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**MODIFIED AUDIT REQUIREMENTS FOR HUMAN SUBJECTS RESEARCH INITIALLY APPROVED
PRIOR TO JANUARY 1, 2008**

Original Posting Date: November 15, 2012

1. ORO is maintaining the exception from regulatory audit requirements for most VA research initiated prior to January 1, 2008.

ORO has decided to maintain the “grandfather” exception from required regulatory audits for most (but not all) VA research initially approved prior to January 1, 2008 (see #2 below).

Note that animal research is considered re-initiated at each triennial review for auditing purposes, and therefore effectively has no “grandfather” exception. All VA animal research should be audited at least once within 3 years of each triennial review. This requirement remains unchanged.

2. ORO is requiring regulatory audits of all studies involving intervention/interaction with human subjects that remain open to enrollment as of May 31, 2014.

ORO has decided to require regulatory audits (i.e., eliminate the “grandfather” exception) for the following limited group of studies:

Regulatory audits will now be required for studies involving interaction or intervention with human subjects that were initially approved prior to January 1, 2008, and remain open to enrollment as of May 31, 2014. An initial regulatory audit for any such studies must be performed in time to be reported on the 2014 Facility Director’s Certification.

3. Three year look-back for auditing and reporting

When performing the initial regulatory audit, ORO only requires that committee actions and issues of concern be reviewed for the 3 year period immediately preceding the date of audit (“3 year look-back”). Auditors may use their own discretion to review materials over the entire history of the study, but compliance issues and other concerns that occurred more than 3 years prior to the date of audit are not required to be reported to ORO.

Subsequent regulatory audits for these studies must be performed as described in ORO’s guidance for all other regulatory audits.

**Facilities with questions or concerns are encouraged to contact ORO directly at
ORORCEP@VA.GOV**