



Creation and Implementation of Educational Seminars in Regulatory Science Core Engagement

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Navigating the regulatory standards that accompany translational research can be challenging for investigators and other members of the NJ ACTS community. The NJ ACTS Regulatory core provides regulatory and quality assurance support for the full spectrum of preclinical to first-in-human studies. The Regulatory Core is currently building a series of videos encompassing regulatory education as part of a media library that will be available to investigators and all members of the NJ ACTS community.

Sources of information primarily include FDA guidance documents and regulation from the Department of Health and Human Services. The videos discuss two branches of regulatory knowledge: industry-driven drug development and human subjects research. The effectiveness of these videos will be assessed through surveys built in REDCap and distributed to NJ ACTS researchers, students, and community members. Participants will complete a pre-test assessing their grasp of either Preclinical Drug Development, Defining and Reporting Adverse Drug Events, Human Subjects Research, or IRBs and then watch a corresponding video.

The post-test will comprise identical questions and performance will be statistically analyzed and used to determine the effectiveness of the videos. A demographics form will be employed to account for any prior subject knowledge and other possible discrepancies. We hypothesize that participants will score higher on the post-test after watching a video on the respective topic.

