

MEMO

To: Applicants for IRB Approval or Exemption for Research Projects

From: J. Walton Senterfitt, Chair and Administrator
Olga Coronado, Deputy Administrator and Office Manager

Subject: Application Packet and Procedures

Attached or enclosed are the forms you need to submit an application for review of research projects involving human subjects under the jurisdiction of the Los Angeles County Department of Public Health Institutional Review Board (IRB). Our jurisdiction includes any research that involves in any way staff members, facilities and/or patients or clients of DPH and any of its programs. By memorandum of agreement, we also serve as the IRB for projects involving the headquarters staff of the Department of Health Services and programs under that staff's direct control.

The "Checklist" document in the packet lists all the components required for a complete application, either by inclusion or by notation that a particular form is not applicable to the proposed project. Note that applications for "Exemption as Non-Research" require fewer forms, only those starred on the checklist. Please submit a cover letter with any type of application, briefly summarizing the purpose of the application and explaining any aspects of it that you think may be unusual or unclear.

A budget must be submitted with the application, including any time of DPH personnel being considered as in-kind contributions to the study. No specific budget form is provided as the level of detail that is appropriate will vary by project and funding source.

Note that several of the forms have been recently revised. Please make sure that you use the latest versions. Also, the checklist now contains a line indicating that you must submit a certificate of completion for an acceptable IRB or human subjects protection training (online is fine), unless we already have one on file.

One section of the packet pertains to the HIPAA Privacy Rule. With few exceptions, any application that will store and transmit any data electronically will need to submit either an Individual HIPAA Authorization Form for Release of Protected Health Information (to be signed by research subjects) or a Request for Waiver or Alteration of Individual Authorization. The forms in this section give detailed instructions and templates for each option.

Many questions frequently arise in the preparation of IRB applications and we encourage you to contact us by telephone or e-mail. We are happy to provide guidance in advance and assist in any way that we can. Please call 213-250-8675 or write ocoronado@ph.lacounty.gov or jsenterfitt@ph.lacounty.gov.

Thank you!

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