

I. Study/Site Information	
Protocol Number: _____	Protocol Name: _____
Principal Investigator: _____	_____
Telephone Number(s): _____	_____
Fax: _____	Site Address: _____
Study Coordinator: _____	_____
Telephone Number(s): _____	_____

II. Board Eligibility/Certification	Yes	No		Yes	No	N/A
Principal Investigator:	[ ]	[ ]	Sub-Investigator(s):	[ ]	[ ]	[ ]
Specialty(ies):			Specialty(ies):			

III. Type Of Facility	
<input type="checkbox"/> 1. Private Practice	<input type="checkbox"/> 5. University Hospital / Medical Center
<input type="checkbox"/> 2. Group / Multispecialty Practice	<input type="checkbox"/> 6. Veteran's Administration Hospital / Medical Center
<input type="checkbox"/> 3. Research Facility	<input type="checkbox"/> 7. Other (specify):
<input type="checkbox"/> 4. Private Hospital (Methodist)	

IV. Prior Site Experience	
Prior experience with this investigative site? Yes [ ] Date of last study initiation _____ Date of last contact _____ Site visit waived Yes [ ] Provide details in Section XII and obtain MICHR Medical Director signature	No [ ] Proceed to Section V

V. Visitor Information		
	<b>Site Staff Present</b>	<b>Position</b>
Date of Pre-Study Visit:	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	<b>Client Staff Present</b>	<b>Position</b>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	<b>MICHR Staff Present</b>	<b>Position</b>
_____	_____	_____
_____	_____	_____

Yes	No	N/A	VI. Study Overview (additional comments in narrative section)
			<b>Investigator Qualifications and Agreements</b>
[ ]	[ ]	[ ]	Education, training and experience
[ ]	[ ]	[ ]	Complying with GCP and applicable regulations
[ ]	[ ]	[ ]	Monitoring and auditing procedures by sponsor and regulatory agencies
[ ]	[ ]	[ ]	Personnel review and delegation of responsibilities
[ ]	[ ]	[ ]	Study dates
[ ]	[ ]	[ ]	Investigator's Brochure
[ ]	[ ]	[ ]	Safety reporting (SAEs)
[ ]	[ ]	[ ]	Informed consent procedures
			<b>Adequate Resources</b>
[ ]	[ ]	[ ]	Can demonstrate a potential for recruiting required number of subjects within agreed trial period
			<b>Communication With IRB</b>
[ ]	[ ]	[ ]	Responsibilities to the IRB
			<b>Compliance</b>
[ ]	[ ]	[ ]	Protocol / amendment(s)
[ ]	[ ]	[ ]	Deviations from approved protocol / amendment(s)
			<b>Investigational Product(s)</b>
[ ]	[ ]	[ ]	Investigational product(s) receipt, return, inventory
[ ]	[ ]	[ ]	Storage conditions
			<b>Records and Reports</b>
[ ]	[ ]	[ ]	Source documentation
[ ]	[ ]	[ ]	Case Report Forms
[ ]	[ ]	[ ]	Data handling / retention

Requested	Obtained	Previously Received	N/A	VII. Regulatory Documents
[ ]	[ ]	[ ]	[ ]	Investigator Curriculum(a) Vitae
				Medical license number(s)
[ ]	[ ]	[ ]	[ ]	Laboratory license / certification
[ ]	[ ]	[ ]	[ ]	Laboratory normals

Yes	No	VIII. Staff Assessment	
[ ]	[ ]	a.	Does Principal Investigator have clinical research experience? If Yes, specify therapeutic area(s): _____ Number of patients enrolled: _____
[ ]	[ ]	b.	Will there be sub-investigators? If Yes, specify name/specialty: _____
[ ]	[ ]	c.	Is the investigator motivated/enthusiastic about the study?
[ ]	[ ]	d.	Is there an experienced Study Coordinator? If Yes, specify training background: _____
[ ]	[ ]	e.	Does the site have the time/staff to conduct this study?
[ ]	[ ]	f.	Are there any competing studies to be conducted concurrently? If Yes, describe: _____
[ ]	[ ]	g.	Is the investigator satisfied with the protocol? If No, issues: _____
[ ]	[ ]	h.	Has the site/investigator been audited by the FDA? If Yes, why: _____ Outcome: _____
[ ]	[ ]	i.	Will the investigator/SC be able to attend the Investigator's Meeting? [ ] N/A

Yes	No	N/A	IX. Facility Inspection
[ ]	[ ]	[ ]	a. Will a pharmacy be used for drug storage? If Yes, name of pharmacist: _____ If No, who will dispense: _____
[ ]	[ ]	[ ]	b. Is drug storage adequate/secure?
[ ]	[ ]	[ ]	c. Will a local laboratory be used? If Yes, name of laboratory: _____
[ ]	[ ]	[ ]	d. Are examination facilities adequate?
[ ]	[ ]	[ ]	e. Can the site perform specialized testing per protocol?
[ ]	[ ]	[ ]	f. Is there monitoring space available?
[ ]	[ ]	[ ]	g. Is there adequate storage/security for CRFs and patient files?

Yes	No	X. Potential Subject Assessment	
[ ]	[ ]	a.	Is there access to a patient population?
[ ]	[ ]	b.	Is the site geographically accessible for travel?
[ ]	[ ]	c.	Is anticipated study enrollment adequate? If Yes, expected numbers: _____
[ ]	[ ]	d.	Will investigator require advertising?
[ ]	[ ]	e.	Will translations be required for Informed Consent or other documents? If Yes, specify language(s): _____
[ ]	[ ]	f.	How will investigator recruit patients? (Check all that apply) [ ] Practice [ ] Referral [ ] Advertising [ ] Other, Specify:

Yes	No	XI. Site Management (Elaborate in Narrative Section)
[ ]	[ ]	a. Are there outstanding actions to be taken by the site?
[ ]	[ ]	b. Are there outstanding issues to be taken by the monitor?
[ ]	[ ]	c. Are there any potential problems noted?
[ ]	[ ]	d. <b>Is site approved for site initiation?</b> [ ] Hold

XII. Narrative / Additional Comments

Action Items:

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name (printed):

Signature of Reviewer: \_\_\_\_\_ Date: \_\_\_\_\_

Name (printed):