

IRBNews

Office for the Protection of Human Research Subjects

December 2015

FOR VA STUDIES ONLY: Several IRB policy revisions were approved this month. A summary of those revisions follows on the next pages.

Review Policies 13 and 15 for all the information.

IMPORTANT MESSAGE:

The policy revisions are related to the enrollment of vulnerable populations in VA research. Please see the next few pages for the details.

If you have questions, please contact Janine Olive at olivef@etsu.edu



EAST TENNESSEE STATE
UNIVERSITY

IRB December 2015 Policy Revisions VA

A. Policy 13 (impacts VA studies only)

Change Rationale: This policy was updated to reflect recent VA handbook changes.

Change Specifics:

1. The section on who can serve as an LAR for VA studies (Section IV.G.) was updated to the following:

Authorized Person. The following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority in accordance with VA regulations at 38 CFR 17.32(e), (g)(3). **NOTE:** *Consent for research is required in addition to the consent that is obtained for the patient's non-research related treatments and procedures.*

(1) Health care agent (i.e., an individual named by the subject in a Durable Power of Attorney for Health Care);

(2) Legal guardian or special guardian;

(3) Next of kin: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or

(4) Close friend.

NOTE: *The persons authorized to consent on behalf of persons who lack decision-making capacity for participation in the research may not necessarily be the same as the persons authorized to provide permission for the use and disclosure of information on a HIPAA authorization on behalf of persons who lack decision-making capacity (see VHA Handbook 1605.1).*

B. Policy 15 (impacts VA studies only)

Change Rationale: This policy was updated to reflect recent VA handbook changes.

Change Specifics:

1. Updated VA criteria for research with children to the following:

VA studies may not involve children unless the research has been carefully reviewed by the IRB for its relevance to VA and has been determined to not be greater than minimal risk. The VA medical facility Director must approve participation in the proposed research that includes children.

2. Updated VA criteria for research with cognitively impaired to the following:

Individuals who lack decision-making capacity may be enrolled in VA research where:

(1) The IRB determines that the proposed research entails:

(a) No greater than minimal risk to the subject; or

(b) Presents a greater probability of direct benefit to the subject than harm to the subject; or

(c) Greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.

(2) In addition to satisfying the conditions above, the IRB determines that:

(a) The research cannot be performed solely with persons who possess decision-making capacity and the focus of the research is the disorder leading to the subjects' lack of decision-making capacity, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke); **or**

(b) The subject of the research is not directly related to the subjects' lack of decision-making capacity but the investigator has presented a compelling argument for including such subjects (e.g., transmission of methicillin-resistant staphylococcus aureus infections in a nursing home where both individuals with and without decision-making capacity are affected).

Determination of Capacity. When planning to enter subjects with impaired decision-making capacity, investigators must address in the protocol how they will determine when surrogate consent (i.e., a LAR) will be required. In general, the research staff must perform or obtain and document a clinical assessment of decision-making capacity for any subject suspected of lacking decision-making capacity. The IRB must review and approve the plan to ensure that it is appropriate given the population and setting of the research. **NOTE:** *Individuals ruled incompetent by a court of law are considered to lack decision-making capacity.*

Surrogate consent. When the potential subject is determined to lack decision-making capacity, investigators must obtain consent from the LAR of the subject (i.e., surrogate consent). **NOTE:** *Investigators and IRBs have a responsibility to consult with the Office of General Counsel (OGC) regarding state or local requirements for surrogate consent for research that may supersede VA requirements.*

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- (4) Close friend.

NOTE: *The persons authorized to consent on behalf of persons who lack decision-making capacity for participation in the research may not necessarily be the same as the persons authorized to provide permission for the use and disclosure of information on a HIPAA authorization on behalf of persons who lack decision-making capacity (see VHA Handbook 1605.1).*

Dissent or Assent. If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Although unable to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.

Responsibilities of LARs.

LARs are acting on behalf of the potential subjects, therefore:

- (1) LARs must be told that their obligation is to try to determine what the subjects would do if able to make an informed decision.
- (2) If the potential subjects' wishes cannot be determined, the LARs must be told they are responsible for determining what is in the subjects' best interest.

3. Updated VA criteria for research with pregnant women to the following:

In addition, for VA studies involving pregnant women, the following criteria must be met as well:

1. The research is relevant to the health of Veterans, or
 - is directly relevant to its role as a health care provider in a period of local or national emergency, or
 - supports the mission of another federal agency through an interagency agreement or similar mechanism.

2. The VA medical facility Director certifies that the medical facility has sufficient expertise in women's health to conduct the proposed research. If the research involves an intervention greater than minimal risk in pregnant women at the VA facility, the VA facility Director must certify that the facility is able to respond to obstetric emergencies.