

FEDERAL AND UNIVERSITY GUIDELINES FOR PROTECTION OF HUMAN SUBJECTS INVOLVED IN RESEARCH

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DHHS OHRP regulations website:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>

Applicability

Activities that meet the definition of “research” as stated by the Department of Health and Human Services (DHHS) and that involve human subjects are subject to the guidelines in this document. Activities that are determined not to be research or that do not involve human subjects do not require review and approval by the UHCL Committee for the Protection of Human Subjects (CPHS).

Definitions (45 CFR 46.102):

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Human Subject: 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.

UHCL has determined that certain activities do not meet the definition of research and are therefore not subject to review:

- Course-related activities designated specifically for educational or teaching purposes, where data are collected from and about human subjects as part of a class exercise or assignment but are not intended for use outside of the classroom.
- Course, program, departmental, and institutional surveys that are not intended to develop or contribute to generalizable knowledge. A list of such surveys can be found in Appendix A.

When an individual believes that an activity not listed in Appendix A does not constitute human subjects research, UHCL requires that the request for determination be sent to the Office of Sponsored Programs for review and for potential future inclusion in Appendix A.

Minimal Risk Research and Expedited Review

Applicable Minimal Risk Research protocols are processed by the Committee for the Protection of Human Subjects (CPHS), UHCL’s Institutional Review Board (IRB), under the “expedited review process.” As defined in 45 CFR 46.102, Minimal Risk to human subjects means research where:

“the probability and magnitude of harm or discomfort anticipated in the research are no greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

The following [categories](#) of research fall within the **Minimal Risk** definition AND are allowed to undergo the expedited review process:

Category #	Description
1	<p>Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</p> <p>(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)</p> <p>(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.</p>
2	<p>Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</p> <p>(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or</p> <p>(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.</p>
3	<p>Prospective collection of biological specimens for research purposes by noninvasive means.</p> <p>Examples:</p> <p>(a) hair and nail clippings in a nondisfiguring manner;</p> <p>(b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;</p> <p>(c) permanent teeth if routine patient care indicates a need for extraction;</p> <p>(d) excreta and external secretions (including sweat);</p> <p>(e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;</p> <p>(f) placenta removed at delivery;</p> <p>(g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;</p> <p>(h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;</p> <p>(i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;</p> <p>(j) sputum collected after saline mist nebulization.</p>
4	<p>Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)</p>

Category #	Description
	<p>Examples:</p> <p>(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;</p> <p>(b) weighing or testing sensory acuity;</p> <p>(c) magnetic resonance imaging;</p> <p>(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.</p>
Social & Behavioral Research Categories 5 through 7	
5	<p>Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)</p>
6	<p>Collection of data from voice, video, digital, or image recordings made for research purposes.</p>
7	<p>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. This listing refers only to research that is not exempt.)</p>
For Continuing Review Only -- Categories 8 and 9	
8	<p>Continuing review of research previously approved by the convened IRB as follows:</p> <p>(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or</p> <p>(b) where no subjects have been enrolled and no additional risks have been identified; or</p> <p>(c) where the remaining research activities are limited to data analysis.</p>
9	<p>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.</p>

Exempt Research

Only appointed UHCL CPHS voting and alternate members provide final determination that human subjects research is Exempt Research. A completed CPHS application, informed consent form(s), and instrument(s) are submitted for this determination. Application documents and CPHS approvals are kept for federal audit recordkeeping.

Note that UHCL does not allow Exempt Research if prisoners, pregnant women, human fetuses, neonates, or children are involved. UHCL mandates stricter guidelines than those found in [45 CFR46.104](#).

Categories of investigation generally exempt from federal requirements for the protection of human subjects include:

Category #	Description
1	Research, conducted in established or commonly accepted educational settings, which specifically involves normal educational practices that are not likely to impact adversely 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) if at least one of the following criteria is met: (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7) .
3	(i) Research involving 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 and at least one of the following criteria is met: (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly

Category #	Description
	<p>or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).</p> <p>(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.</p> <p>(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.</p>
4	<p>Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:</p> <p>(i) The identifiable private information or identifiable biospecimens are publicly available;</p> <p>(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;</p> <p>(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or</p> <p>(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.</p>
5	<p>Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or</p>

Category #	Description
	<p>levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.</p> <p>(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.</p> <p>(ii) [Reserved]</p>
6	<p>Taste and food quality evaluation and consumer acceptance studies,</p> <p>(i) if wholesome foods without additives are consumed or</p> <p>(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.</p>
7	<p>Storage or maintenance for secondary research for which broad consent is required:</p> <p>Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).</p>
8	<p>Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:</p> <p>(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);</p> <p>(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;</p> <p>(iii) An IRB conducts a limited IRB review and makes the determination required by 45 CFR 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and</p> <p>(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.</p>

Informed Consent

Consent by Subject to Participate in *Minimal Risk* Research Under UHCL's CPHS Responsibility

**[Refer to [45 CFR 46.116](#) (b) for basic elements and
(c) for additional elements of informed consent]**

The following basic elements must be addressed on all informed consent (whether written or oral) for any minimal risk research approved at the University of Houston-Clear Lake:

Informed Consent Checklist - Basic Elements

	A statement that the study involves research, an explanation of the purposes of the research 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
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to the subject or to others that may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	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
	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
	Provide name and contact information (phone number and email address) for Principal Investigator(s); or Student Researcher(s) and Faculty Sponsor(s).
	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
	One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: A. 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 B. 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.

	Waiving or appearing to waive any legal rights of subjects is prohibited. Releasing or appearing to release the investigator, the sponsor, the institution or its agents from liability for negligence is also prohibited.
	<p>Include the following statement on ALL written informed consent documents.</p> <p><i>THE UHCL COMMITTEE FOR PROTECTION OF HUMAN SUBJECTS (CPHS) HAS REVIEWED AND APPROVED THIS PROJECT. ANY QUESTIONS REGARDING YOUR RIGHTS AS A RESEARCH SUBJECT MAY BE ADDRESSED TO THE UNIVERSITY OF HOUSTON-CLEAR LAKE COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (281-283-3015). ALL RESEARCH PROJECTS THAT ARE CARRIED OUT BY INVESTIGATORS AT THE UNIVERSITY OF HOUSTON-CLEAR LAKE ARE GOVERNED BY REQUIREMENTS OF THE UNIVERSITY AND THE FEDERAL GOVERNMENT. (FEDERALWIDE ASSURANCE # FWA 00004068)</i></p>

Informed Consent and Informational Research Templates for Adult Participants in Minimal Risk Research

Description	Name of Form*
Informed consent form for minimal risk	Adult Informed Consent Form
Informed consent form with physical injury disclaimer	Adult Informed Consent-Min Risk-Injury Disclaimer
Information about project but no signature obtained so that participant's anonymity is maintained	Adult Informed-Informational Research

*All forms can be found on the [Office of Sponsored Programs website](#).

Informed Consent Process

1. No principal investigator may involve a human being as a subject in research covered by the 45 CFR 46 Common Rule unless the principal investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.
2. A principal investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether to participate and without undue influence or any element of force, fraud, deceit, duress or other forms of constraint or coercion.
3. The principal investigator is expected to explain the proposed activity to a potential subject in enough detail and in language understandable so as to assure that the potential subject fully understands to what he/she is consenting and that the decision is a well-informed one.
4. Each subject should be given a copy of the consent form he or she has signed.

<p>Tips on Informed Consent http://www.hhs.gov/ohrp/policy/ictips.html</p>

Children’s Assent and Parent’s Consent in Minimal Risk Research
[45 CFR 46.408](#)

Child’s Assent and Parent’s Consent

For a child between the ages 7 through 17, **permission** from at least one of the parents must be obtained and documented for a child to participate in research and then a child’s **assent** must be obtained and documented as well. Assent is a positive affirmation of a willingness to participate. Failure to object is not assent. Following the parent’s signed permission, the child’s positive affirmation (written or via a witness attesting to positive affirmation) is also to be obtained.

Precautions

Children should be ensured that they do not have to give their assent to participate because they want to please their parents or because they may fear their parents will be upset if they do not assent. Likewise, if there are children who do not assent to participation, parents should be reminded that it is perfectly fine for their child not to participate. Prevention of embarrassment or other possible feelings for either the child or parents is the primary purpose for such precautions.

Need for Multiple Parental Consent-Assent Form Templates

Because of differences in children’s age, language comprehension, maturity, etc., multiple assent-consent form templates are available. Below is a table guide providing ages and corresponding name of forms that may be used for a majority of research projects involving children.

Children’s Ages	Description	Name of Form*
Under 7 years	Parental Consent Form	Parental Consent form
Ages 7-12	Parental Consent Form & Child’s Assent Form (2 separate forms)	Parental Consent form & Assent Form for Child up to age 12
Ages 13-17	Parental Consent Form & Child’s Assent Form (2 separate forms)	Parental Consent form & Assent Form for Child aged 13-17
Under 7, Education	Education’s Parental Informed Consent Form (combined)	Parental Consent Form for Child under 7 years old for Education Research
Ages 7-12, Education	Education’s Parental Consent & Child Assent Form (combined)	Consent/Assent Form for Parent and Child aged 7-12 for Education Research
Ages 13-17, Education	Education’s Parental Consent & Child Assent Form (combined)	Consent/Assent Form for Parent and Child aged 13-17 for Educational Research

*All forms can be found on the [Office of Sponsored Programs website](#).

Signature or Witness Requirements According to Child’s Age

Parental consent by at least one parent must be obtained and documented by a parent’s signature for children’s involvement in research activities. The following table gives the signatures required according to children’s ages.

Children's Ages	Signatures Required		
	Ages 13-17	Parent	Child
Ages 7-12	Parent	Child	Witness confirming child's assent
Under age 7	Parent	--	Witness confirming child's assent

Request CPHS Waiver of Child's Assent or Parental Consent

45 CFR 46.408 (a) and (c), respectively

Under special circumstances, the requirement to obtain the assent of a child may be waived by the CPHS, see §46.408(a). Refer to §46.408(c) for circumstances regarding waiving the requirement to obtain parental consent.

For CPHS to consider waiving requirements to obtain assent of a child or consent of a parent, the investigator must request and justify in the CPHS application that such waiver(s) is/are appropriate. It is recommended that guidance be received from the Office of Sponsored Programs before submitting such requests for CPHS review.

Documentation of Informed Consent

45 CFR 46.117

Informed consent shall be documented by the use of a written consent form approved by the CPHS and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

Request CPHS Waiver for Documentation of Informed Consent

§46.117(c)(1) and 46.117(c)(2)

The CPHS may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

- (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;
- (3) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

ANONYMOUS SURVEYS: For UHCL human subject research that applies to **46.117(c)(2)** above, investigators may request CPHS to waive documentation of informed consent, esp., if an anonymous survey is used and participants cannot be linked to the survey response. The following justification needs to be included in the CPHS application, **Section 6 - Informed Consent.**

Per 46.117(c)(2), Justification to waive documentation of informed consent:

Project is no more than minimal risk and involves no procedures for which written consent is normally required outside the research context. Investigators/Faculty Sponsors are providing written explanation about the research projects to volunteering participants.

The research consists of an anonymous survey and there are no identifying questions that can reveal an individual from the participating group.

[Only add this statement if appropriate for research project.] There are no individual or societal risks involved in completion of the survey for those who voluntarily wish to participate.

SURVEY/INSTRUMENT EXPLANATION: An explanation that participants are not to write their name or include any other identifying information on the survey/instrument form should be added. The following example statement may be added:

In order to ensure anonymity of all respondents, PLEASE DO NOT PUT YOUR NAME ON THIS SURVEY. Return of the completed instrument will signify your consent to participate in this research. Your participation in this survey is completely voluntary and you may cease your participation at any time. Thank you.

INFORMED-INFORMATION DOCUMENT ABOUT THE RESEARCH TO PARTICIPANTS:

Explanation of the research contained in the standard informed consent form is to be provided to participants. However, the last paragraph on the standard informed consent document needs to be stated as follows:

You have agreed to waive your signature so that your response is completely anonymous. Your voluntary participation in this research project is indicated by completing and returning the survey form (attached). Such participation does not release the investigator(s), institution(s), sponsor(s) or granting agency(ies) from their professional and ethical responsibility to you.

TELEPHONE SURVEYS: Justification to waive documentation of informed consent from participants in a telephone survey can be considered by the CPHS if project meets requirements under §46.117(c)(2): "Project is no more than minimal risk and involves no procedures for which written consent is normally required outside the research context."

Address the following in CPHS application for CPHS review:

Objective: To obtain oral consent or assent to participate in telephone survey.

Describe how subjects are to be recruited in CPHS Application's Section C, Item #5, "Human Subject Source and Selection Criteria."

Include an outline of oral presentation for telephone survey. The basic elements of informed consent need to be addressed in oral presentation of recruitment process. Also provide investigator's name and contact information if participant has questions after the telephone survey.

Provide verbatim copies of any letter, notices, advertisements, etc., that may be used in the recruitment process.

Make sure the following statements are included in oral presentation for CPHS review:

Your voluntary participation in the research project is indicated by your oral agreement to participate in this telephone survey. Your participation is entirely voluntary and you may refuse to participate, or you may decide to stop your participation at any time. You do not have to answer a question if you do not want. Should you refuse to participate in the study or should you withdraw your oral consent and stop participation in the telephone study, your decision will involve no penalty to you.

Continuing Review of Protocol Involving Human Subjects

45 CFR 46.109, part e

Federal regulations and UHCL CPHS procedures require that continuing review of all research activities involving the use of human subjects occur at least annually. Multi-year grants involving human subjects research are to be reviewed annually as well. Unless the protocol is reviewed and re-approved by the CPHS *within* twelve months from the date the protocol was last reviewed by the CPHS, federal regulations require the CPHS to immediately suspend its approval. Except for human research studies that have been granted Exempt registration, DHHS regulations requires the CPHS to continually review ongoing research at intervals appropriate to the potential risk to participants, but at least annually. The appropriate CPHS college representative performs this continuing review.

Continuing Review Process

1. **Notification:** The Office of Sponsored Programs (OSP) will email the investigator approximately 5-6 weeks before the application's project expiration date.
2. **Status report:** The investigator provides a status report via email to OSP, sponsoredprograms@uhcl.edu, by specified deadline.
 - (a) Provide total number of subjects enrolled to date.
 - (b) Provide demographics of subjects enrolled to date.
 - (c) Provide information about additional enrollment of subjects expected for upcoming period.
 - (d) Provide information about subjects recruited:
 - (d.1.) the number from whom data were received:
 - (d.2.) the number who withdrew or were dropped and reasons:
 - (d.3.) complaints received from subjects about the study or their participation:
 - (e) Provide details of any unanticipated problems or adverse events involving risks to subjects encountered to date.
 - (f) Provide current assessment of the research and its related risks and benefits; e.g., any findings in the research that affect the risk-benefit ratio or suggest a need to amend or modify research protocol; any problems with privacy or confidentiality; etc.
 - (g) Provide summarization of modifications made to the original protocol.
 - (h) Provide amended informed consent form in two versions: modified version to be given to newly recruited participants and marked-up version identifying changes to original informed consent form.

3. **CPHS Application:** Investigator provides originally approved protocol as email attachment. If there are no changes in the design or protocol, please state. If there are any modifications to the design or protocol, provide revised protocol with changes indicated.
4. **Informed Consent:** Investigator provides originally approved informed consent as email attachment. If there are no changes to the informed consent form, please state. If the informed consent form needs to be revised, attach modified version for CPHS review and approval and marked-up version of original informed consent form. [See item (h) above].
5. **Instruments:** Provide any new instruments or changes to originally approved instrument for CPHS review and approval. If there are no changes, please state and attach instrument.
6. **Grant award:** If the research protocol is funded as part of a grant, investigator needs to attach originally awarded proposal narrative for documentation purposes.

Site Permission to Recruit Participants from Non-UHCL Institutions

The University requires written permission from institution(s) if an investigator seeks to recruit participants from other than UHCL. Proof-of-documentation should be on institution's letterhead and signed by an appropriate official. However, other proof-of-documentation may be submitted for review and acceptance by the CPHS.

It is suggested that the investigator draft the contents of the letter for the institution's consideration and approval. The following information is a guide for preparing the letter:

1. Institution's knowledge of study being conducted on its site;
2. Statement about what research study involves;
3. Outline specific procedures of the research to be conducted at site;
4. Identify type of instrument(s) used to collect data and duration needed to complete instrument(s).
5. Statement that identities of institution and participants will be kept confidential.
6. Institution's permission granting the use of its facilities or resources.
7. Include copy of Informed Consent document(s) to be used in recruiting volunteers from the institution.

Outside Institution Seeking Permission to Recruit Participants from UHCL

If personnel from another institution want to conduct a research study involving participants from our UHCL campus, the institution's principal investigator(s) need to provide the following for UHCL CPHS review:

1. Names of UHCL faculty or courses for recruitment of student participants
2. Electronic copy of institution's IRB (Institutional Review Board) approval
3. Electronic copy of IRB-approved informed consent document
4. Electronic copy of instrument or survey
5. Contact information for principal investigator (PI) or faculty sponsor--if the non-UHCL PI is a student from the institution. Specifically, provide the name, address, email address, and phone number

Forward all information to SponsoredPrograms@uhcl.edu.

The UHCL CPHS college representative does the following:

1. Reviews the project's human participant documentation for compliance and accuracy.
2. Seeks approval from school's authorized official to conduct study with participants from the school.
3. Submits UHCL CPHS internal expedited review approval form to OSP.

OSP does the following:

1. Prepares UHCL approval letter giving permission for study to be conducted at UHCL.
2. Forwards UHCL approval letter to institution's contact person.

With such occurrences, all the research data and human participants' documentation are the responsibility of the non-UHCL institution for federal audit purposes.

Procedures to Conduct Human Participant Research at UH Main Campus by Non-UH Main Campus Investigators

Non-UH Main campus investigators (i.e., UHCL PIs or UHCL student investigators) do not need to complete a separate UH CPHS application form. In a summary document, non-UH investigators are to prepare and submit the following information along with the electronic UHCL CPHS application package:

- (a) a short summary of the research project, **and**
- (b) faculty investigator's name and contact information, **or**
- (c) student investigator(s)' and faculty sponsor(s)' names and contact information.

- Investigators are to prepare a separate document answering items (a) through (c) above.
- Investigators are to forward this document along with the electronic UHCL CPHS application package.
- Once the UHCL CPHS has approved the project, the Office of Sponsored Programs (OSP) will prepare a signed, written UHCL CPHS approval letter.
- OSP will then forward the (1) summary document and contact information and (2) UHCL CPHS approval letter to the UH CPHS Compliance Specialist.
- After review and approval by UH, the UH CPHS Compliance Specialist will notify OSP via email of UH CPHS approval.
- OSP will forward email to UHCL investigator or faculty sponsor of UH's approval to conduct research project at its campus.
- OSP will file UH CPHS email for documentation.

Human Subjects Protection Training

Training Summary and Certification

All human subjects research requires compliance with the educational mandate for human subjects protection. UHCL requires all individuals involved in the conduct of human subjects research to complete human subjects protection training and to recertify every 3 years. IRB approval will be withheld if these training requirements are not met.

These requirements apply to all persons with a significant role in the research, such as those designated as:

- Principal Investigator and Co-investigators;
- Individuals named on a study grant or contract proposal;
- Individuals named as a contact person in the informed consent document(s) or recruitment materials for research;
- Individuals who obtain informed consent from prospective participants in research; and
- Individuals who obtain individually identifiable health information.

UHCL OSP's preferred method of compliance is to complete the Collaborative Institutional Training Initiative (CITI) Program Protection for Human Subjects and/or Animal Care web-based training materials. Log-in/Register at <https://www.citiprogram.org/>. Walk-through/screenshot information can be found on the [OSP CPHS website](#).

Individuals who are currently listed as research team members on approved UHCL protocols are required to complete the education requirements before the CPHS can approve new studies, modifications, or continuing reviews on which they are listed research team members. ***Documentation of training completion must be submitted with CPHS application documents.***

PIs must retain a copy of completed education certificates for all research team members in their study files. Records of past and current education certificates should be retained for every research team member, for each study in which he/she is involved. Education certificates are subject to audit.

Requirements after CPHS Approval of Protocol

- **Report Problems to CPHS:** Immediately inform OSP (281-283-3015) when any unanticipated problems or injuries (Adverse Event) connected with an approved protocol occurs. Written documentation about the Adverse Event must be submitted to OSP within 5 working days.
- **CPHS Review PRIOR to Changes:** Additions or changes to protocol will be submitted to CPHS for review prior to implementing into research study.
- **Recordkeeping Maintenance:** All research data and signed informed consent forms will be safeguarded by **principal investigator** or **faculty sponsor** (not student investigators) for 3 years after completion of research study. Internal and external audits may occur.

Appendix A
UHCL-Sanctioned Data Collection Instruments that are Not Research

Forthcoming as process is implemented and items are identified

COMMITTEE APPROVAL TRACKING				
Member	Date	VOTE:		
		Affirm	Dissent	Abstain
Durand, Roger (Chair)	3/18/19		X	
Harley, David (non-affiliated non-scientist)	3/18/19	X		
Lehmann, Conni (College of Business)	3/18/19	X		
Lerman, Dorothea (College of Human Sciences & Humanities)	3/14/19	X		
Peters, Michelle (College of Education)	3/13/19	X		
Phalen, Robert (College of Science and Engineering)	3/17/19	X		
Salinas, Rosana (non-scientist)	3/18/19	X		
Terry, Reese (non-affiliated)	3/13/19	X		
<i>Berberich, Steven (provost)¹</i>				

¹ Casts vote in the event of a tie