IRB Docket #:

Study Title:

Principal Investigator:

Nature of Visit: Office of Clinical Research, Quality Improvement conducted an on-site review of the above-referenced protocol

Date of on-site review:

Reviewers:

Overall Assessment: Corrective actions and/or best practice recommendations for addressing deficiencies, if any, and improving upon the existing practices are outlined below. This report is shared only with the Investigator and designated study team members. Any observation that should be reported to the IRB must be submitted via the eIRB system by the study team within 5 working days of the Investigator learning of the deviation.

Observations	Corrective Actions/ Best Practice Recommendations	Reportable to IRB?

CLINICAL TRIALS QUALITY IMPROVEMENT INSPECTION CHECKLIST
University of Massachusetts Worcester –Clinical Research
GENERAL INFORMATION

Principal Investigator	
E-mail Address	
Department	
Co-investigator(s)	
Study Coordinator(s)	
Study Category	( ) drug ( ) device ( ) observational ( ) other:
Date of Review **Reviewer**	
IRB Docket Number	
Study Title	
MCSR Researcher License? **Site where study conducted (school, hospital, community, etc)**	
Sponsor **FDA Regulated?** **NIH Funded?** **Registered on Clinicaltrials.gov**	 Yes No Yes No Yes No
Date of IRB Initial Approval	
Total # Enrollment	#Approved (__) #Enrolled to date (_____)
Study Status (clarify if still enrolling; pending data analysis, etc)	Open to Enrollment

1. REGULATORY DOCUMENTATION

Requirements vary, depending on the type of study and sponsor.

		Yes	No	N/A	Comments
1.1	Approved protocol (original and all revisions are on file?)				
1.2	Signed FDA 1572 (original and revisions in file?) For IDE Studies, is an Investigator Statement on file?				
1.3	Is a Financial Disclosure form on file for each investigator listed on the 1572?				
1.4	CVs of PI/Co-PI are on file? Is a valid licensure on file?				

1.5	Is there a screening log? Is log complete? # of subjects screened? (_)				
1.6	Is there a monitoring log? Is monitoring log complete? How often is site monitored?				
1.7	Is there a signature log? Is signature log complete? Is there a Delegation of Responsibilities on file? Are all staff working on the study documented on the eIRB system?				
1.8	Are copies of site visit monitoring reports on file? If yes, do monitoring reports include Site Initiation report/visit documentation? If yes, do monitoring reports include study close-out report/visit documentation				
1.9	Are all versions of the Investigator Brochure or Device Manual on file? If the product is already marketed, is there a package insert/product information on file? Is the Dept Chair's MA research license current?				
1.10	Are lab tests required?				
1.11	Is a copy of the lab certification on file?				
1.12	Is there a copy of the UMMMC normal lab ranges?				
1.13	Is the lab director's CV on file?				
1.14	Is there a Data Safety Monitoring Plan for this study?				
1.15	Is the study registered on clinicaltrials.gov?				
1.16	Is correspondence with the sponsor on file?				

2. IRB DOCUMENTATION

2.1	IRB Initial Approval	YES	NO	N/A	Comments
	Is the initial IRB approval letter on file? Is the initial stamped consent form on file? Is the original HIPAA form (or waiver of authorization) on file?				

2.2	Continuing Review	Date submitted	Date approved	IRB approval letter on file
	Number of Continuing Reviews (CR)? (____)			

		YES	NO	Unknown	Comments
	Was each CR submitted on time?				
	Was there any lapsed period(s) between approval date and expiration date?				
	Was any subject enrolled during this lapsed period?				
	Have all subject withdrawals or drop-outs been reported to the IRB?				

2.3	Amendments	Date submitted	Date approved	What was amended?	IRB approval letter on file
	Number of Amendments? (__0___) Have there been any sponsor-approved protocol revisions? If yes, has an amendment been submitted to the IRB?				

2.4	Advertisements	YES	NO	N/A	Comments
	Was advertising used to recruit subjects? Was IRB approval obtained?				

2.5	Reportable New Information & Other IRB Notifications	Date submitted	IRB approval letter on file		N/A
	Number of Reportable New Information (RNI) reported to IRB ? (___)		YES	NO	
	Number of other IRB Notifications reported to the IRB? (e.g. waivers) (___)		YES	NO	

3. INFORMED CONSENT PROCESS

		Version #	Approval date	Expiration date
3.1	How many versions of the consent form are there? (____) Number of consent forms that were reviewed : (_____)			

		YES	NO	Comments
3.2	Were all consent forms that were used valid? If no, was a RNI report submitted to the IRB?			
3.3	Did each subject **sign** his/her own consent form?			

3.4	Did each subject **date** his/her own consent form?			
3.5	Did the person obtaining consent sign each consent form?			
3.6	Did the person obtaining consent date each consent form?			
3.7	Were all study team members who signed the consent forms approved by the IRB to obtain informed consent? If no, was a RNI report submitted to the IRB?			
3.8	Is there a note to file to document consent process?			
3.9	Is receipt of the consent form documented?			
3.10	Is the approved HIPAA form being signed & dated?			
3.11	Was informed consent obtained from each subject prior to the start of any study procedure(s), including screening procedures to determine eligibility?			
3.12	Is the consent form on file for each subject the *original* signed and dated version (not a photocopy)?			
3.13	Are all pages of the consent form on file for each subject?			
3.14	Are all yes/no or similar options on the consent form completed/initialed for all subjects?			

4. SUBJECT SELECTION/RECRUITMENT CRITERIA

		YES	NO	Comments
4.1	Is there an inclusion/exclusion criteria checklist?			
4.2	How many subjects were reviewed? (__0_) Did all subjects meet all criteria?			
	Subject #			
	Subject #			
	Subject #			
4.3	Were there any subject withdrawals?			
	Subject #			
	Subject #			
	Subject #			
4.4	Are recruitment methods described in the IRB approved protocol?			
4.5	Have all recruitment materials been approved by the IRB?			
4.6	Are all approved recruitment materials (original and all revisions) on file?			

4.7	Is a pre-screening telephone interview conducted? If yes, is the pre-screen form and phone script IRB approved?			

5. DRUG/DEVICE DISPENSING ACCOUNTABILITY (Not applicable for this study)

		Pharmacy	PI	Sponsor	Other	Comment
6.1	Who is responsible for randomization/registration?					
6.2	Where and how is study agent stored?					
6.3	Who is responsible for shipping? Who is responsible for receiving? Are there shipping receipts?					
6.4	Who is responsible for drug/device administering to the subject?					

		YES	NO	N/A	Comment
6.5	Is there a dispensing drug/device log? Where is it kept?				
6.6	Is there documentation of return or destruction of drug/device?				
6.7	If the study site is responsible for drug/device, were the following procedures performed? Temperature log Locked, secured area Limited staff access				

6. CASE REPORT FORM (CRF) DATA SOURCE DOCUMENTATION (SD)

		YES	NO	N/A	Comments
7.1	Are there CRFs?				Subject records not reviewed
7.2	Are CRF's and source documentation consistent for each subject?				
7.3	Are all of the protocol-required parameters captured in the CRF/SD?				
7.4	Are all changes/cross-outs initialed and dated in SD?				

8. RECORD KEEPING

		YES	NO	Comment
8.1	Is there a binder/folder of regulatory documents?			

8.2	Is there a binder/folder of IRB correspondence?			
8.3	Is there a study file for each subject?			Subject records not reviewed
8.4	Is access to onsite research records restricted?			
8.5	Is access to onsite research electronic records protected?			
8.6	Are portable devices used for data storage?			

9. ALLOCATION OF RESPONSIBILITIES

9.1	**Who prepares:**	**PI**	**Co-PI**	**Coordinator**	**Other**
	Progress reports/updates to the IRB?				
	SAE/AE reports?				

10 FOR SPONSOR-INVESTIGATORS ONLY (Not applicable to this study)

		YES	**NO**	**Comments**
10.1	Is the PI a *sponsor-investigator* (i.e. IND/IDE holder)?			
10.2	IND Exemption granted by the FDA? If no then are the following on file?			
10.3	*Original IND/IDE application* to the FDA			
10.4	FDA letter of no objection			
10.5	*Amendments* to the IND/IDE			
10.6	*Annual reports* to the IND/IDE			
10.7	*Safety reports*			
10.8	General correspondence with the FDA			
10.9	For IND studies, is there a *FDA 1571* on file to accompany all of the above FDA correspondence?			
10.10	For IND studies, note who is listed as the *monitor* in section 14 of the FDA form 1571. Is this person monitoring the study for subject safety and protocol adherence according to the *protocol's data and safety monitoring plan*?			
10.11	Were sponsors and/or Federal agencies (such as the FDA if the investigator is the IND or IDE holder) notified of AEs according to their requirements?			
10.12	Is the investigator responsible for monitoring his/her own investigator-initiated research?			

	Is there a Data Safety Monitoring Plan approved by the IRB? Was a summary of <u>all</u> adverse events submitted to the IRB with the continuing review applications?			

11. POST AUDIT DEBRIEF

Date of Debrief: **Follow-up audit scheduled:**
Recommendations of corrective actions: The following recommendations for corrective actions of the audit findings were reviewed with the investigator.