



Clinical Research Compliance Manual: through 2015 Supplement

Patricia Brent, Lawrence W. Vernaglia

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For anyone receiving or applying for clinical research funding, *Clinical Research Compliance Manual: An Administrative Guide* covers today's most crucial topics, including:

- Human subject protections
- Institutional Review Board regulations and requirements
- Conflicts of interest
- Scientific misconduct
- Reimbursement issues
- And much more!

Clinical Research Compliance Manual helps you establish best practices and carry out all administrative tasks in a compliant manner while keeping you completely up-to-date on the most recent developments:

- Covers the major clinical research issues - with chapters written by experts in the field
- Provides legal explanations of the major regulatory issues in an easy-to-understand format
- Includes summaries of federal regulatory agencies, analysis of major cases, flow-charts, checklists, and footnotes to in compliance program development, auditing and monitoring

Clinical Research Compliance Manual has been updated to include:

- A new chapter on "Protecting Research Materials, Research Results, and Inventions: A University's Perspective"
- A new section on "Recent Proposed Changes to the Common Rule"
- Updated discussion of federal-wide assurance (FWA)
- OHRP's revision of its FAQs to be consistent with its Final Guidance on Engagement of Institutions in Human Subject Research
- Recent OHRP guidance on when institutions are not engaged in human subject research
- And much more!

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