



Description of Technical Amendment (June 29, 2017) to VHA Handbook 1200.05: Requirements for the Protection of Human Subjects in Research

<p>Description of Amendment: Modifies the requirement in Paragraph 5(e) of VHA Handbook 1200.05 describing the two types of non-VA entities that a VA Facility's internal IRB can serve as an IRB of Record by adding the Department of Energy laboratory. This modification is needed to address issues with multi-site human research studies involving VA and the Department of Energy. Further expansion of non-VA entities that can rely upon a VA Facility's internal IRB will be proposed as part of the revision of VHA Handbook 1200.05.</p>	
<p>Non-Amended VHA Handbook 1200.05</p>	<p>Amended (June 29, 2017) VHA Handbook 1200.05</p>
<p><u>Paragraph 5. ASSURING COMPLIANCE WITH THIS POLICY:</u></p> <p>e. A VA facility's own internal IRB cannot serve as an IRB of Record for any non-VA entity except a DoD facility or a VA NPC.</p>	<p><u>Paragraph 5. ASSURING COMPLIANCE WITH THIS POLICY:</u></p> <p>e. A VA facility's own internal IRB cannot serve as an IRB of Record for any non-VA entity except a DoD facility, Department of Energy laboratory, or a VA NPC.</p>

This is the second technical amendment to VHA Handbook 1200.05 since it was issued on November 12, 2014. The amended VHA Handbook 1200.05 can be found at http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3052 and on the VHA Publications Websites:

<http://vaww.va.gov/vhapublications/>

<http://www.va.gov/vhapublications/>

Please send any questions regarding this technical amendment to the ORD Regulatory Mailbox at VHACOORDRegulatory@va.gov.