Committee for the Protection of Human Subjects (CPHS)

University of Houston – Downtown (UHD)

Principles, Procedures and Guidelines

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Part 1 – Principles, Policy and Applicability

Principles

A. The University of Houston – Downtown (UHD) is guided by the ethical principles on the protection of Human Subjects covered by the U.S. Department of Health and Human Services (HHS) Code of Federal Regulations (45 CFR 46). Also known as the Common Rule, this has been gradually updated and adopted between 1991 and the latest revision in 2018. UHD follows these principles regardless of whether the research is subject to Federal regulation, for all collaborative research and for all different sources of funding support.

B. Collaboration with outside investigators and sites will be reviewed by the CPHS to ensure that protections for human subjects are at least equivalent to those procedures at UHD.

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 benefits, if any, and the importance of the knowledge that can reasonably be expected to result. 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.

E. Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless exempted by CPHS under specific situations. The Informed Consent process is specific aspect of the CPHS review. A written copy shall be given to the person signing the informed consent form upon request by participants.

F. Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

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 CPHS shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. 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.

I. 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.

J. 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.

K. 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. It is the responsibility of the principal investigator to obtain clearance from the CPHS prior to the initiation of any research activity involving the use of human subjects.

Institutional Policy

A. As noted, all requirements of 45 CFR 46, will be observed for all applicable federally-sponsored research, and all other human subjects research regardless of sources of funding.

B. As covered in UHD policy on the Protection of Human Subjects, PS 03.A.23, any research, scholarly, creative or educational study that involves human subjects in which the data will not be exclusively used or reported for internal purposes only, falls under the jurisdiction of the CPHS. Studies involving human subjects in which the data will be presented externally to UHD, whether by presentation or publication, must obtain CPHS approval prior to initiation of the study and collection of data. Research on human subjects collected for internal purposes may not ever be used for an external purpose unless CPHS approval and informed consent was obtained prior to the collection of data.

C. In order to approve research covered by this policy the CPHS shall determine that all of the following requirements are satisfied:
    a. Risks to subjects are minimized:
        i. By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
        ii. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

b. Risks to subjects are reasonable in relation to anticipated benefits.
c. Selection of subjects is equitable.
d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
e. Informed consent will be appropriately documented or appropriately waived by CPHS.
f. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
h. Under limited review for specific situations CPHS may determine broad consent for secondary use, storage and maintenance of research data.

D. 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.

E. 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. 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 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).

F. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. 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.

Applicability

A. The Common Rule contains several important definitions to describe the applicability of the policy to human subjects research (Section 46.102):

a. ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research:
i. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

ii. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

b. ***Research*** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

B. Except for research in which the only involvement of humans is in one or more of the specific categories exempted or waived under Section 46.104 of the Common Rule, this document applies to all research involving human subjects. This includes all other activities which even in part involve such research, regardless of the source of funds, if any or more of the following apply
   a. the research is sponsored by UHD; or
   b. 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
   c. the research is conducted by or under the direction of any employee or agency of UHD using any property or facility of UHD; or
   d. the research involves the use of UHD's non-public information to identify or contact human research subjects or prospective subjects.

C. If it is unclear whether the proposed research involves human subjects or is subject to review by the CPHS, investigators should seek guidance from the chair of the committee. The committee shall review all subsequent changes in the approved protocol to ensure compliance with state and federal regulations. Any substantial changes in the protocol, emergence of problems, or development of hazardous conditions involving human subjects must be reported immediately to the CPHS committee chairperson by the responsible investigator.

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:
   a. Research with pregnant women and fetuses – 45 CFR 46 – Subpart B
   b. Research with prisoners – 45 CFR 46 – Subpart C
   c. Research with children – 45 CFR 46 – Subpart D

d. Other potentially vulnerable groups.

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

D. In line with the requirements of 45 CFR 46.107 UHD has established the Institutional Research Board (IRB) under the name of the Committee for the Protection of Human Subjects (CPHS).

E. UHD provides meeting space and staff to support the CPHS review and recordkeeping 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. CPHS shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities, including exempt research activities (OHRP page on Exemptions Categories List).

C. CPHS shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

D. The CPHS is responsible for reviewing the preliminary determination of exemption by Investigators and for making the final determination based on 45 CFR 46.109 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.

E. The CPHS will make the preliminary determination of eligibility for expedited review procedures (see 45 CFR 46.110). Expedited review of research activities will not be permitted where full board review is required.

F. 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.

G. 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.

H. 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.

I. 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.

J. 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.

K. During the academic year, the CPHS will determine exempt and expedited reviews, and arrange full board meetings, when required.

L. 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.

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

N. The CPHS will maintain adequate documentation of its activities in the Office of Research and Sponsored Programs (ORSP). 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.

O. 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.

P. The CPHS will forward to the UHD President any significant or material finding or action, at least to include the following:
    a. any unanticipated injuries or problems involving risks to subjects or others,
    b. any serious or continuing noncompliance with the regulations or requirements of the IRB, and

c. any suspension or termination of IRB approval.

Q. Research covered by this policy that has been approved by CPHS may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by CPHS.

R. In accordance with 45 CFR 46.113, the CPHS will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the CPHS requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the CPHS action and shall be reported promptly to the investigator, appropriate institutional officials, and the funding source as applicable.

S. 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 currently consists of twenty seven (27) voting members (split into two panels to meet output needs) and one *ex officio* member, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. Upon recommendation of the CPHS, the UHD Provost 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 complete or have active on-line CITI Program Human Subjects training, the specific course is named 'IRB Committee Basic/Refresher'.

C. The CPHS shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The CPHS shall therefore include persons knowledgeable in these areas.

D. If the CPHS regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

E. 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.

F. 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. Comments may be submitted by members in advance of the meeting but those who can't attend can't count towards the vote.

G. 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.

H. Reviewers must carefully consider all aspects of the submission, including the protocol, consent form, and other accompanying materials. The CPHS Chair will lead the discussion of the application at the next regularly convened meeting of the CPHS, if full committee approval is required.

I. 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. These individuals may not vote with the CPHS.

J. A quorum consists of at least one more than one-half of the voting members being present at the meeting. This can be in person or by video conference, but members must be able to participate in the meeting actively and equally.

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, and two years on the CPHS.

B. The chair is responsible for:
    a. Presiding over CPHS meetings;
    b. Developing the agenda for each meeting;
    c. Reviewing and approving, when appropriate, expedited submissions in according with regulatory requirements;
    d. Determining exempt submissions in accordance with regulatory requirements;
    e. Determining items to be submitted to the convened CPHS;
    f. Maintaining records for the year (in coordination with the Executive Director of the Office of Sponsored Programs); and
    g. Preparing a 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 in this context include any faculty, staff or students who are planning to conduct research involving human subjects or who will supervise student research.

B. The Principal Investigator (PI) for a human research study is the individual who is responsible for how the activities described in the CPHS Application have been planned and will be conducted and reported on, ensuring the welfare and rights of participants are protected. The PI must be able to devote the time and attention to a study to ensure that is conducted in a responsible manner.

C. Principal Investigator eligibility includes all tenured/tenure-track faculty (Professor, Associate, Assistant and ABD Full-Time Instructors), UHD staff that hold a tenured/tenure track faculty rank, non-tenure-track faculty (Lecturers, Adjuncts, etc.) that have research/scholarly/creative activities as part of their duties in contracts, and Librarians. With Department Chair/Dean approval, the following may also be considered: non-tenure-track faculty that do not have research/scholarly/creative activities as part of their duties in contracts, Emeritus Faculty, Other University Staff, Visiting Faculty and Scholars. With a faculty sponsor, graduate and undergraduate students and individuals not affiliated with UHD may also be eligible.

D. 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.

E. Research investigators must pass the online CITI Program Human Subjects Training and submit verification with the application before the proposal will be considered. The current appropriate CITI course is titled ‘SBR Investigators – Basic/Refresher’ for direct contact with human subjects. There are also courses for data analysis/no direct contact as Life/Physical Sciences Investigators. An investigator is required to take this training once every three years. If transferring from another institution where training is valid for 5 years, investigators seeking to establish protocols at UHD must have valid training under the 3-year validity requirement.

F. 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.

G. 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.

H. 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.

I. 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 shall not be communicated to others unless the following conditions are met:

    a. Information about individuals may be discussed only for professional purposes or only with persons clearly associated with the project;
    b. 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
    c. 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.

J. 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.

K. 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.

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

M. 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. 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.

N. The faculty sponsor for a non-UHD student would still be expected to accept responsibility for supervision of the study at UHD, to ensure the protection of the rights and welfare of UHD participating subjects in accordance with federal regulations and UHD policies. The faculty sponsor also needs to certify that the protocol information is accurate and that the project has scientific merit.

O. The University's current policy is that all research with UHD study participants must include a UHD Faculty (or eligible staff) or be sponsored by a UHD faculty. 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. 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 four categories:
- Non-regulated or non-human subjects research;
- Exempt;
- Expedited;
- Full Committee review.

B. Non-regulated or non-human subjects research

There are activities which do not meet the definition of human subjects research or regulated research under 45 CFR 46.102 and therefore do not require CPHS approval or oversight. However, these submissions do require a determination letter.

The following research is generally considered 'non-human subjects research':
- Repository research, tissue banking and databases – data that is received as de-identified, whereby the researcher cannot readily ascertain the identity of the subject.
- Anonymous pre-existing data sets or specimens – with no personally identifiable information contained in either the original data or attached to original specimen.
- Coded pre-existing or coded prospective data or specimens – the investigator never obtains identifiable specimens.
- Deceased subject research.

The following activities are generally not considered 'research':
- Scholarly and journalistic activities, including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance as requested by a public health authority.

- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- Routine quality improvement.
- Program evaluation.
- Community outreach.
- Case reports.
- Customer satisfaction surveys.
- Class projects.
- Medical quality assurance.

C. Exempt Research

Exempt research applications can receive expedited review by a subset of the CPHS committee. CPHS will review applications and consider whether the new protocol is exempt according to regulations included in 45 CFR 46.104. 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 further 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 3 weeks (to allow time for review).

D. Expedited Review

For applications where the investigator believes that the proposed research presents no more than minimal risk to human subjects and which matches the OHRP Expedited Review categories list, then an expedited review may be requested. The list was amended in the 2018 Common Rule update to expand the types of research qualifying.

However, the final determination is made by a subset of CPHS reviewers, and they may use their discretion as to whether the study should be expedited or requires full committee review. The subcommittee may also 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.

E. Full Committee Review

After presentation by the CPHS Chair and discussion by the CPHS members, the Committee votes on a motion. The Committee is either made up of Panel A or Panel B members, with the panel composition determined at the start of the academic year. 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 as 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 expedited or Full Board reviewed 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

General requirements for Informed Consent, whether written or oral, are set forth in 45 CFR 46.116. A few limited cases may be considered for 'broad consent' of secondary uses of identifiable private information and identifiable biospecimens. Except as provided elsewhere:

(1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.

(2) An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

(3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.

(4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

(5) Except for broad consent situations as approved by CPHS:

(i) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.

(ii) Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.

(6) No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Informed Consent Information given to participants

Except in cases of broad or waived consent, the following information shall be provided to each subject or legally authorized representative (as per 45 CFR 46.116 – paragraph b):

(1) A statement that the study involves research, an explanation of the purposes of the research (including whether the results will be published or made public) and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. UHD 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) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

(9) 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.

(10) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue

participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and

(11) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

(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)".

Additional elements of informed consent - to be included **when appropriate** (as per 45 CFR 46.116 – paragraph c):

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

(6) The approximate number of subjects involved in the study;

(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;

(8) A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

Oral consent may suffice if all 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 not 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.

Informed Consent 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;
- Avoid 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
- Ensure 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: Exempt Categories Checklist

Research activities in which the only involvement of human subjects will be in one or more of the categories listed below may be exempt from the HHS policy requirements on Human Research Subjects based on CPHS determination on the proposed project.

This is a brief summary of Exempt review categories, please review the full list for complete information (OHRP page on exempt categories):

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) – under certain conditions.

(3) Research involving brief benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection – under certain conditions

4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, under specific conditions.

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency.

(6) Taste and food quality evaluation and consumer acceptance studies.

(7) Storage or maintenance for secondary research for which broad consent is required, under certain conditions, per CPHS review:

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, under certain conditions.

ATTACHMENT B: Expedited Review Checklist

Research may be eligible for expedited review by CPHS if:

1) it presents only minimal risk to participants, and

2) involves only procedures on the OHRP Expedited Review categories list.

Critical to this eligibility is the CPHS review which confirms the project has "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), 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, misconduct, 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.

This is a brief summary of Expedited review categories, full list at OHRP:

1. Clinical studies of drugs and medical devices only when certain conditions are met (e.g. existing drugs or devices)

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture under certain conditions:

3. Prospective collection of biological specimens for research purposes by certain noninvasive means.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history,

focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows under limited conditions.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Human Subjects Regulations Decision Charts

OHRP produced a series of decision charts to aid those who need to decide if an activity is research involving human subjects that must be reviewed by CPHS, or whether it is eligible for exemption against specific categories (such as educational practices, benign behavioral interventions, or secondary research purposes).

Please be aware that CPHS likely have additional considerations to take into account and that UHD Policy PS.03.A.23 specifically clarifies jurisdiction of research, scholarly, creative or educational studies in this area:

"Any research, scholarly, creative or educational study that involves human subjects in which the data will not be exclusively used or reported for internal purposes only, falls under the jurisdiction of the CPHS. Studies involving human subjects in which the data will be presented externally to UHD, whether by presentation or publication, must obtain CPHS approval prior to initiation of the study and collection of data. Research on human subjects collected for internal purposes may not ever be used for an external purpose unless CPHS approval and informed consent was obtained prior to the collection of data.

If it is unclear whether the proposed research involves human subjects or is subject to review by the CPHS, investigators should seek guidance from the chair of the committee."

Chart 1: Is an Activity Human Subjects Research Covered by 45 CFR Part 46?

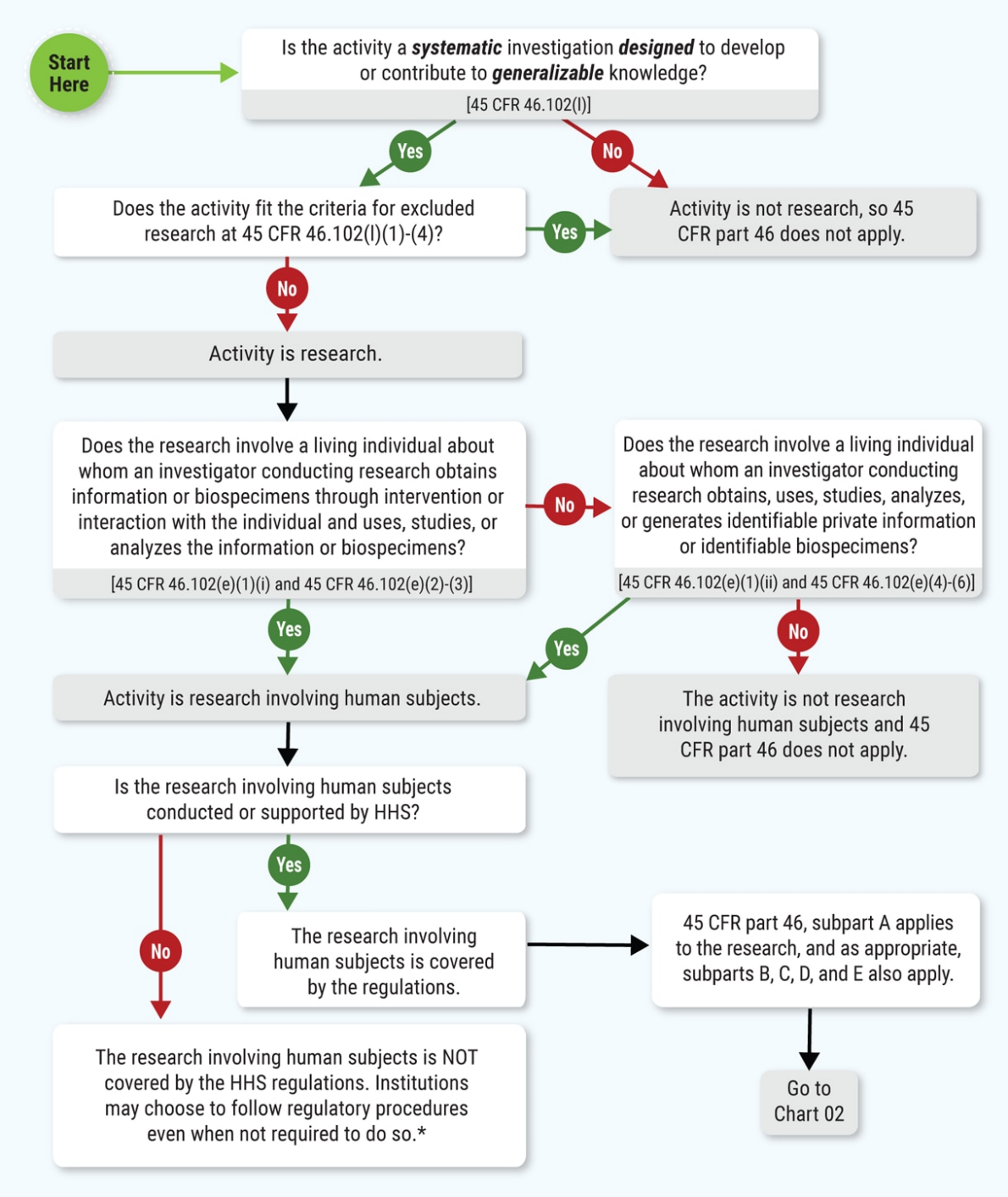

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.104(d)?