Sarah Attwood et al., J Clin Trials 2017, 7:5 (Suppl)
DOI: 10.4172/2167-0870-C1-019

Final revisions to the common rule-How will this affect human subject protection?

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Have you considered how the revisions to the common rule may affect your next research project? There are a number of questions circulating on how these changes will be implemented effectively and efficiently within the academic communities and other institutions, but also the impact that they may have on all industry sponsored research. Important elements in the final rule issued include: The requirement for consent forms to provide potential research subjects with a better understanding; requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies; for studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement; the establishment of new exempt categories of research based on the level of risk they pose to participants; removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects and requirement that consent forms for certain federally funded clinical trials be posted on a public website. This session will look at the changes and discuss the impact on human subject protection, informed consent for research sites and IRBs.

Biography

Sarah Attwood has over 20 years of experience in Operations and Business Development in clinical research and is currently Director of Client Services at IntegReview IRB. Prior to joining IntegReview, she was the Vice President for a research site organization. She was responsible for the clinical operations of their multiple Phase I – IV clinical research sites and developing the CRO business to provide project management and monitoring services. Prior to management, she has held various positions including Clinical Research Coordinator, CRA, Project Manager and Consultant for CROs and Sponsors and has a background in hospital research, pharma, medical devices, nutraceuticals and biotech.

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Melanie Flores is the Vice President of Compliance and is responsible for the daily leadership, management and full responsibility for the Company's compliance program. She has worked in the IRB industry since 1999 and has been with IntegReview since 2001. Prior to leading the Regulatory Compliance Department, her main focus for 9 years was spent providing training to IRB staff and IRB members to ensure compliance with Federal Regulations, ICH Guidelines, IntegReview IRB Standard Operating Procedures and standards of the AAHRPP.

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