

BIOMEDICAL CHECK-OFF LIST FOR NEW & RENEWAL SUBMISSIONS

This check-off list is to assist you in submitting a complete application to the IRB. Please note that an incomplete submission may delay the processing of your application.

Please submit **two complete sets (original and one copy)** of the following required and applicable materials:

REQUIRED:

- ___ application form (Form HS-1, page 1 and answers to all applicable sections)
- ___ informed consent form(s)
- ___ detailed research protocol
- ___ Copy Center Request form (recharge ID number and dated signature only)
(available at <http://www.maildoc.ucla.edu/forms/docform.pdf>)
- ___ this check-off list with indication of the submitted materials

IF APPLICABLE:

- ___ Form HS-1, Section VIII completed by those individuals with a financial interest in the research (if the answer to HS-1 form, Section II, Question 3 is "Yes")
- ___ Form HS-1, Section V and **three copies** of the Investigational Drug Brochure, if an investigational drug is involved
- ___ Investigational Device Exemption (IDE), if an investigational medical device is involved
- ___ **Three copies** of the Grant Application, if seeking support from an extramural funding agency
- ___ surveys, questionnaires, etc., if used
- ___ contact letters, flyers, advertisements, etc., if used to recruit subjects
- ___ letter of compliance, if any non-UCLA facility or agency is utilized as a study site or source of subjects for the proposed investigation. Such letters must be on the facility's letterhead and contain the statement that the agency will "review, abide by and comply with the procedures approved by the UCLA IRB."
- ___ approval notice of the Jonsson Comprehensive Cancer Center-Internal Scientific Peer Review Committee, if cancer patients are involved (see #4 of the Guidelines)
- ___ approval notice of the Medical Radiation Safety Committee, if research involves radiation (see #5 of the Guidelines)
- ___ Form HS-1(a) (HIPAA Application) if the research involves the review of medical records or biological materials with attached medical information, or results in the addition of new information to a medical record
- ___ HS-1 Sub-Application for Requesting Proxy/Surrogate Consent (if the research relates to a subject's incapacity or cognitive impairment and consent will be sought from a Legally Authorized Representative)
- ___ Form HS-1 Navy Supplement for research supported by or in collaboration with the Department of the Navy. For more information, see <http://www.oprs.ucla.edu/human/navy>.