

Minority Clinical Research Center Atlanta, LLC

Site Information Form

A. PRINCIPAL INVESTIGATOR

1. Please provide the Principal Investigator's name and office address.

Contact Name			
Organization			
Country			
Street Address			
City	Stat	Zip Code	
Phone Number	Fax Number		
E-mail Address			

2. Please provide the address of the study site, i.e., where the studies will be conducted, if different than question number 1.

Name			
Institution			
Country			
Street Address			
City	Stat	Zip Code	
Phone Number	Fax Number		
E-mail Address			

3. Please indicate which category(ies) best describes your practice:

<input type="checkbox"/> Private Practice	<input type="checkbox"/> Hospital Based
<input type="checkbox"/> Multi-specialty Group Practice	<input type="checkbox"/> Academic Medical Center
<input type="checkbox"/> Site Management Organization (SMO)	<input type="checkbox"/> Government/Military
<input type="checkbox"/> Oncology Department	<input type="checkbox"/> Hematology Department
<input type="checkbox"/> ICU	<input type="checkbox"/> Anaesthesiology Department
<input type="checkbox"/> Acute Pain Management	<input type="checkbox"/> Infectious Disease Unit
<input type="checkbox"/> Interventional Radiology Department	<input type="checkbox"/> Burn Unit
<input type="checkbox"/> Other(please specify):	

4. Principal Investigator's medical specialty(ies):

	Board Certified	
	Yes	No
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

5. Clinical Trial Capabilities:

<input type="checkbox"/> Inpatient Studies	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Outpatient Studies	<input type="checkbox"/> Yes	<input type="checkbox"/> No

6. How many years of experience does the Principal Investigator have in conducting clinical research?

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Site Information Form

7. Has the Principal Investigator and/or study site been inspected by the FDA or other regulatory agency?

Yes _____ **No** _____

If Yes, please explain and include name of the regulatory agency:

8. Has the Principal Investigator and/or study site received a Form 483 (Inspectional Observations) and/or warning letter from the FDA or other regulatory agency?

Yes _____

No _____

If Yes, please explain:

B. PATIENT POPULATION/DEMOGRAPHIC:

Please indicate the disease indications that primarily affect your patient population and the make up of the patient population per disease category.

	Disease Indication	Sex	Race
1	_____	M _____% F _____%	African American _____% Caucasian _____% Hispanic _____% Asian _____% Other _____%
2	_____	M _____% F _____%	African American _____% Caucasian _____% Hispanic _____% Asian _____% Other _____%

Minority Clinical Research Center Atlanta, LLC

Site Information Form

3		M ____ % F ____ %	African American ____ % Caucasian ____ % Hispanic ____ % Asian ____ % Other ____ %
4		M ____ % F ____ %	African American ____ % Caucasian ____ % Hispanic ____ % Asian ____ % Other ____ %
5		M ____ % F ____ %	African American ____ % Caucasian ____ % Hispanic ____ % Asian ____ % Other ____ %
6		M ____ % F ____ %	African American ____ % Caucasian ____ % Hispanic ____ % Asian ____ % Other ____ %
7		M ____ % F ____ %	African American ____ % Caucasian ____ % Hispanic ____ % Asian ____ % Other ____ %
8		M ____ % F ____ %	African American ____ % Caucasian ____ % Hispanic ____ % Asian ____ % Other ____ %
9		M ____ % F ____ %	African American ____ % Caucasian ____ % Hispanic ____ % Asian ____ % Other ____ %

Minority Clinical Research Center Atlanta, LLC

Site Information Form

10

	M _____ % F _____ %	African American _____ % Caucasian _____ % Hispanic _____ % Asian _____ % Other _____ %
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C. IRB INFORMATION

1. Can you utilize a central IRB/Ethics Committee for future clinical studies?
Yes _____ No _____
2. If no, how often does your local IRB/Ethics Committee meet? _____
3. How far in advance of this meeting must the study application be submitted? _____

D. GRANTS/CONTRACT INFORMATION

1. Please identify the person(s) responsible for **reviewing the Clinical Study Agreement (CSA) and the study participant budget**. If more than one person will be responsible, please add an additional page and provide the contact information.

Name _____
Institution _____
Country _____
Street Address _____
City _____ State _____ Zip Code _____
Phone Number _____ Fax Number _____
E-mail Address _____

2. What is the typical length of time required for Clinical Study Agreement and budget approval? _____

3. Grant checks should be made payable to:

Name _____
Country _____
Social Security or Tax ID # or Employer ID # _____
Institution _____
Street Address (PO Boxes are not acceptable, include c/o) _____
City _____ State _____ Zip Code _____
Phone Number _____ Fax Number _____
E-mail Address _____

Minority Clinical Research Center Atlanta, LLC

Site Information Form

E. Site Personnel

1. Please identify the individual who will assume the responsibilities of **lead study coordinator** for this study.

Name _____
Institution _____
Street Address _____
City _____ State _____ Zip Code _____
Phone Number _____ Fax Number _____ Email _____

2. Please indicate the percentage of time this person will have to dedicate for appropriate chart reviews for patient recruitment? _____%

3. Please identify the individual who will assume the responsibilities of the lead study coordinator in that person's absence.

Name _____
Institution _____
Street Address _____
City _____ State _____ Zip Code _____
Phone Number _____ Fax Number _____ Email _____

4. Please indicate the percentage of time this person will have to dedicate for appropriate chart reviews for patient recruitment? _____%

5. Will there be a Sub-Investigator? **Yes** _____ **No** _____ **Unknown** _____

If yes and the Sub-Investigator has been identified, please complete:

Name _____
Institution _____
Street Address _____
City _____ State _____ Zip Code _____
Phone Number _____ Fax Number _____ Email _____

6. Please identify the individual responsible for **collecting and submitting all regulatory**

Name _____
Institution _____
Street Address _____

Minority Clinical Research Center Atlanta, LLC
Site Information Form

City		Stat e		Zip Code	
Phone Number		Fax Number		Email	

7. Please identify the individual responsible for receipt of all **study supplies excluding the study drug.**

Name					
Institution					
Street Address					
City		Stat e		Zip Code	
Phone Number		Fax Number		Email	

8. Please identify the individual responsible for receipt of the **study drug.**

Name					
Institution					
Street Address					
City		Stat e		Zip Code	
Phone Number		Fax Number		Email	

9. If you use a local lab, please indicate the institution responsible and the contact person.

Name					
Institution					
Street Address					
City		Stat e		Zip Code	
Phone Number		Fax Number		Email	

Minority Clinical Research Center Atlanta, LLC

Site Information Form

F. HIPAA INFORMATION

1. Is your site HIPAA Compliant? Yes No Don't Know
2. Do you provide a "Notice of Privacy Statement" to your patients? Yes No
3. Please provide the name and contact information of your privacy officer:

Name:
Organization:
Street Address:
City/State/Zip Code:
Phone Number:
Fax Number:
E-mail Address:

4. Does your site have a HIPAA training policy? Yes No
5. Does your site have a Privacy Board? Yes No
6. Does your IRB review and approve stand-alone HIPAA authorization forms?
Yes No

G. PATIENT MEDICAL RECORDS

1. Do you maintain original paper patient records? Yes No
2. Do you use both paper and electronic patient records? Yes No
3. Do you store patient records entirely in a computerized system? Yes No
4. Is the computerized system compliant with 21CFR Part 11? Yes No Unknown

H. FACILITY

1. Pharmacy on site? Yes No
2. Clinical Lab on site? Yes No
3. Phlebotomy on site? Yes No
4. Freezer – 20 to -70? Yes No
- Freezer -70 or below? Yes No
5. Centrifuge available? Yes No
6. Radiology on site? Yes No
7. Crash cart on site? Yes No
8. Access to dry ice? Yes No
9. Dedicated office space for clinical coordinator? Yes No
10. Secure drug storage? Yes No
11. Dedicated space for a clinical monitor ?
(conference room, empty office etc.) Yes No

