McLaren HEALTH CARE

Modification Request Form
When Using an External IRB as an IRB of Record

This form is to be used by Karmanos investigators requesting changes to research personnel, conflicts of interest, and/or McLaren sites/departments when using an external IRB as an IRB of Record. Please submit this completed form, along with the required attachments, to the MHC IRB at hrpp@mclaren.org. (Please see SOP: MHC_RP0128_Relying on an External IRB as an IRB of Record) *If this modification request is approved, the Corporate HRPP will provide a letter. The letter must be included with your submission to the external IRB of Record.*

Study Title	

External IRB Information			
Name			
Contact Name	**Email**	**Phone**	**FAX**
Mailing Address			
☐ No ☐ Yes	Has this project been approved to be submitted to the external IRB? (please include a copy of the Corporate HRPP approval letter).		

MHC Principal Investigator (PI)		
Name of Principal Investigator	**Degree (e.g. MD, DO, PhD, RN)**	**Title**
Email	**Phone**	**FAX**
Institutional Affiliation		

Form Completed by		
Name	**Title**	
Email	**Phone**	**FAX**

Study Status: Check one descriptor that applies to status of the study.	
	Study involves only the review/use of data, documents, records, or specimens (i.e. no subject enrollment; Active for data collection).
	Study is open to enrollment.
	Closed to enrollment: In data collection only.
	Closed to enrollment: In data analysis only.
	Not begun.
	On Hold. Please explain:
	Humanitarian Use Devise
	Other: Specify

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Modifications Requested: Check all that apply.	
	A. Change in Study Personnel (**Note: If you are making changes to personnel, please review the potential conflict of interest page and complete**).
	B. Change in Conflict of Interest (COI)
	C. Change in Study Sites/Departments
	D. Change in HIPAA (HIPAA Authorization and/or Request for HIPAA Waiver/Alteration)
	E. Other Important Information (i.e. Local context changes to ICF)

Principal Investigator to be added

Name of Principal Investigator	**Degree (e.g. MD, DO, PhD, RN)**	**Title**	
Email	**Phone**	**FAX**	
Specialty	**Pager Number**	**Mailing Address**	
Study Role: Select all that apply. ☐ Study-related Procedures ☐ Obtaining Consent ☐ Submitting Forms			
Institutional Affiliation		**CITI (date) ****	**COI (date)****

A. CHANGE IN STUDY PERSONNEL

Study Personnel to be added: Please list all changes.

Name	**Title**	**Study Role(s): List all that Apply (i.e. 1,2,3,4,5)**	**CITI ** (date)**	**COI ** (date)**
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other			
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other			
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other			
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other			
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other			
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other			
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other			

Titles: **Co/Sub-I** (Co/Sub-Investigator) **AA** (Academic Advisor) **SC** (Study Coordinator) **Reg** (Regulatory Specialist) **Other**

Study Roles: **1.** Study-related Procedures **2.** Obtaining Consent **3.** Submitting Forms **4.** Regulatory Activities **5.** Supervising Research Activities

** Completion of the COI (Conflict of Interest) course in CITI is required for all Investigators and Academic Advisors.

Principal Investigator and/or Study Personnel to be removed: Please list all changes, including title of the personnel.	
Name	**Title**
	☐ PI ☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other
	☐ Co/Sub-I ☐ AA ☐ SC ☐ Reg ☐ Other

B. CONFLICT OF INTEREST

Potential Conflict of Interest

Policy Statement: McLaren recognizes that collaboration of principal investigators, sub-investigators, and other study personnel with drug, medical device, and biologic manufacturers is essential to the production of effective and efficient research and the development of improvements in patient care. However, such collaboration may give rise to actual, potential, and perceived conflicts of interest for clinical researchers. Conflicts of interest in the research setting may create professional bias, potentially impacting the selection of research subjects; the collection, analysis, and interpretation of research data; reporting of adverse events; and publication of research results.

Definitions

Conflict of Interest (COI): A conflict of interest exists when an investigator's or another research team member's financial, personal or professional interests would potentially or actually compromise his or her professional judgment in conducting or reporting research, OR may be perceived as compromising the investigator or other research team member's professional judgment in conducting or reporting research. Financial, personal or professional interests include not only the research team member's own interests, but also those of his or her immediate family (see definition of "immediate family member" below), if the person has actual knowledge of the family member's financial, personal or professional interests.

Significant Financial Interest: Salaries, royalties and other payments for services (e.g., consulting fees, honoraria, research design, management position, independent contractor, service on advisory or review committees, board membership, seminars, lectures or teaching engagements when totaled together exceed $5,000 during the previous 12 months or are expected to exceed $5,000 over the next 12 months). Any ownership interests including stocks, bonds, or stock options that exceed $5,000 and/or that constitute more than a five percent (5%) ownership interest in a single organization. This does not include any interests held solely by reason of investment in a business by a mutual, pension or other institutional investment fund over which the research personnel or immediate family members do not exercise day-to-day control of investment decisions.

Research Personnel: Investigator, co-investigator, study coordinator or any other personnel involved in the design, conduct, or reporting of the research project.

Immediate Family Member: Those with whom a Covered Individual is related by blood, law (e.g., adoption or guardianship), or marriage and others with whom the Covered Individual resides including but not limited to the following: spouse, domestic partner, parent, child, stepchild, sibling, grandparent, grandchild, or in-laws.

Financial conflict of interests

Are any of the following true for the PI, PI's immediate family (spouse and dependent children), the research personnel, or the research personnel's immediate family?

☐ **No, none of the following are true.**
☐ **Yes, one or more of the following are true (Check all that apply and then complete a separate Financial Interest Disclosure Form for each individual with a financial interest)**

☐ Has a financial interest in the research with value that cannot be readily determined (for example, stock that is not publicly traded);
☐ Has a financial interest in the research with value that exceeds $5,000.00 other than payments for conducting the trial as outlined in the clinical trials agreement;
☐ Has a financial interest in the research with value that exceeds 5% ownership;
☐ Has received or will receive compensation with value that may be affected by the outcome of the study;
☐ Has proprietary interest in the research, such as a patent, trademark, copyright, or licensing agreement
☐ Has received or will receive payments other than payment for conduct of the clinical research from the sponsor that exceeds $5,000.00 in the last 365 days;
☐ Is an employee of the agency or company sponsoring the research;
☐ Is on the board of directors of the sponsor;
☐ Has a financial interest that requires disclosure to the sponsor or funding source; or
☐ Has any other financial interest that the investigator believes may interfere with his or her ability to protect subjects.
☐ Is affiliated with an institution with a lower conflict of interest threshold than the amounts referenced above.

Please complete a separate Financial Interest Disclosure Form for each individual with a financial interest.

Applications may be submitted to the external IRB while the COI and Research Committee review of Financial Conflict of Interest is pending.

By submitting the above COI page, you, as the PI, are attesting that you will update this COI page when new or changes in conflicts of interest arise, and that you will comply with any conflict management plan required by the Conflict of Interest Committee (COIC) and/or Institutional Review Board (IRB) to manage, reduce, or eliminate any actual or potential conflict of interest for the duration of the research.

C. CHANGE IN MCLAREN STUDY SITES AND/OR DEPARTMENTS

Please check all changes that apply:

___Added _____Removed……McLaren Bay Region
___Added _____Removed……McLaren Bay Special Care
___Added _____Removed……Karmanos Cancer Institute:

sites located in:_____

_____

___Added _____Removed……McLaren Central Michigan
___Added _____Removed……McLaren Flint
___Added _____Removed……McLaren Greater Lansing
___Added _____Removed……McLaren Health Care Village at Clarkston
___Added _____Removed……McLaren Macomb
___Added _____Removed……McLaren Northern Michigan

___Added _____Removed……McLaren Oakland
___Added _____Removed……McLaren Orthopedic Hospital
___Added _____Removed……McLaren Visiting Nurse and Hospice
___Added _____Removed……Other McLaren facilities:

Project Impact Statement	
Will this project have significant impact (such as staff time [e.g. pulling records, collect data, prepare or administer medication, etc], additional supplies, equipment, training, etc) on others outside of your own department? If "No", *skip to next section* If "Yes", indicate impacted department(s)site(s).	☐ No ☐ Yes
☐ Nursing ☐ Medical Records ☐ Lab ☐ Pathology ☐ Surgery ☐ Pharmacy ☐ Finance	☐ Radiation Oncology ☐ Medical Oncology ☐ IP ☐ OP ☐ Radiology ☐ Other (List):
☐ The protocol document was provided to the impacted departments/sites listed above. These departments were given the opportunity to review the protocol and the required research related procedures and discuss any questions or concerns related to the impact of their departments (including financial impact).	

D. CHANGE IN HIPAA (HIPAA Authorization and/or Request for HIPAA Waiver/Alteration)			
Will you obtain the subjects' authorization to access their health care records (containing PHI) during the course of the study? *If "Yes", complete and attach the HIPAA Authorization Form* *If "No", complete and attach the Request for Waiver/Alteration of HIPAA Authorization*	☐ N/A	☐ No	☐ Yes

E. OTHER IMPORTANT INFORMATION (i.e. Local context changes to ICF)
Explain:

RISKS/BENEFITS TO SUBJECTS
Will the modification affect the risks and/or benefits to subjects? ☐ **No** ☐ **Yes** **If "Yes", please provide a justification for the modification.** _____ _____

Principal Investigator Affirmation (to be completed by the current Principal Investigator for all modification requests)	
As the Principal Investigator, I verify that I have reviewed all the information provided in the Modification Form and that all information is complete and accurate.	
Principal Investigator Signature	Date Signed

Principal Investigator Assurance (only to be completed by the new Principal Investigator in the event this modification includes a Request to Change the Principal Investigator)	
The Principal Investigator of this study provides the following assurances: • The PI certifies that he/she has read and understands the policy entitled "*Relying on an external IRB as an IRB of record*". • The provided information is complete and accurate. • The PI acknowledges responsibility for the conduct of this project. • The PI has evaluated the protocol and determined that s/he has sufficient resources to conduct the study as submitted and necessary to protect subjects who enroll in the study. • All co- or sub-investigators, study coordinators, and other research personnel to whom the principal investigator delegates study-related responsibilities will receive thorough training in human subjects protections as well as in the specific details of study procedures. • The principal investigator will not begin the study until s/he has received notification of final IRB approval. If Contract Administration approval is required, s/he will not begin the study until s/he has received notification of final Contract Administration approval. • The principal investigator acknowledges his/her responsibility for the accuracy of all documents research personnel submit to the IRB on his/her behalf. • The principal investigator will comply with all IRB requests to report on the status of the study. • The principal investigator will seek and obtain prior approval from the IRB for modifications in the study, including changes in procedures, study enrollment goal, consent forms, etc. • The principal investigator will promptly report any reportable unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study. • The principal investigator will promptly inform the IRB of the results of external audits performed by the FDA, sponsors, contract review organizations (CROs), cooperative groups, or other external groups. • The PI will notify the MHC IRB when his/her research has been completed or terminated.	
Principal Investigator Signature	Date Signed