recruitment and research activities do not raise potential for coercion or harm to the participants. Protections include, but are not limited to, the following.

1. Educational or literacy or non-English language constraints
   a. Recruitment materials, consent documents, surveys, etc. must be presented in a way that will be understandable to the participants. The methods and explanations for selecting those methods must be described in the protocol. Translation of materials shall be done in accordance with HRPP Procedure 201 Writing an Informed Consent Document for Human Subject Research.

2. Cultural constraints
   a. The investigator may need to include someone familiar with the targeted cultural group as a member of the research team to ensure adequate understanding of cultural differences that may impact research participation.

3. Students as research subjects
   a. The student’s participation or lack of participation will not influence class standing, grades, or other benefits under the control of the researcher.
   b. Class time may be used for procedures related to the research study if the research is closely tied to the subject matter the student is studying.
   c. Student participation in “subject pools” is always on a voluntary basis.
   d. Students who do not wish to participate as research subjects may get equivalent credit with equivalent effort.
   e. Students may withdraw from a study at any time without penalty.
f. Someone other than the investigator obtains informed consent and collects data in those cases when the investigator is also the instructor. When it is not feasible to have someone other than the investigator, there must be a method of obtaining consent and collecting data that does not identify whether the student agreed to participate until after final grades have been assigned for the course.

4. Faculty use of class assignments to gather research data

   a. Permission must be obtained from the students in order to use the assignments for research purposes.

   b. The student’s agreement or refusal to participate may not affect the student's grade in any way.

   c. The syllabus or other course handouts should describe the procedures to be used to obtain permission and to assure students that the instructor will not know who has consented until after final grades have been determined.

   d. IRB approval of the research needs to be obtained prior to the collection of class assignments as research data.

5. Patients as research subjects

   a. If the researcher is also the primary care physician of the participant, the IRB may require that another physician advise the participant or provide primary care.

6. Employees or other subordinates as research subjects

   a. The recruitment method that the researcher has chosen protects individuals who choose not to participate from being compromised in any way.

   b. Recruitment is through advertisements or other announcements targeted to a larger audience than just the employees of the investigator.

REQUIREMENTS OF RESEARCH CONDUCTED AT CVAMC

When research involves the Cincinnati Veterans Administration Medical Center (CVAMC), additional protections or restrictions will apply as described in the VHA Handbook 1200.5.
Applicable Regulations and Documents:
21 CFR 50
45 CFR 46
Policy V.01 Protecting Vulnerable Populations in Human Subject Research Policy # II.01
Obtaining Informed Consent in Human Subjects Research
VHA Handbook 1200.5

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<td>C. Norman</td>
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<td>New Procedure to replace Policy V.02 (Students and Employees), add sections relating to other constraints that cause vulnerability, and include excerpted language from Procedure 308 other vulnerable participants, including revisions to wording and formatting for clarity and to be consistent with other Procedures.</td>
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Date __June 2014__     Signature __signature on file____________________________