De Novo Review FAQ's

Q: I am submitting a continuing review report. My study has been approved for 6 years. This will be my 7th year. Do I need to do a De Novo submission?
   A: Yes! Effective February 1, 2010, at your 7th year continuing review, you will complete your e-CPA as usual; however, you will also need to update ALL study documents to current IRB template standards, such as:
   - Protocol Narrative
   - Consent / Assent / Information Sheet
   - Recruitment Materials
   - Data Extraction/ Collection Sheets
   - Stimuli Materials
   - All Applicable Appendices

Q: Do researchers need to submit Appendices that may not have been available when the study was originally submitted?
   A: Yes. To help researchers with this, we will post all current appendices on the ORA website.

Q: Do researchers need to re-request Waivers via the Appendices?
   A: Yes. We want to make sure all study information is up to date on the current forms. Researchers will need to re-complete the appendices if already done.

Q: Does the Study Information Sheet need to be updated too?
   A: Yes, all consent documents will need to be re-submitted on the current IRB templates.

Q: Does this apply to Social – Behavioral researchers?
   A: Yes.

Q: Does this apply to expedited studies (studies that involve minimal risk)?
   A: Yes.

Q: Does this apply to studies that are CLOSED TO ENROLLMENT?
   A: No. Studies that are closed to enrollment DO NOT have to go through the 7th yr De Novo Review process.
Q: Why do researchers need to do this?
   A: The IRB understands that there will be extra steps involved in the 7 yr. De Novo Review, but our goal is to make sure that all documentation is current. This is to help the IRB ensure that researchers are meeting current regulatory and UCI policy standards.

Q: I still have questions. Who can I talk to?
   A: IRB Staff are here for you to help with any questions and address any concerns related to the 7th Year De Novo Review process. You can contact the Office of Research Administration at 949-824-0018 – ask to speak to a member of the IRB Staff.