



VHA Handbook 1200.05 (November 12, 2014): Requirements for the Protection of Human Subjects in Research

Key Facts Regarding CRADO and VA Facility Director Approvals for Selected VA Research Activities

| <u>Pregnant Women</u> | <u>Human Fetuses</u> | <u>Neonates</u> | <u>Children</u> | <u>Prisoners</u> | <u>International Research</u> |
|--|---|--|---|--|--|
| Institutional Review Board (IRB) of Record is required to review VA research involving women who are pregnant and/or their fetuses according to 45 (CFR) §46.204 . | Research in which the focus is either a fetus, or human fetal tissue, in-utero or ex-utero (or uses human fetal tissue) cannot be conducted as VA research. | Interventional research involving neonates cannot be conducted as VA research. | Research involving children cannot be greater than minimal risk. | Only Chief Research and Development Officer (CRADO) waiver that exists in the revision of VHA Handbook 1200.05 applies to VA research involving prisoners. | International research is research involving conduct at international sites or VA research using identifiable or de-identifiable specimens or data originating from or sending to international sites. |
| ORD requirements for VA research involving pregnant women do not apply to VA research involving women of child-bearing potential. | Embryonic stem cells can be used in VA research as governed by the National Institutes of Health's (NIH's) policies. | Prospective observational and retrospective records review studies involving neonates or neonatal outcomes are permitted to be conducted as VA research. | Research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified. | IRB review of approval of specific requirements in 45 CFR Sections 46.301-46.306 is required prior to CRADO approval. | International research does not include studies when VA is one of multiple participating sites, and the Principal Investigator of the overall study is not the VA Investigator. |
| The VA Facility Director must certify that the medical facility has sufficient expertise in women's health to conduct the proposed activity. | The VA Facility Director must certify that the medical facility has sufficient expertise in women's health to conduct the proposed activity. | The VA Facility Director must approve participation of children in the proposed VA research activity. | The VA Facility Director must approve participation of children in the proposed VA research activity. | Research involving prisoners cannot be conducted as VA research unless the CRADO has granted a waiver. | The VA Facility Director must approve the proposed VA international research activity unless it is a VHA Cooperative Studies Program (CSP) study. |

Note: This worksheet is not an all-inclusive list and does not replace Office of Research and Development policy requirements in [VHA Handbook 1200.05](#) (November 12, 2014).