CHAMPIONING A CULTURE OF INCLUSION: RESEARCH DESIGN AND PARTICIPATION

UVM Tangible Takeaways

RPN Workshop, 9/19/23

Diversity in the local News

Winooski outbreak prompts questions about outreach to immigrant residents

There are quite a few articles about this outbreak

UVM Larner College of Medicine, Office of Diversity, Equity and Inclusion

Gender Equity Education Series

Join the Gender Equity Listserv.

Translating Consents (see also p4)

UVM Medical Center Language Access Services (Interpreting and Translation)

OBTAINING AND DOCUMENTING INFORMED CONSENT OF NON-ENGLISH SPEAKING RESEARCH PARTICIPANTS By Melanie Locher, B.S., CIP, Director UVM IRB

UVM IRB Policies and Procedures

24. Subjects Vulnerable to Coercion or Undue Influence

Vulnerability to coercion or undue influence references limitations to a person's ability to provide informed consent to participate in research. These limitations could be due to a person's current circumstances (in the case of prisoners or the educationally or economically disadvantaged), or due to a temporary or permanent lack of capacity (in the case of the children and individuals with impaired decision-making capacity).

The Common Rule changed the categories of subjects that are classified as vulnerable to coercion or undue influence. In addition to replacing the "mentally disabled" with the more accurate and sensitive "individuals with impaired decision-making capacity," the "handicapped" and "pregnant women" have been removed from all lists of vulnerable categories of subjects. When making an assessment, the IRB will take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves the category of subjects who are vulnerable to coercion or undue influence, such as

- Children
- Prisoners
- Individuals with impaired decision-making capacity
- Economically or educationally disadvantaged individuals

Additional populations not specifically discussed within the regulations but for which additional unspecified safeguards could be required by the IRB, are listed below.

1. Students/employees;
2. Terminally ill patients;
3. Subjects with drug and/or alcohol addictions;
4. Subjects with other disabilities; or
5. Non-English speaking subjects.

The IRB reviews research involving vulnerable populations according to applicable requirements and guidelines and makes determinations using the IRB reviewer checklist. If the research includes a vulnerable population that does not have additional protections specified in the federal regulations, the board will evaluate the research proposal to ensure that precautions are taken to protect the participants.

Depending on the research, exclusion of any of the above populations might be construed as unfair and attempts should be made to include these populations, with appropriate protections, if they are applicable to the research question. If the protocol is records or specimen collection only and the vulnerable population cannot be identified or there is no risk to the vulnerable subject and they should not be listed as targeted subjects on your protocol.

24.4 Non-English Speaking Individuals Participating in Research

The Department of Health and Human Services (DHHS) regulations for the protection of human subjects require that informed consent information be presented in "language understandable to the subject," and, in most situations, that informed consent be documented in writing (45 CFR §46.116(b)(2) and §46.117(b) (1).

Steps must be taken to assure true informed consent is obtained when non-English speaking individuals are being approached for research participation. This does not simply mean that a form is signed, but rather that steps are taken to assure the study and voluntary nature of the research is understood by the subject. An interperter may need to be involved in the informed consent discussion and a translated consent document may be needed. Further, the IRB may require the investigator to submit a back-translation of the informed consent.

If the majority of subjects are expected to be non-English speaking, use of the translated Long Form Consent and Authorization Process is required.

If the protocol is already approved for English speaking subjects and a non-English speaking subject presents for participation, the Short Form Consent Process and Authorization Process may be used. Typically, this option is used when a single participant is found to be eligible to participate in research and there is no long form consent translation. A witness to the oral presentation is required.

For information regarding the consent process, see section 9.4 on Informed Consent and HIPAA Authorization Process for Non-English Speaking Individuals.

Ensuring the IRB is diverse

1.2 Committee Membership

Regular Members

Members will be of varying professional and personal backgrounds and must demonstrate a genuine interest in and commitment to the purpose of the Committees. Specific membership criteria will comply with all relevant federal and state regulations. Every effort will be made to fulfill principles which embrace cultural diversity. The Committee Members' duties are delineated in subsequent sections.

8.1.1 Elements Found in a Standard Protocol

Human Subject Protections:

Subject Selection: Provide rationale for subject selection in terms of the scientific objectives and proposed study design.

Include as appropriate:

Inclusion of Minorities and Women: Describe efforts to include minorities and women. If either minorities or women are excluded, include a justification for the exclusion.

For protocols including the use of an investigational drug, indicate whether women of childbearing potential have been included and, if not, include appropriate justification.

If HIV testing is included specifically for research purposes explain how the test results will be protected against unauthorized disclosure. Include if the subjects are to be informed of the test results. If yes, include the process and provision for counseling. If no, a rationale for not informing the subjects should be included.

Special Populations: Explain the rationale for involvement of special classes of subjects, if any. Discuss what procedures or practices will be used in the protocol to minimize their susceptibility to undue influences and unnecessary risk (physical, psychological, etc.). See section: Additional Protections for Special Populations

Inclusion of Children: Describe efforts to include children. Inclusion is required unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. If children are included, the description of the plan should include a rationale for selecting or excluding a specific age range of children. When included, the plan must also describe the expertise of the

investigative team in working with children, the appropriateness of the available facilities to accommodate children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study. If children are excluded then provide appropriate justification. Provide target accrual for this population. See section: Children

8.1.3 Plans for Recruitment/Screening/Retention

Recruitment materials should be placed in areas which allow for equitable recruitment of participants. You need to indicate where the material will be placed.

Advertisements and articles in the English language, and if appropriate, foreign language, newspapers (Public outreach documents should be translated into languages that are common in the area served by the facility where the investigation is being conducted and in the communities from which subjects will be drawn).

Summary materials that are accessible to non-English speaking or homeless populations who reside in the community from which research subjects are likely to be drawn.

9. Consent

Consent Requirements/Elements in the Form:

The information that is given to participants must be in a language understandable to them or their representative. Whether informed consent is written or oral, it must not include any exculpatory language through which the participant or representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, sponsor, institution or its agents from liability for negligence.

9.4 Informed Consent and HIPAA Authorization Process for Non-English Speaking Individuals

The Department of Health and Human Services (DHHS) regulations for the protection of human participants require that informed consent information be presented in "a language understandable to the participant" and in most situations, that informed consent be documented in writing (45 CFR §46.116 and §46.117).

For non-English speaking participants to participate in a research study, steps must be taken to assure true informed consent is obtained. This does not simply mean a form is signed, but rather steps are taken to assure study procedures and risks are understood by the participant. An interpreter may need to be involved in the informed consent discussion as well as a translated consent document. Further, the IRB may require the investigator to submit a back-translation of the informed consent.

Oral Translation with Short Form Consent and HIPAA Authorization process

The Short Form process should also be used when enrolling a non-English speaking participant who may not have a written language (ie. Mai-Mai) that can be translated into a short form consent. In this case, an interpreter will read the oral summary of consent procedures, risks, objectives to the participant but there will be no translated short form to sign. All parties taking part in the consent process will sign the English version consent form. It is imperative that the research team has good consent process documentation to ensure legally effective consent in this rare case.