

Site Information Questionnaire

<u>Site Information:</u>			
Principal Investigator's Name:		Specialty(s): Board certified? Yes <input type="checkbox"/> No <input type="checkbox"/>	
Site Name and Address:		Institution Name and Address (<i>if different</i>):	
Site Phone Number:	Site Fax Number:	Contact Phone Number:	Contact Fax Number:
Contact Person:			
Contact Person's email address:			
PI's email address:			
Our Institution is (check all that apply): Private Practice <input type="checkbox"/> Research Group <input type="checkbox"/> SMO/TMO <input type="checkbox"/> Academic <input type="checkbox"/> VA Hospital <input type="checkbox"/> Other <input type="checkbox"/> _____			
<u>Administrative & Institutional Review:</u>			
Can you use a Central Institutional Review Board Yes <input type="checkbox"/> No <input type="checkbox"/>			
Contact information for individual responsible for regulatory document completion: <input type="checkbox"/> (check if same as contact person)			
Name:	Phone:	Fax:	E-mail:
Estimated time required for start-up (<i>i.e. regulatory documents and contract completion</i>)			
If local IRB approval is required, please complete the following:			
IRB Name:			
Frequency of IRB meetings:			
What is the lead time required for IRB submissions?			
Is other board review required (<i>i.e. Scientific Review, Ethics, Privacy, etc.</i>)? Yes <input type="checkbox"/> No <input type="checkbox"/>			
If yes, provide name:			
What is the lead time required for other board submissions?			
How many weeks from IRB approval to receipt of approval letter?			
Who has authority to negotiate the Clinical Trial Agreement? (<i>i.e. contract and budget</i>)			Name:
Telephone Number:	Fax Number:	E-mail:	
Who will execute the Clinical Trial Agreement? <input type="checkbox"/> Institution: <input type="checkbox"/> Investigator <input type="checkbox"/> Both			

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Name of Institution								
Average number of weeks from Clinical Trial Agreement receipt to execution?								
Staff & Facilities								
What days are patients seen at your site?								
Between which hours are patients seen at your site								
Number of Coordinators		What percentage of time do the coordinators allocate to clinical research?						
How many studies is each coordinator usually responsible?								
What percentage of time does the PI allocate to clinical research?								
Number of years experience as a PI?								
Number of physicians in your practice:			Number of physicians experienced as investigators or sub-investigators:					
At which hospital does the PI have privileges?								
Where will study drug be stored? <input type="checkbox"/> Pharmacy <input type="checkbox"/> Other (Please give address) <input type="checkbox"/> Site address listed above								
If study drug will be stored in a pharmacy, please note the pharmacy hours:								
Are there special pharmacy procedures for study drug storage and dispensing? Yes <input type="checkbox"/> No <input type="checkbox"/>								
If yes, please describe:								
Has the FDA or other regulatory agency ever audited your site? Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please attach all report(s)								
Please check equipment available at your site: ECG <input type="checkbox"/> Treadmill <input type="checkbox"/> Centrifuge <input type="checkbox"/> ECHO <input type="checkbox"/> X-Ray <input type="checkbox"/>								
Internet access <input type="checkbox"/>	RDE <input type="checkbox"/>	Freezer -20C <input type="checkbox"/>	-70C <input type="checkbox"/>	Secure drug storage <input type="checkbox"/>	PFT <input type="checkbox"/>			
Recruitment & Patient Population:								
What methods does your site use to recruit patients for research studies? (Check all that apply)								
Patient Database <input type="checkbox"/> Advertising <input type="checkbox"/> Referrals <input type="checkbox"/> Health fairs <input type="checkbox"/> Other <input type="checkbox"/>								
Please describe:								
Patient population demographics (Percentage)								
Women	Men	Hispanic	African-American	Asian-American	Native American	Caucasian	Other	Over 55 years old
Total number of patients in database/practice:								
What percentage of your patient population is seasonal?								



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Please indicate in which therapeutic areas your site has done research:

<input type="checkbox"/> Hypertension	<input type="checkbox"/> Hyperlipidemia	<input type="checkbox"/> Gastroenterology	<input type="checkbox"/> CHF	<input type="checkbox"/> CNS	<input type="checkbox"/> Neurology
<input type="checkbox"/> Angina	<input type="checkbox"/> Hematology	<input type="checkbox"/> Infectious Disease	<input type="checkbox"/> Oncology	<input type="checkbox"/> Endocrinology	<input type="checkbox"/> Transplants
<input type="checkbox"/> Psychiatry	<input type="checkbox"/> Respiratory Disease	<input type="checkbox"/> Other Cardiovascular	<input type="checkbox"/> Transplants	<input type="checkbox"/> Women's Health	<input type="checkbox"/> Device
<input type="checkbox"/> Other:					

In which study phase(s) does your site have experience? Phase I Phase II Phase III Phase IV

Please complete for the **LAST 4 Cardiology/HTN STUDIES COMPLETED:**

Indication	Enrollment Goal	Number of Subjects Screened	Number of Subjects Randomized	Number of Subjects Completed	Length of Enrollment Period	Length of Subject Follow-up Required	Date Study Closed

Study Specific Information:

How many patients do you treat each month for the following: Unstable angina: _____
 Myocardial Infarction: _____ CHF: _____ Hypertension: _____

Has your site had experience with endpoint studies? Yes No Type: _____

How many patients do you treat each month for Hypertension? Grade 1: _____ Grade 2: _____

Does your site have experience with Ambulatory Blood Pressure Monitoring: Yes No Number of studies done: _____

Will your site be involved in research that involves the same patient population? Yes No

In general, how many patients/month could you realistically screen for	Angina: _____	Arrhythmia: _____	CHF: _____	HTN	MI
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Additional Comments:

This questionnaire was completed by:

Name: (Please print)	Title:	Date:
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Thank you for your attention and response. Please fax this questionnaire, CV and license to 714-210-7088. If you have any questions, please call 877-332-1572

Please feel free to recommend another physician who may also be interested in participating in clinical research studies:

Name:	Phone:	Fax:
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