

Compliance through Collaboration: Partnering with Independent IRBs to Develop and Maintain a Strong Human Research Protection Program (HRPP)

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- Provide an overview of the current regulatory and business climate for IRB review, including the NIH Policy on IRB review and changes to the Common Rule at 46 CFR 46
- Discuss models for IRB review and partnership with academic and commercial IRBs, differentiating and outlining the responsibilities of the institution versus the responsibilities of the reviewing sIRB
- Demonstrate through case studies how differing business models can both achieve and improve compliance with the new federally mandated requirements for the use of sIRB in multi center clinical research studies

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