Research Related Injury
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Overview

• The importance of the issue

• Essential elements of Informed Consent Form (ICF) and Clinical Trial Agreement (CTA) with respect to Research Related Injuries

• Subject's expectations

Why is this issue important?

• To protect Research Subjects
Why is this issue important?
• To try to prevent lawsuits

Essential Elements of the ICF and CTA with respect to Research Related Injury
Who will pay:
• Standard Sponsor Initiated Study
• Investigator Initiated Study
• Non-Profit Institution
• FDA-Approved Drug, Biologic or Device

Essential Elements of the ICF and CTA with respect to Research Related Injury
Standard Coverage Exceptions:
• Negligence
• Natural progression of disease
• Subject non-compliance
• Insurance
Ensuring Consistency
• The Informed Consent Form and the Clinical Trial Agreement must be consistent with respect to Research Related Injury coverage.

Research Subject Expectations
• Abney v. Amgen, Inc., 443 F.3d 540 (6th Cir. 2006).

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