For Office Use Only
Last full review: _____
Assurances 1 2 3 4
Current approval date: _____

APPLICATION FOR *RENEWED* APPROVAL OF A PROJECT INVOLVING HUMAN SUBJECTS

University Committee on Research Involving Human Subjects (UCRIHS)
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WEB SITE - http://www.msu.edu/user/ucrihs/

Office Hours: M-F (8:00 A.M.-Noon & 1:00-5:00 P.M.)

Please write in your IRB # [ ]

DIRECTIONS: 1. Please complete all questions on this form and 2) Attach a copy of your **CURRENT CONSENT FORM**. 3. Responsible Investigator must sign this page.

**NOTE: This Renewal form with its respective enclosures (e.g. current consent forms, revised instruments, etc.) may now be submitted electronically as an email attachment. This email must be sent from the MSU pilot account of the Responsible Principle Investigator (i.e., 1st Investigator of record).

REQUIRED

1. Responsible Project Investigator:
(MSU Faculty or staff supervisor)
Name: _____
Social Security #: _____
Department: _____
College: _____
Rank at MSU:
Mailing Address: _____
Phone _____
Fax: _____
Email: _____

The provided information is complete and accurate; furthermore, I accept continued responsibility for conducting the proposed research in accordance with the protections of human subjects as specified by UCRIHS, including the supervision of faculty and student co-investigators.

SIGN HERE: _____
Date:
Note: Without signature, application can not be processed

IF APPLICABLE

2. Secondary Investigator:
(**Students Must Provide Student ID#**)
Name: _____
Student ID#: or SS# _____
Department: _____
College: _____
Mailing Address: _____
Phone: _____
Fax: _____
Email:

Additional Investigator Information
3. Name: _____
Student ID#: or SS# _____
4. Name: _____
Student ID#: or SS# _____
5. Name:
Student ID#: or SS#

[ ] Check box if there is any change in Co-Investigators

6. Title of Project: _____
[ ] Check box if there is a title change. _____
_____

Form Revised 6/2001 (1)

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Subcommittee _____ Agenda _____

7. Funding sourve: _____
if applicable, MSU Contracts and Grants app. and / or acct. # _____

8. Has the project funding status changed since last reviewed? No [ ] Yes [ ]
If **Yes,** please describe: _____
If Yes, and the changes in funding involve new funding source(s), please submit the UCRIHS Study Revision Form with appropriate documents.

9. Has this protocol been submitted to the FDA or are there plans to submit it to the FDA?
No [ ] Yes [ ] If **Yes**, is there an IND #? No [ ] Yes [ ] #_____

10. Does this project involve the use of Materials of Human Origin (e.g., human blood or tissue)?
No [ ] Yes [ ]

11. How many subjects have been enrolled to date? _____

12. If more subjects will be recruited, how many? _____

13. Contact with subjects was completed and on-going research only involves data analyses. No [ ] Yes [ ]

14. Do you propose **any changes** to your study as last approved by UCRIHS (e.g., title change, changes in investigators, the target population, recruiting methods, surveys or study instruments, or the study protocol)?
No [ ] Yes [ ] If **Yes** (i.e. you wish to revise your protocol as well as renew it), attach the UCRIHS Study Revision Form with appropriate documents.

15. Have there been any previously unreported **adverse events or other negative consequences** suffered by the subjects because of their participation in this research?
No [ ] Yes [ ] If **Yes**, attach the UCRIHS Study Revision Form with appropriate documents.

16. Has there been any previously unreported **change in the research environment or new information** that would indicate greater risk to the human subjects than that assumed when the protocol was initially reviewed and approved? This may include political or cultural changes in the study venue, new information from other studies, or participants' reactions (physical or emotional) while on this study.
No [ ] Yes [ ] If **Yes**, attach the UCRIHS Study Revision Form with appropriate documents.

17. Have there been any previously unreported **complaints** by the subjects or their representatives related to their participation in this study?
No [ ] Yes [ ] If **Yes**, attach an explanation outlining the complaint(s) in sufficient detail for UCRIHS review.

18. Has there been a lapse in approval between your current project expiration date and when this renewal application will be approved for renewal (estimate approx. 15 days after this office receives your Renewal application)?
No [ ] Yes [ ] If **Yes**, then, then include a statement below explaining why there has been a lapse in approval and provide a written assurance explaining what, if any, contact has been made during the lapse in approval.

19. Please provide a brief summary of the study progress to date.

If this study is active and additional subjects will be recruited, a copy of the current Informed Consent Statement **must** be returned with this form (even if it is the same as previously approved). If the research status (See 19 above) involves only on-going data analyses or follow-up, then resubmission of the consent form is not necessary.