



FO 301-B

APPLICATION
FOR
RENEWED APPROVAL OF RESEARCH PROTOCOL

Institutional Research Review Committee (IRRC)

- **The IRRC requires all researchers with projects approved by Committee to have completed, on a bi-annual basis, the Human Subjects Training Tutorial prior to continuing their research. Present verification of current human subjects training along with the renewal application packet. Links provided below:**

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

TITLE OF RESEARCH PROTOCOL:

RESPONSIBLE PRINCIPAL INVESTIGATOR:

Name:
Complete Mailing
Address:

Phone:
Fax:
Email:
Primary Employer:

CO-INVESTIGATOR(S): *Submit additional names on a separate sheet*

Name:
Mailing
Address:

Name:
Mailing
Address:

Phone:
Fax:
Email:
Primary Employer:

Phone:
Fax:
Email:
Primary Employer:

PROFESSIONAL STAFF, AND/OR STUDENT(S):

Name:
Phone:
Fax:
Email:

Name:
Phone:
Fax:
Email:

Please indicate if they are new Investigator(s), Co-Investigator(s), Professional Staff, or Student(s). On a separate page, describe specific qualifications of new investigator(s) and attach their curriculum vitae or resume.

1. **HAVE THERE BEEN ANY CHANGES IN THE APPROVED PROTOCOL SINCE THE LAST IRRC REVIEW?** YES { } NO { }
If yes, please explain:

- HAVE THERE BEEN ANY CHANGES IN THE CONSENT FORM SINCE THE LAST IRRC REVIEW?** YES { } NO { }
If yes, please explain:

2. **WHEN DID THE STUDY ACTUALLY BEGIN AND WHEN WAS THE FIRST SUBJECT ENROLLED OR DATA COLLECTED?**

a) Began: _____

b) First Subject Enrolled: _____

3. **NUMBER OF SUBJECTS WHO HAVE COMPLETED THE PROTOCOL?** _____

4. **NUMBER OF SUBJECTS CURRENTLY ENROLLED OR NUMBER OF CHARTS REVIEWED?** _____

- a) Are new subjects being enrolled? YES { } NO { }
b) Is data still being collected? YES { } NO { }

If the answer is no to either question, please complete 4.c below

- c) Provide an explanation and date of a) closure to accrual of new subjects, or b) completion of data collection.

5. **NUMBER OF SUBJECTS WHO HAVE WITHDRAWN OR HAVE BEEN WITHDRAWN.** _____
This includes death(s) and those injured in any way as the result of the protocol. Give details or reasons for the withdrawals.

6. **LENGTH OF RENEWAL PERIOD REQUESTED** (*maximum one year*) _____

7. **WHAT IS THE ANTICIPATED DATE OF COMPLETION OF THE STUDY?** _____

8. **WHAT IS THE CURRENT STATUS OF FUNDING FOR THIS PROJECT?**

9. **HAS THE DRUG(S), DEVICE(S), OR PROCEDURE(S) BEEN APPROVED BY THE FDA FOR COMMERCIAL USE?** YES { } NO { }

- a) Is this a new indication for an already approved drug? YES { } NO { }

10. **FOR IDE STUDIES ONLY: HAVE YOU IMPLANTED THE DEVICE IN ANYONE OUTSIDE THE RESEARCH STUDY?** YES { } NO { }

If yes, please provide a detailed explanation.

11. **PROVIDE A BRIEF SUMMARY** of the results to-date, including any comments or publications (one brief paragraph).

12. **PROVIDE A CURRENT RISK/BENEFIT ASSESSMENT** based on study results to-date. If no change from the original protocol, please note.

13. **ADDITIONAL MATERIALS REQUIRED before renewal application will be reviewed:**

- a) **Copy of protocol abstract, with explanation of any changes not previously approved by the IRRC.**
- b) **Copy of current consent form, if applicable.**
- c) Reprint of publication derived from this study. If no publication, please note.

14. **HAS THE PRINCIPAL INVESTIGATOR RECEIVED ANY COMMUNICATION FROM THE FDA, SPONSORING COMPANY, OR GRANTING AGENCY REGARDING ANY SIDE EFFECTS OR KNOWN PROBLEMS WITH THE PROTOCOL DRUG OR DEVICE?** YES { } NO { }

If yes, give details below and attach any records from the FDA, sponsoring company or agency and any copies of documents regarding side effects or problems associated with the protocol.

15. **HAS THE PRINCIPAL INVESTIGATOR RECEIVED ANY COMPLAINTS FROM ANY SUBJECTS OR THEIR REPRESENTATIVES?** YES { } NO { }

HAS THE PRINCIPAL INVESTIGATOR RECEIVED ANY ADDITIONAL ADVERSE EVENT INFORMATION PERTAINING TO THE PROTOCOL? YES { } NO { }

If either answer is yes, explain what would indicate greater risk to subjects than when the protocol was reviewed and approved (attach appropriate documentation, if necessary).

16. **HAVE THERE BEEN ANY COMPLICATIONS, ADVERSE SIDE EFFECTS, WITHDRAWALS FROM THE PROTOCOL, OR CHANGES IN MEDICATION(S) IN YOUR SUBJECTS THAT COULD POSSIBLY BE DUE TO THE MEDICATION(S), DEVICE(S) OR PROCEDURE(S)?** YES { } NO { }

If yes, when did they occur and when did you notify the IRRC? Provide details and attach any appropriate documents. Include copies of adverse event reports sent from the sponsor or FDA.

By submission, the principal investigator:

- Affirms that, if applicable, informed consent using the IRRC approved informed consent form was obtained from all subjects.
- Affirms that the protocol and the informed consent being used have not changed since the last IRRC approval and that this protocol is being strictly adhered to.
- Acknowledges that any new or significant side effects or adverse events (including deaths) believed to be due to this study must be reported to the IRRC within 48 hours, but no later than five (5) days of occurrence.
- Attest to the accuracy of the information above, and pledge to maintain the highest ethical and scientific research practices in the conduct of this study.
- Affirms he/she has reviewed the protocol and accepts the responsibility for continuing the research project in accordance with the protections of human subjects as specified in the Federal regulations and Sparrow Health System IRB policies, including the supervision of professional staff and any student(s) investigator(s).

Principal Investigator

Date

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 Lansing MI 48909-7980
 PHONE: 517.364.2150 FAX: 517.364.2763 Email: irrc@sparrow.org
 IRRC Website: <http://sparrow.org/irrc/research.asp>

BEFORE SUBMITTING YOUR RENEWAL APPLICATION, PLEASE REVIEW THE SUBMISSION CHECKLIST ON THE FOLLOWING PAGE.

CHECKLIST: *Did you include the following items?*

YES	NO	NA	FULL COMMITTEE REVIEW and/or EXPEDITED REVIEW
			• Completed application
			• Curriculum Vitae and/or Resume for each investigator
			• Protocol - <i>to include any modifications previously approved by the IRRC</i>
			• Abstract
			• Questionnaires, Surveys, Advertisements, etc.
			• Informed Consent Form
			• Investigator's Brochure
			• Other institutional approval(s)
			• Verification of current Human Subjects Training, if applicable at time of submission
			Other