

Office Use Only: UHD CPHS Application Number _____

Type of Review: [] Not HSR [] Exempt [] Expedited [] Full Category # _____

**UNIVERSITY OF HOUSTON DOWNTOWN
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
APPLICATION TO CONDUCT RESEARCH USING HUMAN SUBJECTS
(must be typed)**

PART A: INVESTIGATOR INFORMATION

Project Title: _____

Principal Investigator (check one): ☐ Faculty ☐ Staff ☐ Student

Note: Principal Investigator must provide an up-to-date [Human Subjects Training](#) certificate to CPHS as part of their application materials.

*Note: Researchers who will have direct contact with human subjects must have a certificate **for the course "SBR Investigators - Basic/Refresher."** Please consult [Principal Investigator eligibility requirements](#) - a letter of support may be required*

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: _____

If others contribute to this project please provide the following information:

Note: All Co-Investigators must also provide up-to-date [Human Subjects Training](#) certificates.

*Note: Researchers who will have direct contact with human subjects must have a certificate **for the course "SBR Investigators - Basic/Refresher."** See [ORSP CITI Training Document](#) to determine which additional training(s) you need to complete.*

Name	Educational Level	Role	Institutional Affiliation*
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**Co-Investigators from partner institutions may be asked to provide evidence of IRB review/approval.*

This project is (check all that are appropriate):

- ☐ Professional Paper _____ ☐ Independent Study
- ☐ Funded Research (Specify Source: _____) ☐ Master's Thesis
- ☐ Other (specify, _____)

If this application supports a proposal for funding, name of agency: _____.

I believe this project may be:

- ☐ Not Human Subjects Research - [OHRP Decision Chart for reference](#)
- ☐ Exempt Category #_____ - [list of Exempt Categories](#)
- ☐ Expedited Category #_____ - [list of Expedited Categories](#)
- ☐ Full Review

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

PART B: RESEARCH PROJECT SUMMARY

1. State the research hypotheses and research questions to be addressed in this study.

2. What is the importance/significance of the knowledge that may result?

3. Proposed Start Date (may not precede approval date): _____ OR

☐ Upon CPHS Approval

4. Subject Population (check all appropriate)

- | | |
|--|--|
| ☐ Adults (18-64) | ☐ Adults (over 64) |
| ☐ Cognitively or Psychologically Impaired | ☐ Prisoners or Parolees |
| ☐ Children or minors (under 18) | ☐ Institutional Residents |
| ☐ Non-English speaking | ☐ UHD Faculty, Staff, or Students |

a. Expected number of participants: []

b. Age of proposed subject(s) (check all that apply):

☐ Infants (under 3 yrs)

☐ Children (3 - 10 yrs)

☐ Adolescents (11 - 14 yrs)

☐ Adolescents (15 - 17 yrs)

☐ Adults (18 - 64 yrs)

☐ Older Adults (65 yrs and older)

c. Inclusion/Exclusion:

Describe criteria for inclusion and exclusion of subjects in this study. Include justification, how it will be determined, and by whom.

Inclusion Criteria:

Exclusion Criteria:

Justification:

Determination:

d. If this study proposes to *include* children, this inclusion must meet one of the following criteria for risk/benefit assessment according to the federal regulations ([45 CFR 46, subpart D](#)). Check the appropriate box:

☐ (404) Minimal Risk

☐ (405) Greater than minimal risk, but holds prospect of direct benefit to subjects

☐ (406) Greater than minimal risk, no prospect of direct benefits to subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

Provide justification for the selected category:

5. If the research involves any of the following, check all that are appropriate:

☐ Interview

☐ Behavioral Observation

☐ Survey/Questionnaire

☐ Study of Existing Data

☐ Other (specify) _____

6. Location(s) of Research Activities:

☐ UHD campus

☐ Other (specify) _____

☐ UHD Qualtrics website/server

☐ Other Online Survey Tool (specify) _____

Note: A letter of approval from sites other than the UHD must be included with the application. If it is not available, please explain:

7. **Informed Consent of Subjects:** Your study protocol must clearly address one of the following areas:

☐ **Informed Consent.** A signed informed consent is the default. A model informed consent form is available at [UHD's CPHS website](#) and should be used as a basis for developing your informed consent document. **A COPY OF THE DRAFT INFORMED CONSENT MUST BE INCLUDED WITH THIS APPLICATION.**

PART C: RESEARCH PROTOCOL

8. **Describe the research study design.** (Describe the research method to be employed and the variables to be studied. Include a description of the data collection techniques and/or the statistical methods to be employed.)

9. **Describe what the subjects will be asked to do.**

10. **Describe how potential subjects will be identified and recruited?** (Attach a script or outline of all information that will be provided to potential subjects. Include a copy of solicitation, recruitment ad, and/or outline for oral presentation.)

11. **Describe the process for obtaining informed consent and/or assent. How will investigators ensure that each subject's participation will be voluntary (i.e., free of direct or implied coercion)?**

12. **Briefly describe each measurement instrument to be used in this study** (e.g., questionnaires, surveys, tests, interview questions, observational procedures, or other instruments) **AND** attach to the application a copy of each (appropriately labeled and collated). If any are omitted, please explain.

13. Describe the setting and mode for administering any materials listed in question 12 (e.g., telephone, one-on-one, group). Include the duration, intervals of administration, and amount of time required for each survey/procedure. Also describe how you plan to maintain privacy and confidentiality during the administration.

14. Approximately how much time will be required of each subject? Provide both a total time commitment as well as a time commitment for each visit/session.

15. Will subjects experience any possible risks involved with participation in this project?

Risk of Physical Discomfort or Harm	☐ YES	☐ NO
Risk of Psychological Harm (including stress/discomfort)	☐ YES	☐ NO
Risk of Legal Actions (such as criminal prosecution or civil sanctions)	☐ YES	☐ NO
Risk of Harm to Social Status (such as loss of friendship)	☐ YES	☐ NO
Risk of Harm to Employment Status	☐ YES	☐ NO
Other Risks	☐ YES	☐ NO

If yes to any of the above, please explain. Describe procedures, if any, to address risk (such as referrals to agency or other source).

16. Does the research involve any of these possible risks or harm to subjects? Check all that apply.

- ☐ Use of a deception (attach debriefing)
- ☐ Use of incomplete information to the subject regarding the actual purpose of the study (attach debriefing)
- ☐ Use of private records (educational or medical records)
- ☐ Manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses (attach debriefing)
- ☐ Any probing for personal or sensitive information in surveys or interviews
- ☐ Presentation of materials which subjects might consider sensitive, offensive, threatening or degrading
- ☐ Possible invasion of privacy of subject or family (may require additional consent)
- ☐ Other, specify: _____

17. What benefits, if any, can the subject expect from their participation?

18. What inducements or rewards (e.g., financial compensation, extra credit, and other incentives), if any, will be offered to potential subjects for their participation?

PART D. RESEARCH DATA

19. Will you record any direct identifiers, names, social security numbers, addresses (physical or digital/IP address), telephone numbers, patient or student ID numbers, etc.?

☐ Yes

☐ No

If yes, explain why it is necessary to record findings using these identifiers? Describe the coding system you will use to protect against disclosure of these identifiers.

20. Will you retain a link between study code numbers and direct identifiers after the data collection is complete?

☐ Yes

☐ No

If yes, explain why this is necessary and state how long you will keep this link.

21. Will anyone outside the research team have access to the links or identifiers?

☐ Yes

☐ No

If yes, explain why and to whom.

22. Where, how long, and in what format (such as paper, digital or electronic media, video, audio or photographic) will data be kept? In addition, describe what security provisions will be taken to protect these data (password protection, encryption, etc.).

PART E. EXPORT CONTROL & INFORMATION SECURITY

23. Select if the project/proposal involves any of the following Critical Export Concerns:

- ☐ Identify as “classified” requiring a security clearance and/or DoD Form 2345 Militarily Critical Data Agreement
- ☐ Involve collaboration with an entity or an individual located in or governed by a high-risk country (China, Belarus, or Venezuela)
- ☐ Involve any program-related transactions or engagement with Treasury/OFAC-sanctioned countries (Iran, Syria, Russia, Cuba, N.Korea)
- ☐ Involve advising, training, or otherwise engaging with any foreign government agency
- ☐ Require work to be performed in whole or in part in a sanctioned or high-risk country

☐ None

24. Select if the project /proposal involves any of the following Significant Export Concerns:

- ☐ Pre-award sponsor information that defines the scope of work as either export controlled under the Export Administration Regulations (EAR) or the International Traffic in Arms Regulations (ITAR)
- ☐ Include publication restrictions of any kind
- ☐ Include citizenship restrictions or qualifications
- ☐ Require procuring or receiving export-controlled instruments, software, or materials of any kind
- ☐ Require the sharing of specialized instrument technology (including vendor-proprietary installation or repair information) or exposure to a party's proprietary instrument or software design technology
- ☐ Require sharing of sources code for 128-bit encryption software or mass-market encryption products
- ☐ Involve instruments, software, materials, or technology specially designed or modified for defense purposes
- ☐ Require international transfer or export (by any means. e.g., shipment, courier, hand carried, or email) of any item (ex. Research samples, prototypes, electronic devices, software, etc.)
- ☐ None

25. Require any of the following Significant Export Concerns related to Information Security:

- ☐ Require DFARS 7012/19/20 - mandated data security requirements to cover Controlled Unclassified Information (CUI), or other data security requirements
- ☐ Require a Non-Disclosure Agreement (NDA) or other Confidential Data Agreement (CDA) to receive proprietary, export-controlled information from the sponsor or a related third party
- ☐ Access to restricted U.S. Government data bases or other restricted and sensitive US Government information
- ☐ Physical access to a U.S. Government research site or facility
- ☐ Personal Health Information (PHI) or Personally Identifiable Information (PII) considered protected data under HIPAA, FERPA, or EU General Data Protection Regulations
- ☐ None

PART F. Conflict of Interest Disclosure:

Significant Financial Interests: A Significant Financial Interest is defined as an interest valued at greater than \$10,000 or an equity ownership of more than 5% held by an investigator and/or the investigator's spouse and/or dependent children.

26. Financial Interests (check all that apply):

- ☐ Members of the investigative team have no significant financial interest related to this research
- ☐ Members of the investigative team are disclosing the following significant financial interests (*check all that apply*):
 - ☐ Salary or other payment for services (e.g., consulting fees or honoraria)
 - ☐ Equity interests (e.g., stocks, stock options, or other ownership interests)
 - ☐ Intellectual property rights (e.g., patents, copyright, or royalties from such rights)
 - ☐ Other significant financial interest that could affect, or be perceived to affect, the results of the research or educational activities funded or proposed for funding
- ☐ **Other Conflicts** (*check all that apply*):

- ☐ Organizational/Institutional
- ☐ Professional/Relational
- ☐ Other: _____

UHD IRB APPLICATION CHECK-LIST

- ☐ Principal-Investigator's up-to-date certificate of [Human Subjects Training](#), specifically the course entitled "SBR Investigator - Basic/Refresher" is included at the end of application or as a separate attachment
- ☐ All Co-Investigators' up-to-date certificates of [Human Subjects Training](#), specifically the course entitled "SBR Investigator - Basic/Refresher" are included at the end application or as a separate attachment
- ☐ If applicable, letters from partner institutions showing evidence of IRB review/approval are included at the end of the application or as a separate attachment
- ☐ All sections of Part A: Investigator Information are filled in
- ☐ All applicable sections of Part B: Research Project Review Summary are filled in
- ☐ All applicable sections of Part C: Research Protocol are filled in
- ☐ All applicable sections of Part D: Research Data are filled in
- ☐ If applicable, letter(s) of approval/understanding from research sites other than UHD campus are included with application
- ☐ A draft informed consent form is included with application
- ☐ All Informed consent forms (paper and digital) include the following language:

Any questions regarding your rights as a research subject may be addressed to the UHD Committee on Standards for Research involving Human Subjects through its current chair, [insert name of current chair] at [current chair's office phone number] or humansubjects@uhd.edu. Projects that are carried out at the University of Houston-Downtown are governed by requirements of the University and the Federal Government
- ☐ Principal-Investigator has signed the signature page of the application
- ☐ If applicable, faculty sponsor has signed the signature page of the application

PART G: 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 Committees 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.
- Written documentation of any unanticipated problems or injuries connected with an approved protocol must be provided to the Committee for the Protection of Human Subjects within 5 working days of the problem/incident.
- 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.)
- I have completed Human Subjects training online and included my up-to-date certificates with this application.

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.

Signature of Faculty Sponsor

Date

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” as pursuant to Federal Uniform Guidance 45CFR46. 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.