LOYOLA
UNIVERSITY MARYLAND

APPLICATION FOR APPROVAL OF INVESTIGATION INVOLVING HUMAN PARTICIPANTS

Loyola University Maryland

(Application must be typed)

1. Principal Investigator:

   Mailing Address:

   Contact Phone: Email Address:

   Co-Investigator(s): (include affiliation if not from Loyola)

2. If you are a student, provide the following:

   Faculty Sponsor: Campus Phone:

   Department:

3. Project Title:

NOTE: NO CONTACT WITH HUMAN SUBJECTS MAY OCCUR UNTIL THIS APPLICATION HAS BEEN APPROVED.

4. Dates during which research with human participants will take place (including all contact with human participants and until analysis of subject identifiable data and records are complete or access to identifiable data and records is no longer necessary):

   Date research with human participants will begin: Click here to enter a date.

   Date research with human participants will end: Click here to enter a date.

5. Has this project been previously considered by Loyola's Institutional Review Board?

   ☐ Yes ☐ No If yes, give log # and approval date: Click here to enter a date.

6. Is a proposal for external support being submitted? ☐ Yes ☐ No

   If yes, you must submit one complete copy of that proposal as soon as it becomes available and complete the following:

   a.) Name of Grant Program:

   b.) Name of Grant Agency:

   c.) Is notification of human subjects approval required? ☐ Yes ☐ No

7. Description of Human Participants: Quantity: _____ Age: _____

Male: _____ Female: _____

8a. In your judgment, does your research fall under one of the six exempt categories? ☐ Yes ☐ No

If you believe it does, indicate the category under which you are claiming exemption. A listing of exempt categories is included in Loyola University Maryland's *Policies and Procedures for Research Involving Human Participants*, found on the Office of Research and Sponsored Programs website.

Category: _____

If you are claiming an exemption, skip numbers 8b and 15-16

8b. Does your project fall under one of the categories eligible for expedited review? ☐ Yes ☐ No

A listing of expedited categories is included as an attachment to Loyola University Maryland's *Policies and Procedures for Research Involving Human Participants* found on the Office of Research and Sponsored Programs website.

9. STUDENT PROJECTS ONLY:

Is this project an independent research project, thesis, or dissertation? ☐ Yes ☐ No

If no, is your project a supervised student project that was assigned as part of the requirements for a course? ☐ Yes ☐ No

Course No. and Name: _____

10. Describe the source(s) of participants and the selection criteria. Specifically, where did you obtain the names of potential participants (i.e. agency files, hospital records, local organizations, etc.)? Where and how will you contact them?

_____

11a. Is any of the information being gathered Protected Health Information covered by the Health Insurance Portability and Accountability Act (HIPAA)? ☐ Yes ☐ No

11b. If yes, are you using an informed consent document that is consistent with HIPAA regulations? (Please attach a sample.) ☐ Yes ☐ No

If the response to 11b is no, you must attach an *Addendum to Application for Approval of Investigation Involving Human Participants*, *Request for Waiver* or *Alteration of Patient Authorization Requirements* to this application.

12. **Procedures:** Provide a step-by-step description of each procedure, including the frequency, duration and location of each procedure.

13. **Description:** Briefly describe the proposed research: Include major hypotheses and research design.

14. **Consent:** Describe the informed consent process and attach all consent documents. For projects involving minors: describe the process through which assent will be obtained and attach copies of assent forms. If you have not indicated that the project is exempt and consent and/or assent will not be obtained, explain why a waiver is requested.

15. **Benefits:** Describe the anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result.

16. **Risks:** Describe the risks involved with these procedures (physical, psychological and/or social) and the precautions you have taken to minimize these risks.

17. Starting June 1, 2009, any faculty member or other Loyola employee conducting independent research or overseeing student-conducted research and any student working on independent research, a dissertation or thesis that involves research with human subjects is required to complete a free online education program prior to the review of his or her *Application for Approval of Investigation Involving Human Participants*.

If the application if for a classroom project, the faculty member who assigned the project is responsible for completing the online program, acquainting students with the human subjects education, and ensuring that classroom-based projects are conducted in accordance with Loyola University Maryland's *Policies and Procedures for Research Involving Human Participants*.

The online education course can be accessed at http://phrp.nihtraining.com/users/login.php

An initial copy of the program certificate of completion must be submitted to the Office of Research and Sponsored Programs, either directly or with an application. Further submission of the certificate is not required unless updated information is released through the online program.

Certificate No: Certificate Date: Click here to enter a date.

18. Principal Investigators must submit a *Request for Amendment* form when seeking to make a change to a study that has already been approved.

Committee approvals for expedited and full review applications are for one-year periods. If the research activity extends past one year, applications must submit a *Request for Renewal* form at least three weeks prior to the expiration of the initial approval period.

Any problems connected with the use of human participants once the project has begun must be reported to the Office of Research and Sponsored Programs and/or the Institutional Review Board immediately.

I agree to provide whatever surveillance is necessary to ensure that the rights and welfare of the human

participants are properly protected. I understand that I cannot initiate any contact with human participants before I have received approval and/or complied with all contingencies made in connection with that approval.

_____ Date: _____

Signature of Principal Investigator/Project Director

19. Approval by Faculty Sponsor (required for all students):

I affirm the accuracy of this application, and I accept responsibility for supervising the conduct of this research project and the protection of human participants as required by law.

_____ Date: _____

Signature of Faculty Sponsor

Please submit the completed application, together with copies of all relevant documents (survey instruments, informed consent, education certificate, etc.) to the Office of Research and Sponsored Programs, Beatty Hall 116, irb@loyola.edu.

For further information on Loyola University Maryland's Institutional Review Board please visit: www.loyola.edu/irb.