



APPLICATION FOR A PROJECT INVOLVING HUMAN SUBJECTS  
INITIAL PROJECT REVIEW

Institutional Research Review Committee (IRRC)

- > **The IRRC requires all researchers bringing projects before this Committee to access the Human Subjects Training Tutorial prior to beginning their research. Present verification of completion of human subjects training along with the application packet. Links to recommended sites below:**

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>  
<http://www.hhs.gov/ohrp/education/index.html#materials>  
<http://www.humanresearch.msu.edu/requiredtraining.html>

1. **TITLE OF PROPOSAL:**

**REQUIRED**

**IF APPLICABLE**

2. **Responsible Principle Investigator:**  
(Professional Staff, Faculty or Staff Supervisor)

Name: \_\_\_\_\_  
Mailing Address: \_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
Email: \_\_\_\_\_  
Primary Employer: \_\_\_\_\_

3. **Co-Investigators:**  
(MSU Students Must Provide Student ID#)

Name: \_\_\_\_\_  
Mailing Address: \_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
Email: \_\_\_\_\_  
Primary Employer: \_\_\_\_\_

By submitting this application, I accept responsibility for conducting the proposed research in accordance with the protections of human subjects as specified by Sparrow IRRC, including the supervision of professional staff and any student(s) investigator(s), and attest to the accuracy of the information contained in this document.

**The IRB requires the Principal Investigator to electronically sign and submit this application form.**

**Attach a separate sheet for additional co-investigators**  
Research Coordinator and/or Contact person

Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
\_\_\_\_\_

Phone: \_\_\_\_\_  
Fax: \_\_\_\_\_  
Email: \_\_\_\_\_



14. **WHEN WOULD YOU PREFER TO BEGIN DATA COLLECTION:** \_\_\_\_\_  
Remember you may not begin data collection without IRRC approval.

15. **WHERE WILL THIS STUDY BE CONDUCTED?**

16. **CATEGORY** (Check applicable category. See Expedited or Exempt policies for instructions.)  
 This proposal requires review by a full committee.  
 This proposal is eligible for expedited review. Specify category or categories: \_\_\_\_\_  
 This proposal is exempted from full sub-committee review. Specify category or categories: \_\_\_\_\_

17. **IS THIS A MULTI-CENTER STUDY?** YES { } NO { }

18. **HAVE YOU, OR THE STUDY SPONSOR, REGISTERED YOUR CLINICAL TRIAL AT [www.clinicaltrials.gov](http://www.clinicaltrials.gov) OR ONE OF THE OTHER ACCEPTED TRIAL REGISTRY SITES?**  
YES { } NO { }

**Note:** The editors of the major medical journals (International Committee of Medical Journal Editors, World Association of Medical Editors) have decided they will no longer publish unregistered research; and in order to be published all new trials must be registered as of July 1, 2005, and all existing trials must be registered by September 13, 2005. At present the IRRC does not require the registration of clinical trials, but it has decided to monitor registration and to encourage all researchers working at Sparrow to register their trials.

19. **ABSTRACT:** *Summarize the research (its purpose, goals, aims, hypotheses and general design) to be conducted. In particular, discuss what will be done to research subjects.*

20. **SUBJECT POPULATION:** *Describe your subject population (e.g., high school athletes, women over 50 with breast cancer, small business owners):*

20a. **The study population may include (check each category where subjects may be included by design or incidentally):**

Minors	{ }*	
Pregnant Women	{ }	
Women of Child-Bearing Age	{ }	
Institutionalized Persons	{ }	(◀ Note: Includes prisoners)
Students (Residents)	{ }	
Low Income Persons	{ }	
Minorities	{ }	
Incompetent Persons (or those with diminished capacity)	{ }*	

\*If you check either of these boxes, be advised that special procedures for informed consent need to be considered (see our policies available at <http://www.sparrow.org/irrc>, Institutional Research Review Committee/Research Center). This in no way is meant to discourage inclusion of this group of subjects, but to inform you that the NIH/DHHS Office of Human Research Protection (OHRP) has special requirements for these potential subjects.

**Please Review the FDA Guidelines for the Study and Evaluation of Gender Differences....**

20b. **Number of subjects (including controls):** \_\_\_\_\_

20c. **If you are associated with the subjects (e.g., they are your students, employees, patients), explain the nature of the association:**

20d. **How will subjects be recruited? (Attach appropriate number of copies of recruiting advertisement, if any.)**

20e. **Will you be selecting patients of other physicians?** YES { } NO { }  
*If yes, describe the procedure for obtaining the attending physician's prior agreement:*

20f. **Will someone receive payments for recruiting the subjects?** YES { } NO { }  
*If yes, explain the amount of payment, who pays it, and who receives it.*

20g. **Will the research subjects be compensated?** YES { } NO { }  
*If yes, give the details concerning payment, including the amount and schedule of payments. This information must be included in the informed consent form.*

20h. **Could the subjects incur additional financial costs, as a result of their participation in this study?**  
YES { } NO { } MAYBE { }  
*If yes or maybe, explain. This information must be included in the informed consent form.*

20i. **Will this research be conducted with subjects who reside in another country or live in a cultural context different from mainstream US society?** YES { } NO { }

- (1) If your answer is yes, will there be any corresponding complications in your ability to minimize risks to subjects, maintain confidentiality and/or assure their right to voluntary informed consent as individuals? YES { } NO { }
- (2) If your answer to 20i.(1) is yes, what are these complications and how will you resolve them?

21. **ANONYMITY/CONFIDENTIALITY:** *Describe procedures and safeguards for insuring confidentiality or anonymity.*

21a. Provide a detailed explanation on how you plan to protect data when it is to be sent electronically (e.g. reporting to the sponsor).

21b. Have you reviewed the Security Guidelines provided on the IRRC's Web site? YES { } NO { }  
<http://www.sparrow.irrc/research.asp>  
*If not, do so before submitting this application.*

22. **METHODS/MATERIALS/PROCEDURES (list and explain in layman terms) ON HUMAN SUBJECTS**  
*What treatment, interventions, special skills or experiments are involved? What safety measures are used for the procedures on human subjects? How long will each subject be involved in the study? If using pre-existing data, describe your analyses and use of information.*
23. **RISKS AND BENEFITS:** *Describe possible physical, psychological, social, legal, economic risks and/or inconveniences associated with this study. Describe benefits to individual or society in general.*
- 23a. Briefly describe the safety monitoring plan that you and/or the sponsor will use to assess unexpected adverse events and the means whereby the IRB is periodically going to be informed about the monitoring results (e.g. summary of safety information or analysis of adverse events provided by the sponsor that describe significant changes in a product's safety profile; reports of individual adverse events only if they have significant implications for human subject safety; reports of aggregate data identifying unexpected adverse events; and reports from a data monitoring committee (DMC) or data safety monitoring board (DSMB) whether these reports describe concerns or identify no problems, etc.). *The study protocol should describe this plan in detail.*
24. **USE & DISCLOSURE OF PROTECTED HEALTH INFORMATION:** Describe how you will comply with the IRRC Policy: Use and Disclosure of Protected Health Information for Purposes of Research.
- 24a. Have you included the appropriately completed HIPAA Use and Disclosure of Protected Health Information (PHI) for Purposes of Research Authorization form to be used in combination with the informed consent form?        YES    { }    NO    { }
- 24b. If your answer to 24a. is no, please answer the following:
- (1) Does the research involve more than minimal risk to the human subjects?  
       YES    { }    NO    { }
- If the answer to 24b.(1) is yes, see 24a. and submit appropriate HIPAA form.  
 If the answer to 24b.(1) is no, describe the following:
- (a) *Describe how you will protect the identifiers, as listed in the Policy, from improper use and disclosure.*
- (b) *Describe how you will destroy the identifiers as soon as possible:*
- (c) Will the PHI be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research, or for other permitted research uses or disclosures?        YES    { }    NO    { }
- (2) Can the research practicably be conducted without receiving a waiver of authorization under the Policy?        YES    ( )    NO    { }
- (3) Can the research practicably be conducted without access to and use of PHI?  
       YES    { }    NO    { }
- (4) *Describe the PHI necessary to conduct the research:*

25. **CONSENT PROCEDURES:** Describe consent procedures to be followed, including how and where informed consent will be obtained. Provide a copy of the proposed consent form.

26. **CONFLICT OF INTEREST:**

26a. Have you or will you or a member of your immediate family receive, from the sponsor of the research, financial or other forms of compensation? YES { } NO { }

26b. Do or will you or a member of your immediate family have a vested interest in the company/agency/firm that is to sponsor the research? (Answer "No" if there is no sponsor for the research.)  
YES { } NO { }

If the answer to either 26a. or 26b. is yes,

(1) Describe below the relationship between you or a member of your immediate family and the sponsor of the research:

(2) Include a statement in the consent form addressing conflict of interest, or state below why you believe such a statement is not necessary for the protection of human subjects.

(3) Are you submitting an FDA form 3454 or 3455 (Conflict of Interest)?  
YES { } NO { }

27. **CONTACTS:**

**The Principal Investigator is responsible for obtaining the approval from the applicable Department Directors/Managers from whom you will require assistance for this study. Be aware that without this departmental approval you may not be able to conduct your study at Sparrow Health System facilities even if the IRB has approved the research project.**

Be sure to explain to the Director/Manager what your needs will be.

**Consider:**

1. staff time (pull records, collect data, prepare or administer medication, etc.)
2. additional supplies
3. equipment
4. training of staff or physicians
5. any other resource needs
6. be in agreement regarding departmental reimbursement of expenses, if applicable

**To the Researcher:** Please identify below any departments within Sparrow Health System which will be affected by this research and obtain the Department Managers approval.

Medical Records	Not Applicable	{ }	Yes	{ }	or	No	{ }
Laboratories	Not Applicable	{ }	Yes	{ }	or	No	{ }
Nursing	Not Applicable	{ }	Yes	{ }	or	No	{ }
Pharmacy	Not Applicable	{ }	Yes	{ }	or	No	{ }
Other (specify)	Not Applicable	{ }	Yes	{ }	or	No	{ }

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Institutional Research Review Committee  
George S. Abela, MD, Chair  
Suzanne Leialoha, CIM, IRB Administrator  
Office of Research Oversight and Compliance/IRB  
1215 E Michigan Avenue PO Box 30480  
Lansing MI 48909-7980

Phone: 517.364.2150 Fax: 517.364.2763 Email: [irrc@sparrow.org](mailto:irrc@sparrow.org)  
IRRC Web Site: <http://www.sparrow.org/irrc/research.asp>

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**BEFORE SUBMITTING YOUR APPLICATION, PLEASE REVIEW THE CHECKLIST BELOW.**

28. CHECKLIST

*Did you submit the following items along with the Application form?*

YES	NO	NA	FULL COMMITTEE REVIEW -
			<ul style="list-style-type: none"> <li>Letter from Principal Investigator requesting Waiver of IRB Review Fees, if project is not funded.</li> </ul>
			<ul style="list-style-type: none"> <li>Curriculum Vitae and/or Resume for each investigator</li> </ul>
			<ul style="list-style-type: none"> <li>Protocol</li> </ul>
			<ul style="list-style-type: none"> <li>Abstract</li> </ul>
			<ul style="list-style-type: none"> <li>Questionnaires, Surveys, Advertisements, Recruitment Information, etc.</li> </ul>
			<ul style="list-style-type: none"> <li>Informed Consent Form</li> </ul>
			<ul style="list-style-type: none"> <li>Investigator's Brochure, if applicable</li> </ul>
			<ul style="list-style-type: none"> <li>Other institutional approval(s), if applicable</li> </ul>
			<ul style="list-style-type: none"> <li>HIPAA Patient Authorization for Use &amp; Disclosure of Protected Health Information for Research form, if applicable.</li> </ul>
			<ul style="list-style-type: none"> <li>Verification of Human Subjects Training for entire research team.</li> </ul>
			<ul style="list-style-type: none"> <li>Other</li> </ul>

Format/WebSite Information Updated 12/7/06; 12/12/06; 01/08/07.; 8/2/07; 8/13/07; 8/27/07.  
Revisions IRRC Approved 2/3/00; 02/05/01/ 05/07/01; 05/10/04; 10/11/04; 09/12/05; 1/9/06.; 12/11/06.

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