Human Research News: Updated Guidance Documents

Date: 2010-07-22

The Policies and Guidance section of the OHRPP website has been reorganized.

The policies and guidance documents are now organized by topic (see example below). Previously, some topics were identified by numbers from 1 - 73 and others were listed in a separate section at the bottom of the page.

UCLA OHRPP Guidance, Policies and Procedures

- Authority and Overview of the Human Research Protection Program
- HRPP Education and Investigator Responsibilities
- Activities that Require IRB Review
- Applying to the IRB
- Recruitment, Screening and Informed Consent
- Protection of Privacy, Confidentiality and Data
- Research Involving Use and Storage of Data and/or Human Biological Specimens
- Types of Research and Procedures
- Populations
- Payments and Financial Considerations
- Post IRB Approval Activity and PI Reporting Requirements
- IRB Activities, Procedures and Responsibilities
- Quality Improvement Activities

Within each numbered section are various related documents with version date.

- Recruitment, Screening and Informed Consent
  - Recruitment Methods and Tools (v. 07-05-07)
  - Subject Pools and Recruitment Databases (v. 03-06-09)
  - Informed Consent Process and Documentation (v. 02-26-09)
  - The Use of Legally Authorized Representatives or Surrogate Consent (v. 06-21-10)

The following guidelines are the most recently updated policies and guidance:

- Persons with Cognitive Impairments
- Gene Transfer Therapy/Recombinant DNA Studies
- The Use of Legally Authorized Representatives or Surrogate Consent
- Planned Emergency Research
- Noncompliance and Allegations of Noncompliance
- IRB Member Conflict of Interest

You will notice that the look and approach of the guidance documents have been updated as well.

The following guidelines are in the process of revision.

You will be notified with the next batch of revisions. All guidelines are being evaluated and most will be updated and revised within the year.

- Recruitment Methods and Tools
- Collaborative Research and Research in Multiple Settings
- Investigational New Drugs and Biologics
- Investigational Devices

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