**INSTRUCTIONS**

This application is for the submission of research for either **EXPEDITED** or **FULL** **BOARD** initial review.

If you believe that your research is **EXEMPT**, submit the Exempt Application Form (F-15).

If you believe that your research **does** **not meet the definition of Human Subject Research (Non-HSR)**, submit the Determination of Human Subject Research Form (F-16).

For a complete list and explanation of **submission requirements**, see G-01, Initial Review Submission Guidelines.

**Use lay language and spell out acronyms. Do not cut and paste from or refer to a grant or abstract.**

**Study activities may not be implemented until the investigator receives written IRB notice of approval.**

**If you have any questions, please contact Research Compliance at:**

[**IRB@baylor.edu**](mailto:IRB@baylor.edu)

**T: 254-710-3708**

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

**PRINCIPAL INVESTIGATOR**

|  |  |  |  |
| --- | --- | --- | --- |
| **1.** | Name: | | Degree(s): |
| Department: | | Phone: |
| Campus Address: | | Email: |
| Faculty  Staff  Student | | |
|  | | | |
| **2.** | **If student:** | | |
| Undergraduate student | Graduate or Professional Student  (degree program): | |
| Faculty Advisor: | | |
| Email: | | |
| Phone: | | |

**ADDITIONAL CONTACT PERSON (if applicable)**

|  |  |  |
| --- | --- | --- |
| You can name a person other than the PI as an additional contact for questions about the research. The PI will still be copied on all correspondence. | | |
| **3.** | Name: | Phone: |
| Title: | Email: |
| BU Home Department: | |

**STUDY LOCATION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **4.** | Will the research be conducted at a physical location in the U.S. external to Baylor University? | | | Yes  No |
| **If yes,** provide the following: ***\*Attach a separate sheet if more than 2 external sites.*** | | | |
| **Name of Site** | **City/State** | **Does this site have its own IRB?** | |
|  |  | Yes – must attach IRB approval or waiver  No – must attach letter of support  **Note**: IRB or support letters must be dated and should be on the site’s letterhead | |
|  |  | Yes – must attach IRB approval or waiver  No – must attach letter of support  **Note**: IRB or support letters must be dated and on the site’s letterhead | |
|  | | | | |
| **5**. | Will any part of this research be conducted outside of the United States? | | | Yes  No |
| **If yes,** complete **SUPPLEMENT: INTERNATIONAL RESEARCH (F-03)** | | | |

**RESEARCH PERSONNEL (other than the PI)**

|  |  |  |  |
| --- | --- | --- | --- |
| **INSTRUCTIONS:** All Baylor and non-Baylor “**key personnel**” must be identified and complete required CITI training. ***Key personnel*** are defined as individuals who participate in the design, conduct (including data analysis), or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, interact with participants, or who collect and/or analyze identifiable 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. ***\*Attach a separate sheet if you need more space for additional personnel.*** | | | |
|  | | | |
| **6.** | **Name & Degree(s)** | **Role** | **Study Responsibilities** |
|  |  |  |
| BU  Other Institution: | | |
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| BU  Other Institution: | | |
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| BU  Other Institution: | | |
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| BU  Other Institution: | | |

**FUNDING**

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| --- | --- | --- | --- |
| **7.** | Indicate the type of funding for this research: | | |
|  | No external or internal funding. | |
|  | Internal funding.  Approved  Pending  Identify source(s):  URC  URSA  AHFRP  Brown Fund  YIDP  FRIP  CFRIP  Department funds  Other: | |
|  | NON-FEDERAL External funding.  Approved  Pending  List source(s) (no initials or acronyms):  Is Baylor the primary awardee?  Yes  No. If no, identify primary awardee:  Has this proposal been submitted to the BU Office of Sponsored Programs?  Yes  No | |
|  | FEDERAL External funding.  Approved  Pending  List source(s) (no initials or acronyms):  \*For Department of Defense research, submit **SUPPLEMENT: DEPARTMENT OF DEFENSE (F-06)\***  Is Baylor the primary awardee?  Yes  No. If no, identify primary awardee:  Has this proposal been submitted to the BU Office of Sponsored Programs?  Yes  No | |
| Does your research meet the definition of a clinical trial\*?  Yes  No  \*Clinical Trial means a research study in which one or more human subjects are prospectively  assigned to one or more interventions (which may include placebo or other control) to evaluate  the effects of the interventions on biomedical or behavioral health-related outcomes. | |
|  | Intend to submit for funding. From whom?  Date of submission: | |
|  | | | |
| **8.** | **a.** | Has the **PI or any other research personnel** ever been debarred, restricted, or disqualified by any federal agency (FDA, ORI, PHS, etc.)? | Yes  No |
| **b.** | Does the **PI or any other research personnel** have any current proceedings for debarment, restriction, or disqualification? | Yes  No |
| **c.** | Is the **PI or any other 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 |
| **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 |

**TYPE OF SUBMISSION**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **9.** | Select the item below that best describes the risk\* level for this research:  Greater than minimal risk.\*\* Full Board review required. Skip to question #11.  Minimal risk but the research includes radiation. Full Board review required. Skip to question #11.  Minimal or no known risks. May be eligible for expedited review – answer question #10 below.  \***Risk** means the potential for harm or discomfort. Risks can be physical, psychology, social, legal, 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)] | | | |
|  | | | | |
| **10.** | If your research involves:  N/A | | | |
|  | Investigational/approved drugs or biologics |  | Submit **SUPPLEMENT: Drugs, Biologics, Supplements and Botanicals** (F-04) |
|  | Investigational/approved devices |  | Submit **SUPPLEMENT: Devices** (F-05) |
|  | Dietary supplements |  | Submit **SUPPLEMENT: Drugs, Biologics, Supplements and Botanicals** (F-04) |

**RECRUITMENT**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **11.** | Identify the age group to include all subjects: | | | | | | | | |
| Proposed number of research subjects: | | | | | | | | |
|  | | | | | | | | | |
| **12.** | Does your research involve: | | | | | | | | |
|  | | | Minors (as defined by the location where the research will occur) | | |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** (F-02) | |
|  | | | Pregnant women, fetuses, or neonates | | |  | Additional regulations apply. | |
|  | | | Prisoners | | |  | Additional regulations apply. | |
|  | | | Adults who are unable to consent for themselves (diminished decision-making capacity) | | |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** (F-02) | |
|  | | | Students recruited in an educational setting (in class or at school; Baylor or non-Baylor) | | |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** (F-02) | |
|  | | | Baylor employees or faculty | | |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** (F-02) | |
|  | | | Non-English speaking | | |  | Submit **SUPPLEMENT: VULNERABLE POPULATIONS** (F-02) | |
|  | | | Non-readers (due to physical impairment, illiteracy, or reading disorder) | | |  | Your consent form must contain a witness signature line. | |
|  | | | | | | | | | |
| **13.** | | Does this research target one gender or a specific social, ethnic, or racial group? | | | | | | | Yes  No |
| **If yes,** provide scientific rationale: | | | | | | | |
|  | | | | | | | | | |
| **14.** | | How do you plan to recruit subjects?  **NOTICE**: **All** recruitment materials must be submitted for IRB review and approval prior to use.   * Materials must be in their final format, including all images, colors, etc. (i.e., how it will be seen by potential subjects). * If eligibility screening over the phone will take place, a script must be submitted. * Placeholders for contact information that is unknown at the time of submission are allowable. | | | | | | | |
|  | Print Materials (flyer, brochure, letter, newspaper ad, etc.) | |  | Online/Mobile/Social Media (website, web posting, Facebook, Twitter, etc.) | | | |
|  | E-mail or text | |  | Personal Contact | | | |
|  | Radio or TV ad\* | |  | From a database of individuals who have given prior permission to be contacted for research | | | |
|  | Referrals, from whom? | |  | Other: | | | |
| \*For radio and TV ads, scripts should be submitted with the recording. To avoid unnecessary production costs, pre-approval of scripts is highly recommended. | | | | | | | |

**CONSENT**

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| --- | --- | --- | --- | --- | --- |
| **15.** | Will any written or verbal screening materials to pre-screen individuals prior to consent be used? (e.g., telephone script, written or web-based screening forms or questionnaires.) | | | | Yes  No |
| **If yes,** describe the screening plan:  **NOTE**: any scripts, forms, or questionnaires used for pre-screening must be submitted to the IRB. | | | | |
|  | | | | | |
| **16.** | Check all that apply to your research: | | | | |
|  | Written consent from adult subjects (or LAR\*) |  | Submit Consent Form(s). | |
|  | Written parental permission from parents/guardians of minor subjects |  | Submit Parental Permission Form(s) | |
|  | Written assent from minor subjects |  | Submit Assent Form(s) (older minors, e.g., 14+, may be assented on the parental permission form) | |
|  | Consent/Permission/Assent will not be obtained |  | Submit **Request for Waiver or Alteration of Consent** (F-07) | |
|  | Verbal or Online consent from adult subjects |  | Submit **Request for Waiver of Documentation Of Consent** (F-08) | |
|  | Verbal or Online permission from parents/guardians of minor subjects |  | Submit **Request for Waiver of Documentation Of Consent** (F-08) | |
|  | Verbal or Online assent from minor subjects |  | Submit **Request for Waiver of Documentation Of Consent** (F-08) | |
| \*LAR = Legally Authorized Representative. This is an individual that consents on behalf of another adult who does not have the legal capacity to consent to research. | | | | |
|  | | | | | |
| **17.** | Will the research involve incomplete disclosure/deception to subjects?  (i.e., some features of the research will not be revealed to subjects until after the research is concluded). | | | | Yes  No |
| **If yes**, answer the following:  1. Explain how the incomplete disclosure is truly necessary to accomplish the goals of the research:    2. Are there undisclosed risks to subjects that are more than minimal?  Yes  No  3. Participants should prospectively agree to incomplete disclosure/deception. Will the consent process contain notice that incomplete disclosure/deception is involved?  Yes  No  If no, explain why not:  4. Describe an adequate plan for debriefing subjects, when appropriate: | | | | |

**SUBJECT INCENTIVES & COSTS**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **18.** | **a.** | Will subjects be paid or offered a monetary incentive?  **If yes,** indicate total possible amount (including any completion bonuses): | | | | Yes No |
| **b.** | **Payment Plan:** Indicate when subjects will be paid (e.g., at the end of each visit, at the end of the study, after each completed survey, etc.), and the amount each time.  **\*Note:** For studies conducted over multiple visits/days, 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 and requires justifiable rationale. | | | | |
| **c.** | How will subjects be paid (e.g., cash, check, gift card, etc.)? | | | | |
|  | | | | | | |
| **19.** | Will subjects be given any tangible gifts (e.g., t-shirt, mug, tote bag) or services without charge?  **If yes**, describe and provide the value of any gifts or services: | | | | | Yes  No |
|  | | | | | | |
| **20.** | Will subjects receive extra credit or course credit?  **If yes**, an equivalent alternative to research participation must be provided. Describe: | | | | | Yes  No |
|  | | | | | | |
| **21.** | Will all subjects receive the same payment, gift, or other incentive?  **If no**, describe the incentive plan and explain why it is appropriate for this research: | | | | | Yes  No  N/A |
|  | | | | | | |
| **22.** | Will subjects be reimbursed for any expenses?  **If yes,** describe:  **\*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. | | | | | Yes  No |
|  | | | | | | |
| **23.** | Are there any potential costs to subjects (or his/her insurance) as a result of participating in the research?  **If yes,** describe the costs: | | | | | Yes  No |
|  | | | | | | |
| **24.** | Who will be financially responsible for treatment of any psychological or physical problems that appear to be caused by participation in the research? (e.g., local infection due to blood draw, emotional distress, etc.)? | | | | | |
|  | | N/A – minimal risk research |  | Study Sponsor | |
|  | | Subject |  | Other. Explain: | |

**SAFETY and DATA MONITORING**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **25.** | Who will review this study on an ongoing basis for purposes of safety, data integrity, and adherence to the protocol? | | | |
|  | Principal Investigator (appropriate for minimal risk/low risk research) |  | Committee managed by the principal investigator |
|  | Independent Monitor (e.g., data monitoring committee or data safety monitoring board) |  | Other: |
| **Note**: A description of the data and safety monitoring plan must be included in the protocol. | | | |

**PRIVACY/CONFIDENTIALITY**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **26.** | Check the identifiers that will be collected **at any point in the research**, even if they will be destroyed at a later time.  No identifiers will be collected or recorded. | | | | | | |
|  | | Names or initials |  | 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 |  | URLs or IP address numbers | | |
|  | | Any identifying number (e.g., BearID, medical record, social security or national ID, health insurance, account, certificate/license, vehicle identifiers and serial numbers, license plates, driver’s license) |  | Full face or other identifying video/photographic images (e.g., tattoos, scars) | | |
|  | | Digital or online identities (e.g., avatars, personas, screen names, etc.) |  | Biometric identifiers (e.g., fingerprints, voiceprints, dental x-rays, retinal scans, handwriting, etc.) | | |
|  | | Genetic information |  | Any other unique identifying number, characteristic, or code | | |
| If any of the above boxes are checked, how long will the identifiers be kept? | | | | | | |
|  | | | | | | | |
| **27.** | If you are collecting identifiers, will a coding system\* be used?  \*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. | | | | | | Yes  No  N/A |
| **If yes**, who will have access to the key?  How long will the key be kept? | | | | | | |
|  | | | | | | | |
| **28.** | Does this study involve collection of information from student school/university records? (If yes, FERPA requirements may apply.) | | | | | | Yes  No |
|  | | | | | | | |
| **29.** | Is it possible or planned that any data collected for this research will be used for other research in the future **not** **related** to the proposed research? | | | | | | Yes  No |
|  | | | | | | | |
| **30.** | | Is this research being conducted at a location outside of BU that is a HIPAA covered entity (such as a health care clinic or hospital)? | | | | Yes  No | |
| **If yes,** identify the location: | | | | | |
| **If yes,** please note that no protected health information (PHI) should be brought onto Baylor campus or saved on any Baylor system unless certain conditions are met.  **Check the appropriate box:**  All data that I receive from a HIPAA covered entity will be DE-IDENTIFIED prior to coming into my possession and/or being transferred to any Baylor system.  This research requires identifiable protected health information to be conducted. I will work with the Office of Research Compliance to make sure appropriate conditions are met. | | | | | |

**CONFLICT OF INTEREST**

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| --- | --- | --- |
| **31.** | 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 |
|  | | |
| **32.** | 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: | |
|  | | |
| **33.** | 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**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **34.** | 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: |  | Other. Identify: | |
|  | | | | | |
| **35.** | Is this research being transferred from another institution (e.g., new faculty member bringing currently active research to BU)? | | | | Yes  No |
| **If yes,** submit a copy of the other IRB’s approval letter and, if applicable, the most recent continuing review approval. More information may be requested. | | | | |
|  | | | | | |
| **36.** | **EXPORT CONTROLS**  As a Principal Investigator, researcher, or faculty member, you are responsible for being aware of and complying with any United States export control laws and regulations that may apply to your project. You are specifically responsible for determining if the research you are performing, the information you are developing, receiving or disseminating, the technology you are developing, receiving or disseminating, or the presence of any individual who is involved in your project is controlled by export controls laws and regulations or how they may apply to your project. Export Compliance is here to assist you in this determination and should be used as a resource.\*  Click here to affirm that you are aware of the above responsibility.  **\***Contact Export Compliance at (254) 710-6613 or via email at [export@Baylor.edu](mailto:export@Baylor.edu) . Additional information available at: <http://www.baylor.edu/export/> | | | | |

**Principal Investigator Attestation**

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| By submitting this form electronically through IRBNet, you (the Principal Investigator or designee) are certifying the following: (check to indicate that you have read each one)  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;  Research records will be kept for at least 3 years after completion of the research (a longer period may be required by the sponsor, funding agency, or the HIPAA Privacy Rule)  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. |