BCM
Baylor College of Medicine

Research Compliance Services
ACTIVE QUALITY ASSURANCE PROGRAM

TEMPLATE FOR SELF-ASSESSMENT

For Assistance, please call Research Compliance Services at (713) 798-6970

Regulatory Documentation Review				
General Review				
	Elements Reviewed	**YES**	**NO**	**N/A**
A.	Approved protocol present?	☐	☐	☐
B.	Signed investigator agreement present?	☐	☐	☐
C.	Are PI & Co-Investigator(s) CV's present?	☐	☐	☐
D.	Are PI & Co-Investigator(s) CV's **signed and dated**?	☐	☐	☐
E.	Are PI & Co-Investigator(s) licenses present?	☐	☐	☐
F.	Are all e-CAT certificates present?	☐	☐	☐
G.	Is documentation of communication with sponsor adequate?	☐	☐	☐
H.	Is documentation of communication with FDA adequate?			
I.	Is signature list of research staff present?	☐	☐	☐
J.	Investigator brochure or device manual present? Version(s): _____	☐	☐	☐
K.	Are Monitoring reports present? Monitor/CRO:_____ Date(s): _____	☐	☐	☐
L.	Are copies of the current CLIA/CAP certification present?	☐	☐	☐
M.	Is range of the normal lab values present?	☐	☐	☐
N.	Was continuous IRB approval for the protocol maintained (no lapse)?	☐	☐	☐
O.	If a DSMB is required, is the charter present?	☐	☐	☐
P.	Is this a multi-center trial with BCM as the coordinating center?	☐	☐	☐

	1. If so, is all appropriate documentation present?	☐	☐	☐
	2. Is communication with other sites adequate?	☐	☐	☐
	3. Are approvals from all sites on file?	☐	☐	☐

Notes:

IRB Submission and Approval

	Elements Reviewed	YES	NO	N/A
A.	Have all annual renewals been submitted to the IRB?	☐	☐	☐
B.	Have all amendments been submitted to the IRB?	☐	☐	☐
C.	Has the sponsor protocol or grant been submitted to the IRB?	☐	☐	☐
D.	Has most recent Investigator Brochure been submitted to the IRB?	☐	☐	☐
E.	Have all DSMB reports been submitted to the IRB?	☐	☐	☐
F.	Have all safety reports been submitted to the IRB?	☐	☐	☐
G.	Have all unanticipated problems involving risks to subjects or others (UPIRSOs) been submitted to the IRB within 5 working days?	☐	☐	☐
H.	Have all other adverse events been submitted to the IRB according to the approved data safety monitoring plan?	☐	☐	☐
I.	Have all deviations been submitted to the IRB?	☐	☐	☐
J.	Has a summary of all monitoring reports been submitted to the IRB at time of continuing review?	☐	☐	☐
K.	Are all advertisements IRB approved?	☐	☐	☐

Informed Consent

	Elements Reviewed	YES	NO	N/A
A.	Are copies of all original IRB-approved consents present? Current version dated _____	☐	☐	☐
B.	Has the IRB approved any translated consent forms? If yes, what language(s): _____	☐	☐	☐
	1. Is a short form approved for use?	☐	☐	☐
	2. Is an approved short form summary present?	☐	☐	☐
C.	Has the informed consent form been revised appropriately when amendments have been submitted?	☐	☐	☐

Drug Research

	Elements Reviewed	YES	NO	N/A
A.	Are there written procedures for dispensing study drug?	☐	☐	☐
B.	Are the procedures being followed?	☐	☐	☐

C.	Is a Research pharmacy being utilized? 1. Which one?	☐	☐	☐
D.	Is there documentation that the study drug is stored at the correct temperature?	☐	☐	☐
E.	Is access to study drugs restricted?	☐	☐	☐
F.	Do the investigational records demonstrate full accounting for study drug received?	☐	☐	☐
	1. Are shipping receipts available for review?	☐	☐	☐
G.	Isa study drug dispensing log maintained and up to date?	☐	☐	☐
H.	Were all unused drugs returned to the sponsor?	☐	☐	☐
	1. Are shipping receipts available for review?	☐	☐	☐
I.	Signed FDA 1572 (IND only) present?	☐	☐	☐
J.	Original signed 1571 (IND - Sponsor) present?	☐	☐	☐
	1. All revisions on file?	☐	☐	☐
Notes:				

Device Research

	Elements Reviewed	**YES**	**NO**	**N/A**
A.	Are there procedures for dispensing study device?	☐	☐	☐
B.	Are the procedures being followed?	☐	☐	☐
C.	Is access to study devices restricted?	☐	☐	☐
D.	Do the investigational records demonstrate full accounting for study devices received?	☐	☐	☐
	1. Are shipping receipts available for review?	☐	☐	☐
E.	Is a study device dispensing log maintained and up to date?	☐	☐	☐
F.	Were all unused devices returned to the sponsor? Are there shipping receipts?	☐	☐	☐
G.	Is Investigator Agreement (Device only) present?	☐	☐	☐
H.	Is IDE application filed with FDA (copy present)?	☐	☐	☐
Notes:				

Serious Adverse Events/Unanticipated Problems				
	Elements Reviewed			
A.	# of Serious Adverse Events (SAEs): and/or unanticipated problems involving risks to subjects or others (UPIRSOs): _____			
B.	Were all SAE's/UPIRSOs reported to the sponsor per data safety monitoring plan?	☐	☐	☐
C.	In light of any SAE's/UPIRSOs, are risks appropriately represented in the consent form?	☐	☐	☐
Notes:				

Research Record Review

GENERAL REVIEW

NUMBER OF SUBJECT FILES REVIEWED (____/____)

	Elements Reviewed	YES	NO	N/A
A.	Is a separate study file maintained for each subject?	☐	☐	☐
B.	Are Case Report Forms filled out completely and appropriately, based on source documentation?	☐	☐	☐
C.	Does the source documentation for each subject include dated signature/initials of the person obtaining the information for each subject?	☐	☐	☐
D.	Is documentation consistent among subject files?	☐	☐	☐
E.	Are changes/corrections initialed and dated using **one line** to mark out the incorrect data in each subject file?	☐	☐	☐
F.	Were all research procedures conducted (enrollment, treatment, study visits, etc.) within protocol approval periods?	☐	☐	☐
G.	Are subject's records (paper and electronic) stored confidentially?	☐	☐	☐
H.	Is the informed consent process being conducted per the approved protocol?	☐	☐	☐
I.	Is the data safety plan being implemented per the approved protocol?	☐	☐	☐
Notes:				

Inclusion/Exclusion Criteria

	Elements Reviewed	YES	NO	N/A
A.	Is Inclusion / Exclusion criteria checklist present in each file (or clearly documented in CRF)?	☐	☐	☐
B.	Did subjects meet all criteria?	☐	☐	☐
	1. If not, did sponsor approve exceptions?	☐	☐	☐
C.	Is source documentation adequate (i.e. does it reflect the inclusion/exclusion criteria appropriately?)	☐	☐	☐

Informed Consent Number of informed consents reviewed (____/____)				
	Elements Reviewed	**YES**	**NO**	**N/A**
A.	Does approved staff obtain informed consent?	☐	☐	☐
B.	Is the consent obtained before the first research procedure for each subject?	☐	☐	☐
C.	Are subjects re-consented appropriately when necessary?	☐	☐	☐
D.	Did the subject sign the consent?	☐	☐	☐
E.	Did the investigator or designee sign the consent?	☐	☐	☐
F.	Did a witness sign the consent?	☐	☐	☐
G.	Is the consent process documented in the research records?	☐	☐	☐
H.	Is there an indication in the research record that a signed copy of the ICF was provided to the subject?	☐	☐	☐
I.	Is a short form used in subject's own language when appropriate?	☐	☐	☐
	Assent: If subjects are <18:			
	1. Are appropriate parental signatures obtained? (Risk levels 3 and 4 require the signatures of both parents, if reasonably available)	☐	☐	☐
	2. Is assent obtained from the child and documented in the research record?	☐	☐	☐
Notes:				

Revised 7/23/08