|  |  |
| --- | --- |
| **STUDY TITLE** |  |

**PRINCIPAL INVESTIGATOR**

|  |  |  |
| --- | --- | --- |
| **1.** | Name: | Degree(s): |
| Title: | Phone: |
| BU Home Department: | |
| Address: | Email: |

**BU Position or Appointment (choose the most appropriate one):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **2.** | |  | | Tenured/Tenure-track Faculty | |  | Visiting Faculty | |
|  | | Research Faculty | |  | Adjunct Faculty | |
|  | | Clinical Faculty | |  | Lecturer Faculty | |
|  | | Joint Appointment. Home Institution: | |  | Postdoctoral | |
|  | |  | |  | Other: | |
| **If student:** | | | |  |  | |
|  | | Undergraduate student | Faculty Advisor:  Department Chair: | | | |
|  | | Graduate or Professional Student  (degree program): |
|  | | | | | | |
| **3.** | **a.** | | Has the PI ever been debarred, restricted, or disqualified by any federal agency (FDA, ORI, PHS, etc.)? | | | | | Yes  No |
| **b.** | | Does the PI have any current proceedings for debarment, restriction, or disqualification? | | | | | Yes No |
| **c.** | | Is the PI excluded from receiving federal contracts, certain subcontracts, and from certain types of federal financial and nonfinancial assistance and benefits [i.e., listed on the Excluded Parties List System (EPLS)]? | | | | | Yes  No |
| **d.** | | Has the PI been audited or investigated by the Office of Human Research Protections (OHRP) or the Food & Drug Administration (FDA) within the last 5 years? | | | | | Yes  No |

**ADDITIONAL CONTACT PERSON (if applicable)**

|  |  |  |
| --- | --- | --- |
| **4.** | Name: | Phone: |
| Title: | Email: |
| BU Home Department: |  |

**RESEARCH PERSONNEL**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **INSTRUCTIONS:** All “key personnel” must be identified and listed. Key personnel are defined as individuals who participate in the design, conduct, or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, or who collect study data. If the individual for an anticipated position is unknown at this time, a “Change in IRB-Approved Research” must be submitted and approved prior to that individual becoming involved in the research. | | | | |
| **NOTE:** Individuals conducting certain research procedures may be required to have special training or certifications. Types of procedures include: psychiatric/psychological assessments, blood draws, body scans, etc. The research record should contain a delegation of duties log and include documentation of appropriate training, experience, and/or certification. The IRB may request this information. | | | | |
| **5.** | **BU Personnel** | | | |
| Name:  Role/Duties: | | Department/School:  Degree(s): | |
| Name:  Role/Duties: | | Department/School:  Degree(s): | |
| Name:  Role/Duties: | | Department/School:  Degree(s): | |
| **Non-BU Personnel** | | | |
| Name:  Role/Duties: | | Department/School:  Degree(s): | |
| Name:  Role/Duties: | | Department/School:  Degree(s): | |
| Name:  Role/Duties: | | Department/School:  Degree(s): | |
|  | | | |
| **6.** | **a.** | Have any research personnel ever been debarred, restricted, or disqualified by any federal agency (FDA, ORI, PHS, etc.)? | | Yes  No |
| **b.** | Do any research personnel have any current proceedings for debarment, restriction, or disqualification? | | Yes  No |
| **c.** | Are any research personnel excluded from receiving federal contracts, certain subcontracts, and from certain types of federal financial and nonfinancial assistance and benefits [i.e., listed on the Excluded Parties List system (EPLS)]? | | Yes  No |

**STUDY LOCATION**

|  |  |  |
| --- | --- | --- |
| **7.** | Will the research take place at locations/sites in the U.S. other than Baylor? | Yes  No |
| **If yes, complete below:** | |
| You must provide the name of the site(s), city/state, and IRB approval, or waiver, or letter of cooperation: | |
| **8**. | Will any part of this research be conducted outside of the United States? | Yes  No |
| **If yes,** complete **SUPPLEMENT: INTERNATIONAL RESEARCH (F-03)** | |

**FUNDING**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **9.** | List each proposed or funded grant or contract relevant to this application. A complete copy of the grant or contract must be submitted with the application.  For Department of Defense research, submit **SUPPLEMENT: DEPARTMENT OF DEFENSE (F-06)** | | | | | | | | | | |
|  | No external or internal funding. | | | | | | | | | |
|  | Internal funding. List source(s): | | | | | | | | | |
|  | External funding. (complete information below for each grant or contract) | | | | | | | | | |
| **Type of proposal** | | | | | | | | | | |
|  | Grant |  | | | Subcontract | |  | | Training/Development Grant | |
|  | Contract |  | | | Other, specify: | | | | | |
| Name of Principal Investigator: | | | | | | | | | | |
| Title of Proposal (if different): | | | | | | | | | | |
| Name of Funding Agency      : | | | | | | | | Agency Number (if assigned): | | |
| Submitted through BU Office of Sponsored Programs? Yes  No, Explain: | | | | | | | | | | |
| **Type of proposal** | | | | | | | | | | |
|  | Grant |  | | Subcontract | | |  | | | Training/Development Grant |
|  | Contract |  | | Other, specify: | | | | | | |
| Name of Principal Investigator: | | | | | | | | | | |
| Title of Proposal(if different): | | | | | | | | | | |
| Name of Funding Agency: | | | | | | | | Agency Number (if assigned): | | |
| Submitted through BU Office of Sponsored Programs? Yes  No, Explain: | | | | | | | | | | |
| **Type of proposal** | | | | | | | | | | |
|  | Grant | |  | Subcontract | |  | | | Training/Development Grant | |
|  | Contract | |  | Other, specify: | | | | | | |
| Name of Principal Investigator: | | | | | | | | | | |
| Title of Proposal (if different): | | | | | | | | | | |
| Name of Funding Agency: | | | | | | | | Agency Number (if assigned): | | |
| Submitted through BU Office of Sponsored Programs? Yes  No, Explain: | | | | | | | | | | |

**TYPE OF SUBMISSION**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **10.** | Select the item below that best describes the risk\* level for this research:  Greater than minimal risk. \*\* Full Board review required. Skip to question #12.  Minimal risk but the research includes radiation. Full Board review required. Skip to question #12.  Minimal or no known risks. May be eligible for expedited review – answer question #11 below.  \***Risk** means the potential for harm or discomfort. Risks can be physical, psychology, social, or economic.  \*\* **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. [FDA 21 CFR 56.102(i); HHS 45 CFR 46.102 (i)] | | | | |
| **11.** | If “minimal or no known risks” was selected, indicate the applicable description(s) of the research (check all that apply): | | | | |
|  | | Data or Specimens:   * Research using records/materials that have been collected or will be collected for non-research purposes. * Prospective collection of specimens or data for research purposes through non-invasive means. * Blood samples from healthy, non-pregnant 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.   * Blood samples from other adults and children. The amount does not exceed the lesser of 50 ml or 3ml/kg in an 8 week period and collection does not occur more than 2 times per week. | | |
|  | | Behavior/Individual Characteristics:   * Collection of data from recordings made for research purposes. * Research on individual or group characteristics or behavior using methods such as, but not limited to surveys, interviews, focus groups, and program evaluation. | | |
|  | | None of the above. Explain: | | |
| **NOTE: The IRB will make the final determination on the type of review.** | | | | | |
| **12.** | Does the research involve any of the following? (Check all that apply.) | | | | |
|  | Collection of biological specimens  (blood, tissue, saliva, urine, hair, tears, etc.) | |  | Recombinant or synthetic DNA (e.g., gene transfer) |
|  | Investigational/approved drugs or biologics  (submit **SUPPLEMENT: Drugs, Biologics, Supplements and Botanicals** (F-04)) | |  | Controlled substances |
|  | Investigational/approved devices  (submit **SUPPLEMENT: Devices** (F-05)) | |  | Radiation exposure |
|  | Dietary supplements  (submit **SUPPLEMENT: Drugs, Biologics, Supplements and Botanicals** (F-04)) | |  | Magnetic Resonance Imaging (MRI) |
|  | Food (medical or non-medical) | |  | Genetic Testing |
|  | Color or food additives | |  | Deception or Sham procedures |
|  | Bio-hazardous substances | |  |  |

**RECRUITMENT**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **13.** | Identify the age group to include all subjects: | | | | | | | | | |
| Proposed number of research subjects: | | | | | | | | | |
| **14.** | Will the subjects from the following “vulnerable” categories be targeted for recruitments? (Check all that apply.) For populations marked with an asterisk (\*), **SUPPLEMENT: VULNERABLE POPULATIONS** (F-02) must be submitted. | | | | | | | | | |
|  | | | Minors (as defined by the location where the research will occur) \* | | |  | Adults who are unable to consent for themselves \* | | |
|  | | | Pregnant women, fetuses, or neonates | | |  | Baylor students \* | | |
|  | | | Prisoners | | |  | Non-Baylor students recruited in an educational setting (in class or at school) \* | | |
|  | | | Non-readers (physical impairment, illiteracy, or reading disorder) | | |  | Nursing home residents | | |
|  | | | Non-English speaking \* | | |  | Baylor employees or Faculty \* | | |
|  | | | Terminally Ill | | |  | Current military personnel to be recruited by other military personnel | | |
|  | | | Economically Disadvantaged | | |  | Other vulnerable subjects susceptible to undue influence/coercion. Describe: | | |
|  | | | Institutionalized (inpatient or outpatient) | | |  |
|  | | | Veterans | | |
| **15.** | | Does this research target one gender or specific social/ethnic group? | | | | | | | Yes  No |
| **If yes,** explain: | | | | | | | |
| **16.** | | How will you recruit subjects? (all recruitment materials must be submitted for IRB approval) | | | | | | | |
|  | Flyer | |  | Website | | | |
|  | Facebook, Twitter, or other social media | |  | Letter | | | |
|  | Brochure | |  | From a database of individuals who have given prior permission to be contacted for research | | | |
|  | Newspaper ad | |  | Personal Contact | | | |
|  | Web Banner | |  | Referrals, from whom? | | | |
|  | Radio or TV ad\* | |  | E-mail | | | |
|  | Testimonials | |  | Other: | | | |
| \*Scripts must be submitted with the recording. To avoid unnecessary production costs, pre-approval of scripts is highly recommended.  **Note**: If eligibility screening over the phone will take place, a script must be submitted. | | | | | | | |

**CONSENT**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **17.** | Will any written or verbal screening materials to pre-screen individuals prior to consent/enrollment be used? (e.g., telephone script, written or web-based screening forms or questionnaires.) | | | | | | | | | Yes No |
| **If yes,** complete below: | | | | | | | | | |
| Indicate type of material and describe the screening plan: | | | | | | | | | |
| **18**. | Will identifiable information be kept on individuals that failed screening? | | | | | | | | | Yes  No |
| **19.** | Check all that apply to your research: | | | | | | | | | |
|  | | Written consent from adult subjects | | | | |  | Request a waiver of documentation of consent (Submit Form) | |
|  | | Written parental permission from parents/guardians of minor subjects | | | | |  | Request a waiver of consent (Submit Form) | |
|  | | Written assent from minor subjects | | | | |  | | |
| **20.** | Please describe the circumstances and location of the consent process: (check all that apply) | | | | | | | | | |
|  | | N/A – requesting a waiver of consent |  | | Internet/Online | | | | |
|  | | In a private room |  | | In public | | | | |
|  | | In a waiting room |  | | Over the phone | | | | |
|  | | In a group setting |  | | Through the mail | | | | |
|  | | In a group setting with follow-up in a private room |  | | Other: | | | | |
| **21a.** | Who will conduct the consent discussion with the subject? | | | | | | | | | |
|  | Principal Investigator | | |  | | Co-/sub-investigator | | | |
|  | Research Coordinator | | |  | | Other (specify): | | | |
| **21b.** | How will it be ensured that the subject has sufficient opportunity to consider whether to consent? | | | | | | | | | |
| **21c.** | How will possible undue influence or coercion be minimized? | | | | | | | | | |

**COMPENSATION**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **22a.** | Will subjects be paid?  **If no,** skip the rest of this section. | | | | Yes  No | |
| **If yes, complete below:** | | | | | |
| **22b.** | Indicate total possible amount (including any completion bonuses): | | | | | |
| **22c.** | **Payment Plan:** Indicate when subjects will be paid (e.g., at the end of each visit, at the end of the last visit, etc.), and the amount each time. | | | | | |
|  | **\*Note:** For studies with multiple visits, payments should be prorated to compensate subjects for time and visits/procedures completed. Holding payment until the end of the study or requiring a subject to complete the entire study is potentially coercive or unduly influencing. | | | | | |
| **23.** | How will subjects be paid? | | | | | |
|  | Cash |  | Debit Card | | |
|  | Check |  | Direct Deposit | | |
|  | Gift Card |  | Other: (explain) | | |
| **24.** | Will the subjects be offered any tangible gifts or services without charge? | | | | | Yes  No |
| **If yes,** explain and provide estimated value of any gifts or services: | | | | | |
| **25.** | Will the subjects be offered course credit or extra credit? | | | | | Yes  No |
| **If yes**, identify the course and/or subject pool and describe the available alternatives to participation: | | | | | |
| **26.** | Will subjects be reimbursed for any expenses? | | | | | Yes  No |
| **If yes,** list eligible expenses: | | | | | |
|  | **\*Note**: Expenses should only be reimbursed with appropriate documentation (e.g., receipt). A flat amount to help cover expenses is considered a payment, not a reimbursement. | | | | | |
| **27.** | Are there any potential costs to subjects (or his/her third-party payer) as a result of  participating in the research? | | | | | Yes  No |
| **If yes,** describe the costs: | | | | | |

**RISKS OR DISCOMFORTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **All reasonably foreseeable risks or discomforts must be described in the protocol (or other protocol materials, e.g. Investigator’s brochure) and the Consent Form.** | | | | | |
| **28.** | Describe the reasonably foreseeable risks to subjects. Consider all physical, psychological, social, legal, economic, and other risks that would be related to participation in the research: | | | | |
| **29.** | Describe the plan to minimize risks to subjects. Include the availability of any medical or psychological resources: | | | | |
| **30.** | Is it reasonably possible that a previously unknown condition (an incidental finding) could be discovered about the subject? (e.g., disease, mental health, thoughts of harm to self or others, genetic predisposition, etc.) | | | | Yes  No |
| **If yes,** explain how the situation will be handled**:** | | | | |
| **31.** | Who will handle an adverse event? Investigator Referral  Other. Identify: | | | | |
| **32.** | Who will be financially responsible for treatment of any medical problems or physical side effects that appear to be caused by participation in the research, including any effects of a blood draw (such as a local infection)? | | | | |
|  | N/A – there are no physical risks |  | Subject or the Subject’s insurer | |
|  | Study Sponsor (For private sponsors, there must be a contract or other written agreement that stipulates the sponsor will pay. For federally-funded research, there may be a national or agency compensation program.) |  | Other. Explain: | |

**BENEFITS**

|  |  |  |
| --- | --- | --- |
| **33.** | Indicate the reasonably foreseeable benefits to the subject or others:  **\*Note: compensation/reimbursement is not a benefit** | |
|  | Prospect of direct benefit to subject. Explain: |
|  | No prospect of direct benefit but likely to yield generalizable knowledge. |
|  | Other: |

**SAFETY and DATA MONITORING**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **34.** | Who will review this study for safety, data integrity, and adherence to the protocol? | | | |
|  | Principal Investigator |  | Data Monitoring Committee |
|  | Independent Monitor |  | Data Safety Monitoring Board |
|  | Other: | | |
| Provide a general description of the data and safety monitoring plan: | | | |

**PRIVACY/CONFIDENTIALITY**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **35.** | Check the identifiers that will be collected at any point in the research, even if they will be destroyed at a later time. | | | | | |
|  | Names | |  | Telephone or fax numbers | |
|  | Any geographical subdivision smaller than a state, including street address, city, county, precinct, and zip code | |  | Any element of a date (except the year) that is directly related to the individual (e.g., birth date, diagnosis date, admission date, etc.) | |
|  | E-mail addresses | |  | Social security numbers | |
|  | Medical record numbers | |  | Health plan beneficiary numbers | |
|  | Account numbers | |  | Certificate/license numbers | |
|  | Vehicle identifiers and serial numbers, including license plates | |  | Biometric identifiers, including fingerprints and voiceprints | |
|  | URLs (web universal resource locators) | |  | Any other unique identifying number, characteristic, or code | |
|  | Full face photographic images and any comparable images | |  | No identifiers collected | |
| How long will the identifiers be kept? | | | | | |
| **36.** | Will a coding system\* be used? | | | | | Yes  No |
| **If yes**, will there be a key to the code? | | | | | Yes  No |
| **If yes**, who will have access to the key? | | | | | |
| How long will the key be kept? | | | | | |
| \*For privacy purposes, **coding system means** a random unique ID is assigned to each subject’s data and a separate document (key) is maintained that links the subject to the ID number. | | | | | |
| **37.** | Where will the data be collected /stored? (check all that apply) | | | | | |
|  | On paper | |  | Mobile device (e.g., flash-drive, external hard drive, tablet, etc.) | |
|  | Computer: Stand-alone  Networked | |  | Cloud. Specify service/vendor: | |
| **38.** | How will confidentiality of the data be maintained? (check all that apply.) | | | | | |
|  | Locked cabinet |  | Password protected files | | |
|  | Encryption |  | Other. Explain: | | |
| **39.** | Will data be shared with others outside of the study? | | | | | Yes  No |
| **If yes,** identify with whom it will be shared: | | | | | |
| Describe how the data will be transferred and how confidentiality will be maintained (e.g., no identifiers will be sent outside, only aggregated data, etc.) | | | | | |
| **40.** | Is it possible or planned that any data collected for research will be used for other research in the future (including secondary data analysis)? | | | | | Yes  No |

**HIPAA**

|  |  |  |
| --- | --- | --- |
| **\*\*Note: BU is a hybrid entity meaning that some areas are designated as health care components under the HIPAA Privacy Rule and are subject to its requirements for research.** | | |
| **41.** | Is this research being conducted in a component of Baylor University that is covered by HIPAA? | Yes  No |
| **If yes,** please submit an Authorization for the Use and Disclosure of PHI for Research. If you are requesting either a waiver of documentation of consent or a waiver of consent, you will need to request a waiver of alteration of authorization. Please contact OVPR. | |
| Is this research being conducted at a location outside of BU that is a HIPAA covered entity? | Yes  No |
| **If yes,** identify the location: | |

**CONFLICT OF INTEREST**

|  |  |  |
| --- | --- | --- |
| **42.** | Does the PI or any research staff have a financial conflict of interest? | Yes  No |
| **If yes,** identify the conflict of interest: | |
| **If yes,** has the conflict of interest been reported to the University Conflict of Interest Committee? | Yes  No |
| **43.** | Are the PI or any research personnel being offered a recruitment or enrollment bonus?    \***A recruitment or enrollment bonus** is an additional payment or incentive to the PI or research personnel dependent on the number of participants enrolled or dependent on the speed at which subjects are enrolled. The payment or incentive could be cash, gift cards, stipend/voucher for educational materials or conference travel, physical items, etc. | Yes  No |
| **If yes,** describe the plan: | |
| **44.** | Is the PI offering a referral or finder’s fee to individuals outside of the research?  \***A referral or finder’s fee** is compensation of any type (e.g. cash, gift cards, office or medical supplies, educational stipends, etc.) to an individual made in exchange for referral or recruitment of a subject to a research study. | Yes  No |
| **If yes,** describe the plan: | |

**ADDITIONAL RESEARCH INFORMATION**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **45.** | Check any other university committees to which this research must be submitted: | | | | |
|  | N/A – no other university committee review is required |  | Institutional Animal Care and Use Committee (IACUC). Status of review: | |
|  | Institutional Biosafety Committee (IBC). Status of review: |  | Radiation Safety Committee. Status of review: | |
|  | Laser Safety Committee. Status of review: |  | Other. Identify: | |
| **46.** | **Anticipated start date** (must not be prior to IRB approval; may be “upon IRB approval” or “upon approval from all required committees”): | | | | |
| **Anticipated completion date** (include time needed for analysis and/or manuscript preparation using individually identifiable data): | | | | |
| **47.** | Is this research being transferred to the BU IRB from another IRB (e.g., new faculty member bringing currently active research to BU? | | | | Yes  No |
| **If yes,** please contact OVPR. | | | | |
| **48.** | **EXPORT CONTROLS**  **\***For questions, or clarification please contact the Export Compliance Office at (254) 710-6613 or via email at [export@Baylor.edu](mailto:export@Baylor.edu) . Additional information available at: <http://www.baylor.edu/export/> | | | | |
| Does the proposed research involve equipment, software, service or technology that is on the United States Munitions List (“USML”) under the International Traffic in Arms Regulations (“ITAR”)? | | | | Yes  No |
| Does the proposed research involve equipment, software, services or technology that is on the Commerce Control List (“CCL”) under the Export Administration Regulations (“EAR”)? | | | | Yes  No |
| Does the proposed research involve technical information or instructions concerning equipment, software or technology on the USML or the CCL? | | | | Yes  No |

**Principal Investigator Attestation**

|  |
| --- |
| By submitting this form electronically through IRBNet, you (the Principal Investigator or designee) are certifying the following:   * The information contained in this report is true, complete, and accurate to the best of your knowledge; * The research will be conducted in accordance with applicable laws, regulations, and Baylor University policies and procedures; * You are aware, as the Principal Investigator, you are ultimately responsible for the conduct of this research and the individuals to whom you delegate research responsibilities. |