

Human Subjects Protection Program Improvements

Spring 2011

The Office for the Protection of Research Subjects (OPRS) and the USC IRBs are constantly monitoring user feedback/requests in order to improve the USC Human Subjects Protection Program (HSPP). The following CQI efforts were implemented in response to mistakes frequently identified in not-for-cause audits, suggestions made in response to the annual IRB survey, and through concerns/questions related during human subjects education sessions.

	Issues Identified	Improvements
1. <u>Dornsife Policy Updated:</u>	During not-for-cause audits OPRS observed that some investigators conducting research at the imaging center were unfamiliar with Dornsife policy.	The Dornsife Director and OPRS revised/simplified Dornsife policy and created an attestation (in the IRB application) to require all Dornsife researchers to read and follow the policy. All fMRI scans will be reviewed by a Keck neuroradiologist. Subjects will be notified of any abnormalities. http://brainimaging.usc.edu/userdocs/human%20subjects.pdf
2. <u>Mandatory Reporting of Abuse:</u>	Gerontology students sought guidance on what is expected if abuse is suspected or disclosed during their research. The respective schools did not have policy in place.	OPRS has provided information on who is a “mandatory reporter” and what to do when a student suspects or encounters child or elder abuse during the conduct of research. www.usc.edu/oprs/private/docs/oprs/ChildElder_Abuse_FAQ_2.15.pdf
3. <u>Witnesses to Informed Consent:</u>	The USC informed consent template unnecessarily required the signature of a witness for the informed consent process.	The policy on informed consent has been clarified to state that witness signatures are only required when a short form is used (as required by federal regulation).
4. <u>Investigational New Drug (IND) and Investigational Device Exemptions (IDE):</u>	Investigators who hold an IDE or IND did not have adequate guidance on compliance.	OPRS has created a new booklet and webpage for investigators holding an IND/IDE. An additional information sheet has been produced on how to perform sponsor-investigator “self-monitoring”. www.usc.edu/oprs/research/indide

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5. <u>IRB ed sessions schedule:</u>	OPRS has limited contact with students before they apply for initial IRB review which resulted in low attendance at ed sessions.	In order to provide guidance for researchers seeking IRB review for the first time, OPRS will only be conducting human subjects research education sessions in classrooms by request and publicize this through deans and faculty.
6. <u>Disclosure of investigator salaries:</u>	Investigators expressed reservations about submitting salary information on the IRB application.	Investigators will not be required to submit salary information on the IRB application.
7. <u>IRB review of recruitment materials:</u>	Investigators involved in large-scale, multi-site studies were unable to satisfy changes requested by the IRB because study sponsors needed to maintain standardization of recruitment materials.	The IRB will not review patient recruitment materials that have been standardized for large-scale, multi-site studies.