# Revision History

|  |  |  |
| --- | --- | --- |
| **Requestor** | **Change(s)** | **Date** |
|  |  |  |
|  |  |  |

Start:

1. What is the nature of the study?
   1. Social/Behavioral/Education
   2. Biomedical/Clinical
   3. HUD Use for Treatment/Diagnosis

Please note: If the study is research that includes a drug/biologic, nutritional product, or device, it is biomedical research. HUD use is not research.

If b), Biomedical/Clinical

* + 1. Select all of the following that will be included in the study: [MULTIPLE}
       1. Drugs/Biologics (Includes both investigational and non-investigational products)
       2. Nutritional Products (includes dietary supplements, medical foods, and infant formulas) [NO PHASE QUESTION, IF ONLY THIS CHECKED]
       3. Devices (Includes both unapproved products and approved products used in non-approved ways) [NO PHASE QUESTION, IF ONLY THIS CHECKED]
       4. N/A (Includes chart reviews and other biomedical/clinical research that does not involve drugs/biologics, nutritional products, or devices) [NO DRUG/DEVICE SECTION, NO PHASE QUESTION]

If c), go to 3

1. Which institution is primarily responsible for this study?
   1. UAMS
   2. ACH/ACHRI
   3. Other

If you choose “Other,” please provide details in the Sites section

Select the institution associated with the Principal Investigator (PI). The Principal Investigator is the individual with overall responsibility for the study. For human subject protection purposes, all studies must have one investigator designated as PI

If b), ACH/ACHRI

* + 1. Is the PI for this study a UAMS faculty member? [YES/NO, REQUIRED]

If b) or c),

* + 1. Are you enrolling any subjects in UAMS? [YES/NO, REQUIRED]

If you have any questions, please contact (501)526-6808 or send your request to CLARABudgetHelp@uams.edu

1. [HUD ONLY] Where will the HUD be used?
   1. UAMS
   2. ACH/ACHRI
2. Which college/department is primarily responsible for this study? *List coming from SAP (College/Department/Sub-Dept.)*

ACH/ACHRI should choose the college/department the PI is associated with at UAMS.

AHEC should choose Regional Program as its college.

Basic Details:

1. What is the title of the study/HUD request?

Make your title specific and detailed. If your application is a revision, do NOT change the title.

Try to stay within the 50-word limitation

If HUD, go to 6

1. Who initiated the study?
   1. Industry
   2. Cooperative Group
   3. Investigator

Initiated: Provided the protocol.

Industry: A manufacturer of a drug, biological, or device who will act as the study sponsor. Examples include Merck, Pfizer, Celgene, and Medtronic.

Cooperative group: A group established for the purpose of conducting multi-center trials. Most, but not all, cooperative groups are established by the National Cancer Institute to conduct multi-center oncology trials. Examples of cooperative groups include NSABP, SWOG, GOG, and ECOG.

Investigator: An individual who is involved in conducting human subject research. Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” with overall responsibilities for the study.

If Investigator Initiated,

* + 1. Which of the following describes the investigator who initiated this study?
       1. Local faculty (UAMS, ACH/ACHRI)
       2. Non-local faculty
       3. Student/Fellow/Resident/Post-doc [Should have at least one staff in Staff page having the mentor role]
       4. Other
          1. If Other, please explain:
    2. Which of the following support types will this study use? (click all that apply)
       1. Industry Support, full funding
       2. Industry Support, partial funding
       3. Industry Support, providing drug/device
       4. Federal grant directly to UAMS/ACHRI
       5. Federal sub-contract from another institution
       6. Non-federal grant
       7. Internal support
       8. No designated support for this study
       9. Other [FREE-TEXT]

Non-federal grants: Includes foundation grants, awards, and gifts.

Internal support: Examples include TRI pilot grants and departmental funds.

If Cooperative Group,

* + 1. Please indicate the Cooperative Group.
       1. Alliance - Alliance for Clinical Trials Oncology
       2. COG - Children's Oncology Group
       3. CTSU - Cancer Trials Support Unit
       4. ECOG-ACRIN - Cancer Research group
       5. NRG Oncology
       6. SWOG - Southwest Oncology Group
       7. Other
          1. If Other, please specify:

1. In which of the following settings will the study take place? (Check all that apply)
   1. Inpatient
   2. Outpatient
   3. Community-based (Schools, Nursing Homes, Churches, etc.)
   4. Research Labs (e.g., exercise facility, BioMed I, etc)
   5. Other
   6. N/A
2. [DRUG/BIOLOGICAL ONLY] What are the phases of this study? (Check all that apply)
   1. Phase 0
   2. Phase I
   3. Phase I/II
   4. Phase II
   5. Phase II/III
   6. Phase III
   7. Phase IV
   8. Feasibility (Pilot) Study
   9. Not Applicable

•Phase 0

Early clinical proof-of-concept studies that offer no possibility of direct clinical benefit, and that require serial blood (and often tumor) samples.

•Phase I

Researchers test an experimental drug or treatment in a small group of people (20-80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

•Phase II

The experimental study drug or treatment is given to a larger group of people (100-300) to see if it is effective and to further evaluate its safety.

•Phase III

The experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the experimental drug or treatment to be used safely.

•Phase IV

Researchers study the side effects of a drug after it is approved and being marketed.

•Feasibility (Pilot) Study

A smaller version of a larger study that is conducted to prepare for that study.

1. What is the lay summary of this study? (This should include a brief description of the overall goals of the proposed study, the specific aims or objectives of the study, and the general experimental approach.)

This section must be understandable to the general public. Use simple, non-technical, common-language at a high-school level. This section can often be taken from the study description in the informed consent document.

Failure to make this section understandable to non-scientists will delay IRB approval.

1. [New Question, HUD ONLY] Describe the device and the indication for use approved by the FDA. Include information on previous use.
2. [New Question, HUD ONLY] Describe the procedure that patient(s) will undergo in relation to use of the device.
3. [New Question, HUD ONLY] Describe the reason use of the device is worth the risk to patient(s) at this time.
4. [New Question, HUD ONLY] Describe the process of clinical consent for use of the device.

If HUD, go to Staff (skip Sites)

Sites:

1. Is this a single-site study or a multi-site study?
   1. Single-site
   2. Multi-site

A single-site study is conducted by one investigator, at locations under the purview of one IRB.

A multi-site study is conducted by more than one investigator, at locations under the purview of separate IRBs.

If b) Multi-site,

* + 1. Will the local site (ACH/ACHRI/UAMS) be the lead entity for this study?

Lead entity: ACH/ACHRI/UAMS is the lead entity for a multi-site study when the PI is the lead researcher for the entire study, or when the site provides study-wide services, such as data coordination.

If Yes,

* + - 1. Describe the communication between sites that might be relevant to the protection of participants, such as unanticipated problems, interim results, and protocol modifications.
      2. Describe IRB oversight arrangements for each site (i.e. who is providing IRB review and approval).

1. Name the location(s) for this study. Be sure to include contact information for each location.

A single-site study may have more than one location (for example, ACH, ACHRI, and UAMS can each be a separate location, if the study is conducted by one investigator).

Industry-sponsored studies should list only those locations that are under UAMS IRB oversight.

Staff:

Please list the staff for your protocol below.

All individuals engaged in the research as UAMS, ACH or other institution subject to the

oversight of the UAMS IRB must be listed as personnel with a description of their role and qualifications.

For HUDs, please list the Treating Physician, as well as personnel obtaining clinical consent and/or assent.

Double click on a staff member’s name to edit their study-specific information.

For HUDs, please list the Treating Physician, as well as personnel obtaining clinical consent and/or assent. [Require Treating Physician for HUDs, not PI]

1. Name (id) [LIST-PANEL]
2. Roles
   1. Principal Investigator [ONLY ONE PI is allowed]

The PI is the primary person responsible for the creation / management of the study.

* 1. Co-Investigator
  2. Sub-Investigator
  3. Study Coordinator
  4. Budget Manager
  5. Budget Administrator
  6. Support Staff
  7. Mentor/Faculty Advisor
  8. Research Pharmacist
  9. Treating Physician

HUD Only

* 1. Research Administrator

1. Responsibilities
   1. Manage CLARA submission

e.g., create, edit, and manager CLARA submission forms

* 1. Recruiting subjects
  2. Obtaining informed consent
  3. Performing non-invasive study activities

e.g., recording observations, administering surveys, obtaining medical histories

* 1. Performing invasive study activities

e.g., drawing blood, collecting tissue samples

* 1. Managing investigational product

e.g., receiving, storing, dispensing, reconciling investigational product

* 1. Managing data

e.g., entering CRFs, completing queries

* 1. Receiving Confidential Information/Materials

For CDAs and MTAs

* 1. Providing Confidential Information/Materials

For CDAs and MTAs

* 1. Receiving Limited Data Set under DUA

For Data Use Agreements

* 1. Providing Limited Data Set under DUA

For Data Use Agreements

* 1. Performing regulatory duties

e.g., assessing UPIRTOs, documenting deviations

* 1. Advising student research

e.g., guiding studies initiated by fellows, residents, post-docs

* 1. Primary Budget Manager

e.g., budget development, budget negotiation with Sponsor, completion of Sponsor’s budget exhibit, terms and conditions with the Financial and Legal Units.

* 1. Budget Manager
  2. Budget Administrator

e.g., billing recondition, Invoicing the Sponsor for payment, managing the research study account

* 1. Data Analysis
  2. Research Not Involving Human Subjects
  3. EMR Study Contact

EMR study contact information will auto-populate in UConnect (Epic) description field. This contract information will display in the eMR system for studies requiring a CLARA budget.

1. Notifications & Conflicts
2. Salary/FTE Estimates
3. Training

Subjects:

1. Provide the total number of subjects (or number of participant records, specimens, etc.) for whom you are seeking UAMS IRB oversight.

The number of subjects is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed, etc.) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval.

For HUDs, provide the total number of patients who will be receiving treatment or diagnosis involving the device.

1. [If multiple site study] What is the total subject accrual goal for all sites for this study (if available)?
2. What age range(s) do the subjects fall into?
   * + 1. In utero
       2. Birth-6 years old
       3. 7-17 years old
       4. 18+ years old

Selection of an age range **does not necessitate inclusion of that entire age range** in the study.

For HUDs, please select the age range(s) for patients who will be receiving treatment or diagnosis involving the device.

If HUD, go to Drugs/Devices (skip HIPAA, Consent, Risks, Data and Safety Monitoring, Miscellaneous)

1. [If Social/Behavioral/Education Study Type] Name and describe the subject population(s) for the study.

Subject Population: A group of subjects that share a role relevant to the research (for example, "providers," "community leaders," etc.). A single study may involve multiple subject populations.

1. Select all of the vulnerable populations that will be, or potentially could be, included in the study:
   1. Pregnant Women [[APPENDIX – A](#AppendixA)]
   2. Nonviable Neonates/Neonates of Uncertain Viability ([APPENDIX – B](#AppendixB))
   3. Prisoners ([APPENDIX – D](#AppendixD))
   4. Fetuses ([APPENDIX – A](#AppendixA))
   5. Children ([APPENDIX – C](#AppendixC))
   6. Non-English Speaking ([APPENDIX – E](#AppendixE))
   7. Wards of the State
   8. Cognitively Impaired ([APPENDIX – F](#AppendixF))
   9. Research Subjects in International Setting ([APPENDIX – G](#AppendixG))
   10. Unknown (for chart review studies only)
   11. N/A

A population is potentially included in a study when its members are present in the recruitment pool, and they are not specifically excluded from the study.

A population is targeted in a study when its members will definitely be selected as study subjects, because of the nature of the research.

Pregnancy: The period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

Neonate: A newborn, from birth to four weeks old.

Fetus: The product of conception from implantation until delivery.

Prisoner: Any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Ward of the State: a child who is placed in the legal custody of the state or other agency, institution, or entity consistent with applicable federal, state, or local law.

Cognitively Impaired: Lacking the capacity to consent, as a result of trauma, mental retardation, some forms of mental illness, or dementia, whether temporary, progressive, or permanent.

1. Select all of the vulnerable populations that will be targeted for participation in the study:
   1. Pre-K-12 Students
   2. College Students
   3. Homeless
   4. Educationally Disadvantaged
   5. Financially Impaired
   6. Terminally III
   7. Substance Abusers
   8. Minorities
   9. Victims of Sexual Abuse
   10. N/A

A population is targeted in a study when its members will definitely be selected as study subjects, because of the nature of the research.

Select College Students only if member of study team is targeting his/her own students.

1. [ONLY IF “PREGNANT WOMEN IS NOT CHECKED”] Will pregnant women be excluded from participation in this research?
   * + 1. **If Yes,**

Explain how the nature of the research requires/justifies their exclusion. Address means of pregnancy screening.

1. [ONLY IF “NON ENGLISH SPEAKING IS NOT CHECKED”] Will non-English speaking subjects be excluded from participation in this research?

The IRB prohibits the exclusion of non-English speaking persons in research studies that have the prospect of direct benefit to subjects, unless there is a compelling justification for their exclusion.

* + - 1. **If Yes,**

Explain how the nature of the research requires/justifies their exclusion. Address means of screening.

Examples of acceptable justifications include:

Study requires use of data collection instruments that have not been validated scientifically in languages other than English;

Study will include participants who are already known to the PI and who all speak English (for "follow-up" studies in which only a known group of current subjects will be eligible to participate); or

Study is of a disease or disorder so rare that local enrollment is expected to be five or less.

1. How will potential subjects be identified?
2. Which types of advertising will be directed at research subjects?
   1. Brochure
   2. Posting circulars
   3. Magazine
   4. Radio
   5. Newspaper
   6. Television
   7. Websites
   8. Phone Screen
   9. “Dear Participant” Letter
   10. Information Article
   11. Public Service Announcement
   12. Social Media
   13. N/A
       1. **If Websites is checked,** 
          * 1. List Websites and their URLs (e.g. UAMSHEALTH.com)

Social media (e.g., Facebook, Twitter, etc. Please indicate the owner of the page, such as "ACH Facebook")

1. What are the *advertised* criteria for this study?
2. Will compensation be provided to the subjects?

Compensation may be of a monetary or non-monetary nature.

**If Yes,**

* 1. Describe the method and amount of compensation, and its appropriateness for the research setting. Identify the recipient of the compensation (participant and/or parent/guardian). Outline plans to pro-rate the compensation, if necessary.

HIPAA

1. Are you obtaining Protected Health Information (PHI) directly from subjects during the course of this research project?

Protected Health Information (PHI): Information that identifies an individual, or that could reasonably be used to identify an individual, and that (i) relates to the past, present or future physical or mental health or condition of the individual; (ii) relates to the provision of health care services to the individual; or (iii) relates to the past, present, or future payment for the provision of health care services to an individual.

**If Yes,**

* 1. Describe the PHI that will be obtained/recorded for the research.
  2. Select the identifiers that will be captured for this study. Check all that apply:
     1. Names; dates; phone numbers; email addresses; street addresses; cities; zip codes; social security numbers; medical records numbers
     2. Ages over 89; fax numbers; counties; precincts; health plan beneficiary numbers; account numbers
     3. Voices; images; other biometric identifiers, including finger prints and retinal prints
     4. Certificates/license numbers; vehicle identifiers and serial numbers, including license place numbers; device identifiers and serial numbers; URLs; IP addresses
     5. N/A
     6. Other identifier

The initial three digits of a zip code would not be considered identifying, if the geographic unit formed by combining all the zip codes with the same three initial digits would contain more than 20,000 people, according to the current publically available data from the Bureau of the Census.

Ages over 89 would not be considered identifying if they were aggregated into a single category of age 90 or older.

1. Are you accessing existing PHI for this research project?

Existing PHI: Protected health information that exists in the databases, charts, records, etc. being accessed for the research, at the time the research is proposed to an institutional official or IRB.

**If Yes,**

* 1. Where is your data source?, check all that apply
     1. UAMS Medical Records /HIM
     2. ACH Medical Records
     3. UAMS Data Extract Request
     4. Other

If “Other”, please explain what other data sources you are using.

* 1. Describe the PHI that will be accessed for the research.
  2. Select the identifiers that will be recorded for this study. Check all that apply:
     1. Names; dates; phone numbers; email addresses; street addresses; cities; zip codes; social security numbers; medical records numbers
     2. Ages over 89; fax numbers; counties; precincts; health plan beneficiary numbers; account numbers
     3. Voices; images; other biometric identifiers, including finger prints and retinal prints
     4. Certificates/license numbers; vehicle identifiers and serial numbers, including license place numbers; device identifiers and serial numbers; URLs; IP addresses
     5. Other identifier. Please describe
     6. N/A

Please Note: Recording includes noting items in your files, even if you do not plan to share the information with anyone.

1. Are you contacting subjects from PHI?
2. Are you receiving or planning on disclosing a limited data set as defined by UAMS POLICY (3.1.27 admin guide – link to “http://www.uams.edu/irb/03-23-2011%20IRB%20Policy%20Updates/UAMS%20Admin%20Guide%203.1.27.pdf”)?

A limited data set must exclude a number of direct identifiers of the subject and of the subject’s relatives, employers, or household members. Follow the policy link above for more information.

* 1. Please list the data files and who is supplying or receiving the data sets.

A Data Use Agreement is required for all studies receiving or planning on disclosing a limited data set. Please contact the Research Support Center for more information.

1. Are you requesting a HIPAA authorization waiver/alteration?

If you plan to use or disclose PHI for research purposes without obtaining a signed HIPAA authorization from each individual who is the subject of the information, prior to undertaking the research, you need to request a waiver/alteration of HIPAA authorization from the IRB.

**PLEASE NOTE:** Obtaining a waiver of authorization does not waive other requirements of HIPAA (such as the minimum necessary rule or accounting for disclosures). It only waives or alters the requirement that each subject sign an Authorization form.

**If Yes,**

* 1. What is the type of waiver/alternation requested?
     1. Partial Waiver (recruitment purposes only)
     2. Full Waiver (entire research study)
     3. Alteration (written documentation)

Full Waiver: A removal of the requirement that HIPAA authorization be obtained before use and disclosure of PHI for a particular research project.

Partial Waiver: A removal of the requirement that HIPAA authorization be obtained for some PHI uses and disclosures in a particular research project, such as disclosing PHI for research recruitment purposes.

Alteration: A change to the HIPAA authorization requirements for a particular research project, such as not requiring written documentation of authorization.

* 1. Provide information below about the PHI involved in the research (e.g., medical record number, health history, diagnosis, test results, etc.). Be as specific as possible.
     1. Explain why access to and/or use of the PHI is essential to conduct the research.
     2. Explain how the PHI described above represents the minimum necessary information to accomplish the objectives of the research.
     3. Explain how the access to, use of, or disclosure of PHI presents no more than a minimal risk to the privacy of the individual.
     4. Describe your plan to protect the identifiers (or links to identifiable data) associated with the PHI from improper use and disclosure, including where PHI will be stored, what security measures will be applied, and who will have access to the information. Describe the safeguards for electronic and/or hard copy records.
     5. Will identifiers (or links to identifiable data) be destroyed?
        1. Yes
        2. No
        3. N/A

N/A: Will not record identifiers or create links or codes to connect the data.

**If Yes,**

* + - * 1. Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include **when** and **how** identifiers will be destroyed.

**If No,**

* + - * 1. Provide the legal, health, or research justification for retaining the identifiers. Legal justification should include a brief description/citation of the legal requirement.
    1. Explain why the research could not practicably be conducted without the waiver/alteration of HIPAA authorization.

Consent:

1. Indicate the consent process (es) to be used in the study. Check all that apply.
   1. Assent
   2. Parental Permission (Pediatric Consent)
   3. Informed Consent
   4. Requesting Waiver of Consent Process [[APPENDIX M1](#AppendixM1), HIDE THE REST OF THE CONSENT QUESTION]
   5. Other

If the research involves a product regulated by the FDA, or the results of the research may be submitted to the FDA as part of a marketing application, the consent process cannot be waived.

Includes both full and partial waivers.

**If Assent, Parental Permission, Informed Consent,**

* 1. Are you requesting a Waiver of Documentation for the Consent/Assent Process?

**If Yes,** [[APPENDIX M2](#AppendixM2)]

1. Who will provide consent/assent/permission?
   1. Participant
   2. Legally authorized representative
   3. Parents and/or guardian
2. Describe the location in which the consent process will occur:
   1. In a private room
   2. Over the phone
   3. Via mail
   4. In a group setting
   5. Via the Internet
   6. Other
3. How much time will be devoted to the consent discussion?
4. What is the waiting period between informing the prospective participant about the study and obtaining consent?
5. Explain how the possibility of coercion or undue influence will be minimized in the consent process.

Coercion occurs when an overt threat of harm is intentionally presented by one person to another to obtain compliance.

Undue influence occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance.

1. Will any other tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension?

If yes, please provide supporting documents

1. If children participate in the study, will their participation continue beyond the time that they are 18 years of age?
   1. Yes
   2. No
   3. N/A

N/A: Will not enroll children as research subjects.

**If Yes,**

* + 1. Please describe the re-consenting process.

Risks:

(Study Procedure)

1. List the resources available to protect human study participants in the research settings.

Resources include, but are not limited to, appropriately qualified research team members, adequate facilities (equipment and space), availability of medical or psychosocial services, and provisions for emergency treatment that are available in the location.

For studies with no subject interaction, please enter N/A.

1. Indicate whether the research records will be:
   1. Coded
   2. Deidentified
   3. Neither

* **Coded:** Identifying information that would enable anyone involved in conducting the research to readily ascertain the identity of the individual to whom the private information or specimens pertain is replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or speciments.
* **De-identified:** The following identifiers of the individual and the individual's relatives, employers, or household members of the individual are removed:   
  A. Names; dates; phone numbers; email addresses; street addresses; cities; zip codes; social security numbers; medical records numbers.   
  B. Ages over 89; fax numbers; countries; precincts; health plan beneficiary numbers; account numbers.   
  C. Voices; images; other biometric identifiers, including finger prints and retinal prints.   
  D. Certificates/license numbers; device identifiers and serial numbers; URLs; IP addresses.   
  E. Any other unique identifying number or characteristic.

**If a) or b),**

* + 1. Describe the process used to code or de-identify the records.

**If c),**

* + 1. Please explain

1. Describe the procedures for record storage. Where will electronic and/or hard copy research records be stored? Who will have access to them? When and how will they be destroyed?

Data retention requirements vary based on type of data collected, subject population, grant or contract terms and FDA regulations, as applicable. Prior to transfer or destruction of any data, you must verify the data retention requirements that apply to your study.

1. Will biological specimens (tissue, blood, saliva, etc.) be obtained?

**If Yes,**

* 1. Will the specimens be collected directly from participants (as opposed to being obtained from a secondary source)?

**If Yes,**

* + 1. Check all the type(s) of specimens to be collected.
       - 1. Blood

**If checked,**

Who is drawing the blood?

How much and over what period of time?

List specific physical location(s) (Lab, Clinic, Office Name, e.g.) where blood draw is to take place

List resources available to ensure participant safety (Specific to blood drawn)

* + - * 1. Tissue <tissue>
        2. Others (urine, saliva, semen, etc.) <other>
  1. Indicate whether the specimen to be collected and/or stored will be:
     1. Coded
     2. De-identified
     3. Neither
* **Coded:** Identifying information that would enable anyone involved in conducting the research to readily ascertain the identity of the individual to whom the private information or specimens pertain is replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or speciments.
* **De-identified:** The following identifiers of the individual and the individual's relatives, employers, or household members of the individual are removed:   
  A. Names; dates; phone numbers; email addresses; street addresses; cities; zip codes; social security numbers; medical records numbers.   
  B. Ages over 89; fax numbers; countries; precincts; health plan beneficiary numbers; account numbers.   
  C. Voices; images; other biometric identifiers, including finger prints and retinal prints.   
  D. Certificates/license numbers; device identifiers and serial numbers; URLs; IP addresses.   
  E. Any other unique identifying number or characteristic.

**If i or ii,**

Describe the process used to code or de-identify the specimens.

**If iii,**

Please explain

* 1. Describe the physical location/equipment and security provisions where the specimens will be stored.
  2. Explain who will manage the stored specimens
  3. Indicate how long the specimens will be stored (e.g., Indefinitely, etc.)
  4. Describe the process for destruction or de-identification of identified/coded specimens at the end of the retention periods (as applicable) or if the PI leaves the University.
  5. Will samples be released to other investigators?

**If Yes,**

* + 1. To whom will the samples be released?
       1. Pharmaceutical Company
       2. Local Investigators (e.g., researchers at UAMS, ACH)
       3. Other

**If Other,** please describe

* + 1. Indicate whether samples to be released will be:
       1. Coded
       2. De-Identified
       3. Neither

Coded: Identifying information that would enable anyone involved in conducting the research to readily ascertain the identity of the individual to whom the private information or specimens pertain is replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key to decipher the code exists, enabling linkage of the identifying information to the private information or speciments.

De-identified: The following identifiers of the individual and the individual's relatives, employers, or household members of the individual are removed:   
A. Names; dates; phone numbers; email addresses; street addresses; cities; zip codes; social security numbers; medical records numbers.   
B. Ages over 89; fax numbers; countries; precincts; health plan beneficiary numbers; account numbers.   
C. Voices; images; other biometric identifiers, including finger prints and retinal prints.   
D. Certificates/license numbers; device identifiers and serial numbers; URLs; IP addresses.   
E. Any other unique identifying number or characteristic.

**If (1) or (2),**

* + - * 1. Describe the process used to code or de-identify the records.

**If (3),**

* + - * 1. Please describe
    1. Describe the process for requesting and releasing samples. State the individual(s) responsible for verifying IRB approval (or exemption) before specimen release and his/her qualifications or training.

Provide copies of all applicable forms/agreements that will be used to request and release samples.

* 1. Will the specimens be collected and/or stored for use in future research (research that falls outside the purview of this protocol)?

**If Yes,** [[APPENDIX – I](#AppendixI)]

(Genetic Testing)

1. Is there any genetic testing planned for this study?

**If Yes,**

* 1. What type(s) of genetic research will be performed?
     1. Pedigree study (to discover the pattern of inheritance of a disease and to catalog the range of symptoms involved)
     2. Positional cloning study (to localize and identify specific genes)
     3. DNA diagnostic study (to develop techniques for determining the presence of specific DNA mutations
     4. Gene therapy research (to develop treatments for genetic disease at the DNA level)
     5. Other

**If iv,**

* + - 1. What type(s) of gene therapy will be performed?
         1. Germline (inherited mutation or genotype)
         2. Somatic (non-inherited mutation expected to be present only in the tissue being studied)
         3. Unknown
  1. Are any proposed tests also clinically available assays?

**If Yes,** Please specify.

* 1. Could proposed testing result in incidental (i.e., unintended) findings?

**If Yes,** Please specify

* 1. Will participants be informed of gene testing results?

Please explain why or why not.

**If Yes,**

* + 1. Describe the plan for informing participants of gene testing results.
    2. Specify the procedures that afford participants a way to opt out of receiving their gene testing results.
    3. Will the results have clinical significance for participants?

**If Yes,** Please describe

* + 1. Could the results have implications for others (e.g. family members)?

**If Yes,** Please describe

* 1. Will counseling, pre- and/or post-, be provided to the participants?

**If Yes,**

* + - 1. Describe, specifying who will perform counseling and the counselor’s qualifications.
      2. Will the participants (or their insurers) incur any costs for the counseling?
  1. Will participants be informed of new developments?

Please explain why or why not.

* 1. Will family members (or their data) be involved in the research?

**If Yes,**

* + 1. Will family member(s) be readily identifiable?

Explain why or why not.

* + 1. Will the primary participant be asked to provide any private information (e.g., health status, health or behavior history) about his/her family member(s)?

**If both g) and i) are Yes,**

* + - 1. Specify methods for recruiting family members (e.g., how, when, where and by whom).

Data & Safety Monitoring:

1. Is a Data & Safety Monitoring Plan (DSMP) in place for this study?

A DSMP describes how accumulating data will be monitored throughout the study to ensure that continuation of research activities is appropriate scientifically and ethically.

A DSMP should be tailored to fit the expected risk level, complexity, phase and size of the particular study.

If this protocol is considered to be more than minimal risk, a DSMP is required.

**If yes,**

* 1. Please describe the specific data that will be monitored.

This should always include safety and efficacy data, and any associated events.

* 1. Who is monitoring the data?
     1. Data and Safety Monitoring Board (DSMB)
     2. Data and Safety Monitor (DSM)

**If ii),**

Please describe the individual’s relevant medical, scientific and ethical, and monitoring expertise, as well as the individual’s relationship to the study (independent or study team member).

* + 1. Other

**If iii),**

Please specify

A DSMB is an independent committee set up to monitor accumulating data throughout the study.

A DSM is an individual assigned to monitor accumulating data throughout the study. In some studies, the investigator, or other member of the study team, may serve as monitor.

* 1. How frequently will the data be reviewed?
     + 1. Monthly
       2. Quarterly
       3. Bi-annually
       4. Annually
       5. Other, please explain (i.e. by dosing level, number of subjects enrolled, etc.)
  2. Please describe the procedures for communication from the data monitor to the IRB.

The IRB should be promptly provided with information from the monitor. This may be the normal processes for communicating with the IRB, if the monitor is part of the study team, or it may require that the investigator provide the IRB with monitoring reports from an outside monitor.

MISC:

1. Will this research be conducted in conjunction with the Translational Research Institute (TRI) Clinical Research Services Core (CRSC)?

CRSC provides infrastructure for investigators conducting human-based research, including specialized research space, nursing support, lab processing, dietary consultation, regulatory assistance, subject recruitment and more.

Investigators seeking CRSC services should complete and submit a [CRSC Resource Request Form](https://base.uams.edu/redcap/surveys/?hash=e4da3b7fbbce2345d7772b0674a318d5) at [UAMS UCORE](https://ucore.uams.edu/).

1. Does this study require registration with ClinicalTrials.gov?

All studies that may be published in any of the International Committee for Medical Journal Editors (ICMJE) publications are required to be registered in a publically accessible database, like ClinicalTrials.gov.

All studies that are conducted under an IND or IDE must be registered in ClinicalTrials.gov to comply with federal law.

For information regarding registration, please contact the Research Support Center at 501-686-6803 or [tlgatlin@uams.edu](mailto:tlgatlin@uams.edu).

For information regarding registration of ACH/ACHRI studies not using a drug or device, please contact the ACHRI Clinical Trials Administrator at 501-364-2760 or [StormentJanetS@uams.edu](mailto:StormentJanetS@uams.edu).

**If Yes,**

* 1. Please enter the NCT number.

If your study involves a drug or device, regardless of IND/IDE status, or if your study includes a budget or financial aspect where potential charges could be added to a subjects account and billed to Medicare, you must register your study with the ClinicalTrials.gov database under the law. It is not necessary to have your IRB approval in order to register a study. Once your study is registered, it will undergo a QA review and the database will assign an NCT number. If you do not have this number when your study is entered into CLARA, leave that field blank as the number can be entered at a later date.  
**If you are new to using the ClinicalTrials.gov database and need a new user account, have questions about registering or are not sure if your study should be registered, please contact the UAMS ClinicalTrials.gov Administrator, Tracy Gatlin, 686-6803 or tlgatlin@uams.edu**

1. [UAMS ONLY] Will this study be registered at TrialSearch?

TrialSearch is the UAMS clinical trial registry. See the TrailSearch's [End User Manual](http://sharepoint.uams.edu/sites/caBIG/caBIG%20Tools%20Wiki%20Library/TrialSearch.aspx) for more information.

**If yes,**

* 1. [Biomedical Study Type ONLY] List the inclusion/exclusion criteria for this study.

Inclusion/exclusion criteria: The characteristics determining whether a person may or may not be allowed to enter a clinical trial. Examples include age, state of health, the type and stage of a disease, previous treatment history, and other medical conditions.

1. [UAMS ONLY] Is this study cancer research or cancer-related research? ]YES/NO]

Research related to the etiology, prevention, treatment, survival or complications of cancer.

**If yes,**

* 1. Disease and Condition Ontology
  2. What is the primary activity of this study?
     1. Observation only
     2. Intervention
     3. Other

Observation: Watching behavior and/or measuring outcomes.

Intervention: Manipulations of the subject’s environment that are performed for research purposes.

**IF OBSERVATION ONLY STUDY,**

* + 1. What is the goal for this study?
       1. To determine incidence/prevalence of disease (epidemiologic trial)
       2. To determine risk factors for disease/outcomes (epidemiologic trial)
       3. To study natural history of disease (epidemiologic trial)
       4. To study behavior (observational trial)
       5. Other

**IF INTERVENTION STUDY,**

* + 1. What is the intervention purpose in this study?
       1. To treat disease (therapeutic trial)
       2. To prevent disease (prevention trial)
       3. To ameliorate disease effects (supportive care trial)
       4. To detect disease in preclinical course (screening trial)
       5. To detect disease with improved accuracy (diagnostic trial)
       6. Other
  1. Has this study gone through a Disease-Oriented Committee (DOC)?

Disease Oriented Committees (DOCs): Disease Oriented Committees (DOCs) serve to optimize resources and support collaborative research ideas focused on distinct cancer-related disease sites. Research projects that are chart reviews, request the use of specimens from the UAMS Biorepository or propose banking specimens are required to obtain approval from the appropriate DOC before study activation. For a list of DOCs and contact information, go to [http://www.cancer.uams.edu/docs.](http://www.cancer.uams.edu/docs)

1. Does the study involve the use of any of the following bio-hazardous materials?
   1. BL2/BL3 infectious agents
   2. Recombinant DNA (rDNA)
   3. Human gene therapy procedures
   4. Experimentation using carcinogenic (known or suspected) compounds
   5. Regulated Toxins (e.g. Botulinum Toxin)

**If Regulated Toxins is checked,**

* + 1. Regulated Toxin List Panel
  1. N/A
  2. Other

Please fill out the appropriate form(s) and submit to the Biosafety Committee for review.

BL2/BL3 infectious agents - [Infectious Agents Form](http://intranet.uams.edu/safety/policy/Infectious_agents_form.pdf)

Recombinant DNA (rDNA) - [Recombinant DNA Form](http://intranet.uams.edu/safety/policy/Recombinant_DNA_form.pdf)

Human gene therapy procedures - [Recombinant DNA Form](http://intranet.uams.edu/safety/policy/Recombinant_DNA_form.pdf)

Experimentation using carcinogenic (known or suspected) compounds - [Toxic and Carcinogenic Agents Form](http://intranet.uams.edu/safety/policy/Toxin_carcinogen_form.pdf)

Regulated Toxins - [Toxic and Carcinogenic Agents Form](http://intranet.uams.edu/safety/policy/Toxin_carcinogen_form.pdf)

1. Does the study involve the use of radiation?

**If Yes,**

* 1. Does the radiation used in the research exceed what is considered “Standard of Care”?

1. Does the study involve the use of strenuous exercise?

**If Yes,**

* 1. Describe the nature of the study exercise. Include where the study exercise will take place, the resources available to ensure participant safety during the study exercise, and the qualifications of the personnel who will be present during the study exercise.

Drugs & Devices:

FOR HUDs, DISABLE DRUG TAB

Drug:

1. Drug name
2. Details:
   1. Does this drug have any of the following:
      1. Package Insert
      2. Investigators Brochure
      3. Neither
   2. What is the drug’s current status?
      1. Investigational New Drug
      2. FDA-Approved Drug for Approved Use
      3. FDA-Approved Drug for Non-Approved Use
   3. How will this drug be administered?
      1. IV
      2. IM
      3. IP
      4. PO
      5. SC
      6. PR
      7. Inhalation
      8. Patch / Topical
      9. IT
      10. Other
   4. Location of Treatment Center (e.g., Chemo infusion center, CRC, etc.)
   5. Is the drug provided for this study?
   6. What is the provider’s name?
   7. What is the dosage form that will be provided?
   8. What’s the IND Number?

Device:

1. Device Manufacturer
2. Details:
   1. What is the device name?
   2. What is the model number of the device?
   3. What is the IDE number?
   4. What type of device is this?
      1. Investigational New Device
      2. FDA-Approved Device for Approved Use
      3. FDA-Approved Device for Non-approved Use
      4. Humanitarian Use Device (HUD)
   5. Is there a device manual? [YES/NO]
3. Risks:
   1. Is this device intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject?
   2. Is this device purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject?
   3. I s for a use of substantial importance of human health and presents a potential for serious risk to the health, safety, or welfare of a subject?
   4. Or, otherwise presents a potential for serious risk to the health, safety, or welfare of a subject?

Funding Sources

Funding Sources Panel

Budget and Coverage

1. IRB Fees

The fees above are determined by the answers provided about this study (study type, etc.)

**If there are no fees listed,** that doesn't mean there will not be a fee. It means Clara cannot determine the fee because some questions have not been answered (like study type).

If you have any questions regarding IRB fees, please contact the IRB Office at [irb@uams.edu](mailto:irb@uams.edu).

1. Does your research involve any of the following:
   * 1. **Procedures that could potentially be billed to a UAMS patient or a third party payer?**
     2. **UAMS Clinics**?
     3. UAMS Inpatient Units?
     4. UAMS Short Stay or Infusion Center?
     5. UAMS Clinical Laboratory Services?
     6. UAMS Radiology Procedures and Services?
     7. Other UAMS Clinical, Diagnostic, or Therapeutic Services (ECG, Pulmonary Functions, ECHO, etc.)?
     8. Any supplies from UAMS Central Supply?
     9. Professional fess billed through the Faculty Group Practice?
     10. Fund, drugs, devices, or other support from industry?

If you have any questions, please contact (501)526-6808 or send your request to [CLARABudgetHelp@uams.edu](mailto:CLARABudgetHelp@uams.edu)

**Does your protocol involve supplies from UAMS Central Supply?**

Answer “YES” if you are obtaining any supplies that are dispensed to an individual patient and could/will be billed to an individual patient (example: hemodialysis catheter to be surgically implanted in a specific patient).

Answer “NO” if you are obtaining bulk supplies that are purchased for the study but are not linked to an individual patient and will not be billed to an individual patient (example: a box of exam gloves that will be used to handle blood specimens in a lab). – Helptext added by RSC

1. [HUD ONLY] Does the device manufacturer plan to charge UAMS for the device?

If No, “No budget needed” screen

1. Does the principal purpose of the trial test whether the intervention potentially improves the participants' health outcomes?

**If No,** please explain

1. Is the trial well-supported by available scientific and medical information or intended to clarify or establish the health outcomes of interventions already in common clinical use?
2. Does the trial unjustifiably duplicate existing studies?

**If Yes,** please explain

1. Is the trial design appropriate to answer the research question?
2. Is the trial sponsored by a credible organization or individual capable of executing the proposed trial successfully?
3. Is the trial in compliance with Federal regulations relating to the protection of human subjects?
4. Are all aspects of the trial conducted according to the appropriate standards of scientific integrity?

Budget Builder Panel

Contract:

1. Do you have a new contract provided by a university, private company, a non-profit, foundation or other entity outside of UAMS?

A contract is required if **one** of the following conditions exists:

* You are receiving funding from an individual or an entity outside of UAMS
* You are receiving a drug from an individual or an entity outside of UAMS
* You are receiving a device from an individual or an entity outside of UAMS
* You are providing research data to an individual or an entity outside of UAMS
* You are providing funding to an individual or an entity outside of UAMS
* You are providing or receiving any biological materials, animals or other materials to or from an individual or an entity outside of UAMS
* You are in a collaborative research arrangement with an individual or an entity outside of UAMS
* You are providing a Limited Data Set of Protected Health Information to or from an entity outside of UAMS
* You are using an individual or an entity outside of UAMS as a subcontractor
* You are subcontractor doing work for an individual or entity outside of UAMS

If you have any questions, please contact (501)526-6808 or send your request to [ResearchContracts@uams.edu](mailto:ResearchContracts@uams.edu).

1. Will you be transferring any data, technology, biological materials, animals, drugs or devices to a foreign entity?

**If Yes,**

* 1. Please provide full contact information for the entity, including name, address, phone number and email.

Epic

1. UConnect (Epic) title

This information appears in the chart of any patient who is linked to the study and can be as informative as is appropriate for the study. The study title will auto-populate in this field; however, studies with sensitive information may only wish to enter IRB# or a study identifier in this field.

**200 character limit**

1. UConnect (Epic) description

This information appears in the chart of any patient who is linked to the study and can be as informative as is appropriate for the study.

This field is often used to list contact information in case a physician has concerns about patient care that might be related to the patient's participation in a study.

EMR study contact information will auto-populate in UConnect (Epic) description field. This contact information will display in the eMR system for studies requiring a CLARA budget.

1. Does your study involve cancer drug treatment?

APPENDIX A (Pregnant Women, Fetuses)

**Pregnant Women and Fetuses**

1. Describe preclinical studies (including studies on pregnant animals) and clinical studies (including studies on non-pregnant women), that provide data for assessing potential risks to pregnant women and fetuses.

You may reference specific pages or sections of the protocol or supporting documents (e.g., package inserts, investigator brochure, etc. Please remember to upload these documents.)

2. Indicate for whom the prospect of **direct benefit** exists:

a. Pregnant woman

b. Fetus

c. Both

d. Neither

The father’s consent must be obtained for research that holds the prospect of direct benefit solely to the fetus, unless he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.

3. The risk to the fetus is (check one):

a. Not greater than minimal risk – prospect of direct benefit for the woman and/or fetus

b. Not greater than minimal risk – without prospect of direct benefit, but the purpose of the research is development of important knowledge that cannot be obtained by any other means

c. Greater than minimal risk – caused solely by procedures that hold the prospect of direct benefit for the woman and/or fetus

4. Explain how the risks are the least possible for achieving the objectives of the research.

APPENDIX B (**Neonates - Only neonates of uncertain viability and nonviable neonates**)

**Neonates - Only neonates of uncertain viability and nonviable neonates**

1. State who (other than investigators and key personnel) will determine the viability of a neonate, and describe what procedures will be used to determine viability.

2. Describe preclinical studies and clinical studies, where scientifically appropriate, that provide data for assessing potential risks to neonates.

3. The viability of neonates to be involved in the research is:

a. Uncertain Viability

b. Nonviable

c. Both

[Only If 3 == a or c]

4. For neonates of uncertain viability, the risk to the neonate is (check one):

a. The least possible risk to achieve the research objective and the research holds the prospect of enhancing the probability of survival to the point of viability

b. No added risk will result from the research and the purpose of the research is development of important knowledge that cannot be obtained by other means

The consent of either parent or either parent’s legally authorized representative (if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity) is required, except that the consent of the father (or his legally authorized representative) need not be obtained if the pregnancy resulted from rape or incest.

Explain how the research meets the condition selected above.

[Only If 3 == b or c]

For nonviable neonates, explain how EACH of the following 4 conditions for inclusion is met:

1. Vital functions of the neonate will not be artificially maintained;
2. The research will not terminate the heartbeat or respiration of the neonate.
3. There will be no added risk to the neonate resulting from the research; and
4. The purpose of the research is the development of important knowledge that connot be obtained by other means.

The consent of both parents is required. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice. If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the consent of one parent will suffice, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

APPENDIX – C (Children)

**Children**

1. Select the category that best describes the research and provide the corresponding information:

a. Not greater than minimal risk

b. More than minimal risk is presented by an intervention or procedure that holds the prospect of direct benefit for the individual child, or by a monitoring procedure that is likely to contribute to the child's well-being

**If b,**

1. Explain how the risk is justified by the anticipated benefit to the individual child.

2. Explain how the relation of the anticipated benefit to the risk is at least as favorable to the child as that which would be presented by available alternative approaches (e.g., other treatments).

c. More than minimal risk is presented by an intervention or procedure that *does not* hold the prospect of direct benefit for the individual child, or by a monitoring procedure that is not likely to contribute to the child’s well-being.

**If c,**

1. Explain how the risk represents a minor increase over minimal risk.

2. Describe how the study interventions or procedures are reasonably equivalent to actual or expected medical, dental, psychological, social or educational situations for the children.

3. Explain how the intervention or procedure is likely to yield generalizable knowledge about the child's disorder or condition that is of vital importance for the understanding or amelioration of the child's disorder or condition.

2. Will the parents or guardians be present with the child during discussions of the research?

3. Will sensitive or private information (e.g., questionnaires, test results) be shared with the parents/guardians?

**If Yes**, Please explain

4. Is there a possibility that any of the research participants will be wards of the State or any other agency or institution?

APPENDIX – D (Prisoners)

**Prisoners**

1. Indicate the category(ies) that best describes the involvement of prisoners in the research:

a. This research will examine the possible causes, effects, or processes of incarceration and/or criminal behavior, provided the study presents no more than minimal risk or inconvenience to the participants.

b. This research will examine prisons as institutional structures or prisoners as incarcerated persons, provided the study presents no more than minimal risk or inconvenience to the participants.

c. This research will examine a condition(s) particularly affecting prisoners as a class of people (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).

d. This research will examine practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant.

e. This research is an epidemiologic study (1) to describe the prevalence or incidence of a disease by identifying all cases, or (2) to examine potential risk factor associations for a disease, provided the study presents no more than minimal risk or inconvenience to the participants and prisoners are not a particular focus of the research.

2. Provide the name, type of facility and location of each local, state, or federal facility to be used.

3. Describe the possible advantages to participating prisoners (i.e., compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison).

4. Describe any additional steps that will be taken to avoid undue influence (i.e., considering the limited choice environment of the prison).

5. Explain how the risks involved in the research are similar to risks that would be accepted by non-prisoner volunteers.

6. Explain how prisoners will be selected for the study and/or assigned to treatment groups.

The selection of participants within the prison and procedures for assignment to various groups within the research (e.g., experimental vs. control groups) should be designed to be fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

### 7. Describe safeguards in place to provide assurances that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole.

Prisoners must be clearly informed in advance that participation in the research will have no effect on their parole.

### 8. Describe follow-up examinations or care of participants to be provided after their participation has ended (including frequency and duration they will be available), as applicable, taking into account the varying lengths of individual prisoners’ sentences.

APPENDIX – E (Non-English Speaking)

1. Which language(s) other than English will be spoken by study participants?

1. Spanish
2. Arabic
3. German
4. Chinese
5. Russian
6. French
7. Hindi
8. Japanese
9. Others [LIST-OTHER]

2. List any investigator(s) and/or key personnel who are fluent in the language(s) of the participants.

3. Describe the provisions in place to provide interpretive services during the participant recruitment and consent processes.

When a potential research subject expresses interest in participating in a study and is unable to speak or read English, they must be presented with a translated informed consent document unless the IRB has approved the use of a short form.

The informed consent process is the same as for English speaking subjects; however, a qualified interpreter must be present to facilitate the consent conversation between the investigator and the potential subject prior to enrollment.

4. Describe the provisions in place to provide interpretive services throughout the participants’ duration in the study.

5. Describe the provisions in place to handle emergency contacts (i.e., questions, problems) from non-English speaking participants.

APPENDIX – F (Cognitively Impaired)

1. Describe the expected range of participant impairment. Explain how, and by whom, the capacity to consent/assent will be determined.

2. Indicate whether assent will be obtained and if so, describe the process. If assent will not be obtained, explain.

3. If capacity is expected to fluctuate during research participation, describe the process for ensuring ongoing consent.

4. Select the one category that best describes the research:

a. Minimal risk

b. Greater than minimal risk *with* the prospect of direct benefit for the individual **If b,**

Explain how anticipated benefits, compared to risks, are as favorable as the alternatives (e.g., other treatments).

c. Greater than minimal risk *without* the prospect of direct benefit for the individual

**If c,**

Explain how the risk presents only a minor increase over minimal risk.

APPENDIX – G (Research in International Settings)

1. Describe the international sites(s). Provide location, name of local contact or investigator, and local contact information, as applicable.

2. Is there an Ethics Board or IRB at the international site(s)?

**If yes**, List contact information for the Board

4. Describe any cultural, political, religious, or other local influences that may affect conduct of the proposed research and how these will be addressed (e.g. issues posing potential threats, requiring changes in recruitment methods, etc.)

5. Describe any local exceptions to the required consent/assent/permission process and how these will be addressed (e.g., a request from outsiders to sign documents would be treated with suspicion based on customs, previous history, etc.)

6. Explain any benefits to the local community that will remain with the community once the research is complete.

7. Describe the researchers’ experience with conducting research (or studying or residing) in the research setting, including any relationship(s) with the community from which participants will be recruited.

8. Provide the name, title, and contact information (including email addresses) for two individuals who are not affiliated with the research, who are knowledgeable about the location and population who could serve as consultants regarding the proposed research.

It is not required that these individuals reside or work in the research location.

9. Describe communication and oversight plans between the researcher(s) who will be on-site and those at UAMS.

10. Describe procedures for the transfer of data between the local setting and UAMS.

11. Indicate if any planned research procedures are considered to be standard of care in the country or location.

APPENDIX M1 (Waiver or Alteration of Consent Process)

1. Is the research subject to FDA regulations (i.e., involves use of a food, drug, biologic, device)?

**If Yes,**

skip rest of appendix and jump to Consent Question 2.

**If No,**

go on to Appendix M1 Question 2.

DHHS regulations permit waivers (or alterations) of the consent process if the research meets certain conditions; however, FDA has no provision for waiver or alteration of consent. If the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application, consent cannot be waived.

2. Is the research subject to the approval of state or local government officials and designed to study public benefit or service programs or procedures for obtaining benefits under those programs, changes in or alternatives to those programs or procedures, or changes in methods or levels of payment for benefits or services under those programs?

**If Yes,**

Explain why the research could not practicably be carried out without the waiver or alteration. Skip rest of appendix and rest of Consent section and Jump to Risks Question 1.

**If No,**

complete appendix and then go on to Risks Question 1. Skip rest of Consent section.

\*If the answer to both of the questions above (1 and 2) is No, complete the following to request waiver or alternation.

3. Explain how the research involves no more than minimal risk.

4. Explain why the waiver or alteration will not adversely affect the rights and welfare of the participants.

5. Explain why the research could not practicably be carried out without the waiver or alteration.

6. Will the participants be provided with additional pertinent information after participation?

Explain why or why not

APPENDIX M2 (Waiver of Consent Documentation)

1. Is the research subject to FDA regulations (e.g., involves use of a food, drug, biologic, device)?

**If Yes,** answer 2 only

**If No,** answer either 2 or 3 [HIDE 3 IF YES]

Documentation of consent cannot be waived if the research involves a product regulated by FDA or the results of the research may be submitted to FDA as part of a marketing application.

2. Both answers below (2a and 2b) must be NO for a waiver of consent documentation:

a. Does the research present greater than minimal risk?

b. Does the research involve procedures for which written consent is normally required outside the research context?

Both answers above must be NO for a waiver of consent documentation.

**If Both No,**

Explain how the research is no more than minimal risk, and how the research does not involve procedures for which written consent is normally required outside the research context.

3. Both answers below (3a and 3b) must be YES for a waiver of consent documentation:

a. Would the only record linking the participant and the research be the consent document?

b. Would the principal risk to the participant be potential harm resulting from a breach in confidentiality?

The participant should be asked whether he/she wants documentation linking the participant with the research; the participant's wishes will govern.

Both answers above must be YES for a waiver of consent documentation.

**If Both Yes,**

Explain how the only record linking the participant and the research would be the consent document, and how the principle risk to the participant would be potential harm resulting from a breach in confidentiality.”

APPENDIX I (Storage of Biological Materials for future research use)

1. Describe the purpose of collecting and storing the specimens for future use.

2. Will there be limits on the specimen’s intended future use (e.g., for cancer research only)?

Please explain why or why not?

3. Specify the procedures by which participants can withdraw their specimens from storage for future research.