Request to Use an External IRB as an IRB of Record

This form is to be used by investigators requesting use of an external IRB. 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 request is accepted, the Corporate HRPP will provide a letter. The letter must be included with your submission to the external IRB.

External IRB Information				
Name				
Contact Name		**Email**	**Phone**	**FAX**
Mailing Address				
☐ No	☐ Yes	Do each of your institutions /facilities have an IRB Authorization Agreement in place with the external IRB cited above? *(To verify if an IRB Authorization Agreement is in place, please contact the MHC IRB office at 248-484-4950.)*		

Study Title *(Must be identical to the title on the official study protocol)*

Is the study posted on www.ClinicalTrials.gov?		
☐ **Yes**	**Specify number:**	
☐ **No**	**Please provide reason:**	

MHC Principal Investigator (PI)

The MHC IRB defines "Principal Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Principal Investigator is the responsible leader of the team (21 CFR 312.3[b]).

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
ALL research personnel are required to complete researcher training prior to engaging in any research-related activities.		
CITI Training (Date)	**Other Training (title & date completed)**	

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

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Research Site(s)

☐ Bay Region ☐ Central MI ☐ Flint ☐ Greater Lansing ☐ Lapeer Region ☐ Macomb ☐ Northern MI ☐ Oakland
☐ Orthopedic Hospital ☐ Port Huron

☐ KCI at (site):

☐ Other:

Study Other Personnel

Individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data.

ALL research personnel are required to complete researcher training prior to engaging in any research-related activities.

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			
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	☐ 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.

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.

The Research COI Committee will review financial disclosures. A request to rely on external IRB will not be granted until the review and management plan (if applicable) is completed.

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By submitting this 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.

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FDA-Regulated ***(Skip if this research is not FDA-regulated)***		
Phase	☐ I ☐ II ☐ III ☐ IV ☐ N/A	
Does the study involve an IND application?	☐ No	☐ Yes, IND #:
Does the study involve an IDE?	☐ No	☐ Yes, IDE #:
Does the study involve a HDE?	☐ No	☐ Yes, HDE #:
Name of the organization or individual who holds the IND/IDE/HDE, or, write ***Not applicable***:		
If the study does not yet have an IND or IDE, please explain the FDA application status:		

Funding	
Source	☐ None* ☐ Federal ☐ Industry ☐ Departmental* ☐ MHC foundation* ☐ Other
Name	**Contact Information**

If this study does not have any funding OR it will be funded through departmental funding or McLaren foundation funding:
☐ ***This study has undergone a review of scientific or scholarly validity (See section 5.1.5 of policy MHC_RP0109, Criteria for IRB Approval). NOTE: If this box is checked, please provide MHC IRB with the signed Scientific or Scholarly Validity Review confirmation worksheet.***

Access to Medical Records			
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 MHC HIPAA Authorization Form.* *If "No", complete and attach the MHC Waiver or Alteration of HIPAA Authorization Form.*	☐ N/A	☐ No	☐ Yes

Other Compliance Considerations			
Does this project need any of the following approvals?			
Karmanos Cancer Institute Protocol Review and Monitoring Committee (PRMC); *If **YES**, you must provide letter of approval from PRMC with this submission*	☐ No	☐ Yes	☐ Pending
McLaren Center for Innovation and Research Protocol Review Committee (MCRI PRC), *If **YES**, you must provide letter of approval from MCRI PRC with submission*	☐ No	☐ Yes	☐ Pending

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 departments below and complete a Project Impact Statement for each (and McLaren site, if applicable).	☐ No ☐ Yes
☐ Nursing ☐ Medical Records ☐ Lab ☐ Pathology ☐ Surgery ☐ Pharmacy ☐ Finance	☐ Radiation Oncology ☐ Medical Oncology ☐ IP ☐ OP ☐ Radiology ☐ Other (List):

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Principal Investigator Assurance	
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 applicable, s/he will not begin the study until the clinical trial agreement is executed. • 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 external audits performed by the FDA, sponsors, contract review organizations (CROs), cooperative groups, or other external groups. The principal investigator will promptly inform the IRB of the results. • The PI will notify the MHC IRB when his/her research has been completed or terminated.	
Signature	Date signed

FOR MHC HRPP USE ONLY		
Date received:		MHC IRB Protocol #: ____________________
IRB Authorization Agreement in place w/External IRB		☐ No ☐ Yes
Intent to apply to an External IRB accepted by:	Director Corporate Research Administration or Designee	
	My signature below indicates that this project has been accepted to be submitted to the external IRB.	
	Print Full Name	Title
	Signature	Date signed

Required Attachments

Have you included electronic copies of all of the following materials with this completed Request to use an external IRB?			
Protocol that will be submitted to the external IRB		☐ Yes	
Consent form that will be submitted to the external IRB	☐ N/A	☐ Yes	
Financial Interest Disclosure Form(s); If "yes"…	☐ N/A	☐ Yes	
SFI Management Plan		☐ Yes	
MHC Project Impact Statement(s)	☐ N/A	☐ Yes	☐ Pending
Written notice from sponsor requiring external review	☐ N/A	☐ Yes	
HIPAA Authorization Form	☐ N/A	☐ Yes	
Waiver or Alteration of HIPAA Authorization Form	☐ N/A	☐ Yes	
MHC Scientific or Scholarly Validity Review confirmation worksheet	☐ N/A	☐ Yes	
Karmanos Cancer Institute Protocol Review and Monitoring Committee (PRMC)	☐ N/A	☐ Yes	☐ Pending
McLaren Center for Research and Innovation Protocol Review Committee (MCRI PRC) approval letter	☐ N/A	☐ Yes	☐ Pending
Copy of the contract (draft)	☐ N/A	☐ Yes	

- *Once all documents have been completed, email the "Request to Use an External IRB as an IRB of Record" and applicable attachments to **hrpp@mclaren.org***
- *In the email subject line, write "Request to Use an External IRB."*
- *Failure to follow these instructions will significantly delay the review and authorization of Request to Use an External IRB for this study.*