

QUALIFIED/PRINCIPAL INVESTIGATOR SUBMISSION FORM



Study # _____ Study Short Name (if applicable): _____ Sponsor: _____

Qualified/Principal Investigator Contact Information For IRB Use:

Qualified/Principal Investigator Name: _____

Admin. Address (if applicable) Use for Billing? Yes No

Name: _____ Tel.: _____

Address: _____ Fax: _____

City: _____ Prov/State: _____ Postal/ZIP code: _____ Email: _____

Contact Information for Subjects/Consent Form:

Study Coordinator Name: _____ Nurse: Yes No

Study Coordinator Tel.: _____ Pager/Cell.: _____

Address where subjects will be seen and where IRBS will send docs:

Clinic Name: _____ Tel. For Consent Doc.: _____

Street Address: _____ 24 hr/Emerg Tel.: _____

City: _____ Prov/State: _____ Postal/ZIP code: _____ Email: _____ Research Site Fax: _____

Subject Reimbursement: No Yes, if Yes: Expense, amount varies **OR** Fixed amt: Max. per Visit \$ _____

Explanation if >\$50/visit: _____ **NB: If no amount indicated, IRB Max \$50/visit will be inserted in consent form**

Language for consent/assent form: Eng. ___% Fr. ___% Other ___% Describe _____

Qualified/Principal Investigator Qualifications to Conduct This Study:

Qualified Investigator (licensed MD/DDS supervising medical care/medical decisions in respect of the study at this site)

Med/Dent License #: _____ Prov/State: _____ License Restrictions: No Yes

If license restrictions, what are they? _____

GP/FM Gen. Practice only GP/FM with Special Interest: Describe: _____

Specialist: Board Certified (USA) Yes No Royal College Fellow (Canada) Yes No Certified Yes No

Research Experience: Experienced investigator/staff (≥3 previous trials) Yes No If inexperienced please describe

GCP/research ethics training to be given to the investigator/research staff prior to initiation of the trial _____

Practice Description: Practice Breakdown (please fill in all that apply): REQUIRED ANNUALLY

Previously filed this year: No Yes, if yes which study: Study #: _____ Study Short Name: _____ Sponsor: _____

Cardiol ___% Neurol ___% Psych ___% Geriatric ___% Pediatric ___% Endocrine ___% Rheumatol ___% Derm ___%

Respirol ___% Allergy ___% Infec. Dis. ___% GI ___% Urol ___% Dental ___% Women's Health ___% Men's Health ___%

Other ___% (describe) _____

Subjects Age (yr.): 0-6 ___% 7-12 ___% 13-18 ___% 18-65 ___% > 65 ___% **Subjects Sex:** M ___% F ___%

Ethnicity: Caucasian ___% African ___% S. Asian ___% Oriental ___% Other ___% (describe) _____

Linguistic Group: Eng ___% French ___% Spanish ___% Other ___% Describe _____

On-Site Facilities: Lab/Collection Station X-Ray ECG Endo/Gastroscopy Lung Function EEG CT

Scan MRI Ophthal Stress Testing Other: _____

Planned Source of Subjects: Own Practice Advertising Referral Other: _____

**Information provided on this form is considered to be confidential and is for internal IRB/IRBS use only.*

I request IRB SERVICES to act for me as the IRB/IEC/REB for the above study, and certify that I will conduct the study according to relevant clinical trial regulations and Good Clinical Practices, the approved protocol and consent form, and that I will not bill the public health system for costs of the study to be borne by the sponsor. I further certify that I will abide by the decisions of this IRB/IEC/REB, and comply with IRB/IEC/REB requirements, including timely filing of progress reports, end of study reports, significant protocol deviations, safety reports, etc.

Qualified/Principal Investigator Name (printed) _____

Qualified/Principal Investigator Signature (or designate) _____ DATE: day ___ mo ___, yr _____