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Problem Statement: Academic institutions are faced with how best to support SIs, individuals who serve as both the clinical investigator and the sponsor, when conducting investigational drug and device research. An ideal model of institutional support for SIs is one that provides necessary education of the SI’s responsibilities and facilitates regulatory and institutional compliance. However, institutions struggle with identifying and providing access to services necessary to navigate the complex and challenging IND/IDE requirements. Many do not have a centralized IND/IDE office, but rather, only have access to limited resources and expertise embodied in different individuals/departments across the institution. The result is that academic centers have various models of IND/IDE support based on numerous factors such as institution size, type of research conducted, organizational structure, budget, and number of SI held INDs/IDEs. For an institution considering a deployment of new or improved IND/IDE services, functions have been classified, and individual institutional models have been identified. However, three of the major missing components are identifying (1) how many employees are required to effectuate various IND/IDE support models; (2) required types of expertise/skill sets/background that would constitute an effective IND/IDE support model; and (3) how institutions without resources may regionally create basic toolkits and share education and learning.

Method: To assist institutions in providing support for SIs in meeting regulatory requirements for their ongoing and/or new research studies, 13 volunteer experts from eight different academic and hospital institutions met to share resources, education, and experiences. Given the diversity of the institutional structures and cross-departmental functions, we were able, through discussion and surveys, to cross-map the models and functions with the human resource component to elucidate a diverse range of scalable and adaptable tools, education that any institution can adopt, and access to enable IND/IDE support functions within their own institutions and networks.

Result: A contributory network, sharing policy, form development, and educational resources elucidated the diversity in the provision of institutional assistance to IND/IDE holders and offered compelling benefits to SIs and institutions by extending services to, expanding learning of, and assistance to employees to be more productive and responsive.

Scalability: Through this effort, institutions seeking models to manage IND/IDE obligations can access our resources and implement their own network model to co-create value, instill a collective identity and ultimately deliver high quality IND/IDE support services seamlessly.