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UPDATED AND NEW OHRPP GUIDANCE

Date: 2011-07-07

In an effort to continuously improve the UCLA Human Research Protection Program, several new guidance documents have been created and many of the existing ones have been updated. Although the OHRPP web page for OHRPP Policies and Guidance indicates the date of the most recent version of the guidance, the ones that are **NEW** or significantly **UPDATED** have been highlighted.

New Guidance

Examples of new guidance that may be particularly useful for some investigators are:

- [Determining When Use of Data and Specimens Requires IRB Review](#)
- [Conducting Risk-Benefit Assessments and Determining Appropriate Level of IRB Review](#)
- [Tip Sheet: Protected Health Information and Personal Identifying Information](#)
- [Media Interviews](#)
- [ClinicalTrials.gov Registry](#)
- [Use of Drugs and Biologics in Clinical Research and Treatment](#)
- [Summary Sheet of Post-Approval Reporting Requirements for Investigators](#)

Updated Guidance

Examples of updated guidance include:

- [Determining which Activities Require UCLA OHRPP/IRB Review](#)
- [Research Involving Multiple Performance Sites or Collaborations](#)
- [Post-Approval Reporting Requirements for Investigators: Reporting of Unanticipated Problems, Including Adverse Events as well as Protocol Violations, Deviations and Incidents and the Reporting of Updated Study Safety Information](#)
- [Consent monitoring](#)

Stay Tuned

Additional guidance is being updated including the guidance for **Obtaining and Documenting Informed Consent, Waiving Consent, Recruitment and Screening, Non-English Speaking Participants**, and **Investigator Conflicts of Interest**, as well as others. Examples of new guidance being prepared are **Use of Devices in Clinical Research and Treatment and Working with UCLA Accounting to Pay Research Participants**. We will alert you when these have been updated which should be sometime within the month of July.

Suggestions

If there is other guidance you would like to see written or updated, please let the OHRPP know either by talking to someone directly or through the [Program Feedback](#) section of the website.