OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

ORD Guidance on Conducting Research Involving Children

Date: October 20, 2014

SCOPE: VA is authorized to care for Veterans and to conduct research that supports the mission of VHA and that enhances the quality of health care delivery to Veterans. Therefore, research involving children should be reviewed carefully by the IRB for its relevance to VA and cannot be greater than minimal risk. Children are persons who have not attained the legal age to consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. Research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified.

This guidance is to assist IRBs, R&D Committees, and facility Directors in their review and approval of VA research that meets the definition of children's research.

1. Under what circumstances can research involving children be conducted in VA?
2. What information should be provided in a research proposal and/or review materials that involve children in research?
3. What should the VA IRB of record review and document for approving research involving children?
4. What should the R&D Committee review and document for approving research involving children?
5. What are the requirements for the facility Director memo of approval?

1. Under what circumstances can research involving children be conducted in VA?

- The research is relevant to the health of Veterans, or
  - is directly relevant to VA's role as a health care provider in a period of local or national emergency, or
  - supports the mission of another Federal agency (e.g., DoD or NIH) through an interagency agreement or similar mechanism.

- The research represents no greater than minimal risk as determined by the IRB if the research requires IRB approval.

- The research could not be done if children or their biological specimens/data were not entered in the research.

- The IRB reviewing the research has appropriate membership to represent children's interests and pediatric expertise.

- The IRB reviewing the research has specific SOPs regarding children in research.

- The research meets all requirements in 45 CFR 46, Subpart D, Additional Protections for Children Involved as Subjects in Research, Sections 46.401 through 46.404, and 46.408.

- The VA facility Director certifies that the facility is able to respond to pediatric emergencies if the research includes interactions with children at the VA facility.

2. What information should be provided in a research proposal and/or review materials that involve children in research?

- For studies involving the use of pre-existing children's biological specimens or data:
  - A description of the relevance of the study to the health of Veterans.
  - Documentation that the institution that collected the children's research biological specimens or data had an active FWA at the time the research was conducted.
  - Documentation that the research under which children's biological specimens or data were collected was approved by an Institutional Review Board under the requirements of 45 CFR 46 Subpart D.
  - Documentation that authority exists to reuse the children's biological specimens or data in VA approved research. Such documents may include the consent, waiver of consent, or protocol from the study under which the specimens were collected.
- For research involving interaction with living children as research subjects:
  - A description of the relevance of the study to the health of Veterans
  - Justification for enrolling children or their specimens/data into the study.
  - A copy of the study protocol, the informed consent form, the assent document (if applicable), and HIPAA authorization. The informed consent document signed by the parent or guardian is the vehicle for parent or guardian permission. Provisions for permission by parents or guardians should be documented in accordance with, and to the extent required by, 38 CFR 16.117.
  - Documentation of any additional safeguards that have been incorporated into the clinical or research site where children will be studied.
- Information on the funding source for the research.

3. What should the VA IRB of record review and document for approving research involving children?

- Review the risks of the study and determine that the study is no more than minimal risk.
- Review the research proposal and additional materials to determine that all criteria for IRB approval have been satisfied in accordance with VHA Handbook 1200.05.
- Review and approve consent documents in accordance with VHA Handbook 1200.05, or a waiver of consent or documentation of consent if these criteria are met.
- If the study involves use of pre-existing biological specimens or data, the research under which it was collected was reviewed by an IRB meeting all requirements under 45 CFR 46, Subpart D,

- If the study involves use of pre-existing biological specimens or data, review the consent or authorization under which these specimens or data were collected and determine whether there is the proper authority for reuse.

- The study meets all requirements in 45 CFR 46, Subpart D, Additional Protections for Children Involved as Subjects in Research, Sections 46.401 through 46.404, and 46.408.

- Document in the minutes the discussion regarding level of risk, the informed consent and assent forms, the investigators' qualifications to conduct research involving children, and any additional safeguards incorporated into the protocol.

4. What should the R&D Committee review and document for research involving children?

- The proposed research is relevant to the VA's mission and the care of Veterans.

- There is scientific merit to the research proposed.

- There are adequate protections for participating human subjects (including privacy and confidentiality), and adequate safety measures for research subjects and personnel engaged in the research.

- The required resources are available and the locations are appropriate where the research will be conducted.

- The research investigator and research team are qualified to conduct the study.

- All appropriate subcommittee approvals have been obtained.

5. What are the requirements for the facility Director memo of approval?

- CRADO approval is not required for a VA investigator to conduct VA research involving children. However, the facility Director should approve the conduct of such research before it is initiated.

- The facility Director should review the minutes of the VA IRB and R&D Committee meeting at which the protocol was approved to ensure that all criteria in item #1 of this guidance were satisfied.

- If the study includes an interaction with children at the VA facility, the VA facility Director should certify that the facility is able to respond to pediatric emergencies.

- If the sponsor of the research is not VA, the facility Director makes certain that the sponsor of the research has procured appropriate liability insurance.

- The memo documents for the record that the facility Director is aware of and approves the request for his/her facility to participate in the proposed research that includes children. The memo should be kept with the R&D file in the Research Office and a copy should be in the investigator's files.

REGULATORY AND VHA POLICY REFERENCES:

38 CFR 16, Protections of Human Research Subjects

45 CFR 46.401 through 46.404 and 46.408, Additional Protections for Children Involved as Subjects in Research (Subpart D).

VHA Handbook 1200.01, Research and Development (R&D) Committee.

VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research.