Internal Monitoring and Auditing

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Sponsor-Investigators are responsible for the selection of qualified study monitors and ensuring that the trials are adequately monitored throughout the life of the trial. At UCLA, the Office of Regulatory Affairs offers assistance with monitoring and quality assurance auditing for investigator-initiated studies. This service helps ensure compliance with FDA, GCP, and IRB regulations, and UCLA Health System policies and guidance, as related to clinical research. Please contact the Office of Regulatory Affairs for more informaton.

The ORA monitoring program provides a proactive (rather than “for cause”) regulatory assessment and has a strong educational component. Investigators are required to provide monitoring findings to the IRB according to their policies.

The ORA auditing program includes routine and for-cause reviews (requested by institutional officials). The purpose of routine reviews is to assist investigators with achieving and maintaining regulatory compliance. The reviews are meant to be educational rather than punitive in nature. The ORA summarizes and reports the findings directly to the investigators and the CTSI DSMB.

When writing a grant proposal, Investigators are encouraged to include costs for monitoring and auditing of their study. Contact the Office of Regulatory Affairs for details.

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