

Standards & Compliance

Mission: To communicate and educate researchers in the NTR network on regulatory requirements and guidelines governing the clinical translation of technology.

<i>Center Needs</i>	<i>Core deliverables</i>
Data acquisition & archiving standards	Coordinate with Information Technology Core to review current data acquisition & archiving practices
Resources for presentations, templates, protocols, SOP, document control	Provide information to be used to prepare Guidance Documents
Methods for adopting GLP and/or GMP	Assist NTR Centers in best practices for product development
Coordinated effort in working with FDA Assistance in designing developmental programs for IND submissions and FDA PMAs, 510(k), etc.	Provide presentations to NTR Centers describing regulatory requirements for bringing products from laboratory to clinical trials