BIMO SITE AUDIT CHECKLIST

[insert name] Clinical Trial

Item		
AUTHORITY AND ADMINISTRATION FOR STUDIES INVOLVING HUMAN DRUGS, BIOLOGICS AND DEVICES		
1.	Compare the Investigator Agreement with the information provided by the assigning Center.	Auditor will check it. Keep the investigator agreement ready in the file. As the study investigator, your responsibilities are to ensure - IRB approval of protocol and subject informed consent - Subjects are consented and the process is adequately documented - Report adverse events and deviations to IRB & Sponsor as per IRB requirement and the protocol. - Prior approval of deviations with Sponsor, if possible - Conduct study in accordance with the approved protocol and report on deviations, if any - Maintain subject/ study records and IRB/ Sponsor communication - Periodic (annual or as per IRB policy) reports are submitted to the IRB - Proper use of the investigational system (storage w/ limited access to authorized personnel) - Personally conduct or supervise investigation and ensure rights, safety and welfare of study subjects - Maintain adequate staff, facility and time to conduct study
2.	Obtain a list of all studies performed by the investigator. Include: Protocol Number Protocol title Name of sponsor Study dates	Located on most recent CV (Reg file)
3.	**Document** the following in the EIR:	
a.	Address of all locations which study subjects were seen.	
b.	How the sponsor provided information to the investigator about the test article, protocol and obligations of the investigator.	As part of Site initiation visit, sponsor representatives provided an in- person training on protocol, investigational drug/device, and investigator responsibilities. In addition, the sponsor representatives trained the research staff who is identified to participate in the study.
c.	Whether the authority for the conduct of the varioius aspects of	Authority to conduct various aspects of the study was delegated to qualified persons and was not in delegation of authority log.

	the study was contracted and/or delegated properly so that the investigator retained control and knowledge of the study. Include a list of delegated tasks.	Information about qualifications of the person performing the task e.g. CV, medical or other license, relevant experience was reviewed.
d.	The following dates:	
i.	IRB approvals including initial review, all amendments, the IC documented and all revised IC documents.	Maintained in the Regulatory file
ii.	When was the Investigator Agreement signed by the clinical investigator	XX/XX/XXXX – Maintained in the Regulatory file
iii.	When the first subject was screened.	XX/XX/XXXX
iv.	When the first subject signed the IC	First subject consented on XX/XX/XXXX
v.	First administration of test article	XX/XX/XXXX
vi.	Last follow-up for any study subject.	Obtain this date from the subject file.
e.	If investigator discontinued his/her participation in the study and **describe** the reason(s).	
4.	**List** the name and address of the facility(ies) performing laboratory or diagnostic tests required by the protocol. **Describe** the investigator's documentation of the laboratory or diagnostic testing facility's qualifications (e.g. certification under CLIA)	
5.	**Determine** the process used to recruit subjects. If recruitment materials or phone recruitment scripts were employed, **document** their review and approval by the IRB. **Document** instances in which the investigator utilized methods or distributed information that appeared to be coercive in nature, any promotion material representing the test article as safe and effective for the purpose which it is under investigation or implied	Describe process: In conjunction with PI and Sub I, RC screened the potential subject list. - Were recruitment material or phone recruitment scripts used?

	favorable outcomes or other benefits beyond what is outlined in the ICF and protocol.	

PROTOCOL FOR HUMAN DRUG, BIOLOGIC OR DEVICE STUDY					
1.	Compare the copy of the protocol provided with the assignment to the Investigator's copy of the protocol and amendments	Protocol versions are maintained in the Regulatory file.			
2.	Did the investigator follow the protocol with respect to:				
a.	Subject selection (inclusion/exclusion criteria)	☒ Yes	☐ No	☐ NA	
b.	Number of subjects enrolled		Ex: XX subjects signed consent, XX were screen fails XX subjects were treated with the investigational device.		
c.	Randomization scheme (where applicable)	Was there randomization in the study or were all subjects treated with the investigational product.			
d.	Required procedures and evaluations (e.g. blinding procedures)	Was there a blinding procedure?			
e.	Administration of the investigational product:	Investigational device was administered in XX. Only those subjects who signed consent and met inclusion/exclusion criteria were treated with the investigational system.			
i.	For devices- used according IFU (where applicable)	The equipment was used as per the IFU and the clinical protocol.			
a.	Identify the circumstances resulting in termination.				
3.	**Verify** that the investigator followed the protocol approved by the IRB. Review any changes to and deviations from the protocol.	Protocol and its amendments were submitted to the IRB before being used in the clinical study. There were XX deviations noted. The XX major categories of deviation were:			
	Determine whether deviations to the protocol were:				
i.	Documented, showing dates of and reason for each deviation.	Maintained in the subject file			
ii.	Documented, with prior approval from the sponsor for deviations if the investigational plan except if emergency use.	Maintained in the subject file			

iii.	Documented, with prior approval from the reviewing IRB and FA for deviations from the investigational plan that may affect the scientific soundness of the plan or the rights, safety or welfare of human subjects, except in an emergency.	There were no deviations that affected the scientific soundness of the plan or the rights, safety or welfare of human subjects and hence not reported to WIRB.
	Collect correspondence or other documentation that supports adverse inspectional observations.	

INSTITUTIONAL REVIEW BOARD FOR DRUG, BIOLOGIC OR DEVICE STUDY		
1.	**Identify** name, address and chairperson for the IRB for the study.	Western IRB (WIRB) was used. IRB roster is in Regulatory file.
2.	**Determine and describe** if the investigator obtained IRB approval of the items listed below before initiation of study-specific procedures on subjects:	
a.	The protocol and any amendments;	Yes
b.	The informed consent documents; and	Yes
c.	Advertisements and other information provided to study subjects.	No study specific advertisement material was used.
3.	**Describe** the nature and frequency of communication with the IRB. Determine whether the investigator submitted information promptly to the IRB, in compliance with the protocol and applicable regulations, of all deaths, SAEs, and unanticipated problems involving risk to human subjects.	WIRB requires only unanticipated adverse events to be reported. There were no unanticipated AEs in the study. WIRB requires only those deviations that affect the scientific soundness of the study or the rights, safety or welfare of human subjects to be reported. There was no such deviations in the study. Annual reports were submitted to the IRB and the approvals are maintained in the Regulatory file
4.	If there is a question as to whether the correct consent document was used, obtain a copy of each version of the IC approved by the IRB.	All subjects signed correct and current version of the informed consent form.
5.	**Collect** correspondence or other documentation that supports adverse inspectional observations.	
HUMAN SUBJECT'S RECORDS		
1.	Informed Consent	
a.	Describe the informed consent process. For the study being inspected, include the following information:	Subjects were identified by….. Eg. Subjects were approached and provided consent form, they were explained the study, risk, rights and responsibilities. Consent form was provided to them to take home to review.

		Once subject was satisfied, they signed the consent form in the hospital. RC singed the consent form concurrently. The form was give to the subject to take home.
i.	Who (SC, investigator, nurse, etc.) explained the study and consent document to prospective study subjects and was it provided in a language understandable to each subject?	Study Coordinators who were delegated to obtain informed consent were… They consented the subjects and subjects were given sufficient time to ask any questions they might have.
ii.	How did the IC process take place? (e.g. was this explanation given orally, by video, through a translator, etc)?	The IC process took place orally. No videos were used.
iii.	Was consent obtained prior to enrollment in the study (prior to performance of any study related tests and administration of test article)?	Yes
iv.	After signed and dating the IC, was each subject or the authorized representative given a copy of the IC?	Yes
v.	Was the appropriate IRB-approved consent document used for all subjects?	Yes
vi.	If the short form was used (21 CFR 50.27 (b)(2), was the IC process appropriately documented?	☒ NA
a.	Did the subject or the subject's representative sign the short form?	☒ NA
b.	Was a witness present, who signed the short form and the copy of the summary?	☒ NA
c.	Did the person actually obtaining the consent sign a copy of the summary?	☒ NA
d.	Is the case history documented to show whether a copy of the summary and short form were given to the subject or the subject's representative?	☒ NA
vii.	**Review** the IRB approval letter for the study. Did the IRB stipulate any conditions for the IC process and, if so, did the investigator follow those stipulations?	No

b.	**Review** the IC documents signed by the subjects. If number is small (e.g. 25 or fewer) review 100% of the IC documents. **Determine** the following:	
i.	Did the subject or the subject's legal representative sign the IC document prior to entry into the study? If subject did not sign the IC, **determine** who signed it and that person's relationship to the subject. **Describe** how the investigator determined that the person signing the IC was the subject's legally authorized representative.	All subjects singed the IC themselves prior to entry in the study.
ii.	Determine whether subjects signed the version of the IC that was current at the time of entry into the study.	Yes
iii.	For pediatric studies, was assent obtained from the subjects in addition to the permission of the parents?	☒ NA
iv.	Determine whether the written consent document or oral consent complies with the 8 required elements in 21 CFR 50.25(a)	The following are the basic elements of the informed consent form and were included in the form (1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental. (2) A description of any reasonably foreseeable risks or discomforts to the subject. (3) A description of any benefits to the subject or to others which may reasonably be expected from the research. (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. (5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records. (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and

		whom to contact in the event of a research-related injury to the subject. (8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
2.	Source Documents	
a	**Determine** whether the records contain:	
i.	Observations, information and data on the condition of the subject at the time of entry into the clinical study, as required by the protocol;	Yes, subject medical history was reviewed against inclusion / exclusion criteria prior to their participation in the study.
ii.	Documentation of the subjects exposure to the test article as required by the protocol;	Yes, that is included in the procedure notes.
iii.	Observations an data on the condition of the subject throughout participation in the investigation, including results of lab tests, development of unrelated illness and other factors which might alter the effects of the test article;	Subjects were followed up …… What procedures were SOC –vs—research driven? How long? Adverse events were collected.
iv.	Identification of key personnel involved in collecting and analyzing data at t he site.	The data collection happened at URMC or subject's PCP / cardiologist. The tests (EKG and Echos) were reviewed and confirmed by the trained personnel.
3.	Case Report Forms	
a.	**Describe** the process for obtaining and recording information in CRFs.	The information on the case report form is obtained using source documents such as subject's medical history, results of the tests and procedures etc.
i.	Who obtained and recorded the information;	
ii.	The source of the information (e.g., were data transcribed from another document or were data recorded directly onto the CRF); and	The source of the information was transcribed from another document into the CRF.
iii.	Whether corrections were made to the CRF data entries. If corrections were made, determine who made them, the reason(s) for the changes, and whether the investigator was	Yes, corrections were made to the CRF entry using sponsor provided "Data Clarification Forms" . Corrections were made by RC who was delegated the responsibilities for CRF completion and data clarification. Significant changes (like changes to AE form) were signed by the investigator.

	aware of these changes.	
b.	Compare the source documents with the CRFs and any background information provided (e.g. data tabulations provided by the sponsor) per the assignment memorandum and sampling plan (if applicable). **Determine** whether:	
i.	The study subjects met the eligibility requirements (inclusion/exclusion):	Yes
ii.	Protocol specified clinical laboratory testing (EKGs, x-rays, etc.) was documented by laboratory records;	Yes
iii.	All AEs were documented and appropriately reported;	Yes
iv.	The investigator assessed the severity of the AE and documented the relationship of the event to the test article including any AE that was previously anticipated and documented by written information from the sponsor; and	Yes (Investigator assessed the AE, documented its seriousness, causality, relationship with the test equipment and signed the AE Form)
v.	All concomitant therapies and inter-current illness were documented and reported.	Yes
	Determine whether the investigator reported all dropouts and the reasons to the sponsor.	
OTHER STUDY RECORDS		
1.	Study-related information may also be recorded in other documents. **Determine** if the investigator maintains other records pertinent to the study, e.g., administrative study files, correspondence files, master subject list appointment books, sign-in logs, screening lists and MedWatch forms. Review these records to ensure that all pertinent information has been reported to sponsor. **Document** any discrepancies.	Administrative study files, correspondence files, subject list, sign-in logs, screening lists are maintained.
FINANCIAL DISCLOSURE		
1.	Ask the investigator if and when he disclosed information about his financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and	The financial information was disclosed in the beginning of the study and at the end of the study.

	dependent children. (21 CFR 54.4(b)	
2.	Ask the clinical investigator if and when he updated the information about such financial interests, to report changes that occurred in the value of the financial interests during the course of the clinical investigation or within one year following completion of the study (21 CRF 54.4(b).	There was no change in the information about financial interest of the investigator during the course of the study.
ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES		
Refer to the guidance manual		
Test Article Control		
1.	Accountability 812.140(a)(2)	
a.	**Determine** who is authorized to administer or dispense the test article.	The Sub-Is are authorized to administer the catheter. The Generator was operated by the RC / lab staff who was trained and documented on the delegation log.
b.	**Determine** whether the test article was supplied to a person not authorized to receive it.	No
c.	**Compare** the amount of test article shipped, received, used and returned or destroyed. **Verify** the following:	
i.	Receipt date(s), quantity received, and the condition upon receipt;	Included in the device accountability log
ii.	Date(s), subject number, and quantity dispensed; and	Included in the device accountability log
iii.	Date(s) and quantity returned to sponsor. IF not returned to sponsor, **describe** the disposition of the test article.	Included in the device accountability log
d.	**Determine** where the test article is stored, whether it was stored under appropriate conditions as specified in the study protocol, and who had access to it.	Test articles are stored in locked area with access to authorized personnel only
e.	If the test article is a controlled substance:	☐ NA
i.	**Determine** how it is secured; and	☐ NA – Sponsor sends the test article to the RC.
ii.	Determine who had access.	☐ NA – Only the RC had access to the investigational equipment. RC provided it the lab staff / investigators prior the

		case and double locked everything after the case.
2.	**Inspect** unused supplies and verify that the test article was appropriately labeled.	All unused equipment has been returned to the sponsor. This is documented in the device log.
RECORDS CUSTODY AND RETENTION		
Determine whether study records are retained according to the protocol and 21 CFR 812.140(d) and (e).		There is no record retention policy but records are not destroyed. Sponsor requires records to be maintained for at least 2 years after end of the study.
REPORTS TO SPONSOR		
Determine if required reports (including CRFs) are submitted to the sponsor in accordance with the study protocol and 21 CFR 812.150.		The sponsor required notification regarding Unanticipated adverse events, serious adverse events or death within 48 hours. Attempts were made to inform sponsor about the deviations. IRB approvals were submitted to the sponsor.
MONITORING		
1.	**Determine** if the sponsor monitored the progress of the study to assure that the investigator compiled with the protocol and regulations.	Yes,…
2.	Describe the monitoring activities. Examples:	
a.	Pre-study contacts with the investigator (e.g. meetings, visits, correspondence);	Site initiation visit.
b.	Frequency and nature of monitoring (e.g., on-site visits, telephone calls, fax, email);	Every 2-3 months to verify subject and regulatory data
c.	**Determine** if the study records include a log of on-site monitoring visits, written reports or other communication provided to the investigator. Obtain a copy of the log (if any) and examples of monitor reports and communications; and	Yes monitoring log and monitoring visit follow up letters.
d.	Follow-Up activities performed by the investigator when the monitor found deficiencies or recommended changes, for example, in the conduct of the study or records associated with the study.	Once the monitoring letter was received, RC worked on the correction and presented it to the PI for review and to update him on the status of action items.. The PI signed the post monitoring letter and a copy was provided to the sponsor.

3.	For sponsor-investigators, **determine** if any monitoring was done for the study and, if so, **describe.**	☒ NA
Clinical Research Associate (print name)		
Clinical Research Associate Signature:		Date:

SUMMARY OF FINDINGS: