

**Institutional Review Board (IRB)**

2700 Bay Area Boulevard

Houston, Texas 77058-1098

Telephone: (281) 283-3015 Fax: (281) 283-2143 Email: sponsoredprograms@uhcl.edu Website: uhcl.edu/research

**Faculty/Sponsor Application for Investigation Involving Human Subjects**

**Submission Date:** Click or tap here to enter text.  **Proposed project end date:** Click or tap here to enter text.

**Title:** Click or tap here to enter text.

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| **Principal Investigator/Co-Principal Investigator(s)** | **UHCL Email *(REQUIRED)*** |
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| **Faculty Sponsor** | **UHCL Email *(REQUIRED)*** |
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| **Student Researcher(s)** | **UHCL Email *(REQUIRED)*** | **Alternate Email *(REQUIRED)*** |
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**All applicants are to review and understand the responsibilities for abiding by provisions stated in UHCL’s Federal-wide Assurance (FWA00004068), approved by the Office of Human Research Protections (OHRP) on March 9, 2004: (a) The Belmont Report provides ethical principles to follow in human subject research; and (b) Federal regulations 45 CFR 46 and all of its subparts A, B, C and D are the minimum standards applied to all of UHCL’s human subject research.**

**See** [**http://www.uhcl.edu/research**](http://www.uhcl.edu/research) **- Protection of Human Subjects,** [**Federalwide Assurance**](file:///B%3A%5CRI%5CCPHS%20Info%5CFWA_IORG_IRB%20Registration%20w-DHHS%5C2017%5Cfwa2017.pdf)**.**

**For questions, contact the Office of Sponsored Programs (OSP) at (281) 283-3015 or** **sponsoredprograms@uhcl.edu****.**

How will this project be funded?Click or tap here to enter text.

If grant, this project is:[ ]  **Pending** [ ]  **Funded/Federal** [ ]  **Funded/Other**

Grant title and/or contract number (if available):Click or tap here to enter text.

Will this project be included on the SONA Research Participation System? [ ]  **Yes** [ ]  **No**

**Principal Investigator (PI)/Faculty Sponsor (FS) Responsibilities Regarding Research on Human Subjects:**

* PI/FS acknowledges reviewing UHCL’s FWA (Federal-wide Assurance) approved by the Office of Human Research Protections (OHRP). PI/FS understands the responsibilities for abiding by provisions of the Assurance.
* The PI/FS cannot initiate **any** contact with human subjects until final approval is given by the IRB.
* Additions, changes or issues relating to the use of human subjects after the project has begun must be submitted for IRB review as an amendment and approved **PRIOR** to implementing the change.
* If the study continues for a period longer than one year, a continuing review must be submitted **PRIOR** to the anniversary date of the study’s approval date.
* PI/FS asserts that information contained in this application for human subjects’ assessment is complete, true and accurate.
* PI/FS agrees to provide adequate supervision to ensure that the rights and welfare of human subjects are properly maintained.
* Faculty Sponsors are responsible for student research conducted under their supervision. Faculty Sponsors are to retain research data and informed consent forms for three years after project ends.
* PI/FS acknowledges the responsibility to secure the informed consent of the subjects by explaining the procedures, in so far as possible, and by describing the risks and potential benefits of the project.
* PI/FS assures the IRB that all procedures performed in this project will be conducted in accordance with all federal regulations and university policies that govern research with human subjects.
1. **Data Collection Dates:**
2. From: Click or tap here to enter text.
3. To: Click or tap here to enter text.
4. Project End Date: Click or tap here to enter text.
5. **Human Subjects Description:**
6. Age range: Click or tap here to enter text.
7. Approximate number: Click or tap here to enter text.
8. % Male: Click or tap here to enter text.
9. % Female: Click or tap here to enter text.
10. **Project Summary:**

**Complete application using commonly understood terminology.**

1. **Background and Significance**

Provide a **CONCISE** rationale for this project, based on current literature, information or data. Include references as appropriate.

* ***[Student/PI describe rationale here:]*** Click or tap here to enter text.
1. **Specific Aims**

Purpose, Hypotheses/Research Questions, Goals of the Project. **BRIEFLY** describe the purpose and goals of the project (include hypotheses or research questions to be addressed and the specific objectives or aims of the project. Describe or define terms or methods as needed for the IRB reviewer’s understanding.

* ***[Student/PI describe specific aims here:]*** Click or tap here to enter text.
1. **Research Method, Design and Procedures**
2. Provide an overview of research methodology and design; e.g., how the data are to be collected, analyzed and interpreted.
3. Provide step-by-step description of procedures and how they are to be applied. Procedures are to begin from IRB approval and end when data compiled and results reported. Possible information to include: What are participants asked to do? When and where are they to participate? How long will it take to participate? Describe type of research information gathered from participants, i.e., data being collected.

Note that ethical responsibility of researcher to participant does not end until participant’s information has been destroyed. Research documentation cannot be destroyed for up to three years after completion of a study.

* ***[Student/PI describe method, design and procedures here:]*** Click or tap here to enter text.
1. **Instruments for Research with Human Subject**

Indicate instruments to be used.

1. Submit copies electronically, if possible.
2. Submit copy of copyrighted questionnaire for IRB review. Copy kept on file by IRB.
3. Examples of instruments are as follows: (1) Educational Tests, (2) Questionnaires/Surveys, (3) Psychological Tests, (4) Educational Materials, i.e., curriculum, books, etc., (5) Interview or Phone Script, or (6) Human Subjects Recruitment Advertisements.
* ***[Student/PI describe instruments here:]*** Click or tap here to enter text.
1. **Human Subjects Source and Selection Criteria**

Describe the procedures for the recruitment of the participants. Indicate when a human subject involvement is expected to begin and end in this project. Example information to include:

1. Characteristics of subject population, such as anticipated number, age, sex, ethnic background and state of health.
2. Where and how participants are drawn for selection criteria. Coercion or undue influence needs to be considered and eliminated.
3. How ensuring equitable subject selection.
4. If applicable, criteria for inclusion and/or exclusion and provide rationale.
5. Children are classified as a vulnerable population. See Subpart D, §46.01, of federal guidelines for additional safeguards aimed to protect the rights and welfare of these subjects.
* ***[Student/PI describe human subjects source and selection criteria here:]*** Click or tap here to enter text.

1. **Informed Consent**

For more details, see “Federal & University Guidelines” document, “Informed Consent” section.

1. Describe procedure for obtaining informed consent.
2. Use language that is appropriate for age or understandability of subjects.
3. Attach informed consent page.
4. If applicable, attach the following documents for review: (1) Parental permission form for participation of minors (under 18 years of age). (2) Assent form for children between ages 7 and 17: (2a) ages 12-17 must sign assent form; (2b) ages 7-11 must have witness sign attesting to child’s positive assent.
5. **Request IRB waiver for documentation of informed consent, if appropriate.** Justification is required. See “Federal & University Guidelines.”
* ***[Student/PI describe consent procedure here:]*** Click or tap here to enter text.

1. **Confidentiality**

Describe how data will be safeguarded: (a) how confidentiality maintained; use of personal identifiers or coded data; (b) how data collected and recorded; (c) how data stored during project; (d) who has access to data or participant’s identifiers; (e) who is to receive data, if applicable; (f) what happens to data after research is completed.

Note that research documentation, including signed informed consent forms, are safeguarded for three years after completion of study for federal audit purposes. Faculty sponsors are responsible for safeguarding research documentation completed by students.

* ***[Student/PI describe data security measures here:]***Click or tap here to enter text.
1. **Research Benefits**

Describe any anticipated benefits to subjects as well as reasonably expected general results.

* ***[Student/PI describe anticipated research benefits here:]*** Click or tap here to enter text.
1. **Risks**

Describe any foreseeable risks to the subjects, whether physical injury, psychological injury, loss of confidentiality, social harm, etc., involved in the conduct of the research. Explain precautions taken to minimize these risks. If there are any foreseeable risks, provide contact information of organization(s) for professional treatment.

* + ***[Student/PI describe foreseeable risks here:]***  Click or tap here to enter text.
1. **Other Sites or Agencies Involved in Research Project**

Indicate specific site if not UHCL, .e.g., school districts or school, clinics.

1. Obtain written approval from institution. Approval should be signed and on institution’s letterhead. Other proof of documentation may be reviewed for acceptance by IRB.
2. Institution should include the following information: (B1) institution’s knowledge of study being conducted on its site; (B2) statement about what research study involves; (B3) outline specific procedures to be conducted at site; (B4) identify type of instrument(s) used to collect data and duration needed to complete instruments; (B5) statement that identities of institution and participants will be kept confidential; (B6) institution’s permission granting the use of its facilities or resources; and (B7) include copy of Informed Consent document(s) to be used in recruiting volunteers from the institution.
3. If at all possible, electronic copies of letter or other documentation are to be submitted with IRB application.
4. If letters are not available at the time of IRB review, approval will be contingent upon their receipt.
* ***[Student/PI describe other sites or agencies involved in the research project here:]*** Click or tap here to enter text.