

**U.S. Department of Veterans Affairs, Veterans Health Administration, Addendum to the
U.S. Department of Health and Human Services Federalwide Assurance for the
Protection for Human Subjects**

Facility Name: _____
assures that all of its activities related to human subjects research will comply with all requirements of the U.S. Department of Veterans Affairs' (VA) regulations at Title 38 Code of Federal Regulations Part 16 (38 CFR 16), **and** all other applicable VA policies and procedures, including policies and procedures of the Office of Research Oversight (ORO) and the Office of Research & Development (ORD), issued in Handbooks and other relevant authorized Directives.

Use of an Institutional Review Board (IRB) operated by another institution requires a Memorandum of Understanding (MOU) between the institutions. VA Signatory/Institutional Official certifies on this Addendum that any MOU executed for the purpose of using an IRB operated by another institution will contain a commitment from that institution to provide complete access to all IRB records and related documents to the VA medical facility and to ORO. This commitment applies to VA-affiliated medical and dental schools or any other IRBs approved for use by VA.

The Signatory Official must be familiar with the requirements set forth in the Federal Policy for the Protection of Human Subjects (Common Rule) and the ethical principles governing human subjects research as outlined in the Belmont Report (accessible at <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>). A summary of these requirements and principles is available on the Department of Health and Human Services Office for Human Research Protections (HHS-OHRP) website at <https://www.hhs.gov/ohrp/education-and-outreach/human-research-protection-program-fundamentals/index.html/assurance-training>.

Human Protections Administrator (HPA listed on the Federalwide Assurance):

First Name: _____ Middle Initial: _____ Last Name: _____
Degree or Suffix (e.g., MD, PhD): _____ Institutional Title: _____

Official Legally Authorized to Represent the Institution (VA Medical Facility Director):

Signature _____ Date: _____
First Name: _____ Middle Initial: _____ Last Name: _____
Degree or Suffix (e.g., MD, PhD): _____ Institutional Title: _____

Department of Veterans Affairs Approval

This revision to the Federalwide Assurance of Protection for Human Subjects and VA addendum is hereby approved.

VA Approving Official Signature _____ Date: _____
_____, _____, Office of Research Oversight (10RO)

Any Additional Comments: