CLOSE OUT VISIT REPORT (NO 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.				
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 any)? • 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.				
Was Source Documentation sufficient? • 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?				

PROTOCOL & INVESTIGATOR RESPONSIBILITIES				
Activity	**YES**	**NO**	**NA**	**COMMENTS**
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?				
Other:				

INFORMED CONSENT				
Please complete all questions.	**YES**	**NO**	**N/A**	**COMMENTS**
For files ready to be archived, is there a signed/ dated ICF for each subject screened or enrolled?				
Are there any informed consent discrepancies / violations that need to have follow-up completed? • 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:				

ADVERSE EVENT OR UANTICIPATED DEVICE EFFECT REPORTING				
Please complete all questions.	**YES**	**NO**	**N/A**	**COMMENTS**
Has the Investigator / staff learned of 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
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?				
Has the PI submitted the final (close out) report to the IRB? Collect copy of submission and any final IRB correspondence /acknowledgment.				
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 there been any changes to the IRB Roster(s)? Collect copy of new roster				
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:
NEW ACTION ITEMS FOR SITE:

ACTIONS/FOLLOW UP PLAN
• **List all action items and plan for completion – identify responsibility.**
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: