

## SUPPLEMENT TO CLINICAL TRIALS APPLICATION

*These supplemental questions to the Lexington application are mandatory. They are designed to provide additional information that will enable Underwriters to better assess the Insured's exposures.*

*These questions are important and will enhance understanding of risk management procedures in many areas. Please answer them fully.*

### **Clinical Trials**

1. Have any bio-studies or clinical trials involving the company's products been suspended or discontinued due to safety reasons in the last 5 years? *(If yes, please provide details).*

If you are involved with human clinical trials please answer the following questions:

- A. Any clinical trials discontinued or suspended due to safety reasons? *(If yes, provide details).*
- B. Do you allow any of the following: Clinical Investigator's enrolling their own patients, enrollment bonuses, contacting patients directly via patient databases, or patient referral fees?
- C. Have any of your Clinical Investigator's been cited for regulatory violations involving your trial activities? *(If yes, provide details).*

- D. Have you had any evidence of serious regulatory non-compliance or fraud by your Clinical Investigator's and their staff in the past 5 years? *(If so, provide details).*
- E. Do you put all your informed consent documents through well-established readability testing, for example, the Flesch-Kincaid Grade level Scoring?
- F. Are you in compliance with the FDA requirements concerning financial disclosures?
- G. Do you incorporate financial disclosures in your informed consent documents or process?
- H. What has been the maximum compensation you have offered trial participants?

**By:** \_\_\_\_\_

\_\_\_\_\_

**Title:** \_\_\_\_\_

**Date** \_\_\_\_\_