

## **UCLA Sponsor-Investigator ClinicalTrials.gov Guidance**

The International Committee of Medical Journal Editors (ICMJE) and the World Health Organization (WHO) define a **clinical trial** as "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

[“Applicable Clinical Trials”](#) (ACTs) are the subset of clinical trials that fall under Section 801 of the Food and Drug Administration Amendments Act ([FDAAA 801](#)), where registration within 21 days after the first subject enrolls and reporting results within 12 months of completion are requirements specified in the law.

By applying the ICMJE/WHO definition and registering a clinical trial *prior to enrollment of the first participant*, the trial will be eligible for publication in ICMJE member journals and journals that follow [ICMJE requirements](#). (For more information, see *N Engl J Med* 2004;351:1250-1.)

### **Study Initiation Checklist:**

- Determine whether registration is required by FDAAA801 (ACT) and/or ICMJE (intent to publish in ICMJE journal).<sup>5</sup>
- For ACTs, include IRB-required language in consent form.<sup>1</sup>
- Obtain PRS user account.<sup>2,3</sup>
- Register trial with ClinicalTrials.gov prior to enrollment (recommended) or within 21 days of first enrollment (required by law for ACTs).
- Keep record up-to-date as required by ClinicalTrials.gov and outlined below.<sup>4</sup>

### **Study Closeout Checklist:**

- Submit results for primary endpoint within 1 year of Primary Completion Date.<sup>5,6</sup>
- Submit results for other endpoints as the data are analyzed, within 1 year of collection.

### **PI Transfer Checklist:**

#### ***If the PI is not taking the study to a new institution:***

- Identify new UCLA PI for trial.
- Transfer study to the PRS user account of the new UCLA PI.
- If the study is not continuing, see study closeout checklist above.

#### ***If the PI is taking the study to their new institution:***

- Notify the IRB and grants offices.
- Contact PRS Administrator<sup>2,3</sup> and request assistance in transferring the trial from the UCLA PRS account to the new Institution’s PRS account.

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1. The [UCLA IRB consent form](#) for a study that meets the [NIH/FDA Definition](#) of an “Applicable Clinical Trial” must include the statement below regarding ClinicalTrials.gov in the section “WHO CAN I CALL IF I HAVE QUESTIONS ABOUT THIS STUDY”: [Note: This statement may not be altered, per federal regulation]

### **Public Information about this Study:**

*ClinicalTrials.gov* is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

2. Investigator-initiated trials should be registered by the PI or the PI in collaboration with the PI’s study team. The PI is the Responsible Party for initial registration and for keeping the record updated. To register a cancer related study, please contact the Jonsson Comprehensive Cancer Center (JCCC) PRS Administrator, Mark Glover ([mglover@mednet.ucla.edu](mailto:mglover@mednet.ucla.edu)).
3. **To obtain a User Account for the ClinicalTrials.gov Protocol Registration System (PRS):** contact the UCLA PRS Administrator, Elaine Cooperstein ([ecooperstein@mednet.ucla.edu](mailto:ecooperstein@mednet.ucla.edu)). You will receive an e-mail confirmation within two business days when the user account has been created.
4. A process for maintaining the study record in ClinicalTrials.gov is imperative:
  - Records must be updated within 30 days following a change to Recruitment Status or Completion Date.
  - Records must be updated within 12 months following an amendment that affects the study record (i.e. inclusion/exclusion criteria, study contact(s), outcome measures, adding/removing/revising study arms, changes in interventions/dosage).
  - The Verification Date in the record must be modified every 12 months, even if there are no changes to the record.
  - The results of an Applicable Clinical Trial must be submitted no later than 12 months after the date of final interaction/data collection for the Primary Outcome Measure (Primary Completion Date).
5. The CTSI Office of Regulatory Affairs (ORA) can assist with:
  - Determining whether a clinical trial is an ACT required to comply with FDAAA801.
  - Writing outcome measures during the protocol development and registration process.
  - Results reporting format and review criteria; addressing Reviewer Comments.
  - For CTSI-ORA assistance, email: [ecooperstein@mednet.ucla.edu](mailto:ecooperstein@mednet.ucla.edu).
6. For assistance with the statistical design of your trial or with the preparation of results for reporting to ClinicalTrials.gov, please contact the CTSI, <http://ctsi.ucla.edu/researcher-resources/pages/consult>. Oncology trials can contact the JCCC Biostatistics, Analytical Support and Evaluation (BASE) Unit for statistical assistance, [baseunit@mednet.ucla.edu](mailto:baseunit@mednet.ucla.edu).