ATTACHMENT B

OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH
Review Questionnaire / Report Packet

Study Name_____

HSRC #_____ PI Name_____

Total # of subjects enrolled at time of review_____ Total # of subjects to be reviewed_____

_____ Expedited **_____Full Committee**

_____ Single Center **_____ Multi-center**

_____ Drug **_____ Device** **_____ Hybrid**

_____ Industry **_____ Federal** **_____ Investigator-Initiated**

Auditor's Name_____Date_____

Area of Review	Measure for Compliance	Yes	No	N/A	Comments (number consecutively)
External Monitoring	Sponsor monitored? Monitoring Log present?				
	Monitor Follow up letters reviewed?				
	Significant observations?				
	Is communication between the sponsor and research site on file?				
	EPIC access obtained for external monitor?				
Regulatory	Is there a Site maintained Regulatory File/Binder? Hard copies or electronic?				
HSRC	Is there a HSRC approved protocol (original and all revisions)?				
	Is there a HSRC approved consent form (original and all revisions)?				
	Did the protocol and informed consent receive initial approval before the study was initiated?				
	Are there approval documents from other required committees, i.e., HCMC Radiation Committee (original and all revisions)?				
	Are there HSRC approved recruiting materials (original and all revisions)?				
	Are all changes to the protocol, informed consent, and recruiting materials approved by the HSRC prior to implementation?				
	Is there an Investigator Brochure or Device Manual (original and all revisions)?				

	Are all HSRC renewals submitted in a timely fashion so that there is no lapse of approval?				
	Were any subjects enrolled if there was a lapse of approval?				
	Serious Adverse Events submitted per HSRC policy?				
	Unanticipated Problems submitted per HSRC policy?				
	External New Information submitted per HSRC policy?				
	Non-Compliance submitted per HSRC policy?				
	Are all submissions to and responses from the HSRC on file?				
	Are HSRC member lists on file for the duration of the study?				
	Is all relevant communication between the HSRC and research site on file?				
Personnel	Is there a signed FDA 1572 for IND studies (original and revisions as appropriate)?				
	Is there a signed Investigator Statement for IDE studies (original and revisions as appropriate)?				
	Is there a CV or relevant documents for all Investigators? Updated within the past 2 years? Signed and dated?				
	Valid licensure for each investigator/staff member on the 1572/Investigator Statement?				
	Is there a Delegation of Authority/Signature Log identifying all persons obtaining Informed Consent?				
	Is there a Delegation of Authority/Signature Log identifying all persons with delegated study-related responsibilities?				
	Has the HSRC been notified of all personnel changes?				
	Is there a current (and previous) Clinical Investigator Financial disclosure form on file for each investigator?				
	Is a Training Log maintained for study-specific training requirements?				
	Are all research support personnel compliant with HHRI's educational requirements?				
	Are research personnel able to locate Clinical Research SOPs?				
Laboratory	Is there an up to date laboratory certification?				
	Is there a copy of normal laboratory values?				
Subjects	Is there a screening/enrollment log?				
	Are subject records maintained appropriately to protect subject confidentiality?				
Investigational Product	Is the test article properly stored?				
	Is there a dispensing log?				

	Are there decoding procedures for blinded trials?				
	For marketed products, is there a package insert/product information?				

COMMENTS

HSRC #_____ Subject Study #_____

Auditor's Name_____Date_____

Area of Review	Measure for Compliance	Yes	No	N/A	Comments (number consecutively)
Informed Consent	Is the correct consent form being used?				
	Was consent obtained prior to any study procedures?				
	Did the subject/legal representative sign the consent?				
	Did the person obtaining consent sign the consent?				
	Does the study site have the original signed consent?				
	Is a copy of the consent in the medical record and/or study file?				
	Did the subject receive a copy of the consent?				
	Is there documentation in the medical record and/or study file documenting the consent process?				
	Are subjects re-consented on an updated consent if necessary?				
Subject Management	Was an FYI, if applicable, created in EPIC re: Study Participation?				
	Was FYI inactivated when no longer applicable?				
	Is there an eligibility criteria checklist dated and signed/initialed by person determining eligibility?				
	Were significant observations/deviations noted by sponsor monitor?				
	Are missing data, visits, examinations, and lab tests documented and explained?				
	Is there documentation in the medical record and/or study file of oversight by the Principal Investigator?				
Serious or Unanticipated Adverse Events	Are SAEs and/or UAEs reported to the HSRC and sponsor in accordance with regulatory regulations?				
	Is documentation in the medical record and/or study file documenting subject discontinuation due to SAEs and/or UAEs?				
Protocol Violations	Are major protocol violations reported to the HSRC? (i.e. erroneous inclusion, erroneous investigational product assignment, overdose)				
Source Documents and CRFs	Does the medical record and/or study file contain documentation of subject enrollment into the study?				
	Does the medical record and/or study file contain documentation of exposure to the investigational product?				
	Are Source Document corrections and clarifications made correctly?				

	Are CRFs electronic or paper?				

COMMENTS

Area of Review	Subject ID #	Preliminary Finding	Recommendations or How Resolved by Study team	Date PI Notified	Date and Method of Resolution

Signature of Auditor_____ **Date**_____