**Confirmation of Scientific or Scholarly Review for Validity**

**Investigator Initiated Studies**

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| **Instructions:**  Scientific or scholarly review is performed by the members of the IRB reviewing the study and is based on the criteria required by federal regulations for IRB approval of a human research study. See [Policy MHC-RP0109\_Criteria for IRB approval](http://www.mclaren.org/Uploads/Public/Documents/Corporate/MHC_RP0109_CriteriaForIRBApproval.pdf). Although the IRB will review issues of scientific design and participant safety as needed, that role will be a secondary one.   * **All prospective interventional studies** will be reviewed by the convened MHC Protocol Review Committee (PRC). This includes medical residents/fellows. Send request for review to [mcri@mclaren.org](mailto:mcri@mclaren.org) [**Subject line in email should state “PRC Review”**] Do not use this form. * **For all other studies** scientific or scholarly review will occur as follows using the **form below**: * **Medical residents/fellows affiliated with MHC GME Program** – Scientific or scholarly review and signatures must be obtained from Program Director. If the Program Director is the PI on the study, then review/signature is done by the Assistant Program Director. If the Assistant Program Director is the PI or if there is no Assistant Program Director, the review/signature is done by Chief Medical Officer (CMO). * **All others not associated with MHC GME Program** - The MHC IRB will provide review of the scientific validity of the proposed research. |

1. **Principal Investigator Information:**

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| --- | --- | --- | --- |
| **Name & Degree** |  | | |
| **Title** |  | | |
| **Mailing Address** |  | | |
| **Phone** |  | **Fax** |  |
| **E-mail** |  | **Alternate e-mail** |  |

1. **Program Director, Assistant Program Director or Chief Medical Officer, if applicable:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name & Degree** |  | | |
| **Title** |  | | |
| **Mailing Address** |  | | |
| **Phone** |  | **Fax** |  |
| **E-mail** |  | **Alternate e-mail** |  |

1. **Study Title:**

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1. **Is this a multi-site study?  Yes  No**

|  |  |
| --- | --- |
| |  | | --- | | **Select all that apply.** | |
| |  |  | | --- | --- | |  | McLaren Bay Region | |
| |  |  | | --- | --- | |  | McLaren Bay Special Care | |
| |  |  | | --- | --- | |  | McLaren Central Michigan | |
| |  |  | | --- | --- | |  | McLaren Orthopedic Hospital | |
| |  |  | | --- | --- | |  | McLaren Greater Lansing | |
| |  |  | | --- | --- | |  | McLaren Lapeer Region | |
| |  |  | | --- | --- | |  | McLaren Flint | |
| |  |  | | --- | --- | |  | McLaren Macomb | |
| |  |  | | --- | --- | |  | McLaren Oakland | |
| |  |  | | --- | --- | |  | McLaren Karmanos Cancer Institute of:Click or tap here to enter text. | |
| |  |  | | --- | --- | |  | McLaren Health Clarkston | |
| |  |  | | --- | --- | |  | McLaren Medical Group | |
| |  |  | | --- | --- | |  | McLaren Visiting Nurse and Hospice | |
| |  |  | | --- | --- | |  | McLaren Northern Michigan | |
| |  |  | | --- | --- | |  | McLaren Port Huron | |  | McLaren Thumb Region | |  | McLaren Caro | |
| |  |  | | --- | --- | |  | Other (please specify): Click or tap here to enter text. | |

1. **The MHC IRB will rely on your careful consideration and review of the following 3 questions**
   * + - 1. Are the research procedures the least risky procedures that can be performed consistent with sound research design?  **Yes  No**
         2. Is the research likely to achieve its aims?  **Yes  No**
         3. Is the proposed research of sufficient scientific importance to justify the risks entailed? **Yes  No**

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**Printed Name** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Title** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Signature of the Reviewer \*** **Date**

**\*The Reviewer’s signature confirms the soundness of the research design and the ability of the research to achieve its aims. The Reviewer must be someone other than the PI. For Medical Resident and Fellows that are part of MHC Graduate Medical Education Program the reviewer must be:**

* *Program Director*
* *Assistant Program Director (if Program Director is the PI)*
* *Chief Medical Officer (if Assistant Program Director is the PI or if no Assistant Program Director)*

**For Medical Resident and Fellows that are part of MHC Graduate Medical Education Program please include the following:**

**Printed Name of PhD** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Signature of PhD** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_