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## HUMAN RESEARCH NEWS V10, N2: APPLICATION OF EXPIRATION DATE TO HUMAN SUBJECTS RESEARCH EXEMPT CERTIFICATIONS

**Date: 2010-01-07**

January 7, 2010

OHRPP policy has been changed to apply expiration dates to exempt certifications so that continuing review can be conducted to establish that protocols are still active and maintain exempt status.

Therefore, **effective January 1, 2010**, all human subjects research protocols that are certified by the UCLA OHRPP to be **exempt from IRB review will have a limited 5 year certification period**.

Researchers are required to request continuing review and certification of exemption for projects that continue after 5 years.

Protocols that were **certified exempt prior to January 1, 2010** were not marked with an expiration date but are now considered valid for **5 years from the original certification date**.

Please contact Alison Orkin at [aorkin@research.ucla.edu](mailto:aorkin@research.ucla.edu) or (310) 206-3969 with any questions.

### FREQUENTLY ASKED QUESTIONS

- **Will I receive written notice of the pending expiration of my research protocol?**

Individual email notices will be issued to all applications which were certified exempt on January 1, 2005 or later. No written notice will be issued to applications which were originally certified exempt on or prior to December 31, 2004.

- **How do I request continuing review and certification of exemption?**

Continuing review and certification of exemption may be obtained by resubmission of the appropriate exempt application form, updated to reflect all completed research activities and to indicate what remains to be completed. The HS-7 form is no longer accepted. The new exempt application forms are available on the "Forms" page of the OHRPP website: <http://ohrpp.research.ucla.edu/pages/forms-main>

- **At what point is continuing review and certification of exemption no longer required?**

Continuing review and certification is NOT required if ALL of the following apply:

- Participant recruitment/enrollment is complete
- Research-related interventions and/or follow-up are complete
- Data and/or biological specimens no longer contain any personally identifiable information

- **Do I need to submit anything if my research is complete?**

For projects that were originally certified exempt on or before December 31, 2004, which will not receive individual written notification of expiration, no further action is required if your research is complete. We recommend that you print a copy of this notice and add it to your research records as documentation.

For projects that were originally certified exempt on or after January 1, 2005, which will receive individual written notice of expiration, investigators may choose to complete and submit the Final Study Close-out Report Form (HS-8), available at: <http://ohrpp.research.ucla.edu/pages/forms-main>. Completion and submission of the HS-8 form is NOT required in order to close exempt studies.

The OHRPP will consider studies closed if no request for continuing review is received 90 days after the date of expiration, and will archive the related records at that time.

- **What if my project was originally certified prior to December 31, 2004, and the research is continuing?**

There will be a 90 day grace period after the date of this notice to allow time for submission and review of continuing review requests for expired submissions, and those that will expire in the first three months of 2010.

- **My project was originally certified prior to December 31, 2004, but amendment applications have been certified subsequent to January 1, 2005. How does the new policy apply to me?**

The original certification date is the one that is used to determine a project's expiration date.

Projects originally certified prior to December 31, 2004, but amended subsequent to January 1, 2005 are considered to have expired December 31, 2009, and will NOT receive individual written notification of expiration.