Supplemental Questionnaire: **Trial Sponsor**

Instructions:

1. This application must be completed in conjunction with the Pro-Praxis Clinical Research Application.
2. Answer ALL questions completely, leaving No blanks. If any questions, or part thereof, do not apply, print "N/A" in the appropriate space. Any spaces left blank will be interpreted to not apply.
3. This application must be completed, dated and signed by a Principal or Officer of your firm. Underwriters will rely on all statements made in this application.

Applicant Name: _____

SECTION 1. SERVICES

1. Please indicate your phases of research:
   ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Other

2. Please indicate your type of research:
   ☐ Biotech/ Pharmaceutical ☐ Medical Device ☐ Other

3. Is this request specifically for products currently in commercial sales? ☐ Yes ☐ No

4. Do you participate in collaborative trials? ☐ Yes ☐ No

5. Do you:
   - Provide investigator(s) with the necessary information to conduct the clinical trial ☐ Yes ☐ No
   - Ensure proper monitoring of the clinical study ☐ Yes ☐ No
   - Ensure all the necessary ethic review(s) and approval(s) are obtained ☐ Yes ☐ No
   - Prepare and submit clinical trial application(s) and amendment(s) to the appropriate regulatory agencies ☐ Yes ☐ No
   - Refrain from engaging in promotional activities and other prohibited activities such as commercializing an investigational medical device ☐ Yes ☐ No

6. Please list all active studies:

Product	**Description and Protocol #**	**Country***	**Patients Entire Trial**	**Patients Next 12 mos.**	**Trial Phase**	**Trial Length**

7. Have any of your clinical trials been approved by an IRB or Ethics Committee that were previously rejected by a different IRB or Ethics committee? ☐ Yes ☐ No
   If Yes, please explain:
8. Have any of your products or services been involved in class action or multi-district litigation? ☐ Yes ☐ No

If Yes, please explain:

SECTION 2. RISK MANAGEMENT

1. Do you require a certificate of insurance evidencing product liability coverage and limits from:
   - Each Independent Site ☐ Yes ☐ No
   - All Third Party Vendors ☐ Yes ☐ No
   - Other: (specify) ☐ Yes ☐ No

2. Do you asses the financial solvency of:
   - Each Independent Site ☐ Yes ☐ No
   - All Third Party Vendors ☐ Yes ☐ No
   - All Other: (specify) ☐ Yes ☐ No

   If Yes, do you agree, pursuant to such contracts, to indemnify and hold harmless such entities? ☐ Yes ☐ No

3. Do you have a conflict of interest policy? ☐ Yes ☐ No

4. Do you have a formal risk management program in place? ☐ Yes ☐ No

5. Is Good Clinical Practice training a requirement for all clinical research personnel? ☐ Yes ☐ No

6. Do you ever act at as both trial sponsor and clinical investigator? ☐ Yes ☐ No

This application does not bind YOU or US to complete the insurance, but it is agreed that the information contained herein shall be the basis of the contract should a policy be issued.

APPLICANT'S NAME AND TITLE: _____

APPLICANT'S SIGNATURE: _____ ___ DATE: _____
(Must be signed by an active owner, partner or executive officer.)

PRODUCER'S SIGNATURE: _____ DATE: _____ _____