

INVESTIGATOR DATABASE FORM

Please complete **all** sections and fax this form as well as the Potential Investigators current CV to **(631) 828-6788** or email to cfranco@symbioresearch.com at your earliest convenience.

A. INVESTIGATOR INFORMATION			
Potential Investigator Name:		Specialty:	
Company Name / Institution:			
Street Address:			
City:		State:	Zip Code:
Telephone:	Fax:	Email:	
1. Is the investigator board certified? If Yes, specify area(s):			<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Will studies be conducted at the location listed above? If No, specify:			<input type="checkbox"/> Yes <input type="checkbox"/> No

B. CLINICAL RESEARCH EXPERIENCE	
1. Does the investigator have clinical research experience? If Yes, what year did this investigator start research? _____ (e.g. 1979)	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. What is the approximate number of trials currently being conducted by the investigator?	
3. Has the investigator ever been audited by the FDA? If Yes, was a 483 issued? <i>If yes, please attach a copy of the 483(s).</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Please list <i>all</i> indications in which you have <i>conducted studies in the last 3-5 years:</i>	
5. Please list indications you would like to be considered for/contacted regarding future studies:	

C. SITE INFORMATION			
1. How many sub-investigators are currently at the site?			
Please list below all sub-investigators at the site (e.g. John Smith, MD):			
2. How many coordinators are currently at the site?		2a. How many are certified?	
3. Does the site have clinical research experience? If Yes, what year did the site start research? _____ (e.g. 1979)			<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Has the site ever been audited by the FDA? If Yes, was a 483 issued? <i>If yes, please attach a copy of the 483(s).</i>			<input type="checkbox"/> Yes <input type="checkbox"/> No
5. How would you classify the site?	<input type="checkbox"/> Hospital <input type="checkbox"/> University	<input type="checkbox"/> Private Practice <input type="checkbox"/> SMO	<input type="checkbox"/> Dedicated Research Site <input type="checkbox"/> Other _____
6. What is the site's setting?	<input type="checkbox"/> Urban <input type="checkbox"/> Rural	<input type="checkbox"/> Suburban	Setting's population size:
7. What is the closest airport to your site?			
8. Approximately how long does it take to finalize Clinical Trial Agreements?		<input type="checkbox"/> ≤ 1 week <input type="checkbox"/> ≤ 3 weeks	<input type="checkbox"/> ≤ 2 weeks <input type="checkbox"/> ≥ 1 month
9. Are there any satellite offices where studies would be conducted? If Yes, specify miles apart from primary location:			<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Is there locked storage on site?			<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Is there sufficient storage on site for CRF binders post study archiving?			<input type="checkbox"/> Yes <input type="checkbox"/> No
12. Is there sufficient storage for retain samples?			<input type="checkbox"/> Yes <input type="checkbox"/> No

D. IRB INFORMATION			
1. What type of IRB does the site use?	<input type="checkbox"/> Local <input type="checkbox"/> Central	Local IRB Name:	
Street Address:			
City:		State:	Zip Code:
2. If Local IRB, Timeframe for approvals?	2a. How often does the Local IRB Meet?	2b. Next scheduled IRB Meeting?	

E. CONTACT INFORMATION*General Information Contact Person*

Name:	Telephone:	Fax:
Email:		

Site Contact Person

Name:	Telephone:	Fax:
Email:		

Regulatory Contact Person

Name:	Telephone:	Fax:
Email:		

Financial Contact Person

Name:	Telephone:	Fax:
Address (if different from site):		
Email:		

EDC Contact Person

Name:	Telephone:	Fax:
Address (if different from site):		
Email:		

F. PATIENT POPULATIONS / RECRUITMENT / ENROLLMENT

What is the approximate average number of studies being managed at the site at any one time? _____

From where are subjects typically recruited for trials? (e.g., Newspaper, radio ads, subject database, etc) _____

The following are questions regarding the highest number of subjects enrolled in one study at this site:

1. What was the highest number of subjects enrolled in any one study? _____
2. How long did it take to enroll that number of subjects? _____
3. What was the indication (e.g., Rosacea, Psoriasis, etc.)? _____
4. Did you advertise? Yes No (If Yes, answer 4a and 4 b)
 - a. How much was spent on advertising? _____
 - b. What type were used to recruit subjects? (e.g., Print, Radio, TV) _____

The following are questions regarding the site's most recent study completed.

1. What was the final number enrolled in the site's most recent study? _____
2. How long did it take to enroll that number of subjects? _____
3. What was the indication (e.g., Rosacea, Psoriasis, etc.)? _____
4. Did you advertise? Yes No (If Yes, answer 4a and 4 b)
 - a. How much was spent on advertising? _____
 - b. What type were used to recruit subjects? (e.g., Print, Radio, TV) _____

What is the approximate distribution by age of site's patients?

- Patients _____ years of age <10 10-20 21-50 >51
- Patients _____ years of age <10 10-20 21-50 >51

G. ELECTRONIC DATA CAPTURE

1. Does the site have EDC experience? Yes No (If Yes, answer 1a and 1b)
 - a. In how many trials has EDC been used? _____
 - b. Please provide the name(s) of systems used _____
2. Does the site have a preferred EDC vendor? Yes No (If Yes, please provide vendor name below)
EDC vendor name(s) _____

H. ADDITIONAL COMMENTS

Please do not forget to attach the Potential Investigator's current CV!