

## Clinical Trials Risk Audit

*Underwriters evaluate a number of factors when quoting clinical trials coverage. They will price the coverage differently depending on the degree of risk. Audit your risk profile now.*

What **Phase** is the trial - I, II or III?

How many **patients** are involved? Are they healthy individuals, or are they sick? Are they terminally ill? What is the age range of the patient population – any elderly or children?

Have you supplied the **investigators brochure** to provide specifics on the study drug?

Has the **informed consent form** (ICF) been checked to make sure it has all the required sections as outlined by the FDA? Can it be read by the lay person (standard is 8<sup>th</sup> grade level)? Do the inclusion/exclusion criteria match the protocol? Are there any approved drugs that may be used in the trial as a comparison? Does the document over-promote the treatment in any way?

Do the risks, benefits and alternatives in the ICF match those in the **protocol** and address any issues found in previous studies? Does it include risks for all treatments being provided (whether approved drug or study drug) as well as other procedures to which the patient will be exposed (MRI, blood draw, etc). Are the potential benefits described appropriately, not be stated in an overly positive manner, and does the ICF state there may be no benefit. Are alternative treatments documented to ensure the participant is making a truly informed decision?

Does the ICF state that the participant can take time to review the document? Does the clinical investigator test subjects on their comprehension of the ICF?

What amount of kind of **compensation** is being provided to the participants? Some is ok but participants should not be economically swayed into participating.