

Approved by IRB Executive Committee: May 21, 2008
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AAHRPP Element I.3.D. and I.3.E.

Research activities that meet all applicable criteria set forth by the federal regulations (45 CFR 46.101 (b)) and involve no greater than “minimal risk” may qualify for exemption from IRB review. An exemption must be determined by the IRB, not an individual investigator. The exemption categories are posted on the IRB web site. The IRB may rule a proposal is exempt if it fits into one of the exemption categories and is no greater than minimal risk. However, the IRB may determine that there are studies that may pose ethical concerns and are reviewed as with any other new study application.

The IRB administrator or IRB coordinator conducts a preliminary review. The IRB Chair, IRB Director, or IRB Vice-Chair makes the final determination for all claims for exemption. Such claims of exemption are recorded and stored in the ERICA online system.

1. Exempt Research Activities

- 1.1. The investigator submits a new study application in ERICA.
- 1.2. The IRB administrator or IRB coordinator conducts an administrative review of the research proposal using the IRB internal checklist (Determining if Human Research is Exempt from IRB review) within the ERICA online system. When one or more of the exemption categories are applicable to the research, the IRB administrator or IRB coordinator documents the applicable category(ies) using the internal checklist.
- 1.3. Once the administrative review is complete and an exemption determination appears applicable, the research proposal is sent to the IRB Chair, IRB Director, or IRB Vice-Chair for review and final determination.
- 1.4. The IRB Chair, IRB Director, or IRB Vice-Chair conducts a review of all materials submitted by the investigator. The IRB Chair, IRB Director, or IRB Vice-Chair uses a reviewer checklist (Exemption Checklist) to make the final exemption determination within the ERICA online system. The reviewer documents the applicable exemption category(ies) in the reviewer.
- 1.5. Research that involves the VASLCHCS receives the same administrative review as noted above and is forwarded to the IRB Chair or an IRB Vice-Chair for review and final determination. VA research determined exempt from IRB review must be reviewed by the R&D Committee prior to initiation and must be included in annual R&D Committee Review of research projects.
- 1.6. All exemption determinations are communicated to the investigator via the ERICA online system, and includes the applicable category(ies) justifying the exemption determination.

