integrium Clinical Research

Site Information Questionnaire

Principal Investigator & Site Information

Principal Investigator Name:	Degree (MD, DO, PhD, etc):
PI Phone Number:	PI Fax Number:

PI email address:

PI Specialty(s):

1. ____________________ Board Certified? ☐ Yes ☐ No
2. ____________________ ☐ Yes ☐ No

Site Name and Address:

Site Phone Number:	Site Fax Number:

Our Institution is (check only one):

☐ Private Practice ☐ Research Group ☐ SMO/TMO ☐ Academic ☐ VA Hospital

☐ Other ____________________

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

Cardiovascular

- ☐ Angina
- ☐ Arrhythmia
- ☐ Atherosclerosis
- ☐ Cardiomyopathy
- ☐ Endocarditis
- ☐ Coronary Artery Bypass Graft (CABG)
- ☐ Carotid Artery Disease
- ☐ Myocardial Infarction (MI)
- ☐ Coronary Artery Disease (CAD)
- ☐ IVUS
- ☐ Stroke
- ☐ STEMI (ST Elevation Myocardial Infarction)
- ☐ Peripheral Artery Disease
- ☐ Congestive Heart Failure
  - ☐ Diastolic Heart Failure
  - ☐ Systolic Heart Failure
- ☐ Hypertension
  - ☐ Systolic Hypertension
  - ☐ Diastolic Hypertension

Dermatology

- ☐ Acne
- ☐ Actinic Keratosis
- ☐ Atopic Dermatitis
- ☐ Aesthetics
- ☐ Onychomycosis
- ☐ Psoriasis
- ☐ Rosacea
- ☐ Other ____________________

Metabolism

- ☐ Type I Diabetes
- ☐ Type II Diabetes
- ☐ Obesity
- ☐ Hypercholesterolemia/Hyperlipidemia

Other Therapeutic Areas

- ☐ Device
- ☐ Hematology
- ☐ Gastroenterology
- ☐ Infectious Disease
- ☐ Neurology
- ☐ Oncology
- ☐ Psychiatry
- ☐ Respiratory Disease
- ☐ Transplants
- ☐ Women's Health
- ☐ Other ____________________

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Site Information Questionnaire

Staff	
Primary Contact Person:	Contact Person Position/Title:
Contact Person Phone Number:	Contact Person's Fax Number:
Contact Person Email Address:	
Sub-Investigator Name (1):	Sub-I Email Address:
Sub-I Phone Number:	Sub-I Fax Number:
Sub-I Specialty(s): __________ __________	Board Certified? ☐ Yes ☐ No ☐ Yes ☐ No
Sub-Investigator Name (2):	Sub-I Email Address:
Sub-I Phone Number:	Sub-I Fax Number:
Sub-I Specialty(s): 1. __________ 2. __________	Board Certified? ☐ Yes ☐ No ☐ Yes ☐ No
Sub-Investigator Name (3):	Sub-I Email Address:
Sub-I Phone Number:	Sub-I Fax Number:
Sub-I Specialty(s): 1. __________ 2. __________	Board Certified? ☐ Yes ☐ No ☐ Yes ☐ No
Coordinator Name (1):	Coordinator Email Address:
Coordinator Phone Number:	Coordinator Fax Number:
Coordinator Name (2):	Coordinator Email Address:
Coordinator Phone Number:	Coordinator Fax Number:
Who has authority to negotiate the Clinical Trial Agreement (CTA)? *(i.e. contract and budget)*	
CTA Contact Name:	CTA Contact Email Address:
CTA Contact Phone Number:	CTA Contact Fax Number:

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Site Information Questionnaire

Institutional Review Board

Can you use a Central Institutional Review Board? Yes ☐ No ☐

Contact information for individual responsible for regulatory document completion: ☐ (Check if same as Contact Person)

Name:	Email Address:
Phone Number:	Fax Number:

Estimated time required for start-up *(i.e. regulatory documents and contract completion)*

If ***local*** IRB approval will be required, please complete the following:

Local IRB Name:

Local IRB Address:

Local IRB Phone Number:	Local IRB Fax Number:

Frequency of IRB meetings:

What is the lead time required for IRB submissions?

Facilities

Please check equipment available at your site:

☐ ECG ☐ Centrifuge ☐ X-Ray ☐ Freezer ☐ -20C ☐ -70C ☐ Secure drug storage ☐ Internet Access

Do you have experience with Electronic Data Capture (EDC)? ☐ Yes ☐ No

If yes, which EDC systems is your site familiar with?

☐ Phase Forward Inform ☐ DSG eCaselink ☐ Medidata Rave ☐ Other ____________________

Ambulatory Blood Pressure Monitoring (ABPM) Experience:

Do you have experience performing ABPM? ☐ Yes ☐ No

If Yes, how many studies have you done in the last 2 years using ABPM? ____________________

Does your office have an analog telephone line that can be used for downloading the ABPM data? ☐ Yes ☐ No

Do you have experience with Pharmacokinetic sample collection? ☐ Yes ☐ No

Does your site have the capability to perform serial PK collection for up to 12 hours? ☐ Yes ☐ No

Site Information Questionnaire

Does your site have domiciling capabilities if required? ☐ Yes ☐ No		
Has the FDA or equivalent Regulatory Agency ever inspected your site? ☐ Yes ☐ No If Yes, please attach all report findings and your response. (Note, if the FDA has conducted an audit in the past and your site is still pending the findings please indicate “Yes” with an explanation that your site is awaiting the findings)		
This questionnaire was completed by:		
Name: *(PLEASE PRINT)*	**Title:**	**Date:**

Thank you for your attention and response.

Please fax to 714-541-5601 or email to integriumstudies@integrium.com

If you have any questions, please call 877-332-1572.