

Supplemental Questionnaire: **Institutional Review Board & Data Safety
Monitoring Board**



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. Are you a:

<input type="checkbox"/> Commercial IRB	<input type="checkbox"/> Institutional Review Board	<input type="checkbox"/> Cooperative Research	<input type="checkbox"/> DSMB	<input type="checkbox"/> Other (specify): ____
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2. Please indicate which phases of research are being reviewed:

<input type="checkbox"/> Phase I	<input type="checkbox"/> Phase II	<input type="checkbox"/> Phase III	<input type="checkbox"/> Phase IV
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3. If you are a DSMB/ DMC, how many charters do you currently manage? ____
4. How often to you meet? ____

SECTION 2. RISK MANAGEMENT

1. Do you require the following documents as part of your review process?

Letters of approval on letterhead from cooperating agencies, schools, boards of education etc.?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Participant recruitment materials	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Informed Consent Assent forms	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Surveys, questionnaires, interview instruments, etc.	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Debriefing statement or explanation sheet, if applicable	<input type="checkbox"/> Yes	<input type="checkbox"/> No
2. Do you regularly monitor and disclose conflicts of interest to other board members? Yes No
3. Do you compensate your members for favorable decisions? Yes No
4. Do you have a formal risk management program in place? 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: _____