NEW CENTER INFORMATION

Version: 01 Sep 2011

Current Ability to Participate in Trials

Please complete and fax to the PRCSG Coordinating Center at 513-636-5990

	YES	NO	NOT SURE
1. Is your center able to participate in formal pharmacokinetic (PK) studies? Formal pharmacokinetic studies are designed to determine the metabolism and pharmacologic actions of the drug in humans after animal studies are complete. These studies require staff time and lab facilities to do numerous, timed blood draws, for example several blood draws over a 24-hour period.	☐ 1	☐ 2	☐ 3
2. Is your center able to participate in early dose-finding studies? Early dose-finding studies are small, open-labeled studies requiring close monitoring by a dedicated study nurse and a willingness to participate in the early steps of drug development before safety and efficacy are established.	☐ 1	☐ 2	☐ 3
3. Is your center able to participate in multi-center placebo-controlled efficacy trials? Efficacy trials (Phase III trials) include larger numbers of patients to evaluate efficacy and the overall benefit-risk relationship of the drug. These studies require enough support staff to collect large amounts of data on many subjects.	☐ 1	☐ 2	☐ 3
4. Is your center able to participate in post-approval safety and surveillance studies? Post-approval (or post-marketing) (Phase IV) studies are designed to collect on-going information on drug safety and efficacy. These studies are often referred to as Registries and require less intensive data acquisition, but longer periods of follow-up. For example, a study may require following a patient for 3 years or longer.	☐ 1	☐ 2	☐ 3

Investigative Center Specifications

5. Does your center employ a dedicated study coordinator/s or Nurse Coordinator/s?

☐$_1$ YES ⟶

☐$_2$ NO

5a: How many Study Coordinators: _____

5b**.** What percent time is this individual/s able to contribute to study-related tasks?

- ☐$_1$ 0-10% FTE
- ☐$_2$ 11-25% FTE
- ☐$_3$ 26-50% FTE
- ☐$_4$ 51-75% FTE
- ☐$_5$ 76-100% FTE

6. Nurse Coordinators: _____

6a**.** What percent time is this individual/s able to contribute to study-related tasks?

- ☐$_1$ 0-10% FTE
- ☐$_2$ 11-25% FTE
- ☐$_3$ 26-50% FTE
- ☐$_4$ 51-75% FTE
- ☐$_5$ 76-100% FTE

7. What certification or specialized training does this individual/s have?

_____

_____

_____

8. Is your center required to submit protocols to a contract office at your organization?

☐$_1$ YES ⟶

☐$_2$ NO

9. Please list the name and address of the contact individual:

_____

_____

_____

_____

10. Does your institution have a mandated indirect cost rate (or minimum allowable indirect rate) for drug-company sponsored studies?

☐$_1$ YES → **11.** What is the rate? _____

☐$_2$ NO

12. Which description best fits your institutional requirements for the use of Institutional Review Boards (IRBs)?

☐$_1$ There is a requirement that all studies must use the IRB of my institution.

☐$_2$ Studies are permitted to use a free-standing, independent IRB.

13. Is there an IRB submission fee for drug-company supported protocols?

☐$_1$ YES → **14.** What is the fee? _____

☐$_2$ NO

15. Does your institution allow concurrent IRB and contract submission or does it require sequential IRB and contract review (or in reverse order contract then IRB)?

☐$_1$ CONCURRENT

☐$_2$ SEQUENTIAL → **16**. Which requires approval first?

☐$_1$ Contract/Budget
☐$_2$ IRB approval

_____

(Investigator completing this survey)

_____

(Center)

_____

(Date)