Supplemental Questionnaire: **Contract Research Organization**

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 for which phases of research coverage is being sought:
   ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ Other

   If "Other" is selected above, please check all that applies
   ☐ Pre-clinical ☐ Non Biomedical Research ☐ Social Sciences Research ☐ Government Sponsored Research

   Please check the corresponding box below if the clinical trials engaged in by the Applicant are for:
   ☐Pharmaceuticals ☐ Biologics ☐ Medical Devices ☐Other (specify):

2. Will all phases perform in accordance with FDA approved protocol? ☐ Yes ☐ No
   If No, please explain:

3. Do you manufacture products approved by the FDA for commercial sales? ☐ Yes ☐ No

4. Please provide the percentage of projected revenue by source:

Contract Manufacturing	___%	Lab Services	___%
Research Management- Pre Clinical	___%	Sales & Marketing incl. Commercialization	___%
Clinical Trials Management- Early Stages	___%	Pharmacovigilance	___%
Clinical Trials Management- Late Stages	___%	Data Management Services	___%
Pre-formulation/ Formulation Development	___%	Other:	___%

5. Please list all active studies:

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

6. Are you familiar with the laws of the jurisdiction where active studies are taking place? ☐ Yes ☐ No

SECTION 2. RISK MANAGEMENT

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

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

   If Yes, do you agree, pursuant to 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 as trial sponsor and/or clinical investigator? ☐ Yes ☐ No

7. Do you ever act as a trial collaborator? ☐ 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: _____