OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION

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Guidance on Informed Consent Form Modifications Addressing VA Record Retention Requirements

Recently a message went out to the field stating that until a schedule for local research records is published, ALL records including identifiers must be retained. Consent forms and HIPAA authorization forms should not include a timeframe for destruction. If there is language in the informed consent form or HIPAA authorization form about destruction of identifiers or research records, it must only say “in accordance with the record control schedule.” ORO is working with the Privacy Office and ORD to get this situation resolved as soon as possible.

All research consent forms for active protocols should be modified to include language indicating that destruction will be in accordance with the VA record retention schedule. ORO and ORD have determined that this modification of the informed consent form represents a minor change in previously approved research and can be submitted for IRB approval under expedited review procedures (38 CFR 16.110(b)(2)). If the IRB does not use expedited review procedures, review and approval of the modification of the informed consent form must be done by the convened IRB. ORO and ORD do not recommend further actions by the IRB beyond approving a new version of the informed consent form to be used to consent new subjects enrolled into the protocol.