CLOSE OUT VISIT REPORT (CRF TO MONITOR)

Protocol:	
PI Name:	
PI Address:	
Date of Visit:	
Monitor(s):	
Other Sponsor Personnel Present:	
Site Personnel Present at Visit (include names and titles):	

FINAL PATIENT RECRUITMENT STATUS	
# Screened:	
# Screen fails:	
# Enrolled:	
# Discontinued or Withdrew (for any reason):	
# Completed:	
# Lost to Follow-up:	
# Enrollment violations:	

PROTOCOL & INVESTIGATOR RESPONSIBILITIES				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Have facilities remained adequate? • If no, provide reason in comments.				
Has the staff remained the same? • If no, provide reason in comments. For Change of Investigators, all regulatory paperwork must be completed – Investigator Agreements, CV, license, financial disclosure form(s), etc.) For change in CRC, please obtain contact information and arrange for training.				
Is the protocol being followed? • If no, list protocol deviations in comments.				
Have deficiencies / action items from previous monitoring visit been corrected? • If no, provide reason in comments.				
Have today's deficiencies / action items been discussed with the Investigator and staff? • If no, provide reason in comments.				
Are GCP, FDA and ICH requirements being met by the Investigator and staff? • If no, provide reason in comments.				
Were subject numbers assigned correctly? • If no, add comment.				
Did all enrolled subjects meet eligibility requirements?				

PROTOCOL & INVESTIGATOR RESPONSIBILITIES				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Were there any missing visits, examinations or tests required by the protocol? If yes, document in the protocol violation / deviation section.				
Were any remaining un-monitored CRFs reviewed for completeness, legibility, accuracy, and in agreement with source documents? • List patient IDs and visits reviewed in CRF Review and Retrieval Documentation section.				
Was Source Data Verification done?				
Was Source Documentation sufficient? • If no, add comment.				
Is there any evidence of falsification or fabrication of data? (includes medical charts, study records, laboratory reports, etc.).				
Are there any instances where data is recorded in the CRF that cannot be found in source documentation / medical records?				
Is the Investigator supervising the study, reviewing and signing the CRFs? • If no, add comment.				
Were all data correction issues discussed with the investigator and/or site staff and did they agree to correct deficiencies? • If no, add comment.				
Has the investigator been informed of the potential for an FDA audit and to immediately notify the Sponsor should any audit be scheduled?				
Were there any omissions in the reports of specific data elements such as the administration of concomitant test articles or the development of an intercurrent illness?				
Have any subjects failed to complete the study? List and provide reason or supporting documentation.				
Discuss plans for final study report, publications and presentations and clarify roles and responsibilities of investigators.				
Other:				

TEST ARTICLE				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Are the device accountability logs accurate and completed for final disposition? • If no, add comments and action item.				
Do the device accountability logs show that investigational devices have only been used according to the protocol? (Were any study devices used for non-study subjects? Other?) • If no, add comments and action item.				
Are any devices un-accounted for? • If yes, please comment.				
Are any devices being returned to the Sponsor / Manufacturer this visit?				
Were there any device malfunctions / breakages that occurred that need reporting to the Sponsor?				
Is the current Manual of Operations present?				
Other:				

CRFs RETRIEVED AT THIS VISIT		
Subject ID #	**CRF Retrieved**	**COMMENTS**

INFORMED CONSENT				
Please complete all questions.	**YES**	**NO**	**N/A**	**COMMENTS**
Were all consent forms, reviewed to date, signed prior to patient participation? • If no, provide reason in comments.				

Please complete all questions.	**YES**	**NO**
Is there a signed/ dated ICF for each subject screened or enrolled?		
Were informed consent discussions done by the investigator or delegated to study personnel on the delegation of duties list? Describe any deviations:		
Is there documentation that a copy of the signed ICF was given to each subject?		
Is there documentation in the medical or study records that the informed consent discussion took place?		
Are there any informed consent discrepancies / violations? • Unapproved version of ICF used / signed? • Use of wrong version of ICF? • Date discrepancies? • Backdating / dating for another person? • Lack of required signature? • Lost original ICF documents? • Other:		

For consents monitored at this visit:

Subject ID #	**ICF** Version/ date	**ICF** Version/ date	**ICF** Version/ date	**ICF** Version/ date	**ICF** Version/ date	**ICF** Version/ date

ADVERSE EVENT OR UNANTICIPATED DEVICE EFFECT REPORTING			
Please complete all questions.	**YES**	**NO**	**COMMENTS**
Have any adverse events (AEs) or unanticipated device effects occurred since last visit? • If yes, provide the following information below. **MONITOR TO RETRIEVE SUPPORTING DOCUMENTATION.**			
Has all the follow-up information on previous AEs and / or unanticipated device effect been reported to the sponsor per guidelines ? If no, provide reason in comments.			
Have all required reports been submitted to the IRB per their guidelines? If no, provide reason in comments.			

Subject Initials or Identifier	Adverse Event or Unanticipated Device Effect	Event meet Serious Criteria? Expected / Unexpected	Date Reported to IRB (or NA)	Documented in CRF and Source? Of no, explain in comments section.
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No
		☐ Yes ☐ No ☐ E ☐ U		☐ Yes ☐ No

Comments:

PROTOCOL VIOLATION / DEVIATIONS			
Please complete all questions.	**YES**	**NO**	**COMMENTS**
Have there been any protocol deviations / violations since the previous monitoring visit? If yes, please list below. MONITOR TO RETRIEVE SUPPORTING DOCUMENTATION.			

Subject Initials or Identifier	Deviation / Violation	Reported to the IRB (if required)
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
		☐ Yes ☐ No
Were the above documented violations / deviations reviewed with the PI? If no, explain.		☐ Yes ☐ No

Describe any corrective actions taken to ensure that the violations do not recur for each deviation:

Comments:

STUDY MATERIALS				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Describe final disposition of unused study supplies (such as CRF, lab supplies). Destroyed? Returned to Sponsor?				
Other:				

MONITORING / REGULATORY AUDITS				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Did the monitor meet with the PI at this visit? If not, indicate how monitor will follow-up with PI:				
Was the monitoring visit log signed?				

REGULATORY				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Final Signed protocol/Investigator Agreement(s) / copies of 1572 documents present in Regulatory Files?				
Are CVs of the Investigator, Sub-Investigators and study personnel (if applicable) and state license information current and present?				
List any IRB approvals that have occurred since last visit: Collect a copy of all IRB correspondence and approvals.				Date
Has the IRB approved any new ICF version or HIPAA Authorization (US Sites only) since last visit? Collect a copy of all IRB correspondence, approvals and new consent / HIPAA documents.				
Have there been any updates or changes to the FDA 1572 or Investigator Agreements since last visit? Collect a copy of all IRB correspondence and approvals. Obtain originals and leave site a copy of documents.				
Have there been any updates to the Investigator Brochure since the last visit? Collect copy of IRB acknowledgment.				
Has the PI submitted any continuing review / annual renewals for the study since the last visit? Collect a copy of all IRB correspondence and approvals.				
Has the PI submitted the final (close out) report to the IRB? Collect copy of submission and any final IRB correspondence /acknowledgment.				

REGULATORY				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Have any serious adverse events, reports of unanticipated device events, protocol violations/deviations been reported to the IRB since the last visit? Collect a copy of all IRB correspondence and acknowledgments.				
Compare the master list (from Sponsor) of external adverse events (IND Safety Letters / Safety Reports, MedWatch reports) to those in the site's regulatory books. List any missing documents in the comments section. Remind investigator of his/her obligation to review these reports and submit to the IRB per the IRB's policies and procedures.				
Have any new investigators been added to the site since the last visit? Collect copies of IRB correspondence and approvals. Collect copies of new investigator required documents: • CV and current medical license • Investigator Agreement • FDA 1572 (if applicable) • Financial Disclosure / Certification • Certificate of training (if applicable)				
Have there been any changes to the IRB Roster(s)? Collect copy of new roster				
Have there been any IRB approved advertisements since the last visit? Obtain copy of all IRB correspondence and approvals. Obtain copy of print ad as run by site.				
Have there been any changes or updates to any of the following? If yes, collect copy of new documents. Investigator CVs Investigator Medical Licenses Investigator Agreements FDA 1572 Laboratory Certifications (CLIA) or CAP Laboratory Licenses Laboratory Normals Radiation License Mammography Certification Communications between site and sponsor				List documents retrieved:
Collect Originals of the following documents (leave copy at site): Protocol and/or Amendment Signature Page(s) Final Site signature log Final Delegation of Duties Log Final Monitor Visit Log Final Test Article Accountability Log(s)				List documents retrieved:

REGULATORY				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
Describe where study records will be archived. Did the CRA discuss the Sponsor's requirement for(i) length of study document storage; and, (ii) the investigator to get approval in writing from the sponsor prior to destroying any study documents. Per 21 CFR 812.140 Retention period. An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. Records custody. An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in paragraph (d) of this section and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of Sec. 812.145. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs.				

List all Regulatory Documents at site with version # and dates:	
Item	**Version / Date**
Protocol	
Amendment(s)	
CRF	
CRF Instructions	
Manual of Operations	
Investigator Drug Brochure (if applicable)	
Procedure Manual	
Laboratory Manual	
Newsletters	
Memos from Sponsor	
Current IRB Roster	
Other:	

ACTIONS/FOLLOW UP PLAN
• **List all action items and plan for completion – identify responsibility.**
ACTION ITEMS RESOLVED FROM PRIOR VISITS:
ACTION ITEMS STILL PENDING FROM PRIOR VISITS:

ACTIONS/FOLLOW UP PLAN
• **List all action items and plan for completion – identify responsibility.**
NEW ACTION ITEMS FOR SITE:
NEW ACTION ITEMS FOR SPONSOR:

COMMENTS
List all comments that would add information to report (not mentioned above). Detail important discussions with investigator and /or staff.

Signature CRA		Date:
Signature Sponsor		Date: