

Appendix D
Institutional Review Board
Medaille College
Buffalo, New York 14214

Renewal Application for Research Project Using Human Subjects

Name and Department of Investigator or Faculty Advisor:

Name and Department of Co-Investigator(s) (if applicable):

Name of Student Investigator(s) (if applicable):

Project Title:

IRB Number Assigned to Project:

Date Previous Approval Expires:

PLEASE NOTE:

- If you wish to continue using human subjects or collecting data for your project, it must be reviewed by the Institutional Review Board (IRB) before the date indicated above. Please submit a renewal application no later than 30 days prior to the project expiration date.
- All changes to the approved research, which have occurred since the initial review or the last annual renewal, must be submitted to the IRB. Also, you may NOT continue to use human subjects beyond the previous approval date unless you have received approval from the IRB. To do so constitutes a violation of the IRB Policy at Medaille College.

Who Must Renew?

Please indicate YES or NO for each of the following questions to determine whether or not your use of human subjects requires renewal:

1. Will you in the next year be obtaining data through intervention or interaction with human subjects? YES NO

2. Will you in the next year be continuing to obtain private information on human subjects? YES NO

3. Will you in the next year be analyzing or manipulating data previously collected from human subjects in a way that increases risk to human subjects beyond the level previously approved for this project? YES NO

4. Is the principal investigator on the continuing project different from the principal investigator approved by the IRB? YES NO

5. Is this project currently receiving external funding or do you anticipate receiving external funding for this project? YES NO

* If you answered "yes" to either question 1, 2, 3, or 5, please submit the number of copies of this renewal application indicated below.

* If you answered "yes" to question 4, the new principal investigator must submit an initial application for new research involving human subjects.

** If you do not plan to continue this project and have checked "NO" for **all** of the above renewal questions, please check here and it will be terminated from our active files upon receipt of this document.

Thank you very much.

CONTENTS OF THE RENEWAL APPLICATION:

1. Present a description of the project that was proposed in the original application. If any materials relevant to the use of human subjects have been or will be modified, please include a copy of the proposed modifications. Include a final draft copy of the consent form(s), if applicable, for review. This completed renewal application (including signatures) should be the first two pages of your renewal request. See below to determine the number of copies to submit.

2. Indicate whether the project was undertaken. Indicate how many subjects have participated and summarize briefly what you have learned thus far. Provide a summary of relevant recent literature, if any.

3. Indicate whether there have been any problems (such as adverse effects or complaints) involving human subjects since the previous IRB review. If there have been problems, describe how they have been handled.

4. Indicate whether there will be any modifications in procedures using human subjects, types of subjects, or the consent process since the previous IRB approval. Please describe ALL such changes. Please provide copies of any modified forms or instruments for approval.

5. Do you expect the project to be funded by an external agency? If so, and it is an agency different from the one originally reported, please provide the name and address of the agency that you expect will provide the funding.
6. Indicate the specific location (building and room number) in which the official records of this research project will be retained.

If your project originally received an expedited review and remains unchanged from what was originally proposed (see #4 above), and there have been no problems involving human subjects (see #3 above), please submit **four copies** of the renewal application.

If the original application received an expedited review, there were no problems during this project, and all proposed changes from the previously approved project are minor, please submit **four copies**.

Twelve copies are required if there were any problems involving human subjects or if any substantial changes have been made to the project which was originally approved. **Twelve copies** are also needed if the original proposal received a full board review.

The Principal Investigator(s) (and Student Investigator, as appropriate), in signing this renewal application, certify that they have followed the recommendations of the IRB, that the IRB Co-Chairs have been notified of all additions or changes in the procedure subsequent to the last review, and that any consent forms used in connection with the project have been retained by the Principal Investigator.

_____ Principal Investigator or Faculty Advisor	_____ Date
_____ Co-Investigator (if applicable)	_____ Date
_____ Student Investigator (if applicable)	_____ Date