LOYOLA
UNIVERSITY MARYLAND

# APPLICATION FOR APPROVAL OF INVESTIGATION INVOLVING HUMAN PARTICIPANTS

Loyola University Maryland

(Application must be typed. Changing the document requirements or questions is prohibited and would result in an automatic decline of your application)

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

**Researcher Information**

1. **Principal Investigator**:

   **Department:**

   **Mailing Address:**

   **Email Address:**

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

   *Please list all the study personnel on your project indicating whether they are faculty, staff or students. List their affiliation if they are not from Loyola University Maryland. If you have yet to hire your project staff, please list them as TBD and submit an amendment when you hire them.*

| Name | Affiliation | Research responsibility |
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2. (#2 required if you are an undergraduate or graduate student)

   **Faculty Sponsor:**

   **Department:**

**Proposed Research Description**

3. **Project Title:**

4. **Requested dates[1] 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:**

**Date research with human participants will end:**

5. **Has this project been previously considered by Loyola's Institutional Review Board**? **Yes** ☐ **No** ☐

**If yes, give log # HS-and approval date**:

6. **Is a proposal for external support being submitted? Yes** ☐ **No** ☐
**If yes, submit one complete copy of that proposal as soon as it becomes available and complete the following:**

**Name of Grant Program:**

**Name of Grant Agency**:

**Is notification of human subjects approval required**? **Yes** ☐ **No** ☐

7. **Briefly describe the proposed research. Include major hypotheses and research design**.

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8. **Provide a step-by-step description of each procedure of your research project including the frequency, duration and location of each procedure**.

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**Type of Review**

9a. **In your judgement, does your research fall under one of the exempt categories? Yes** ☐ **No** ☐

**If yes, indicate the category under which you are claiming exemption.** ***A listing of exempt categories is included on Loyola University Maryland's IRB webpage.***

**Exemption Category:** 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐

9b. **In your judgement, does your research require limited IRB review?** ***(Is it exemption #2 or #3 with identifiable information being collected?)*** **Yes** ☐ **No** ☐

[1] Regardless of the date selected, no research with human participants may occur until authorization is received from the IRB. Therefore, the IRB will automatically change the start date to the date of authorization if the requested start date is prior to the date of authorization.

9c. **If no, are you submitting your application for expedited review? Yes ☐ No ☐**

*A description of expedited review can be found on Loyola University Maryland's IRB webpage.*

10. **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 ☐ **If yes, provide course name and number**:

**Participants**[2]

11. **Description of human participants:** **Quantity** **Age**

**Male** **Female**

**List any vulnerable populations that will be included as participants.**

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

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13. **Will you be collecting identifiable information from participants? Yes ☐ No ☐**

**Explain your procedures for collecting and storing data. Who will have access? What will happen to the information when the study is over?**

[2] If you are accessing information from an agency such as a hospital, clinical center (including Loyola Clinical Centers), or other institution, you must ascertain what approvals or permissions are required from the agency. You should obtain these approvals prior to submitting an application to the IRB and attach the approval documents to your application.

14a. **For applications claiming an exemption under category 2 ONLY:**
**Will information be recorded in a way that participants can be identified directly or through identifiers?**

**Yes** ☐ **No** ☐

**14b. If "yes" would disclosure of information obtained reasonably place subjects at risk of criminal or civil liability or be damaging to subjects financial standing, employability or reputation?** **Yes** ☐ **No** ☐

*A description of exempt category B is included in Loyola University Maryland's IRB webpage.*

(If you answered yes to BOTH 14a and 14b, your application does NOT qualify for exempt review.)

**Consent**

15. **Are you using a written consent form that the participant reads and signs?** **Yes** ☐ **No** ☐

**If "no," skip to question 18. If "yes," continue to 16.**

16. **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.**

17. **Are you requesting a modification or waiver of informed consent (i.e. deception or incomplete disclosure part of the research design or not seeking informed consent)?** **Yes** ☐ **No** ☐

If "yes," respond to question 18. If "no," continue to 19.

**Waiver or Modification of Documentation of Written Informed Consent**

**The federal regulations allow instances in which the IRB may approve a consent procedure that waives the consent or modifies some of the elements of the informed consent process, provided the protocol meets the following criteria:**
**(a) The research involves no more than minimal risk to the participants,**
**(b) The waiver or modification will not adversely affect the rights and welfare of the subjects,**
**(c) The research could not practicably be carried out without the waiver or modification, and**
**(d) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**

18a. **Will the only record linking the participant and the research be the consent document, and the principal risk to the participant would be potential harm resulting from a breach of confidentiality?**

**Yes** ☐ **No** ☐

18b. **Do you consider this project to be no more than minimal risk of harm to subjects, and involve no procedures for which written consent is normally required outside of the research context?**

**Yes** ☐ **No** ☐

18c. **Please explain why you are requesting a waiver or modification of documentation of written consent, how your project meets the requirements above, and a description of how consent will be obtained.**

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**Protected Health Information**

19. **Is any of the information being gathered Protected Health Information (PHI) covered by the Health Insurance Portability and Accountability Act (HIPAA)?**

**Yes** ☐ **No** ☐

*For information related to accessing PHI that is covered by HIPAA, visit Loyola University Maryland's IRB webpage, Relevant Policy Documents.*

20. **If yes, will PHI be obtained from a covered entity without authorization for its use by the patients?**

**Yes** ☐ **No** ☐

21. **If yes, you must attach a written request for waiver or alteration of patient authorization requirements to this application. In your written request, you must demonstrate how the following three criteria are satisfied:**

**a.** **The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on the presence of the following:**
**-an adequate plan to protect the identifiers from improper use and disclosure,**
**-an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a research justification for retaining the identifiers, and**
**-adequate written assurances that the PHI will not be reused or disclosed to any other person or entity.**

**b.** **The research could not practicably be conducted without the waiver or alteration.**

**c.** **The research could not practicably be conducted without access to and use of the PHI.**

**Benefits/Risks**

22. **Describe the anticipated benefits to participants and the importance of the knowledge that may reasonably be expected to result from your procedures.**

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

**Training certificate and Signatures**

24. **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 is 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 CITIprogram.org.***

**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. Renewal completion of the certificate is required when the certificate expires.**

**Certificate No:** **Certificate Date:** **Copy of Certificate is attached**: **Yes** ☐ **No** ☐

25. **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.**

**By signing below, I certify that all information included in this application accurately reflects my research plans involving human participants. Furthermore, I understand that no contact with human participants can occur before IRB approval of this application.**

**_____ Date:**

**Signature of Principal Investigator**

**Approval by Faculty Sponsor (required for all undergraduate and graduate 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, Knott Hall 102F, irb@loyola.edu.**

***For further information on Loyola University Maryland's Institutional Review Board please visit: Loyola's IRB page .***