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Independent Writer



## Regulatory Writing: Services and Opportunities

Navigating the world of clinical trials can be frustrating. To lead a trial in your group or clinic, you need continuing approval by oversight groups. To gain that approval, you must wade through overwhelming amounts of paperwork, often dictated by conflicting regulations by different committees and organizations.

Focus on what you do best – helping patients and conducting research. With an experienced, expert regulatory professional on your side, you can cut through the clutter and get your trial moving.

### ***Key Benefits***

- Guide your trials from sponsor/primary investigator submission through IRB approval
- Write an informed consent document that effectively protects your patients and complies with regulations
- Gain approval from other oversight organizations, including the GCRC, VA, hospitals, and other university/group entities
- Get expert advice and editing for your independent protocol
- Keep your trial up to date and compliant easily with approval for amendments, serious adverse events, protocol violations, and more
- Create effective, approved trial advertising

### ***Regulatory Expertise***

*Years of experience writing and editing:*

Protocol submissions • Informed consent documents • University Institutional Review Board documents • Trial advertising • Protocol amendment submissions • Serious adverse event reports

*In-depth knowledge of practice areas including:*

Cardiology • Gastroenterology • Hematology/Oncology • Pulmonary and Critical Care • Urology • Psychiatry • Internal Medicine • OB/GYN • Rheumatology • Dermatology • Neurological Surgery

*Coordination and negotiation experience and expertise with:*

Institutional Review Boards • Primary investigators and staff • Pharmaceutical Companies • CROs • University leadership, including section heads and deans • Hospitals • VA units • GCRC units • Other inter-university/group entities and clinics

### ***The Difference for Your Research***

With a regulatory partner on your side, you can conduct research with confidence. Don't waste time worrying about regulations and documents. Rely on a regulatory affairs writer with years of experience writing and negotiating complex trial documentation for university clinics and independent medical groups. Rest easy knowing that your trial will be understood, communicated effectively, and conducted with ease. Get back to what you do best.