PRE-STUDY QUALIFICATION VISIT REPORT

Study Name:
Monitor(s): Sponsor personnel also present:
Investigator name:
Investigator address:
Person(s) present at visit: (Include names and titles)

RECRUITMENT	
Anticipated first patient enrollment date:	
Anticipated/planned number of patients per site agreement:	
Anticipated enrollment/month:	
Estimated completion date:	

INVESTIGATOR AND STAFF **Please complete all questions. For documents, answer YES only if the document is present and correct.**	YES	NO	NA	COMMENTS
Does investigator have sufficient investigational research and therapeutic expertise to conduct the study? • Obtain a copy of CV for documentation.				
Has the PI taken an Investigator Training course through DIA, ACRP, RAPS, or other accredited program? (note: this is different than training at investigator meetings for prior studies) • Is the PI certified as an Investigator (ACRP or DIA or other organization)?				
Does the investigator have the time to conduct the study properly? • Provide the number of studies the site is currently performing.				No of studies at site: No of studies for PI:
List all sub investigators for the site and their role in the study:				
Are any conflicting ongoing studies at the site? • Provide details if conflicting studies are being conducted.				
Is the PI aware of his/her responsibilities as outlined on the FDA 1572 or Investigator Agreement?				
Does the site have adequate, experienced and qualified staff (including CRC) to conduct the study? • Do(es) the coordinator(s) have prior research experience? Have they attended an accredited CRC course (ACRP, DIA, etc)? Are they certified through ACRP or SoCRA? • Obtain appropriate staff CVs and provide observations in the comment section.				
Does the site have any GCP SOPs? • Obtain copy of table of contents • When were they last updated?				Date of SOPs: Date of last revision:
Has the FDA or other regulatory agency (such as DHHS) ever inspected the investigator? • Provide a summary of the results, if applicable, in comment section. • Obtain copy of any FDA 483s, Warning Letters or other reports / correspondence and any response letter(s) from the site to FDA.				

Please complete all questions. For documents, answer YES only if the document is present and correct.	YES	NO	NA	COMMENTS
Has the Principal Investigator agreed to accept his/her obligations to conduct the study according to GCP, FDA and ICH regulations?				
Discuss with the Principal Investigator and staff the investigational nature of the study and all protocol requirements and test article accountability.				
Is any investigator's name is on the FDA ineligible or restricted / debarment lists? • http://www.fda.gov/ora/compliance_ref/debar/default.htm • http://www.fda.gov/ora/compliance_ref/bimo/disqlist.htm				Date lists checked:
Does the IRB meet DHHS and FDA regulations for written records and have an appropriate membership? • Obtain copy of IRB roster, and FWA (if applicable) • Obtain IRB meeting schedule for next 3 months. • Obtain IRB contact Name and Number for correspondence • Obtain IRB Fee Schedule				

FACILITY/ OPERATIONS				
Please complete all questions. For documents, answer YES only if the document is present and correct.	**YES**	**NO**	**NA**	**COMMENTS**
Does the site have adequate office space, laboratory, and hospital facilities necessary for conduct of the study?				
Is the test article storage area secure and adequate? Describe.				
Is the laboratory adequate and licensed (pathology)? • Obtain copy of license (State license) and CLIA certificate				
Is the radiology department licensed? • Obtain copy of state license.				
Other certifications certified? • Obtain copy of certification.				
Is the site able to conduct eCRF and web based clinical trials (adequate storage, space for equipment, wired for the internet, previous experience with web based or electronic CRF, scanners, etc.)?				

STUDY PATIENT POPULATION				
Please complete all questions. For documents, answer YES only if the document is present and correct.	**YES**	**NO**	**NA**	**COMMENTS**
Were patient inclusion/exclusion criteria discussed?				
Does the investigator have access to the required patient population? • If information is available, list the total # of patients seen/month for • <insert specific protocol requirements>				
Will patients be referred from an outside practice? • Provide an estimate of referred patients in comment section.				

SOURCE DOCUMENTATION				
Please complete all questions. For documents, answer YES only if the document is present and correct.	**YES**	**NO**	**NA**	**COMMENTS**
If this is an eCRF or web based trial, does the site have the IT infrastructure necessary to support trial documentation activities?				
Does the staff have experience with eCRF, remote data capture or web based CRF? Describe.				
Did the CRA discuss source documentation requirements for the protocol? Can the site meet those requirements?				

REGULATORY COMPLIANCE/ADMINISTRATIVE PROCEDURES				
Please complete all questions. For documents, answer YES only if the document is present and correct.	**YES**	**NO**	**NA**	**COMMENTS**
Name of IRB(s) and Chairperson(s) that will be involved in reviewing study. • Attach IRB Calendar and submission deadlines • Attach copy of FWA and/or IRB Roster • Attach IRB Accreditation Status (if applicable)				
Has the reviewing IRB had a regulatory audit by FDA, OHRP or NIH within the last <insert time frame> years?				
Does the Principal Investigator have a copy of the protocol? Version date / /				
Does the Investigator have any budget questions to refer to Sponsor?				

ATTACHMENTS / COMMENTS
Attach documents listed on the Monitoring Visit Checklist. Retrieve a copy of other relevant documents for the in-house Study Master File as applicable at the end of the study.
Comments:

ACTIONS/FOLLOW-UP REQUIRED			
List all action items and plan for completion. Record any important discussions with the Investigator and/or staff.			
CRA Signature:		Date:	

FOR SPONSOR ONLY

Is the Invesgigator/ site qualified to conduct the study?	☐ Yes ☐ No		
Study Director Signature:		Date:	