**Office Use Only:** UHD CPHS Application Number

Type of Review: [ ] Not HSR [ ] HSR

**UNIVERSITY OF HOUSTON DOWNTOWN**

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

**DETERMINATION OF NON-HUMAN SUBJECTS RESEARCH**

## PART A: INVESTIGATOR INFORMATION

Project Title:

Principal Investigator (check one): [ ]  Faculty [ ]  Staff [ ]  Student

*Note: It is recommended that the Principal Investigator provide an up-to-date* [*Human Subjects Training*](https://about.citiprogram.org/en/homepage/) *certificate to CPHS as part of their application materials.*

Name: \_\_\_\_\_\_\_\_\_\_

Phone # \_\_\_\_\_\_\_\_\_\_

Department: \_\_\_\_\_\_\_\_\_\_

College: \_\_\_\_\_\_\_\_\_\_

E-mail Address: \_\_\_\_\_\_\_\_\_\_

Mailing address (student investigators): \_\_\_\_\_\_\_\_\_\_

Faculty Sponsor (required for all student investigators and PIs who are not UHD faculty)

Name: \_\_\_\_\_\_\_\_\_\_

Phone #: \_\_\_\_\_\_\_\_\_\_

Department/College: \_\_\_\_\_\_\_\_\_\_

E-mail Address: \_\_\_\_\_\_\_\_\_\_

This project is (check all that apply):

[ ]  Professional Paper [ ]  Independent Study

[ ]  Funded Research (Active or Pending) [ ]  Master’s Thesis

[ ]  Other (specify, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) [ ]  For External Presentation

If this application supports a funding proposal, provide name of external sponsor: .

**PART B: RESEARCH PROJECT SUMMARY**

The Committee for Protection of Human Subjects (CPHS) is required under federal regulations to review and approved all research involving human subjects. The following questions, and [further information below](#_FURTHER_INFORMATION) on page 4, will help determine whether the proposed project falls under **Human Subjects Research** or **Non-Human Subjects Research (NHSR).**

**Select the category/categories that apply to your project:**

[OHRP Decision Chart for reference](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1)

[ ]  Literature Review – data is only from published books, journals, or public-facing websites (please consider whether the data is truly public domain and/or sensitive)

[ ]  Scholarly and Journalistic Activities – (e.g. oral history, biography, literary criticism, legal research, collection and use of information that focuses directly on the specific individuals about whom data is collected)

[ ]  Public Health Surveillance Activities – conducted, supported, or requested by a public health authority

[ ]  Collection and analysis of information by or for a criminal justice agency for activities authorized by a law or court order solely for criminal justice or investigative purposes

[ ]  Quality Improvement/Course Development – for UHD internal use only

[ ]  Publicly Accessible Data Sets – please provide details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Market Research – on customer or client needs or preferences only, not generalizable beyond market

[ ]  De-identified data from another organization, with no access to the data key for the UHD PI under any circumstances. Please provide details including any data use agreement or applicable policy of other organization \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  No [intervention or interaction](#_FURTHER_INFORMATION) with living individuals

[ ]  No activity proposed to obtain or use [private identifiable information](#_FURTHER_INFORMATION) or specimens of living individuals

[ ]  No [systematic approach](#_NHSR_-_FURTHER)

[ ]  No intent of proposed activity to develop or contribute to [‘generalizable knowledge’](#_FURTHER_INFORMATION)

[ ]  Other, please specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: A final determination of the status of this project will be made by CPHS.*

**1. Provide a concise summary of the purpose and rationale of the project, including the endpoints. If this is proposed as a Quality Improvement project, please explain why you believe this is not research.**

**2. Describe the proposed methods and study procedures:**

**3. Describe the role(s) of UHD faculty, staff or students in the design and/or conduct of the proposed activity:**

**4. Describe how data collection will occur and the type of information to be collected about the subjects:**

**5. Indicate whether data will be de-identified, identifiable or coded. If the data are** [**identifiable**](#_FURTHER_INFORMATION) **or coded, please elaborate in your response below:**

**6. Proposed Start Date** (may not precede approval date): OR

 [ ]  Upon CPHS Approval

**7. Describe any potential risks to participants:**

 **7 a) How will you manage these risks?**

# **NHSR - FURTHER INFORMATION**

**KEY DEFINITIONS:**

* **RESEARCH:** Determine if your investigation is a form of "research" under the definitions of [PART A: 45 CFR 46.102](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102): Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
	+ **SYSTEMATIC INVESTIGATION -** A systematic approach involves a predetermined system, method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. A systematic approach includes the collection of information and/or biospecimens, and analysis either quantitative or qualitative.
	+ **GENERALIZABLE KNOWLEDGE** - Activities designed to draw general conclusions, inform policy, or generalize outcomes beyond the specific group, entity, or institution.
* **HUMAN SUBJECTS:** a living individual about whom an investigator (whether faculty, student, or staff) conducting research obtains: (1) information or biospecimens through intervention or interaction with the individual; or (2) identifiable private information or biospecimens.
	+ **INTERVENTION** - includes both physical procedures by which information is gathered and manipulations of the subject or the subject’s environment that are performed for research purposes.
	+ **INTERACTION** - includes communication or interpersonal contact between investigator and subject.
	+ **PRIVATE INFORMATION** - includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.
	+ **IDENTIFIABLE PRIVATE INFORMATION** – information or biospecimens for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information/biospecimen.
	+ **CODED DATA** - means a living individual’s identifiable information such as name or social security number has been replaced by a code, such as a number, letter, or combination thereof and there is a key to link the code to the identifiable information of that individual. Coded data are considered identifiable private information (if the investigator possesses the key to identify a particular subject).

**LINKS:**

[Office for Human Research Protections (OHRP)](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html) – Human Subjects Regulations Decision Charts

[CITI Program website](https://about.citiprogram.org/) – Human Subjects Training Modules may be also used for reference after completion

UHD Policy – [PS 03.A.23](https://www.uhd.edu/provost/office-research-sponsored-programs/human-subjects/Documents/PS03A23.pdf) – Protection of Human Subjects

[UHD CPHS webpages](https://www.uhd.edu/provost/office-research-sponsored-programs/human-subjects/Pages/default.aspx) – including policy, guidelines and a page dedicated to Non-Human Subjects Research determination

Email: humansubjects@uhd.edu​

**PART C: SIGNATURE PAGE**

**PRINCIPAL INVESTIGATOR** – **I hereby acknowledge and accept the responsibility for protecting the rights and welfare of all participating subjects in accordance with federal and institutional policies and procedures. Furthermore, I certify that:**

* NO involvement of human subjects in this project will begin before written approval of the Committee for the Protection of Human Subjects has been received.
* Any additions or changes to this protocol will require the submission of a Request for Revision form and for the review and approval by the Committee for the Protection of Human Subjects prior to initiation.
* All signed consent documents will be retained for at least 3 years past the completion of the research activity. (Note: Faculty sponsors are responsible for retaining signed consents for student projects.)

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Signature of Principal Investigator Date

**FACULTY SPONSOR** (***required for all students or primary investigators who are not UHD faculty or students***) – **I hereby acknowledge and accept the responsibility for supervision of this study to ensure the protection of the rights and welfare of all participating subjects in accordance with federal and institutional policies and procedures. After careful review of this application, I further certify:**

* The accuracy of the information stated in this application AND
* The scientific merit of the proposed project.

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Signature of Faculty Sponsor Date

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| --- |
| The Committee for Protection of Human Subjects defines protection as, “A legally binding written document that commits investigators to compliance with applicable federal minimum standards for the protection of human subjects prior to engagement in research. Please read this document carefully. It outlines the principles and policies of the University of Houston Downtown as well as the responsibilities of each area involved in human subjects research – from the investigator to CPHS to UHD. All investigators are expected to be familiar with this information prior to submission of an application to the Committee for the Protection of Human Subjects. |