McLaren HEALTH CARE		**Policy Title:**	Investigational Drugs and Biologics Used in Clinical Research
Effective Date:	May 8, 2014	**Policy Number:**	MHC_RP0127
Review Date:	April 24, 2014	**Section:**	Human Research Protections Program (HRPP)
Revised Date:		**Oversight Level:**	Corporate
Administrative Responsibility:	Corporate Director, HRPP Institutional Official, HRPP		

1. Purpose

1.1. The purpose of this policy is

1.1.1. To establish procedures for the proper control, storage, use and handling of investigational drugs and biologics to ensure that adequate safeguards are in place to protect the patients, the staff, the facility and the quality of the study

1.1.2. To describe the process for approval for the use of an Investigational New Drug including emergency use at the McLaren Health Care and its subsidiary hospitals

1.1.3. To describe the process for the use of medications and investigational new drugs in clinical research studies at the McLaren Health Care and its subsidiary hospitals

2. Scope

2.1. This policy applies to all members of McLaren Health Care including, but not limited to, employees, medical staff, volunteers, students, physicians office staff, and other personnel performing work for or at McLaren Health Care and its subsidiary hospitals

2.2. Oncology related studies conducted through Karmanos Cancer Center will follow policies and procedures established at the Karmanos Cancer Institute

3. Definitions

3.1. Certificate of Analysis: A document relating specifically to the result of testing a representative sample drawn from the specific batch or lot of material it is purported to represent. Specifically:

3.1.1. gives the exact details about its quality and compliance to specifications

3.1.2. documented evidence of the quality control testing carried out on the drug or formulation

3.2. Compassionate Use: The term “compassionate use” is erroneously used to refer to the provision of investigational drugs outside of an ongoing clinical trial to a limited

number of patients who are desperately ill and for whom no standard alternative therapies are available.

3.2.1. The term “compassionate use” does not appear in FDA or HHS regulations.

3.2.2. The names of the specific access programs shall be used instead of “compassionate use” when discussing the use of investigational articles outside of formal clinical trials

3.3. Clinical Investigation: Any experiment that involves a test article and one or more human subjects and that either is a subject to requirements for prior submission to the FDA or is not subject to requirements for prior submission to the FDA, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit

3.4. Investigational New Drug (IND): A new drug or biologic drug that is used in a clinical investigation in which the PI or a sponsor has filed an IND application (21 CFR Part 312) or an approved drug that is being studied for an unapproved or approved use in a controlled, randomized, or blinded clinical trial

3.5. IND: An investigational new drug application in accordance with 21 CFR Part 312

3.6. Institutional Review Board (IRB): An IRB is a board designated by the Organization to review, to approve the initiation of, and to conduct periodic review of research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The IRB may be assigned other review functions as deemed appropriate by the Organization

3.7. Medication Incident: any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient or consumer (Adopted from The National Coordinating Council of Medication Error Reporting and Prevention)

3.7.1. Study Medication Incident: may involve, in addition to that covered under the definition of a medication incident, any deviation from the study protocol or procedures outlined for a given study, including disposal of study drug visits.

3.8. Principal Investigator (PI): The MHC IRB recognized term for the individual the IRB holds ultimately responsible for the design, conduct and evaluation of human subjects’ research activities

3.8.1. The responsibilities of the Principal Investigator encompass the DHHS and FDA regulatory requirements for conducting human subjects’ research activities

3.9. Protocol Violation are those that:
3.9.1. Affect the rights, safety or welfare of study subjects
3.9.2. Change the risk/benefit ratio
3.9.3. Affect the scientific design of the study OR
3.9.4. Violate an ethical principle

3.10. Research: The Common Rule defines research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge

3.11. Sponsor: The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization that takes responsibility for and initiates a clinical investigation

3.11.1. The sponsor doesn't actually conduct the investigation unless the sponsor is a sponsor-investigator

3.12. Sponsor-Investigator: An individual (usually the study Principal Investigator), who both initiates and conducts a clinical investigation and under whose immediate direction the investigational drug is dispensed and administered

3.12.1. The term does not include any person other than an individual investigator

3.12.2. The requirements applicable to a sponsor-investigator under FDA subpart (21 CFR 312 Subpart D) means that sponsor investigators must follow the regulations for both an investigator and a sponsor [21 CFR 312.3(b)]

3.13. Subject: A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease

3.14. Emergency Use: use of an investigational drug or biological product with a human subject in a life-threatening situation in which no standard acceptable treatment is available and in which there is not sufficient time to obtain IRB approval

4. Policy

4.1. When conducting clinical research using medications and investigational new drugs, all McLaren Health Care employees must comply with all applicable federal and state statutes, rules and regulations and McLaren's policies regarding approval and use including procurement, storage, dispensing, administration, disposal, reporting and record keeping requirements

4.2. All clinical research, single-patient, compassionate and emergency use protocols, including the informed consent process, must be submitted by the Principal Investigator (PI) to a McLaren Health Care Corporate Institutional Review Board (MHC IRB) for approval

4.2.1. Exceptions apply to Investigational Drugs or Biologics from another institution and an Emergency Use

4.3. The Office of Research Compliance and Quality Improvement will conduct periodic routine and for cause monitoring

4.4. When applicable, the Pharmacy Department will receive reimbursement for study activities from the PI for all studies that require additional work from the Pharmacy Department

4.4.1. Expectations for pharmacy reimbursement will be discussed with the PI prior to the initiation of the study according to Appendix II "*Pharmacy reimbursement fee for Investigational Drug Study Participation"*

4.4.2. The Director of Pharmacy shall have the flexibility to alter or waive the fees for particular projects based on circumstances

4.5. Investigational Agent Accountability form (Appendix I) shall be created and maintained for each investigational drug used on each active research protocol

4.5.1. If a protocol contains more than one investigational drug, a separate accountability record must be maintained for each drug

4.5.2. Site or sponsor-specific investigational agent accountability log may be utilized based on approval from the Pharmacy Director or another qualified individual

5. Sources of Investigational New Drugs:

5.1. Federal Government – Various agencies within the Department of Health and Human Services will make available, through cooperative group, sponsor-investigator, or other sponsored clinical trials, INDs for specific disease sites

5.1.1. Typically, such studies are coordinate through a primary clinical center, research institution or division of the National Institute of Health (NIH)

5.2. Licensed Pharmaceutical Companies – A pharmaceutical company will make INDs available to physicians via sponsored clinical trials or investigator initiated clinical trials for which the investigator serves as the sponsor-investigator

5.3. Individual or Entity other than Licensed Pharmaceutical Company – Pharmacy will rely upon FDA review of the chemistry, manufacturing and control information contained in the Investigational New Drug Application (INDA)

5.4. McLaren Pharmacies – Pharmacies may be called upon to store and dispense to inpatients or outpatients an investigational drug, or to provide non-investigational drugs which by indication, dose or route of administration are considered investigational in a specific area

5.4.1. If any of the McLaren Pharmacies are used for research projects, Investigators will be requested to complete a Project Impact Statement

5.4.2. A completed Project Impact Statement will be submitted to the MHC IRB with the proposed research project for approval

6. Procedure

6.1. Dispensing of Investigational Drugs and Biologics

6.1.1. Dispensing of investigational drugs and biologics must meet all safety requirements provided by federal and state law for non-investigational drugs

6.1.2. The PI works closely with the Pharmacy Staff to ensure that protocol procedures are followed

6.1.3. McLaren's pharmacies typically do not engage in the ordering/providing, dispensing, or compounding of drugs used in research, unless the drug is controlled substance, in which case the item is ordered/received by the Pharmacy and re-issued in appropriate quantities to researchers for human studies, pursuant to a study-specific and patient-specific medication order developed by the Pharmacy in collaboration with the Researcher

6.1.4. If the Pharmacy is used:

6.1.4.1. The Pharmacy will store, prepare and dispense investigational drug or biologics: the pharmacy will maintain inventories, information and dispensing records of investigational drugs used

6.1.4.2. The Director of Pharmacy is primarily responsible for the accountability of all investigational drugs; however, all pharmacies are authorized to dispense according to policy and procedure

6.1.4.3. The Pharmacy will maintain an inventory of the drug and keep a file of all drug requests and quantities dispensed

6.1.4.4. The Pharmacy will inform the PI when supply is running low

6.1.4.5. The Pharmacy will label each medication with the usual prescription label and with the following additional information:

6.1.4.5.1. Example label: "Investigational Drug – not for General Use / Protocol Number _____"

6.1.4.6. Drug not administered will be returned to the Pharmacy and added back to the inventory for future use, destroyed according to specific protocol procedures, or returned to the study sponsor or appropriate agency consistent with the current IRB approved protocol.

6.1.4.7. Inventory Records will be maintained on Investigational Agent Accountability Form (*Appendix I*)which will be maintained in the Pharmacy until the study closes, at which time they must be maintained with the study's Regulatory Binder

6.1.5. If the Pharmacy is not used:

6.1.5.1. The Principal Investigator (PI) PI will store, prepare and dispense investigational drugs or biologics: the PI will maintain inventories, information and dispensing records of investigational drugs used

6.1.5.2. It is the responsibility of the PI to assure that all Institutional, State, Federal, Healthcare Facilities Accreditation Program (HFAP), and Joint Commission on Accreditation of Hospital Organization (JCAHO) requirements are met

6.1.5.3. At a minimum, PI will maintain shipping and inventory records on Investigational Agent Accountability Form (*Appendix I*)

6.1.5.4. Investigational Agent Accountability Form will be maintained in the study's Regulatory Binder

6.1.6. It is the PIs responsibility to report to the IRB, Sponsor and FDA when investigational drugs or biologics have been used and suspected of eliciting an adverse drug reaction or serious adverse event

6.2. Receipt of Investigational Drugs

6.2.1. Upon receipt of the investigational agents from pharmaceutical manufacturer, governmental agency or other external source, the PI or pharmacist enter the following information on the Investigational Agent Accountability Form (*Appendix I)* form (as applicable);

6.2.1.1. Date
6.2.1.2. Subject's Initial's if known
6.2.1.3. Subject ID Number, if known
6.2.1.4. Dose
6.2.1.5. Quantity Received
6.2.1.6. Balance
6.2.1.7. Manufacturer and Lot Number
6.2.1.8. Recorder's Initials

6.2.2. If there are any discrepancies, the sponsor of the study will be notified immediately

6.3. Administration of Investigational Drugs

6.3.1. Individuals administering investigational drugs or other research related treatments are considered research personnel and must obtain prior IRB approval

6.3.2. A medication or Investigational New Drug (IND) for research may be administered by:

6.3.2.1. A member of the full-time medical staff of the hospital;

6.3.2.2. A member of the voluntary medical staff/licensed independent practitioner;

6.3.2.3. PGY 2, PGY3, physicians or fellows

6.3.2.4. Registered nurses, Registered Pharmacists, Nurse Practitioners, and Physician's Assistants under detailed written directions of the physician authorized to prescribe the medication once IRB approval has been granted and all protocols and requests for administration have been followed

6.3.3. Only individuals who are licensed by the State of MI to practice medicine may make medical decisions regarding a clinical research subject's care and treatment

6.3.3.1. Non-clinical coordinators, PhDs, and unlicensed clinically trained staff cannot perform these tasks

6.3.3.2. Documentation must be made by a licensed medical practitioner

6.3.3.3. Non-clinical staff may prepare documentation and paperwork for review, concurrence and signature by licensed clinical staff

6.4. Investigational Drugs and Biologic Accountability

6.4.1. If using the Pharmacy, a study binder for drug accountability should be established for each research study.

6.4.2. Records of receipt (shipping documents), disposition, destruction and/or return must be retained as documentation the investigational drug or biologic has been used according to the protocol.

6.5. Storage of Investigational Drugs and Biologics

6.5.1. Storage facilities for investigational drugs and biologics must be in compliance with Institutional, State, Federal [Food and Drug Administration (FDA)], HFAP, and JCAHO requirements.

6.5.1.1. If the investigational drug or biologic is subject to the Controlled Substances Act, the item must be stored in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure to which access is limited.

6.5.2. Investigational drugs and biologics must be stored under appropriate environmental control in limited access areas separate from routine drug stock

6.5.2.1. Investigational drugs subject to the Controlled Substances Act for use in inpatients will be stored and distributed by the Hospital Pharmacy in accordance with the Controlled Substance Policy.

6.5.3. All Investigational drugs or biologics used in the context of research may be stored in appropriate areas in another facility other than the Pharmacy under the

direct supervision of the Principal Investigator and in accordance with the sponsor, if applicable

6.5.4. If using the Pharmacy, the investigational drug storage areas should be segregated from regular stock and accessible to assigned pharmacy personnel

6.5.5. Investigational drugs must be clearly marked and separated by protocol number

6.5.5.1. Example label: "Investigational Drug – not for General Use / Protocol number _____"

6.6. Investigational Drug or Biologic from another Institution

6.6.1. If McLaren is not initially selected as a research site but its employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis (e.g., an oncologist at the institution administers chemotherapy to a research subject as part of a clinical trial because the subject unexpectedly goes out of town, or is unexpectedly hospitalized), McLaren would be considered NOT engaged in the research, provided that **all** of the following conditions also are met:

6.6.1.1. an investigator from an institution engaged in the research determines that it would be in the subject's best interest to receive the study interventions being tested or evaluated under the protocol;

6.6.1.2. the institution's employees or agents do not enroll subjects or obtain the informed consent of any subject for participation in the research;

6.6.1.3. investigators from the institution engaged in the research retain responsibility for:

(i) overseeing protocol-related activities;
(ii) ensuring the study interventions are administered in accordance with the IRB-approved protocol; and
(iii) ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the engaged institution, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol; **and**

6.6.1.4. an IRB designated on the engaged institution's FWA is informed that study interventions being tested or evaluated under the protocol have been administered at an institution **not** selected as a research site:

6.6.1.5. the admitting physician or a consulting physician with hospital privileges must prescribe the study medication with a suitable order which will be retained in the patient's medical record.

6.6.2. When a patient is hospitalized on an investigational drug or biologic obtained elsewhere, the Pharmacy will be notified by the admitting physician.

6.6.3. Investigational Drugs from other Institutions will be handled by the Pharmacy.

6.6.4. The admitting physician or Pharmacy manager/designee will obtain a summary or copy of the approved investigational protocol and a copy given to a pharmacist

6.6.5. The Pharmacy manager or designee will review the protocol, the study drug, drug dosage form, re-label the medication once identified, input the order into the Pharmacy system and dispense the medication as allowed by the respective protocol.

6.6.6. The admitting physician or designee will obtain a copy of the informed consent and place it in the medical record and a copy given to a pharmacist.

6.6.7. The admitting physician or designee will obtain a copy of the protocol outlining potential study medication adverse effects and interactions which will allow hospital staff sufficient detail to adequately monitor the patient status.

6.6.8. The admitting physician or delegate will contact the PI to assure that the patient is appropriately followed, and that all relative information is provided regarding the investigational drug or biologic, its effects, contraindications, drug interactions, etc.

6.7. Emergency Use of Investigational Drug or Biologic

6.7.1. The emergency use of an unapproved investigational drug or biologic requires an IND. If the intended subject does not meet the criteria of an existing study protocol, or if an approved study protocol does not exist, the usual procedure is for the Investigator to contact the manufacturer and determine if the drug or biologic can be made available for the emergency use under the company's IND.

6.7.1.1. The need for an investigational drug or biologic may arise in an emergency situation that does not allow time for submission of an IND. In such a case, FDA may authorize shipment of the test article in advance of the IND submission. Requests for such authorization may be made by telephone or other rapid communication means.

6.7.2. The Investigator will notify the Pharmacy of the intent to use the drug or biologic and arrange for shipping of emergency supply of the drug or biologic directly to the Pharmacy along with any pertinent information regarding the pharmacology and preparation of the drug.

6.7.3. The Investigator must notify the IRB within 5 working days after the use of the test article according to MHC IRB Policy *MHC_RP0119_Emergency Use of Investigational Drugs and Devices*.

6.7.4. The Investigator will provide drug information to the staff treating and monitoring the patient.

7. Responsibilities:

7.1. Principal Investigator:

7.1.1. The PI or designee is responsible for the accountability of medications and drugs used in their clinical investigation, but may delegate these duties to an appropriate health system pharmacist.

7.1.2. The PI or designee is responsible for the education of co-investigators, study personnel, and other personnel who prescribe, distribute, or administer the investigational drug or biologic.

7.1.3. The PI will work with the Pharmacy regarding the appropriate storage, handling (Compounding), and dispensing of investigational drugs and biologics.

7.1.4. The PI is responsible for working directly with the Pharmacy regarding the costs for the storage, handling (compounding), and dispensing of investigational drugs and biologics.

7.1.4.1. The PI and the Pharmacy will work in conjunction to assure adequate funding for these pharmacy costs is incorporated into the grant, contract proposal, or from other internal sources.

7.1.5. The PI or designee is responsible for obtaining a signed Project Impact Statement from the Impacted Pharmacy prior to initiating the study

7.1.6. The PI or designee is responsible for obtaining a signed informed consent from the subject or subject's legally authorized representative

7.1.7. The signed Project Impact Statement must be submitted to the MHC IRB prior to receiving an approval of the research study

7.1.8. The PI or designee is responsible for the return of unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies.

7.1.9. The PI or designee is responsible for reporting all adverse events and protocol violations related to the administration of investigational drugs in accordance with IRB and FDA policy

7.2. Pharmacy

7.2.1. For each study that drug inventory is managed by the Pharmacy, the Pharmacy will maintain a protocol specific binder which will be utilized by Pharmacy staff when dispensing the drug or biologic. The binder will contain:

7.2.1.1. Copy of the current IRB approved protocol

7.2.1.2. Copy of the IRB approved Investigator's Brochure, if applicable

7.2.1.3. IRB Approval letter

7.2.1.4. Investigational Agent Accountability Form

7.2.1.5. Receipt, Return, Transfer, and Destruction Records

7.2.1.6. Any other information necessary for the Pharmacy to distribute the drug or biologic in accordance with requirements of the sponsor and McLaren

7.2.2. The Pharmacy will maintain a drug accountability record for each investigational drug stored in the Pharmacy. To the extent permitted by the study design, this record shall contain the drug's name, dosage form, strength, lot number and expiration date. This record shall contain dated information regarding the disposition of drug or biologic (amounts received, transferred, wasted, dispensed, returned to sponsor or sent for destruction). Names or codes of patients receiving the drug and the name of the Principal Investigator shall be documented and each entry shall be initialed by a Pharmacy staff member.

7.2.3. The Pharmacy will dispense the investigational drug or biologic only on the order of the PI or co-investigator

7.2.4. Good Clinical Practice guidelines of the International Committee for Harmonization (ICH) will be followed by the Pharmacy when distributing investigational drugs and biologics.

7.2.5. Pharmacy dispensing errors, study medication incidents or drug inventory discrepancies will be reported in detail to the Director of Pharmacy, and the PI or study coordinator, along with a description of steps taken to prevent a reoccurrence

7.2.5.1. Information will be entered into the hospital incident reporting / medication variance reporting system for review to determine a course of action to prevent a reoccurrence

8. References:

8.1. "Guidance on Engagement of Institutions in Human Subject Research" dated October 16, 2008

8.2. *Appendix I* "Drug Accountability Record Form"

8.3. *Appendix II* "Pharmacy reimbursement fee for Investigational Drug Study Participation"
8.4. Project Impact Statement
8.5. MHC_RP0119_Emergency Use of Investigational Drugs and Devices.

9. Previous Revisions: None

10. Supersedes Policy: Existing Subsidiary Policies

11. Approvals:

_____ _____

Michael McKenna, MD **Date**
Executive Vice President/CMO
Institutional Official

McLaren HEALTH CARE

Appendix I

Investigational Agent Accountability Form

Name of Institution:	Sponsor:
Agent Name:	Dose Form and Strength:
Protocol Number / Title:	Dispensing Area:
Investigator Name:	Investigator No (when applicable):

Line No.	Date	Subject's Initials	Subject's ID No.	Dose	Quantity Dispensed or Received	Balance	Manufacturer and Lot No.	Recorder's Initials
1.								
2.								
3.								
4.								
5.								
6.								
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19.								
21.								

Appendix II

Investigational Pharmacy Services Budget Estimate

STUDY INITIATION: (One choice only)		
☐ **$400** • Review and clarification of protocol • Preparation of patient enrollment and drug accountability records • Meet with sponsors, investigators, and study coordinators • Receive initial supplies and inventory • Budget Preparation	• Pharmacy involvement limited to Monday through Friday 7:30am – 6:00pm • Preparation of dispensing guidelines • Creation of protocol into pharmacy computer system • Pharmacy provided randomization • Full handling, dispensing of study medications • Preparation of drug information sheet	
☐ **$200** • Review and clarification of protocol • Preparation of patient enrollment and drug accountability records • Meet with sponsors, investigators, and study coordinators	• Pharmacy involvement limited to Monday through Friday 7:30am – 6:00pm • Main responsibility is drug storage, minimal handling and dispensing involvement • Received initial supplies and inventory • Budget preparation	

STUDY CLOSURE: $200		
• Balance drug accountability records • Return remaining inventory	• Return expired meds • Correspondence / supply drug information	

STUDY MAINTENANCE FEES (Variable)		
STUDY MAINTENANCE: $50-$75 active*month (dependent on study complexity)		
☐ $50 per month (moderate involvement) ☐ $75 per month (complex involvement) • Storage / inventory control / labeling • Maintain drug accountability records • Maintain sufficient inventory • Monitor / sponsor visits	Study Duration: _____ • Return expired medications • Correspondence • Supply drug information to pharmacists and nurses • Daily temperature monitoring of drug supply / storage	**$600/year maximum**
*Active month indicates any month in which medication is dispensed for a study patient, or for which there is a study monitoring activity, or additional sponsor requirements beyond standard drug management		

PREPARATION / DISPENSING FEES (Variable*)

PREPARATION / DISPENSING Medication type:_____
Maximum # of doses per study subject: Varies per dosing, surgical needs

	Cost	# of doses, hrs, RX	#of subjects	Sub Total
☐ Patient Randomization	$10/Randomization			
☐ Dispensing only	$50/dose or visit			
☐Preparation and dispensing	$75/dose or visit			
☐ Biologics/Cancer Chemotherapy	$75/dose or visit			
☐ Miscellaneous compounding	$50/hour			
☐ Outpatient prescription	$10/prescription			

*Cost dependent on medication type, doses per subject, subject enrollment, and extra preparation requirements
*Stated fees assume study sponsor supplies all necessary medications / supplies

TOTAL ESTIMATE:_____

Pharmacy Authorized Signature (Printed)	Authorized Signature	Date

I have received and agree with the Budget Estimate

Investigator Authorized Name (Printed)	Authorized Signature	Date

Human Research Protections Program
McLaren Health Care
1198 N. Belsay Rd. Bldg #1
Burton, MI 48509
Phone: (810) 342-1003
Fax: (810) 342-1514
e-mail hrpp@mclaren.org

PROJECT IMPACT STATEMENT

This form may be duplicated as needed.

Researcher/Principal Investigator:

Identify any department (e.g. Medical Records, Pharmacy, Laboratory, Nursing, Finance, Radiology, Surgery, etc.) of your subsidiary hospital that will be affected by this research and obtain the Department Manager/Director's written approval.

You must provide this signed statement to the MHC IRB Office either by mail:
1198 N. Belsay Rd., Bldg #1
Burton, MI 48509

OR Fax: (810) 342-1514

MHC IRB Approval letter will not be issued until MHC IRB office receives a signed copy.

Department Manager/Director:

Be sure you have a clear understanding of the role(s) your department plays in this research project, and the reimbursement of expenses, if applicable.

You may request that the researcher provide you with documentation of the outcome of the MHC IRB's review ***before*** the project is initiated in your department.

Department Manager/Director

I have reviewed the project, entitled <insert full title>, and have had the opportunity to discuss with <insert PI name> (the researcher/PI) the impact this project will have on the department.

Approved by:

_____ _____

Signature of Department Manager/Director granting approval **Date**

_____

Printed name of Department Manager/Director

<insert department name>
Department

McLaren - <insert subsidiary>
McLaren Subsidiary