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Human Research News v9, n1: OPRS Human Research Protection Program Improvement Plan Rollout Update

Date: 2009-03-27

OPRS Human Research Protection Program Improvement Plan Rollout Update

Several of the HRPP Improvement Plan Rollouts as described in the March 16th Memo from Dr. Peccei and posted on the What's New section of the Human Research website have been implemented and are described below:

ELIMINATION OF REQUIREMENT for Administrative IRB Review: The requirement for administrative IRB review of projects that lack definite plans to involve human subjects (45 CFR 46.118) has been removed. **Effective today**, investigators no longer need to obtain Administrative IRB review and approval for: (a) center grants, (b) program project grants, (c) training grants, or (d) projects whose definite plans to involve human subjects will depend upon completion of instruments, prior animal studies, or purification of compounds. As soon as there is a definite plan, of course, IRB approval will be needed for any and all of the individual projects.

The OPRS is in the process of issuing written notification to all investigators whose projects previously received administrative approval under 45 CFR 46.118 that this administrative approval is no longer required and that the approval is now closed. If you have any questions about the grants and contracts aspect of this change in procedure, please contact Associate Vice Chancellor for Research, Marcia L. Smith, at (310) 206-8459 or marcia.smith@research.ucla.edu.

REVISED Post Approval Reporting ? Adverse Events, Violations and Incidents, Updated Safety Information: Revised guidance, decision trees and forms for post approval reporting requirements to the IRB have been posted on the OPRS website. The revisions to adverse event reporting are slight refinements though the forms have been expanded. However, there is now considerably more guidance on reporting violations, deviations and incidents so that it should now be clearer to investigators not only ***what and when to report***, but also ***what not to report***. This guidance will be relevant not only for biomedical researchers but also for social behavioral, education, and health services researchers as it includes information about reporting breaches of confidentiality, subject complaints, and intentional and accidental deviations from the approved protocol.

There is also more specific guidance and a form for reporting updated study safety information. A Summary Sheet for PIs: What, When and How to Report to the IRB has been created for easy reference.

NEW FORM AND DECISION TREE for Non Human Subjects Determinations for Research Involving Coded Private Information and/or Biological Specimens: A form for PI Self-Certification Form for Determining Whether Human Subjects are Involved in Research When Using or Obtaining Coded Private Information and/or Biological Specimens and the accompanying Decision Tree are now posted. Researchers should use this form when their research involves access ***only to coded private information and/or biological specimens***. Researchers may complete this form, retain a copy in their records and/or provide a copy to funding agencies; the completed form should ***not*** be submitted to the OPRS. The decision tree will assist the researcher in determining whether this form is sufficient or whether exempt certification or expedited IRB review is required.

REVISED Exempt Certification Forms: The application for certification of exemption from IRB review has been replaced with two new applications. The forms have been designed to request the information specific to the categories of research that qualify for certification of exemption and thereby to facilitate the process for the researchers. As of today, these forms replace the former HS-7 application for certification of exemption.

EXPANDED IRB Assistance and Contact Information: The OPRS Human Research office has expanded its on-campus program of providing consulting services to UCLA investigators and research staff preparing IRB submissions (new, continuing and amendments) or preparing responses to committee correspondence. Information about Campus Consults and expanded HRPP contact information is now available on the OPRS website.

REVISED Social and Behavioral Consent Templates: The informed consent templates for social behavioral, education, and health services have been reformatted to present information to participants in a more accessible question and answer style for the research participants.

NEXT: Within the next two weeks, the remainder of the new and revised applications forms and the CITI online human research training program will be available as will additional translations of the Research Participants Bill of Rights and surveys for researchers and research participants to provide feedback to the OPRS Human Research Protection Program.

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