McLaren HEALTH CARE

Human Research Protection Program

QA/QI Review Self-Assessment

Instructions on Completing Self-Assessment:

This optional audit tool is designed for use by investigators and research staff to assess compliance with federal regulations and guidance's, MHC HRPP policies, ICH GCP guidelines and overall conduct of study activities. This audit tool follows the basic principles and procedures of a QA/QI audit as one would expect from an internal or external auditor.

This tool has six sections and three appendices. Not all sections of the checklist may apply to your study:

Section A: General Information
Section B: Essentials Documents & Record Keeping
Section C: Subjects and Subject Records
Section D: Reportable Events & Protocol Deviations
Section E: Data and Safety Monitoring
Section F: Investigational Product Accountability

Appendix A: Individual Subject Assessment
Appendix B: Sponsor-Investigator Additional Assessment
Appendix C: Corrective Action Preventative Action Worksheet

If using this checklist shows that non-compliance has occurred, it should be promptly corrected. Consider sponsor and IRB reporting requirements for protocol deviations/violations and/or non-compliance and submit reports accordingly. Address significant or repeated issues of non-compliance with a written corrective and preventative action (CAPA) plan.

For studies that enroll a large number of subjects, it may not be practical to audit every subject. A predetermined sample number can be used in these cases. Once the self-assessment review checklist has been completed, it is a good idea to share the findings with your entire study team, including clinical investigator. Keep the checklist as evidence of your self-assessment, which supports the overall conduct of the study and the oversight of the PI and study team.

The EQuIP office is available to assist research teams and discuss your checklist findings.

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A. General Information					
Principal Investigator				Protocol Number	
Study Title					
Investigator- Initiated Study: □ Yes □ No					
Study Start Date		Date of QA/QI Self-Assessment		Study Status: Enrollment □ open □ closed Enrollment goal_____ Number enrolled _____ Completed _____ Withdrawn _____ LTF_____	
Study Team Member(s) performing self-assessment:					

B. Essential Documents & Record Keeping: Essential documents serve to demonstrate the compliance of the clinical investigator. Depending on the type of study and sponsor, different regulatory documents are required. This section is consistent with Good Clinical Practice guidelines, FDA regulations and MHC HRPP Institutional Policy. Review you study's regulatory documents to complete this section. It is best practice to organize documents into binders.

Quality Indicators		Yes	No	NA
Consents, Protocol, HIPAA				
B1	Is the most recent IRB approved version of the *protocol* on file?			
B2	Are previous IRB approved versions of the *protocol* included in the file?			
B3	Is the most recent IRB approved version of the all *ICFs/Assents* on file?			
B4	Are previous IRB approved versions of all *ICFs/Assents* included in the file?			
B5	Is there a current Research *HIPAA authorization document* (inclusive or exclusive to the informed consent)?			
B6	Have there been any amendments to the HIPAA authorization document?			
B7	Are all *investigator brochures*, *package insert and/or device manual* version present?			
B8	Has the IRB been submitted the most current version *of IB, manual, ICFs/Assents, protocol*?			
B9	Were *all modifications/amendments* approved by the IRB prior to implementation?			
B10	Has the study maintained *continuous active IRB approval*?			
	• If no, during the *lapse* or prior to approval did any of the following activities occur? Check all that apply: □ Recruitment □ Informed Consent Process □ Enrollment □ Data Collection			
Contracts/Agreements				
B11	Are all applicable signed agreements/contracts between parties on file (e.g. between PI and sponsor; between PI and CRO, protocol signature page)?			
B12	Has the PI/sub-I signed the sponsor conflict of interest form/financial disclosure (in addition to IRB forms)?			
B13	Are there copies of all signed versions of the Form FDA 1572 (drug or biologic) or investigator Agreement (device)?			
B14	Were all the appropriate investigators listed on the 1572/Investigator Agreement?			
Correspondences, Advertisements, Recruitment				
B15	Are all IRB approval letters/correspondences (initial, amendments, reports, continuing			

	review and reportable events) present?			
Quality Indicators		**Yes**	**No**	**NA**
B16	Are all correspondences to and from sponsor on file?			
B17	Does the study files include all FDA correspondences?			
B18	Are all IRB approved study advertisements present?			
B19	Were there changes to the research without IRB approval?			
B20	Do the files contain any documents requiring IRB approval that werenot approved by the IRB?			
B21	Are copies of most recently approved case report forms (CRF) on file?			
B22	Are copies of all previous versions of case report forms (CRF) on file?			
B23	Were blank copies of all versions of case report forms (CRF) submitted to the IRB?			
Study Staff				
B24	Is there a delegation of duty/staff signature log?			
	• Is every person working on study listed?			
	• Are responsibilities assigned to each person appropriate in terms of that person's licensure, training and qualifications?			
	• Is each entry up-to-date with start date (and stop date if applicable)?			
	• Has the PI signed the delegation log with each update?			
	• Does all study staff have IRB approval to participate?			
	• Is CITI certification current for all study team members?			
B25	Do the investigators have active COI training certification?			
B26	Is there documentation of all required study-specific training for all study staff prior to start of study?			
B27	Do you have documentation that each study team member has completed subsequent study specific training?			
B28	Are there licenses covering dates of the research for all investigators MD or DO, Research Nurses, etc. listed on the 1572/Investigator Agreement?			
B29	Are there CVs of PI/Sub-I and all study staff on file?			
	If yes, are they updated within the past 2 years?			
	If yes, are they signed and dated?			
Biological Sampling and Shipping ☐ **NA**				
B30	What types of biological samples are collected as part of this study?			
B31	Whose is responsible for packing/sending/shipping samples?	☐ Study Coordinator/Research Nurse ☐ Investigator ☐ Lab department ☐ Other		
B32	Is there documentation of IATA training for all study staff who package and ship biological material?			
B33	Is there documentation of CLIA certification on file?			
B34	Is there documentation of College of American Pathologist certification?			
B35	Is there documentation of normal range values of medical/laboratory/technical procedures present?			
B36	Is the lab director's CV on file?			
Record Keeping				
B37	Are all regulatory documents kept in an appropriate and secure place?			
	• Do file cabinets have locks?			
	• Are the doors locked?			
	• Are computers password protected?			

Quality Indicators		Yes	No	NA
B38	Are all research documents organized in chronologic reverse order and are complete?			
B39	Do you keep a study file for each subject?			
B40	Have there been any disclosures of confidential information in this study?			
B41	Does sponsor, CRO or other external organization monitor the study on regular basis?			
B42	Is there a monitoring log documenting the dates of the monitoring visits?			
B43	Are copies of site visit (external) monitoring reports on file?			
B44	Has all monitoring queries/finds been addressed and corrected?			
B45	Are all monitoring reports included in files?			
B46	Is there documentation of validation or calibration test methods? (e.g. stadiometer, scale calibration, refrigerator, EKG machine, etc.)			
Subject Recruitment and Subject Education				
B47	Is the study registered with clinicaltrials.gov			
B48	Is there an enrollment/screening log and if yes, it is completed and up-to-date?			
B49	Are all recruitment methods utilized IRB approved? • How are subjects identified: □ investigator referral, □ medical chart review □ clinical database □ subject response to recruiting material • What recruitment measures are used? □ posted advertisement □ flyers □ radio/newspaper □ letters □ none			
B50	Is a pre-screening telephone interview conducted using a script? • If yes, was the script IRB approved?			
B51	Are all educational/recruitment), original and amended material supplied to subjects IRB approved?			

C. Subjects and Subject Records Randomly choose the number of at least 10% of the total number of subjects enrolled to audit or 2 charts, whichever is greater. Randomly pull the number of subject charts for review. Make as many copies of appendix A as needed. You may decide to review 100% subject *ICFs/Assents* and 10% or more of the entire subject research chart.

Quality Indicator		Yes	No	NA
C1	IRB approved subject enrollment number _____ Number of subject who signed consent/screened _____ Number of subjects enrollment/randomized _____ • Has study enrollment been less than or equal to the number approved by the IRB?			
Consenting of Subjects				
C2	Is there an original signed/dated informed consent document on file for each subject?			
C3	If subjects withdrew, were these withdrawals reported to the IRB at continuing review?			
C4	If the IRB or sponsor required re-consent of subjects, were all subjects appropriately re-consented?			
C5	Were any invalid *ICFs/Assents* used to consent subjects?			
	• Was the IRB notified?			
	• Is there a timeline when the subject(s) should re-consent?			
	• Did the subject(s) re-consent?			

Quality Indicator	Yes	No	NA

C6	Since study commenced, list all *ICFs/Assents* and versions associated with this study: □ Genetic: version _____ approval _____ to _____ □ HIPAA: version _____ approval _____ to _____ □ Main ICF: version _____ approval _____ to _____ version _____ approval _____ to _____ version _____ approval _____ to _____ version _____ approval _____ to _____ □ Other:

Enrollment of Subjects				
C7	For subjects who did not meet eligibility criteria (screen failures), is there documentation in the record of why they were not eligible?			
C8	For subjects who did not meet eligibility criteria but who were enrolled in the study, was a request for waiver/exceptions to continue subject in study obtained from the sponsor?			
C9	Individual Subject chart reviewed for completeness (use Appendix A attachment) No. of subjects audited? →			

D. Reportable Events & Protocol Deviations				
Quality Indicator		**Yes**	**No**	**NA**
D1	Is there documentation of review, grade, and attribution of adverse events by the PI or other qualified study team member?			
D2	Were all AE/SAE/UPIRSO appropriately reported to the Sponsor and/or FDA (where applicable)?			
D3	Have all AE/SAE/UPIRSO that require prompt reporting been reported to the IRB?			
D4	Have all events that require periodic reporting been reported at the time of continuing review?			
D5	Have all protocol deviations/violations been reported appropriately to the sponsor as required by the sponsor?			
D6	Have all protocol deviations/violations meeting the IRB's reporting criteria for deviations been reported to the IRB?			
D7	Were any waivers/exceptions for protocol deviation obtained from the sponsor?			
	• If yes, were they reported to the IRB?			
D8	Did the Sponsor's monitoring reports reveal any significant non-compliance issues?			
D9	Did the monitoring reports reveal any patterns of ongoing or unresolved non-compliance?			
D10	Did the sponsor take action in response to non-compliance?			
D11	Have all instances of noncompliance been reported to the sponsor, as required by the sponsor?			

E. Data and Safety Monitoring				
Quality Indicator		**Yes**	**No**	**NA**
E1	Is there a data safety monitoring board (DSMB) or DMC for this study?			
E2	Has the data and safety monitoring board (DSMB) or equivalent met in accordance with the IRB approved data and safety monitoring plan?			
Quality Indicator		**Yes**	**No**	**NA**

E3	Are all DSMB reports or indication of DSMB review and recommendations on file?			
E4	Were all the DSMB/DSMC reports submitted to the IRB appropriately?			
E5	Is this a NIH funded study?			
	• Were all the NIH progress reports submitted to the IRB appropriately?			

F. Investigational Product Accountability					
Quality Indicator			**Yes**	**No**	**NA**
F1	Are there emergency "unblinding" mechanisms in place?				
F2	Are shipping /receiving receipts on file?				
F3	Was the investigational product handled and stored according to instructions? □ Temperature logs □ Locked secured area □ Limited staff access				
F4	If a device study, was the *device* kept in a secure place and labeled investigational?				
F5	Was the *device* maintained and dispensed in accordance with the IRB approved plan for device maintenance?				
F6	Is there documentation for the return of *drug/device* by subject?				
F7	Is there a receiving, dispensing and accountability log maintained?				
F8	Who is responsible for shipping and receiving?	□ Study Coordinator □ Research Nurse □ Investigator □ Research Pharmacy □ na □ Other			
F9	Who dispenses drug to subject?	□ Study Coordinator □ Research Nurse □ Investigator □ Research Pharmacy □ na □ Other			
F10	Who administers drug to subject?	□ Study Coordinator □ Research Nurse □ Investigator □ Research Pharmacy □ na □ Subject □ Other			
F11	Have there been any drug/device related errors to date?				

Summary: Explanation/Comments/ (Address all "no" responses)

Recommendations for Improvement or CAPA Plan

Plan for next follow-up review

Subject ID:				
Consenting Process				
Quality Indicator		**Yes**	**No**	**NA**
C10	What is the date subject signed initially sign *ICFs/Assents* to participate in research trial?			
C11	Did the subject sign all the applicable and valid IRB approved *ICFs/Assents*? Comments:			
C12	Is there an original copy (ies) of all applicable IRB approved valid *ICFs/Assents* form?			
C13	Did subject personally sign all applicable IRB approved valid *ICFs/Assents*?			
C14	Did subject personally date all applicable IRB approved valid *ICFs/Assents*?			
C15	Did subject personally initial are applicable pages of IRB approved valid *ICFs/Assents*?			
C16	Did the subject sign *ICFs/Assents* prior to research interventions?			
C17	Did the subject give written HIPAA authorization by signing and dating the IRB acknowledged research HIPAA authorization form? (consented on or after April 14, 2003)			
C18	Did the person who conducted the consent discussion and signed the *ICFs/Assents* document have IRB approval to participate in this study?			
C19	Did the consenter print, sign and date all applicable *ICFs/Assents*?			
C20	Is there documentation of the *ICFs/Assents* process in the research record, including receiving a copy of the signed and dated *ICFs/Assents* form, etc.?			
C21	As informed consent is an ongoing process, is there documentation (e.g. notes or re-consent when applicable) of the subject's willingness to continue,			
C22	If the subject requested their primary physician be notified of their participation in the research study, is there a copy of the letter in the subject's research records?			
C23	Did the *ICFs/Assents* forms contain signature line for witness?			
	• Did a witness sign the *ICFs/Assents*?			
	• Did the witness meet criteria as a witness according to HRPP policy?			
C24	Did the subject require an authorized legal representative (LAR)?			
	• Did the legal authorized representative meet criteria according to HRPP policy?			
	• Did the LAR sign, date and initial pages?			
C25	Is this subject a minor?			
	• Was consent from parent(s)/guardian obtained according to HRPP policy or approval?			
	• Was assent obtained according to HRPP policy or approval?			
C26	Are the *ICFs/Assents* documents free of any handwritten changes, additions that modify the content of the approved document?			
C27	Did subject and consenter date *ICFs/Assents* on same day? (If no, note-to-file to explain discrepancy)			
Quality Indicator		**Yes**	**No**	**NA**
C28	Did the subject speak English?			
	• If no, was a translated *ICFs/Assents* form or short form, along with translator			

	utilized?			
C29	Are all the *yes/no* or *choice of options* on the *ICFs/Assents* form answered by subjects?			
C30	Did subject's primary physician get informed by letter that his or her patient was participating in a research trial? (letter should be filed in subject study files)			
Documentation and Data Collection				
C31	For each visit, are all data points collected?			
	• For missing data points, is there a note of "NA" or other explanation?			
C32	Have errors in transcription been corrected properly? (one line, date and initials, no scribbles or white out)			
C33	Overall, the documentation adheres to the "ALCOA" standard. (Study data **A**ttributable, to the person collecting and recording the data, **L**egible, **C**ontemporaneous (dated and signed/initiated at the same time it was collected or assessed), **O**riginal and **A**ccurate)			
C34	Do the source documentation/CRFs/worksheets for each subject include dated signature/initials of person obtaining the information for each subject?			
C35	Is the research file organized?			
C36	If source verification was performed, was the data accurately recorded on the case report forms?			
Protocol Adherence				
C37	Is there source documentation to support that all procedures/tests were completed per protocol?			
C38	Is there documentation that all labs, EKGs, reports, etc. had been evaluated by the investigator or other qualified research team member within sponsor/department SOP?			
C39	If a procedure was missed, was the reason appropriately documented (annotation or note-to-file, dated in real-time) and reported to sponsor and IRB as applicable?			
C40	Any protocol deviation not already noted as such and has been reported to sponsor and IRB as applicable?			
C41	Was there documentation to support that all biologic samples were obtained and stored appropriately?			
C42	Did all the subject visits occur within window?			
	• If no, is there note of explanation?			
	• If no, was the sponsor or IRB notified per reporting requirements?			
C43	Is this subject participating in genetic research?			
	• Did subject sign IRB approved *ICFs/Assents*?			
	• If yes, were samples coded/de-identified and protocol procedures followed?			
Supplemental Data				
C44	Is there a concomitant medication form maintained for the subject?			
	• If yes, has the form been updated throughout the study?			
Treatment				
C45	Did the subject take any protocol-prohibited medication during the study?			
C46	Was the subject dosed/treated according to protocol (compliance)?			
C47	Was the drug or device dispensed according to the protocol?			
C48	Did subject complete drug diary or event diary for study?			
C49	Was the correct dose/treatment schedule followed by patient?			
Quality Indicator		**Yes**	**No**	**NA**
C50	If the subject is non-compliant according sponsor protocol, is there documentation of			

	sponsor notification and counseling/education of the subject?			
C51	Is study drug dispensation and returned documented on accountability log?			
Adverse Events				
C52	Was there documentation of prompt review of all adverse events by the PI or other qualified study team member?			
C53	Was there documentation of type, grade, and attribution an dates/duration for all adverse events?			
C54	Have all adverse events/unanticipated problems been captured and reported according to sponsor and IRB?			

(Investigator Initiated Studies)

G. Investigator-Sponsor Investigators conducting studies under Investigational New Drug (IND) or Investigational Device Exemption (IDE) are required to maintain additional regulatory documentation.				
Quality Indicator		**Yes**	**No**	**NA**
G1	Is the PI a sponsor-investigator (IND/IDE holder)			
G2	If yes, is the following on file:			
	• Original IND/IDE application and supporting documents to the FDA?			
	• FDA letter of "no objection"			
	• Amendments to the IND/IDE			
	• Annual reports to the IND/IDE?			
	• Safety reports?			
	• All general correspondence to and from the FDA?			
Drug Trials				
G3	For IND studies, is there a signed FDA 1571 on file to accompany all of the above FDA correspondence?			
G4	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?			
G5	Have annual IND progress reports been submitted to the FDA?			
G6	Have annual IND progress reports been included with continuing review submission to IRB?			
G7	Is there a plan for regularly reviewing and analyzing safety information regarding the test article from other studies and reporting the results of such review to the FDA in accordance with FDA reporting requirements?			
G8	Is there a process for preparing IND safety reports and submitting the reports to the FDA?			
G9	Is there a Form FDA 1572/Investigator Agreement, signed by each investigator?			
G10	Is there a financial disclosure statement for each investigator?			
G11	Have all investigators been provided a copy of the Investigational Brochure/Investigational Plan?			
G12	Have all regulations been followed to ensure the safe receipt, labeling, disposition, and return of investigation drugs/devices?			
G13	Have all participating investigators been advised as to reporting requirements for serious adverse events, study endpoints and non-serious adverse events?			
G14	Is there a system for reviewing and analyzing the information received from these investigator reports to determine whether they warrant an IND safety report?			
G14	Is there a system for providing IND safety reports to the FDA and to participating investigators and communicating to participating investigators and other safety information?			

Quality Indicator	**Yes**	**No**	**NA**

Device Trials				
G16	Is there an IDE application that contains all the required elements?			
G17	Who is the monitor for this study? _____ • Is this person/entity actively monitoring the conduct and progress of the study?			
G18	Have the following reports been submitted:			
G19	a. Current investigator list (to be submitted every 6 months) – submit to the FDA			
G20	b. Progress reports (to be submitted at regular interval, no less than yearly) – submit to reviewing IRB and for significant risk device to the FDA?			
G21	c. Final report for significant risk devices (to be submitted 6 months after termination or completion of investigation) – submit to FDA, reviewing IRBs and participating investigators?			
G22	Is there a plan for regularly reviewing and evaluating unanticipated adverse device effects reports regarding the test article and reporting the results of the evaluation to the FDA, reviewing IRB and participating investigators?			
G23	Is there an Investigator Agreement, signed by each investigator?			
G24	Is there a financial disclosure statement for each investigator?			
G25	Have all investigators been provided a copy of the investigational plan?			
G26	Have all regulations been followed to ensure the safe receipt, labeling, disposition, and return of investigational devices?			

Date CAPA opened_____ Date CAPA closed_____

Category/Area:				
Observations:				
Root Cause Analysis:				
Corrective action(s): (Include applicable supporting document i.e. training log, note-to-file, policy, etc.)				
Action:		Assigned Study Personnel	Planned Completion Date	Actual Completion Date
1.				
2.				
3.				
4.				
MHC HRPP Policies, Federal Regulations, Other Applicable Policies:				
Preventative actions to prevent reoccurrence :				
Follow-up Evaluation				

Principal Investigator_____ Date _____