COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
University of Houston Downtown (UHD)

Principles, Procedures and Guidelines

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PART 1 – Principles, Policy and Applicability

Principles

A. This University is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"], regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e., sponsorship).

B. All institutional and non-institutional performance sites for UHD, domestic or foreign, will be obligated by UHD to conform to ethical principles which are at least equivalent to those of UHD, as cited in the previous paragraph or as may be determined by the Secretary of the U.S. Department of Health and Human Services.

C. All activities involving humans as subjects at UHD must provide for the safety, health, and welfare of every individual. Rights, including the right to privacy, must not be infringed.

D. All activities involving human subjects at UHD should be structured such that the possibility of harm to anyone participating is minimized or eliminated. All foreseeable risks to subjects should be reasonable in relation to the good, if any, from which they are expected to benefit and the importance of the knowledge that can reasonably be expected to result.

E. Participation in projects must be voluntary, and informed consent must be obtained from all subjects unless this requirement is specifically waived by the CPHS. If a subject is not legally capable of giving informed consent or is of questionable competence, a legally authorized representative may do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Parents may not expose their child to more than minimal risk except for the child's benefit.

F. An individual does not abdicate any rights by consenting to be a research subject. A subject has the right to withdraw from a research project at any time or can refuse to

participate without loss of benefits to which the subject would otherwise be entitled. Further, a subject has the right to receive appropriate professional care, to enjoy privacy and confidentiality and to be free from undue embarrassment, discomfort, anxiety, and harassment.

G. The safeguarding of information about an individual that has been obtained in the course of an investigation or data collection is a primary obligation of the research investigator.

H. The University encourages collaboration with investigators external to the University; however, additional requirements will be imposed (see Part 2).

I. The Committee for the Protection of Human Subjects (CPHS) at UH-Downtown values high quality and responsible research that protects the rights of all participants. Since research is conducted for a variety of reasons and by a variety of individuals (faculty, staff, students), CPHS procedures require clear explanation of the research plans, benefits, and risks.

J. The CPHS operates on the principles of efficiency and effectiveness and is the primary university body that reviews all research that involves human participants. Through its procedures, CPHS is committed to open communication between researchers and the committee, is supportive of quality research, and strives to provide a timely response to all applications.

K. Projects will be given initial and continuing review by the CPHS as set forth in these guidelines. All members of the UHD community involved in investigation and training are responsible for continual monitoring to assure compliance of their research with these principles.

L. The research investigator should show practical regard for the UHD community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles could impugn the investigator's own name and the reputation of UHD. The investigator does not abdicate ethical and legal responsibility merely by complying with these guidelines.

Institutional Policy

A. All requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all applicable federally-sponsored research, and all other human subject research regardless of sponsorship, except as otherwise noted in this document. Federal (all departments and agencies bound by the Federal Policy) funds for which this document applies may not be expended for research involving human subjects unless the requirements of this document have been satisfied.

B. Except for those categories specifically exempted or waived under Section 101(b)(1-6) or 101(i), all research covered by this document will be reviewed and approved by an Institutional Review Board (IRB) named the Committee for the Protection of Human Subjects (CPHS). The involvement of human subjects in research covered by this document will not be permitted until the CPHS has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative (see Sections 111, 116, and 117 of the CFR), unless properly waived by the IRB under Section 116(c), (d), or by any applicable waiver under Section 101(i).

C. UHD assures that before human subjects are involved in nonexempt research presented to the Committee, the CPHS will give proper consideration to:

1. the risks to the subjects,
2. the anticipated benefits to the subjects and others,
3. the importance of the knowledge that may reasonably be expected to result, and
4. the informed consent process to be employed.

D. Description of UHD's policy for the protection of human subjects is contained in its internal written Policy Statement (PS)03.A.23, which is available on UHD's website.

E. As provided for in 45 CFR 46.118, federally funded applications and proposals lacking definite plans for involvement of human subjects or information about human subjects will not require CPHS review and approval prior to award by outside federal sponsor. However, except for research exempted or waived under Section101 (b) or (i), no human subject may be involved in any project supported by such awards until CPHS review and approval has been certified to the appropriate Federal department or agency. As required under 45 CFR 46.119, the CPHS will review *proposed* involvement of human subjects in Federal research activities undertaken without prior intent for such involvement, but will not permit such involvement until certification of the CPHS review and approval is received by the appropriate Federal department or agency.

F. Before approving applications involving collaboration between a UHD investigator and an outside investigator, the CPHS will review the outside investigator(s) plan to protect human research subjects to ensure that they are at least equivalent to those procedures provided for in the ethical principles to which UHD is committed (see Part 1).

G. UHD will comply with the requirements set forth in 45 CFR 46.114 of the regulations regarding cooperative research projects. When research covered by this document is conducted at or in cooperation with another entity, all provisions of this document remain in effect for that research. UHD may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another Department of Health and Human Services approved assurance. Such acceptance must be (a) in writing, (b) approved and signed by an the chair of the UHD CPHS, and (c) approved and

signed by correlative officials of each of the other cooperating institutions (i.e., a Cooperative Agreement*).*

H. UHD will exercise appropriate administrative overview to ensure that UHD's policies and procedures designed for protecting the rights and welfare of human subjects are being effectively applied in compliance with the Code of Federal Regulations.

Applicability

A. Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under Section 101(b)(1-6) or 101(i), this document applies to all research involving human subjects, and all other activities which even in part involve such research*,* regardless of sponsorship, if one or more of the following apply:

1. the research is sponsored by UHD or
2. the research is conducted by or under the direction of any employee or agency of this University in connection with his or her institutional responsibilities; or
3. the research is conducted by or under the direction of any employee or agency of UHD using any property or facility of UHD, or
4. the research involves the use of UHD's non-public information to identify or contact human research subjects or prospective subjects.

B. All human subject research which is exempt under Section 101(b)(1-6) or 101(i) will be conducted in accordance with: (1) the Belmont Report, (2) this University's administrative procedures to ensure valid claims of exemption, and (3) orderly accounting for such activities.

PART 2 – RESPONSIBILITIES AND PROCEDURES

The Institution

A. UHD acknowledges its responsibility for monitoring the performance of all research involving human subjects, including complying with Federal, state, or local laws as they may relate to such research. To fulfill this responsibility, the CPHS conducts a thorough review of each application and relies on information from the researcher to carry out this responsibility.

B. UHD will require appropriate additional safeguards in research that involves: (1) fetuses, pregnant women, or human ova in vitro fertilization (see 45 CFR 46 Subpart B),

(2) prisoners (see 45 CFR 46 Subpart C), (3) children (see 45 CFR 46 Subpart D), (4) the cognitively impaired, or (5) other potentially vulnerable groups.

C. UHD acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research.

D. In accordance with the compositional requirements of 45 CFR 46.107, this University has established the IRB as described below. The name of this IRB for UHD is the Committee for the Protection of Human Subjects (CPHS).

E. UHD provides both meeting space and staff to support the CPHS review and record keeping duties.

The Committee for the Protection of Human Subjects (CPHS)

A. The CPHS will receive from investigators all research protocols which involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them. A protocol is defined as "a detailed plan of a scientific or medical experiment, treatment, or procedure."

B. The CPHS is responsible for reviewing the preliminary determination of exemption by investigators and for making the final determination based on Section 101 of the regulations. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator. All non-exempt research will be reviewed by the Committee.

C. The CPHS will make the preliminary determination of eligibility for expedited review procedures (see Section 110). Expedited review of research activities will not be permitted where full board review is required.

D. The CPHS will review all research (whether exempt or not) and decide whether UHD will permit the research. No office of the University may approve a research activity that has been disapproved by the CPHS.

E. The CPHS is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

F. The CPHS will review and have the authority to approve, require modification in, or disapprove all research activities, including proposed changes in previously approved human subject research. For approved research, the CPHS will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous CPHS review and approval.

G. Decisions and requirements for modifications made by the CPHS will be promptly conveyed to investigators in writing via email or other written means of communication. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or in writing.

H. The CPHS will determine, in accordance with the criteria found at 45 CFR 46.111 and Federal policies and guidelines for involvement of human subjects in HIV research, that protections of human research subjects are adequate.

I. During the academic year, the CPHS will meet monthly and these dates will be published on the UHD website. During the summer, meetings can be scheduled if applications are submitted to the CPHS. Applications must be submitted at least 2 weeks in advance of the meeting date. The primary reviewer and secondary reviewer will be assigned by the Chair of the CPHS. Copies of the applications will be distributed to the members of the CPHS for review prior to the next scheduled meeting.

J. No applicant involved in the conduct, supervision and/or participation of the research project, who is also a member of the CPHS, shall vote on its approval or disapproval. That member, however, may provide information to the Committee for its review.

K. Minutes of the meeting will be taken by the Director of Office of Sponsored Programs or a designate in his/her absence and approved by the voting members at each subsequent meeting.

L. The CPHS will maintain adequate documentation of its activities in the Office of Sponsored Programs. A separate file for each new application and revision will be kept and will contain the original application, any correspondence regarding the application and the final letter of disposition.

M. The CPHS may elect to impose some additional restrictions or recommendations under which the project must be conducted. The research investigator may be asked to meet with the Committee should it be apparent that clarification or modification in the application is required.

N. The CPHS will forward to the UHD President any significant or material finding or action, at least to include the following:

- any unanticipated injuries or problems involving risks to subjects or others,
- any serious or continuing noncompliance with the regulations or requirements of the IRB, and
- any suspension or termination of IRB approval.

O. In accordance with Section 113, the CPHS will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

P. The CPHS will ensure effective input (consultants or voting or nonvoting members) for all initial and continuing reviews conducted on behalf of projects where there will be human research subjects. The minutes will document the attendance of those other than regular voting members.

Members of the CPHS

A. The CPHS shall consist of nine (9) voting members and one *ex officio* member. Upon recommendation of the CPHS, the UHD President shall appoint members, usually for three-year overlapping terms. Members can be reappointed by the President for another term.

B. All new members are required to go through the current on-line Human Subjects training.

C. Members are responsible for attending all convened CPHS meetings for their full duration. If a member cannot attend a meeting or part of a meeting, he/she is responsible for notifying the Chair and for ascertaining whether a quorum will be present at the meeting.

D. CPHS members are responsible for reviewing in advance of the meeting those materials provided and identified as being items to be considered at the meeting.

E. The primary and secondary reviewers for an application will be chosen from the membership. Both the primary and secondary reviewers must have sufficient expertise to fulfill these roles adequately. If a member feels that he/she cannot be a reviewer for a particular application for any reasons, including but not limited to a lack of expertise or to a conflict of interest, the Chair should be notified.

F. Both the primary and secondary reviewers must carefully review all aspects of the submission, including the protocol, consent form, and other accompanying materials. Both reviewers will lead the discussion of the application at the next regularly convened meeting of the CPHS, if full committee approval is required. If the primary reviewer is unable to present an application to the CPHS meeting due to absence, the secondary reviewer will be expected to do so. The primary reviewer would submit his/her comments to the secondary reviewer in writing (i.e., email, memo, etc.).

G. If the CPHS membership lacks sufficient expertise for a specific protocol, it has the option of seeking additional expertise outside the membership of the CPHS. A request for outside expertise would be given to the Chair by a member or members of the CPHS.

H. A quorum consists of at least one more than one-half of the voting members.

The CPHS Chair

A. The chair shall be selected from the voting members. The chair will have served as the "chair elect" for at least one year prior to becoming chair.

B. The chair is responsible for:

Presiding over CPHS meetings;
Developing the agenda for each meeting;
Reviewing and approving, when appropriate, expedited submissions in according with regulatory requirements;
Determining exempt submissions in accordance with regulatory requirements;
Determining items to be submitted to the convened CPHS;
Maintaining records for the year (in coordination with the Director of the Office of Sponsored Programs); and
Preparing final report for President at the end of each year.

C. In the absence of the Chair, the Chair-elect shall preside over the meeting. In the absence of the Chair-elect, any members can be appointed by either the Chair or the Chair-Elect to preside over the meeting.

Research Investigator

A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of these guidelines.

B. Research investigators must pass the Online Human Subjects Training and submit verification of passing it with the application before the application will be considered. An investigator is required to take this training once per calendar year beginning September 1 of each year (new academic year) or at least prior to submitting a new application to the CPHS in a new academic year.

C. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal regulations or provisions of these guidelines. This determination will be made by the CPHS based on information provided by the investigator.

D. All research projects involving the use of human subjects or data about human subjects must be submitted to the CPHS for approval. If it is unclear whether the proposed research involves human subjects, the research investigator must seek guidance and assistance from the Chair of the CPHS. Failure to obtain approval for research projects that involve human subjects may endanger all federal funding, as well as lead UHD to limit further research. The CPHS will bring any such incidences to the attention of the research investigator's Department Chair and Dean, as well as to the Vice President for Academic Affairs.

E. Research investigators are responsible for providing a copy of the CPHS-approved informed consent document to each subject at the time of consent, unless the CPHS has specifically waived this requirement. Multi-year/multi-stage projects may require separate informed consent documents. The informed consent documents should be safeguarded by the researcher during the project and retained for three years after the termination of the project.

F. Safeguarding information about an individual that has been obtained in the course of an investigation or data collection is a primary obligation of the research investigator. An investigator's protocol should indicate how that data will be protected. In addition, such information shal not be communicated to others unless the following conditions are met:

- Information about individuals may be discussed only for professional purposes or only with persons clearly associated with the project;
- Written and oral reports should present only data germane to the purposes of the project, and every effort should be made to avoid invasion of privacy; and
- Provisions must also be made for maintaining confidentiality in the preservation and ultimate disposition of any data collected. Adequate security measures must be described to the CPHS and carried out by the research investigator until the records are destroyed. Records that contain private information shall be destroyed as soon as possible in keeping with the long-range goals of the project.

G. Research investigators will promptly report proposed changes in previously approved human subject research activities to the CPHS. The proposed changes will not be initiated by the investigator without prior CPHS review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

H. Research investigators are responsible for reporting progress of approved research to the CPHS, as often as and in the manner prescribed on the basis of risks to subjects, but no less than once per year.

I. Research investigators will promptly report to the CPHS any injuries or other unanticipated problems involving risks to subjects *or* others.

J. If the research investigator is a student, it will be his or her faculty sponsor who is responsible for ensuring that the student follows these guidelines and who is responsible for complying with all UHD CPHS requirements, if there are two institutions involved in the study. Faculty sponsors are responsible for assuring compliance of all CPHS policies and procedures for their students.

K. If the research investigator is from another institution, it will be his/her responsibility to ensure that he/she follows the guidelines of both institutions and keeps both institutions informed.

L. Investigators external to UHD who wish to petition review from the UHD CPHS must:

- Provide documentation of review and approval from their local institution's human subjects review process. The CPHS may make an exception to this requirement; however, applicants must show evidence that their entity/organization does not have an IRB; and
- Secure the research involvement of a collaborator from the UHD faculty who will be locally responsible and accountable for the protection of human subjects. In the case where there is no UHD faculty collaborator, the outside investigator/entity would present an application for their project directly to the CPHS. The CPHS would determine if it is in the best interest of the University and its students to approve the project. If approved by the CPHS, there may be additional reporting requirements imposed; and
- Complete UHD's standard protocol forms and submit them for review to the CPHS. This submission should include a copy of the approval letter from their institution/entity.

If the external investigator is a graduate student working on a thesis or dissertation, the application to the UHD CPHS must include the written endorsement of the chair of the student's faculty committee (or faculty advisor), verifying the scientific merit of the proposed study. If the graduate student is an employee of UHD, the application must include the written endorsement of the chair of the students faculty committee or advisor, verifying the scientific merit of the proposed study.

The CPHS reserves the right to request additional information from any external investigator.

PART 3 – CPHS Review and Approval Process

Initial Review

A. A new application to the CPHS may fall into one of three categories. These are

Exempt
Expedited
Full Committee Review

B. Exemption of New Application.

This type of application can be reviewed by the EERS (Exempt/Expedited Review Subcommittee), a subcommittee which consists of the Chair (or his/her designee) as the primary reviewer and an assigned secondary reviewer. This subcommittee determines whether the new project application is exempt according to regulations included in 45 CFR 46.101. Even if the application fulfills the criteria for exemption according to the regulations, the subcommittee may use its discretion as to whether a study should be exempt or requires CPHS review. The subcommittee may request minor revisions and/or clarifications before approval for exemption is granted. Written notification of exempt approval is communicated by the CPHS Chair to the investigator within 7 to 10 days.

C. Expedited Review of New Application

The research investigator may request expedited approval for the application. (See Attachment A to be used by research investigator to make this initial determination.) However, this final determination is made by the EERS. This determination is based on the regulations included in 45 CFR 46.110 and 21 CFR 56.110. Even if the application fulfills the criteria for expedited review according to the regulations, the subcommittee may use its discretion as to whether the study should be expedited or requires full committee review. The subcommittee may request minor revisions and/or clarifications before approval for exemption is granted. Written notification of exempt approval is communicated by the CPHS Chair to the investigator within 7 to 10 days.

D. Full Committee Review of New Application

After presentation by the primary and secondary reviewer and discussion by the Committee members, the Committee votes on a motion. For a motion to pass, the majority of voting members (quorum) present must vote affirmatively. The following actions may be taken by the CPHS:

1. APPROVED: The research investigator is informed in writing of the approval and its duration. The letter of approval includes the following:

- It is necessary to retain signed consents by all subjects for three years after the termination of the project unless a waiver is granted.

- Participants must sign a consent form. Any and all modifications (amendments or changes) to the protocol and consent form must be submitted to and approved by the CPHS before implementation.

- All serious adverse events must be reported to the CPHS within ten (10) working days of being made known to the research investigator. In the case of death, the report must be made to the CPHS immediately or as soon after the research investigator learns about the death.

- Continuing and final reports on the status of the project are required.

The same elements for the letter of approval are also applicable to approved expedited new applications.

2. CONDITIONALLY APPROVED WITH MINOR REVISIONS AND/OR CLARIFICATIONS REQUIRED: The CPHS specifies what action(s) need to be taken and who has the authority to review the revised or requested materials. A memo (via email) is sent indicating the specific action(s) required of the research investigator. No study may be initiated until there has been full compliance with the required revisions and/or clarifications. The Chair will send approval to the research investigator within 7 working days of receipt of the requested materials. The Chair will make every effort to send the approval letter in a shorter timeframe.

3. TABLED, PENDING SUBSTANTIAL REVISIONS AND/OR CLARIFICATIONS: A memo is sent indicating the specific action(s) required of the research investigator. If the research investigator provides a response, the application cannot be approved unless there is a convened meeting of the CPHS. The research investigator can be asked to attend a scheduled meeting to address the CPHS concerns.

4. DISAPPROVED: A memo is sent to the research investigator describing why the CPHS has taken this action. The investigator may respond with written justification for a reversal of the decision or a proposal to change the protocol, which may be the basis for CPHS reconsideration. The investigator can request to attend a scheduled meeting to discuss the disapproval; however, approval of such a request is at the Chair's discretion.

The CPHS must determine for each new application whether continuing reports are to be submitted on an annual basis or whether it is necessary for continuing reports to be submitted more frequently. This is based on whether the risks are of a sufficient magnitude that annual review is inadequate. Although the magnitude of the risks is in part determined by the study procedures, other factors that pertain to the study (e.g., age of participants) may also be considered.

At the time of review of new applications and continuing reports, the CPHS must also determine which applications require verification from sources other than the research investigator that no material changes from those described in the application have occurred. The need for independent verification may be based on the history of the research investigator or specifics of the project. If such verification is required by the CPHS, it should then determine the individual(s) who is (are) to perform the verification and the frequency with which it should occur.

CONTINUING REVIEW

Federal regulations require investigators to submit continuing reports for all CPHS-approved studies if the study continues past the one or two year interval indicated in the approval letter. This report will request continuation of the project.

When a continuing report is not approved because of a delay in submission, the investigator must provide an explanation for the late submission before the report will be considered at the next CPHS meeting.

INFORMED CONSENT

Oral consent may suffice if all of the following conditions are met:

1) **no** subject-identifying information is attached to the study materials (i.e., subjects do not give their names and cannot be identified);

2) **no** vulnerable subjects are participants;

3) **no** participant is exposed to more than minimal risk;

4) **no** procedures are involved for which written consent is normally required outside the research context.

The informed consent may be adequately communicated to potential subjects in a letter of information and oral exchanges between investigators and potential subjects. The oral consent must be documented by the investigator.

If any of conditions 1-4 is <u>not</u> met:

then, a written and signed consent document is essential. In the case of vulnerable participants, consent may have to be obtained from the legally authorized representative of the subject, e.g. where children are involved, parental consent must be obtained, in addition to the assent of the child.

The consent process has three elements:

Information

The consent letter shall contain:

1) A statement that the project is a research project and an explanation of its scope, aims and purposes. The statement should include whether the results will be published or made public.

2) A statement regarding the amount of time a subject will have to spend in order to participate and a description of the research procedures.

3) A description of any reasonably foreseeable risks or discomforts subjects may incur and actions taken to minimize such risks.

4) A statement describing the potential benefits to subjects or others.

5) In cases where research is done with contact groups, alternatives to participation will be outlined in the letter of consent

6) A statement regarding any payment or reimbursement for expenses. If there is more than minimal risk, a statement as to whether any compensation and/or medical treatment is available if injury occurs. UH will not provide any compensation if injury occurs.

7) A statement of what incentive (e.g., extra course credit), if any, is available to subject and information regarding any alternative means of obtaining the incentive.

8) A statement describing the extent to which confidentiality of records identifying the subject will be maintained or whether subjects will be anonymous. This should include, where applicable, information concerning the storage and disposition of any recordings.

9) A statement that participation is voluntary and that a subject may discontinue participation at any time. Non-participation will not result in penalty or loss of benefits to which the subject is otherwise entitled.

10) An offer to answer any questions, which should include the research investigator's name, phone number and mailing address; the faculty sponsor's name and phone number if the investigator is a student; the name of any sponsoring or funding source.

11) A statement that a copy of the informed consent form must be given to subjects or their legally authorized representative.

12) The following statement must be placed at the end of ALL consent documents immediately after the signature lines. "THIS RESEARCH STUDY HAS BEEN REVIEWED AND APPROVED BY THE COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS AT THE UNIVERSITY OF HOUSTON - DOWNTOWN. For additional information concerning your rights as a human subject please contact Dr. (insert name and phone number of current chair of CPHS)".

B. *Comprehension*

Information given to the subject must be stated in simple, easily understood language. While there is always a moral and professional obligation to ascertain that information is complete and adequately comprehended by a subject, this obligation increases when **any** of the conditions, outlined in A. under Informed Consent above applies. Special provisions may need to be made to insure comprehension, particularly where there is significant risk or where a subject is immature, mentally disabled or incompetent.

C. Participation

Research investigators must provide opportunities for the potential subject freely to consider whether to participate. Particular attention should be paid to minimizing the possibility of coercion. Therefore, subjects must be informed that participation is voluntary and that choosing not to participate will result in no cost or negative consequences to the individual. Nor should any undue influence in the form of an offer of an excessive, unwarranted or inappropriate reward be used in order to obtain participation. On this account, the investigator has the responsibility to avoid:

- mandating participation of a research subject as a requirement for a course;
- maintaining dual relationships with subjects. Individuals employed by the researcher may not be asked during work time to participate in a study as a subject. If extra credit is afforded potential subjects to encourage participation, options commensurate in time and involvement must be provided so that research participation is not the only extra credit option available; and
- Ensuring that if an investigator (faculty or student) is utilizing course time from another faculty member or from another department to collect data, that he/she has the permission of that faculty member and/or that department.

ATTACHMENT A: Expedited Review Checklist

Research is eligible for expedited review if it involves only minimal risk to participants. "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102).

More than minimal risk describes research that includes vulnerable participants, sensitive research topics, or intrusive methods. Vulnerable participants include children (under 18) and prisoners, fetuses, and pregnant women; some institutionalized groups without the ability to make uncompromised decisions about consent also are considered vulnerable. Sensitive research topics include any information about illegal activities or other topics whose disclosure would harm a participant's reputation; examples include: sexual topics (attitudes, behavior, and specific diseases, such as HIV/AIDS, STDs, or preferences); drug or alcohol use; illegal behavior; or information pertaining to an individual's mental health.

To determine if a project exempt, the following questions should be answered by the Research Investigator:

1. ____ Do you have identifying information on your protocol?

2. Are your participants:
   ____ children (under 18 years old)?
   ____ fetuses?
   ____ institutionalized?
   ____ pregnant women?
   ____ prisoners?

3. Is your research about:
   ____ sexual topics (attitudes, behavior, specific diseases, or preferences)?
   ____ drug or alcohol use?
   ____ illegal behavior?
   ____ participants' mental health?

4. Do your methods pose any risk for participants?
   ____ Are participants asked to ingest any nonfood substance?
   ____ Are measurement methods intrusive (e.g., draw blood)?

If all of the above questions were answered “No”, the project is eligible for expedited review by UHD CPHS. Two copies should be submitted to the Office of Sponsored Programs or to the Chair of the CPHS. The review should be completed within 7-10 days and a response will be either mailed or the investigator will be called and followed up with written notification.