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How to open oncology clinical trials: Staying compliant

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Many areas of business and government are heavily saturated in regulatory requirements throughout their daily operations. The field of research — especially in oncology — is no exception, and regulatory requirements are present in every aspect of conducting clinical research. Regulatory compliance can be very cumbersome and resource intensive, encompassing all phases from opening a new trial, to approval from the Institutional Review Board (IRB), assigning a principal investigator, managing the consent process, and from enrolling patients to study close-out. In fact, the regulatory burden is so complex that most research sites struggle with the daily management of regulatory compliance. In a survey conducted in 2015 by a joint Initiative from the American Society of Clinical Oncology (ASCO) and the Association of American Cancer Institutes (AACI), 47% of respondents indicated a lack of adequate staff to handle regulatory burdens, and 41% lacked adequate staff for monitoring regulatory compliance.[1] It is of utmost importance to maintain regulatory integrity in accordance with the federal guidelines to ensure clinical trial requirements are being met.

In oncology clinical research, regulations are put forth and ultimately overseen by the Food and Drug Administration (FDA). The FDA requires oversight by an IRB that has the authority to review protocols at the site level and approve or disapprove research from being carried out at a particular institution. The main purpose of the IRB is to ensure that patient rights are protected.[2] IRBs and research sites must adhere to the principles of Good Clinical Practice (GCP), which is universally recognized as a critical requirement in conducting research involving human subjects.