

## Request to Use an External IRB as an IRB of Record

***This form is to be used by Karmanos 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](mailto: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			
<input type="checkbox"/> No	<input type="checkbox"/> 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 <a href="http://www.ClinicalTrials.gov">www.ClinicalTrials.gov</a> ?	
<input type="checkbox"/> Yes	Specify number: _____
<input type="checkbox"/> No	Please provide reason: _____

MHC Principal Investigator (PI)
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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

<b>Study Role: Select all that apply.</b>		
<input type="checkbox"/> Study-related Procedures	<input type="checkbox"/> Obtaining Consent	<input type="checkbox"/> Submitting Forms
<b>ALL research personnel are required to complete researcher training prior to engaging in any research-related activities.</b>		
CITI Training (Date)	Other Training (title & date completed)	

Form Completed by		
Name	Title	
Email	Phone	FAX

## Request to Use an External IRB as an IRB of Record

Research Site(s)
<input type="checkbox"/> Bay Region <input type="checkbox"/> Central MI <input type="checkbox"/> Flint <input type="checkbox"/> Greater Lansing <input type="checkbox"/> Lapeer Region <input type="checkbox"/> Macomb <input type="checkbox"/> Northern MI <input type="checkbox"/> Oakland <input type="checkbox"/> Orthopedic Hospital <input type="checkbox"/> Port Huron
<input type="checkbox"/> KCI at (site):
<input type="checkbox"/> Other:

Study Other Personnel
<p><b>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.</b></p> <p><b>ALL research personnel are required to complete researcher training prior to engaging in any research-related activities.</b></p>

Name	Title	Study Role(s): List all that apply (i.e. 1, 2, 3, 4, 5).	CITI (Date)	COI** (Date)
	<input type="checkbox"/> Co/Sub-I <input type="checkbox"/> AA <input type="checkbox"/> SC <input type="checkbox"/> Reg <input type="checkbox"/> Other			
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	<input type="checkbox"/> Co/Sub-I <input type="checkbox"/> AA <input type="checkbox"/> SC <input type="checkbox"/> Reg <input type="checkbox"/> 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.

## Request to Use an External IRB as an IRB of Record

### 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 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.

## Request to Use an External IRB as an IRB of Record

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

Funding	
<b>Source</b>	<input type="checkbox"/> None* <input type="checkbox"/> Federal <input type="checkbox"/> Industry <input type="checkbox"/> Departmental* <input type="checkbox"/> MHC foundation* <input type="checkbox"/> Other
<b>Name</b>	<b>Contact Information</b>
<p><b>*If this study does not have any funding OR it will be funded through departmental funding or McLaren foundation funding:</b>  <input type="checkbox"/> <b>This study has undergone a review of scientific or scholarly validity (See section 5.1.5 of policy <a href="#">MHC RP0109, Criteria for IRB Approval</a>). NOTE: If this box is checked, please provide MHC IRB with the signed Scientific or Scholarly Validity Review confirmation <a href="#">worksheet</a>.</b></p>	

Access to Medical Records			
Will you obtain the subjects' authorization to access their health care records (containing PHI) during the course of the study? <i>If "Yes", complete and attach the <a href="#">MHC HIPAA Authorization Form</a>.</i>  <i>If "No", complete and attach the <a href="#">MHC Waiver or Alteration of HIPAA Authorization Form</a>.</i>	<input type="checkbox"/> N/A	<input type="checkbox"/> No	<input type="checkbox"/> Yes

Other Compliance Considerations			
<b>Does this project need any of the following approvals?</b> Karmanos Cancer Institute Protocol Review and Monitoring Committee (PRMC); <i>If YES, you must provide letter of approval from PRMC with this submission</i>  McLaren Center for Innovation and Research Protocol Review Committee (MCRI PRC); <i>If YES, you must provide letter of approval from MCRI PRC with submission</i>	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> Pending
	<input type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> 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? <i>If "No", skip to next section</i> <i>If "Yes", indicate impacted department(s)/site(s).</i>	<input type="checkbox"/> No <input type="checkbox"/> Yes
<input type="checkbox"/> Nursing <input type="checkbox"/> Medical Records <input type="checkbox"/> Lab <input type="checkbox"/> Pathology <input type="checkbox"/> Surgery <input type="checkbox"/> Pharmacy <input type="checkbox"/> Finance	<input type="checkbox"/> Radiation Oncology <input type="checkbox"/> Medical Oncology <input type="checkbox"/> IP <input type="checkbox"/> OP <input type="checkbox"/> Radiology <input type="checkbox"/> Other (List):

## Request to Use an External IRB as an IRB of Record

### 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 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).
- 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		<input type="checkbox"/> No <input type="checkbox"/> 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

## Request to Use an External IRB as an IRB of Record

### Required Attachments

<p><i>Have you included electronic copies of all of the following materials with this completed Request to use an external IRB?</i></p>			
Protocol that will be submitted to the external IRB	<input type="checkbox"/>	Yes	
Consent form that will be submitted to the external IRB	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
<a href="#">Financial Interest Disclosure Form(s)</a> ; If “yes”... SFI Management Plan	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Written notice from sponsor requiring external review	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
<a href="#">HIPAA Authorization Form</a>	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
<a href="#">Waiver or Alteration of HIPAA Authorization Form</a>	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
<a href="#">MHC Scientific or Scholarly Validity Review confirmation worksheet</a>	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	
Karmanos Cancer Institute Protocol Review and Monitoring Committee (PRMC)	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	<input type="checkbox"/> Pending
McLaren Center for Research and Innovation Protocol Review Committee (MCRI PRC) approval letter	<input type="checkbox"/> N/A	<input type="checkbox"/> Yes	<input type="checkbox"/> Pending
Copy of the contract (draft)	<input type="checkbox"/> N/A	<input type="checkbox"/> 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](mailto: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.*