**The University of Texas at Tyler**

**The University of Texas Health Science Center at Tyler**

**UT Health East Texas Healthcare System**

**Form 26- Project Summary**

**Complete this form in layman’s (very simple) language.**

**It should be understandable to anyone who reads it and is not knowledgeable about your field of study.**

**Today’s Date:**

**Study Title:**

**\*Sponsor / Funding Source:**

**Does this project include any funding?** **[ ]  Yes** **[ ]  No**

**If yes, please list the funding source:**

**Is this study industry sponsored: [ ]  Yes [ ]  No**

**If yes, please list the industry sponsor:**

**[ ]  If you are a student or resident AND this study is for a student or resident project (Capstone, etc.), please check this box. You will be listed as the PI and your Faculty Advisor will be listed as the Sub-Investigator. In the event that you are not available your Faculty Advisor will assume all Principal Investigator responsibilities.**

**Principal Investigator (PI): Department:**

 **Email:**

 **Phone:**

**Research Coordinator (if applicable): Department:**

**Phone Number:**

 **Email:**

**Sub-Investigator (Sub-I): Department:**

**Phone: Email:**

*Add lines as needed for more Sub-Investigators or Research Staff*

**Department Chair: Email:**

**Assurance of the Principal Investigator and Sub-Investigators:**

* To safeguard human subjects involved in this research, I agree to use procedures that conform to the policies of The University of Texas Health Science Center at Tyler, the regulations of the Department of Health and Human Services, and the Food and Drug Administration.
* Unless it is necessary to eliminate apparent immediate hazard to a human subject, I shall seek prior approval from the Institutional Review Board (IRB) for substantive changes in the investigative procedures involving human subjects that may be required during the research covered by this application.
* I shall agree to follow the advice of the IRB.
* I agree to report immediately to the IRB any unanticipated, life-threatening, or fatal complications with respect to human subjects.
* My signature certifies that I assure compliance with the ethical principles and institutional policies regarding the protection of human subjects in research as stated in Title 45 Code of Federal Regulations Part 46 (revised June 18, 1991; reprinted April 2, 1996) and the Federal Wide Assurance.

**Assurances of Department and Collaborating Chair:**

* I understand that responsibility for assessing the quality of research must be shared by both the department and the IRB.
* My signature certifies that I assure compliance with the ethical principles and institutional policies regarding the protection of human subjects in research as stated in Title 45 Code of Federal Regulations Part 46 (revised June 18, 1991; reprinted April 2, 1996) and the Federal Wide Assurance, and that I have reviewed the proposed research for proper use of human subjects.
* This review encompassed experimental design, scientific merit, and accuracy of the proposed research.

Is the investigator requesting that this study be reviewed for a Non-Human Subject Research Determination (NHSR)?

 **[ ]  Yes [ ]  No**

Is the investigator requesting that this study be reviewed as an exempt study? **[ ]  Yes [ ]  No**

If yes, complete the two questions below using the attached OHRP Exempt Categories at the end of this document and then proceed with completing the remainder of this form.

**Indicate what exemption category best fits this study: \_\_\_\_\_\_**

**Explain how this category fits the study:**

Is the investigator requesting that this study be reviewed as an expedited study? **[ ]  Yes [ ]  No**

If yes, complete the two questions below using the attached list of OHRP Expedited Review Categories at the end of this document and then proceed with completing the remainder of this form.

**Indicate what expedited category best fits this study: \_\_\_\_\_\_**

**Explain how this category fits the study:**

**Purpose:**

**Background:**

**Concise Summary of Project:**

**Study Procedures. Please list all study procedures that will take place for this study:**

\* Please attach all questionnaires, surveys, flyers, advertisement, data collection tools, etc. with this form for proper review.

\*\*If this study involves a review of records, please list out the specific data points that will be queried and collected. Additionally, include the source of the data and the data collection procedures. This can be attached as an excel spreadsheet.

**Risk Classification:**

As the Principal Investigator, what risk classification would you assign to this research project overall?

Note: According to the federal regulations minimal risk means “The probability and magnitude of harm or discomfort anticipated in the research are not greater in of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

 [ ]  Minimal Risk

 [ ]  Greater than Minimal Risk

Indicate the number of subjects to be enrolled in this study:

Does this study involve any of the following categories of individuals that will be recruited as subjects (check all that apply):

 [ ]  Children/Infants

 [ ]  Prisoners

 [ ]  Pregnant Women/Neonates (viable and/or non-viable)

 [ ]  Employees or Students

 [ ]  Cognitively Impaired Individuals

 [ ]  Wards of the State

 [ ]  Inpatients

 [ ]  Outpatients

 [ ]  Healthy Volunteers

 [ ]  None of the Above

**Will people unable to read English be enrolled in this study?**

[ ]  Yes (explain below and specify the language. Discuss if a translator will be available throughout the process of obtaining consent and if a translated consent form and study documents will be available the subject)

[ ]  No (explain)

**Describe how subjects/specimens/or data will be involved in the study, including total time involved:**

**If applicable, describe when, where, and how potential subjects will be recruited:**

**Performance Sites. Indicate the primary site where the research procedures will be conducted and subjects will be seen.**

**\*\*If procedures will take place at more than one location or site, please indicate the supplementary sites as well.**

**Protocol Inclusion Criteria:**

**Protocol Exclusion Criteria:**

**Sources of Research Material:**

**Please indicate if any of the following will be used in the recruitment of subjects. Please select all that apply:**

 [ ]  Paper Medical Records

 [ ]  Electronic Medical Records

 [ ]  Clinical Databases

 [ ]  Investigator’s Patients

 [ ]  Internet/Social Media

 [ ]  None of the above apply

**Which of the following apply to this research with regard to informed consent:**

 [ ]  Informed consent will be obtained from all subjects and documented with a signed, written consent form.

[ ]  Informed consent will be obtained, but no signed consent form will be used. This includes oral consent and implied consent (e.g. completing a survey). An alteration of documentation of consent is requested.

 [ ]  Fully informed consent will not be obtained from subjects. A waiver or alteration consent is requested.

**If a waiver or alteration of informed consent is being requested, justify the request by answering the following questions. If you are not requesting a waiver or alteration, move to the next section titled investigational drugs and devices.**

 Does the research involve no more than minimal risk\* to subjects? [ ]  Yes [ ]  No

 Will the waiver or alteration adversely affect the rights and welfare of the subjects? [ ]  Yes [ ]  No

 Could the research practicably be carried out without the waiver or alteration? [ ]  Yes [ ]  No

 Whenever appropriate, will subjects be provided with additional pertinent information after participation [ ]  Yes [ ]  No

\*\*”Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research is 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” 945 CFR 46)

**Does this study involve an investigational drug or device?** [ ]  Yes [ ]  No

 **If yes, please list all investigational drugs and/or devices to be used in this research:**

**Does this study involve any of the following (check all that apply):**

 [ ]  Any Data from this study that will be stored for future use in other potential research projects

 [ ]  Any Biological specimens collected for this study that will be stored for future use in other potential research projects

[ ]  Use of social media or online platforms for recruitment of subjects

[ ]  Data collection will utilize online platforms such as Qualtrics, Redcap, Survey Monkey, etc..

 [ ]  International research site locations

 [ ]  Collaborative research being conducted at multiple sites, where UTHET or UTHSCT is considered the lead site

 [ ]  None of the above

**Describe all of the possible risks to subjects, discomforts, or harms associated with each research procedure involved in the study:**

**Describe any special precautions that will be taken to minimize possible risks to subjects, discomforts, or harms:**

**Describe the potential benefits of this study (i.e. benefits to science/society, and benefits to subjects):**

Are there any alternatives to participation in this research? [ ]  Yes [ ]  No

 If yes, please explain:

**Will subjects be offered compensation for participating in the research?** [ ]  Yes [ ]  No

**Will the subject incur any costs for participating in the research?** [ ]  Yes [ ]  No

**Describe the data analysis plan for this study, including any statistical procedures:**

**Data Statement:**

Does this project involve any software application, web app, mobile app, or anything similar? [ ]  Yes [ ]  No

If yes, any software application, web, or mobile app will be used to process or store University data, must submit a software request with the Information Security department, and the application, web, or mobile app must be approved for use by the Information Security department. **You must provide a letter or the email with the approval from Information Security.**

**Procedures to Maintain Confidentiality:**

All study related information and electronic data will be kept confidential and protected by providing password-protected access only to the Principal Investigator, Sub-Investigator, Coordinator, Monitor, or Others ***(same as named in the consent)*** who are actively involved in the collection and analysis of data, and who have completed all institutionally required HIPAA, privacy, and confidentiality trainings, and are IRB-approved to conduct this study.

[ ]  Yes [ ]  No

The date collected for this study will be stored on a secured server in secured files. Subject’s source data will only be linked to the study data via a unique identification number.

[ ]  Yes [ ]  No

Any source documentation leaving the study site will be completely deidentified to maintain confidentiality.

[ ]  Yes [ ]  No

Information resulting from this study that is collected and reported in any publications will be deidentified. No personal identification information (e.g., name, address) will be reported.

[ ]  Yes [ ]  No

All efforts will be made to ensure confidential information collected from participants will be fully protected. If applicable, during study administration, any unusual or unanticipated events, particularly those related to a breach of confidentiality, will be reported to the PI immediately. The PI will be responsible for responding appropriately following policies and procedures set forth by The University of Texas Health Science Center at Tyler and will be reporting to the Institutional Review Board and Privacy Official or Compliance Officer.

[ ]  Yes [ ]  No

If anyone involved in the study utilizes any computer other than a State issued computer, the VDI (Virtual Desktop Infrastructure) solution to connect off campus will be utilized.

 [ ]  Yes [ ]  No

**Will this research involve obtaining; creating; using; and/or disclosing individually identifiable health information?** [ ]  Yes [ ]  No

If yes, how will Individual Authorization be obtained? (HIPAA)

 [ ]  Request for authorization will be included in the informed consent document

 [ ]  Investigator requests a Waiver of Authorization

**If a waiver of Authorization is being requested, justify the request by answering the following questions. If you are not requesting a waiver of Authorization, move to the next section.**

Does the use or disclosure of PHI involve no more than minimal risk\* to subjects? [ ]  Yes [ ]  No

 Will the investigator destroy identifiers at the earliest opportunity? [ ]  Yes [ ]  No

 Could the research practicably be carried out without the waiver of authorization? [ ]  Yes [ ]  No

 Confirm that the PHI will not be reused or disclosed to any other person except as required by law [ ]  Yes [ ]  No

**Does the investigator have sufficient time to conduct and complete the study?**

 [ ]  Yes

 [ ]  No

**Will other resources be needed for the protection of subjects and conduct of this research? Some examples may include: interpretation services, language translation of documents, etc..**

[ ]  Yes

[ ]  No

**Might counseling or social support services/referrals be required as a consequence of research participation?**

[ ]  Yes [ ]  No

**Will psychological, social, or medical monitoring, ancillary care, or equipment be needed to protect subject?**

[ ]  Yes

[ ]  No

**Biospecimen Samples:**

Will this study include the use biospecimen samples?

 [ ]  Yes

 [ ]  No

**If biospecimen samples will be used for this study, will the samples be imported or shipped to the local investigator from outside sources?**

[ ]  Yes –If yes, please provide evidence of a Material Transfer Agreement or Clinical Trial Agreement

[ ]  No

[ ]  Not applicable as this study will not include the use of biospecimens being shipped to the local investigator

**If biospecimen samples will be used for this study, will the samples be exported or shipped outside of the institution?**

[ ]  Yes --If yes, please provide evidence of a Material Transfer Agreement or Clinical Trial Agreement

[ ]  No

[ ]  Not applicable as this study will not include the use of biospecimens being shipped outside of the institution for analysis

**If biospecimen samples will be used for this study, what is the status of the samples?**

[ ]  Infectious—If yes, please provide documentation from the IORRC (Infectious Organism Research Review Committee)

[ ]  Not Infectious

[ ]  Not applicable as biospecimen samples will not be used in this study

**Electronic Data:**

Will this study include the use of electronic data? [ ]  Yes [ ]  No

**If electronic data will be used for this study, will the data be imported to the local investigator from an outside source?**

[ ]  Yes –If yes, a data transfer use agreement may be required. Please confirm with the IRB office.

[ ]  No

[ ]  Not applicable as this study will not include the use of data being imported to the local investigator from an outside source.

**If electronic date will be used for this study, will the data be exported outside of the institution?**

[ ]  Yes –If yes, a data transfer use agreement may be required. Please confirm with the IRB office.

[ ]  No

[ ]  Not applicable as this study will not include the use of data being exported outside of the institution

**Radiation Exposure:**

All protocols involving radiation exposure to subjects involved in human research, when exposure is not considered standard of care, must be referred to the Radiation Safety Committee for review in addition to IRB Review.

Examples of procedures which would review by the RSC:

* Any radiation exposure to healthy normal subjects regardless of age
* Any use of an investigational radiation device
* Any use of an investigational radiopharmaceutical or investigational implant/seeds
* Any use of an investigational contract medium with radiation
* Any use of imaging where it is the subject of the investigation, such as special CT sequences to guide a new surgical procedure
* Any radiotherapy that is not standard of care
* Standard of care imaging that exceeds certain dose thresholds, these may include protocols requiring:
	+ Over five CT chest scans
	+ Over two CT scans of the abdomen and pelvis
	+ Over five PET scans
	+ Extended fluoroscopy beyond 5 minutes

**Will this study involve any procedures from the list above?**

[ ]  Yes –If yes, please provide documentation of Radiation Safety Committee Review

[ ]  No

**Will this study involve any radioactive procedures or materials that are not considered standard of care?**

 [ ]  Yes --If Yes, please provide documentation of Radiation Safety Committee Review

 [ ]  No

**If you answered yes to either of the questions above related to radiation exposure, please use the space below and discuss the following information:**

* What is going to be irradiated? Patients, Blood, Cell Cultures
* Please discuss the method and procedure of irradiation as well as who will be performing the radiation

**Human Gene Transfer (HGT) and the use of DNA and/or rDNA:**

Human Gene Transfer (HGT) is an approach to the treatment of human disease based on the transfer of genetic material (DNA) into an individual. In this way, HGT attempts to treat disease in an individual patient by the administration of DNA rather than a drug. Gene transfer involves the administration of genetic material to alter the biological properties of living cells for therapeutic use. Gene transfer is accomplished by one of two methods: In vivo (in the body), and Ex vivo (outside the body). The transfer of genes is typically accomplished in one of two ways: by placing the genetic sequence inside of a vehicle known as a vector, or by injecting the DNA directly into the cell without the use of a vector.

**Will this study involve the use of any DNA or rDNA materials?**

[ ]  Yes --If yes, an Institutional Biosafety Committee (IBC) review is required in addition to this IRB review.

 Please attach documentation of IBC review

 [ ]  No

***Other Paperwork Required for Submission:***

1. ***Each person listed on the protocol will have to provide a copy of their CV and verification of completion of required training courses via the CITI website.***
2. ***As applicable, informed consent document, information sheet, brochure, or script for verbal consent***
3. ***As appliable, recruitment materials (posted notices, advertisements, telephone scripts, letters, etc.)***
4. ***As applicable, data collection form***

*By signing this document, I attest that this form is complete and accurate.*

 Principal Investigator Date

**OHRP Exempt Categories**

**Effective January 20, 2019 – New Common Rule Update**

§46.104   Exempt research.

(a) Unless otherwise required by law or by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the categories in paragraph (d) of this section are exempt from the requirements of this policy, except that such activities must comply with the requirements of this section and as specified in each category.

(b) Use of the exemption categories for research subject to the requirements of subparts B, C, and D: Application of the exemption categories to research subject to the requirements of 45 CFR part 46, subparts B, C, and D, is as follows:

(1) Subpart B. Each of the exemptions at this section may be applied to research subject to subpart B if the conditions of the exemption are met.

(2) Subpart C. The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

(3) Subpart D. The exemptions at paragraphs (d)(1), (4), (5), (6), (7), and (8) of this section may be applied to research subject to subpart D if the conditions of the exemption are met. Paragraphs (d)(2)(i) and (ii) of this section only may apply to research subject to subpart D involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section may not be applied to research subject to subpart D.

(c) [Reserved]

(d) Except as described in paragraph (a) of this section, the following categories of human subjects research are exempt from this policy:

**Category 1:**

(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.

**Category 2:**

 (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 §46.111(a)(7).

**Category 3:**

 (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 or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief, 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.

(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.

**Category 4:**

(4) 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:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(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;

(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

(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.

**Category 5:**

(5) 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 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.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site 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.

(ii) [Reserved]

**Category 6:**

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

(i) If wholesome foods without additives are consumed, or

(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.

**Category 7:**

(7) Storage or maintenance for secondary research for which broad consent is required: 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 §46.111(a)(8). **(UTHSCT WILL NOT BE USING BROAD CONSENT)**

**Category 8:**

(8) 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: **(UTHSCT WILL NOT BE USING BROAD CONSENT)**

(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);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §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 (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.

(Approved by the Office of Management and Budget under Control Number 0990-0260)

**EXPEDITED RESEARCH CATEGORIES**

The following types of research may be reviewed by the IRB under an expedited review procedure (45 CFR 46.110 and 21 CFR 56.110). These research activities 1) present no more than minimal risk to human subjects, and 2) involve only procedures listed in one or more of the following categories. [Note: The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.]

CATEGORY 1

Clinical studies of drugs and/or devices only when

1. Research on drugs for which an investigational new drug [IND] application is not required (21 CFR Part 312). (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.) or
2. Research on medical devices for which
3. an investigational device exemption application [IDE] is not required (21 CFR Part 812); or
4. the medical device is cleared / approved for marketing and the medical device is being used in accordance with its cleared / approved labeling.

Information Required for Justification

1. State the name of the commercially available drug to be used as described in the above requirements,

or

State the name of the approved device and confirm its use as described above.

1. Confirm that the research does not increase the risks or decrease the acceptability of the risks associated with the use of the product.

CATEGORY 2

Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

1. 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
2. from other adults and children\* 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.

Information Required for Justification

1. State how the blood sample(s) will be collected.

b) Provide the health status of the research population and state whether pregnant women are eligible to participate.

(a) For healthy, nonpregnant adults who weigh at least 110 pounds -

Confirm that the amounts of blood to be drawn will not exceed 550 ml in an 8 week period *and* will not occur more frequently than 2 times per week.

(b) For other adults (e.g., with an illness) or children\*

Confirm that the amount of blood to be collected will not exceed the lesser of 50 ml or 3 ml p/kg in an 8 week period and not occur more frequently than 2 times per week.

\*Children are defined in the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of jurisdiction in which the research will be conducted.” 45 CFR 46.402(a).

CATEGORY 3

Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

1. hair and nail clippings in a non-disfiguring manner;
2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
3. permanent teeth if routine patient care indicates a need for extraction;
4. excreta and external secretions (including sweat);
5. 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;
6. placenta removed at delivery;
7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
8. 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;
9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
10. Sputum collected after saline mist nebulization.

Information Required for Justification

1. State the biological specimen(s) to be collected.

2. Describe the noninvasive method by which the specimens will be collected.

CATEGORY 4

The 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.) Examples of such procedures:

1. physical sensors applied 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;
2. weighing or testing sensory acuity;
3. magnetic resonance imaging (MRI);
4. electrocardiography (ECG or EEG);
5. thermography;
6. detection of naturally occurring radioactivity;
7. electroretinography;
8. ultrasound;
9. diagnostic infrared imaging;
10. doppler blood flow;
11. echocardiography;
12. moderate exercise. . . where appropriate, given age, weight, and health of the individual.

Information Required for Justification

1. State the type of data to be collected.
2. State the source of the data and the procedure that will be used to collect the data.

CATEGORY 5

Research involving materials (data, documents, records, or specimens) that have been, or will be, collected solely for *non-research* 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. 45 CFR 46.101(b) (4). This listing refers only to research that is not exempt.)

Information Required for Justification

1. State the type of materials and the purpose for which it was, or will be, collected.
2. Statethe source of the material andwhether it is currently existing (i.e., on the shelf at the present time) or will be collected prospectively.

CATEGORY 6

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

Information Required for Justification

1. State the type of data and its original (clinical or research) purpose(s); how data will be stored; and who will have access.
2. State whether there will be identifiable information on the tapes and when the tapes will be destroyed.

CATEGORY 7

Research on individual or group characteristics or behavior including, but not limited to, research on:

1. perception,
2. cognition, Research employing -
3. motivation, i) survey
4. identity, or j) interview
5. language, k) oral history
6. communication, l) focus group
7. cultural beliefs or practices, and m) program evaluation
8. social behavior, n) human factors evaluation, or

o) 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.)

Information Required for Justification

1. State whether this is research on individual or group characteristics or behavior.
2. State the method to be used to gather the data.