**CHECKLIST: NEW IRB Protocol Application (Biomedical Studies)**

***PI must type an “x” for each item included (or “n/a” for not applicable).***

|  |  |
| --- | --- |
| **Principal Investigator** |  |
| * Confirm: The PI has a faculty appointment at RFUMS as professor, associate professor, assistant professor or instructor. |  |
| * Confirm: The PI is not listed on the FDA debarment list and isn’t disqualified or restricted in any way from clinical research. |  |
| **Application Documents** |  |
| * Fully completed application form |  |
| * PI and research team members most recent CITI training certificates (OHRP training verification may be provided in lieu of CITI certificate for community partners engaged in research) |  |
| * Research instruments (e.g. tests, interviews, surveys, questionnaires, etc.) |  |
| * Letters of support/permission from recruitment or performance sites outside of RFUMS |  |
| * Recruitment materials (e.g. flyer, letter, printed ad, e-mail text, phone script, etc.) |  |
| * Other relevant documents (e.g. investigator brochures from sponsor) |  |
| * Certificate of Confidentiality *(Only if applicable)* |  |
| * Data Use Agreement / Limited Data Use Agreement *(Only if applicable)* |  |
| * Conflict of Interest (COI) committee management plan (*Only if applicable*) |  |
| **Informed Consent Document** |  |
| * Informed Consent form(s) |  |
| * Assent form – minor subjects |  |
| * Parent/guardian permission form – for minor subjects |  |
| * Appendix W – Waivers Involving the Informed Consent Process *(if applicable)* |  |
| * HIPAA Authorization to Disclose PHI for Research Purposes *(if applicable)* |  |
| **Relevant Appendices *(if applicable)*** |  |
| * Appendix V(B) – Special Protections for Pregnant Women, Fetuses, Neonates |  |
| * Appendix V(C) – Special Protections for Prisoners |  |
| * Appendix V(D) – Special Protections for Children |  |
| * Appendix E – Electronic Data Security Assessment |  |
| * Appendix P – Use of Protected Health Information (PHI) |  |
| * Appendix T – Tissue and Biological Sample Use and Storage |  |
| **Other Application Documents for Collaborative Studies *(if applicable)*** |  |
| * These may include: Individual Investigator Agreements, IRB Authorization Agreement SMART IRB participation, sIRB status, other agreements. |  |
| * **You have marked the attestation box and typed your name and date on the last page.** |  |

**Approval by Institutional Review Board:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name/Signature Date**

**Application For New Research Protocol Involving Human Subjects:**

**Biomedical Research**

*This application should contain all information that is central to the IRB’s understanding of your research project (there is no separate “protocol” form that accompanies this document)*

**Part I: Administrative Information**

**A. Protocol Information**

|  |  |
| --- | --- |
| Title of Protocol |  |
| IRB protocol number\* |  |

*\*will be assigned upon submission*

**B. Principal Investigator (PI)**

|  |  |
| --- | --- |
| Name |  |
| Degree/Title |  |
| Dept. & College at RFUMS |  |
| Email |  |
| Phone |  |
| Most recent CITI training\* |  |

**C. If this is a postdoctoral or student project (supervised and sponsored by the faculty PI) provide name of the trainee:**

|  |
| --- |
|  |

**D. List all current members of the research team** *(add rows as needed):*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name, Degree | Email | RFUMS Dept. & College  Work Address *(if non-RFUMS)* | Role in project Role in project  *(indicate if consenting and/or interacting with subjects or other role)* | Date of most recent CITI training\* |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*\* Include pdfs of all training certificates with the application.* ***Note-*** *community partners engaged in research may complete OHRP training on human subjects research in lieu of completing CITI training. See IRB’s “Guidance for Community Partners Engaged in Human Subjects Research” policy for more information..*

**E. Funding information**

|  |  |
| --- | --- |
|  | Federal funding agency (direct award) |
|  | Federal flow through funds (subcontract/collaborator) |
|  | Non-federal grant or sponsor |
|  | Other |
|  | None |

External funding agency/sponsor information including Grant Agency, Number or Sponsor’s Project ID number:

|  |
| --- |
|  |

**F. PI’s Assessment of Risk Level for this project**

|  |  |
| --- | --- |
|  | **Minimal\* risk** |
|  | **Greater than** minimal risk |

*\*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.*

**G. Are the research activities subject to FDA regulation?**

*A research activity is subject to FDA regulation if: 1) the activity involves any use of a drug, other than the use of marketed drugs in the course of the practice of medicine; 2) the activity involves the evaluation of a device for safety or efficacy; or 3) data will be submitted to or held for inspection by FDA.)*

|  |  |
| --- | --- |
| **Yes** | **No** |
|  |  |

***If YES, your study is not available for review by RFUMS’ IRB and you must use an external IRB.***

***Contact the IRB administrator for a list of commercial IRBs.***

**H. Type of Review you are requesting:**

|  |  |
| --- | --- |
|  | FULL Board Review |
|  | EXPEDITED Review\* |

*\*Studies eligible for Expedited Review must be minimal risk, not subject to FDA regulation, and fit into one or more of the categories below.*

**If requesting expedited review status, please check the expedited review category(ies) that apply to the proposed project.**

|  |  |
| --- | --- |
|  | **Category 1**. Clinical studies of drugs and medical devices only when condition (1) or (2) is met.  1. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)  2. Research on medical devices for which (i) an investigational device exemption is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. |
|  | **Category 2.** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:  1. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; OR  2. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week. |
|  | **Category 3.** Prospective collection of biological specimens for research purposes by noninvasive means.  Examples:  1. hair and nail clippings in a nondisfiguring manner;  2. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;  3. permanent teeth if routine patient care indicates a need for extraction;  4. excreta and external secretions (including sweat);  5. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;  6. placenta removed at delivery;  7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;  8. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;  9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;  10. sputum collected after saline mist nebulization. |
|  | **Category 4:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.  Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:  1. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;  2. weighing or testing sensory acuity;  3. magnetic resonance imaging;  4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;  5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |
|  | **Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).  (NOTE: Some research in this category may be exempt; This listing refers only to nonexempt research). |
|  | **Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes. |
|  | **Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.  (NOTE: Some research in this category may be exempt; This listing refers only to nonexempt research). |

**Part II: Study Overview**

**A. Non-technical Overall Summary**

*Provide a layperson summary of the overall study purpose, the general research question/hypothesis and objectives, and a general but complete overview of what will be done with human subjects (details will be provided below in the application). This lay summary should not contain complex terms or undefined abbreviations and should be easily understandable to a high school age student. If possible, limit to 500 words.*

|  |
| --- |
|  |

**B. Background, Rationale and Significance**

*Briefly describe the background that provides the rationale for this research study and also the potential significance of the findings. (500 words)*

|  |
| --- |
|  |

**C. Type of project: Select ALL of the categories of work that apply to this proposed project**

|  |  |
| --- | --- |
|  | Active collection of data from subjects (not biological materials or physiological data) |
|  | Active collection and use of biological materials or physiological data from subjects |
|  | Use of physiological or biomedical devices, drugs, biologics, or chemicals with subjects |
|  | Use of existing data (not human biological materials) |
|  | Use of existing human biological materials *Attach Appendix T Tissue and Biological Sample Use* |
|  | Other |

*Briefly describe “Other” activities (if checked):*

|  |
| --- |
|  |

**D. Select ALL of the methods/instruments of data collection that will be employed in this study:**

|  |  |  |
| --- | --- | --- |
|  | Type of Method/Instruments | Required Materials for submission |
|  | Educational test(s) | *Submit copy with application* |
|  | Psychological test(s) | *Submit copy with application* |
|  | In person interviews | *Submit script with application* |
|  | Paper surveys | *Submit copy with application* |
|  | Telephone surveys | *Submit script with application* |
|  | RFUMS Qualtrics | *Submit surveys with application* |
|  | Internet surveys (Survey Monkey, Google forms, REDCAP, any other internet survey other than RFUMS Qualtrics) | *Complete Appendix E and*  *Submit surveys with application* |
|  | Data collection using other communication/electronic devices (i.e., texting) | *Complete Appendix E and*  *Describe below* |
|  | Live observation | *Describe below* |
|  | Use of social media sites | *Complete Appendix E and*  *Describe below:* |
|  | Use of a mobile app | *Complete Appendix E and*  *Describe below* |
|  | Wearable device | *Complete Appendix E and*  *Describe below* |
|  | Electronic recording or conferencing | *Complete Appendix E and*  *Describe below* |
|  | Cognitive or behavioral measures, including daily diaries | *Describe below* |
|  | Focus groups | *Describe below and attach script* |
|  | Self-health monitoring (food diaries, etc.) | *Describe below* |
|  | Audio/Video recording (not applicable for videos that only include markers from 3D motion capture systems from which a person’s identify could not be ascertained) | *Describe below*  *Ensure that this specific approval is included in the consent form* |
|  | Anthropometric measures (e.g. height, weight, waist circumference, etc.) | *Describe below; if transmitted electronically (i.e., wireless scales), complete Appendix E* |
|  | Other activities or interventions | *Describe below* |

*(****Details of the procedures selected above will be described fully in the sections below; ensure that relevant privacy and confidentiality issues are addressed in Part V of the application and the consent form****)*

**E. Experimental Design:**

1. **Describe the experimental design of your study**

|  |
| --- |
|  |

1. **Summarize your analytic plan. Include whether you will examine heterogeneity in your results by different subgroups (e.g., racial, ethnic identities, gender identity…)** *This is not meant to be an exhaustive discussion of background information or statistics.*

|  |
| --- |
|  |

1. **Is this a clinical trial** (i.e., “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 those interventions on health-related biomedical or behavioral outcomes.”

|  |  |
| --- | --- |
| **Yes** | **No** |
|  |  |

**If yes,** have you registered the trial? Have all investigators and affiliated research staff completed the good clinical practice CITI modules? Check all that apply.

|  |  |
| --- | --- |
|  | The trial has been registered: *specify location*: |
|  | All investigators and research staff included in this application have completed CITI training |

**F. Describe the actual source records or measures that will be used to collect data about participants.** *(All surveys, interview scripts, and data collection forms will be attached with the submission of the application. Do not add these other documents to this form!).*

|  |
| --- |
|  |

**G. Describe the course of data collection to be done in this research study.** Include the interventions as well as tasks that the participants will be asked to perform for each phase of the study, in temporal order, as well as what will be recorded as data. Provide pertinent information about the research instruments (indicated in section IID above) that will be used.

|  |
| --- |
|  |

**H. Study Interventions:** Provide details regarding any drug, device, physical procedures, manipulation of the subject or the subject’s environment that will be done. *(Clearly identify procedures, tests and interventions performed exclusively for research purposes or more frequently than standard of care. Include a brief description of follow-up, if relevant).*

|  |
| --- |
|  |

**I. If using placebo control, discontinuation of or delay of standard therapies, provide justifications** and ensure that this is clearly presented in the informed consent document.

|  |
| --- |
|  |

**J. Describe the study timelines including an estimate of the time commitment from each participant for each phase of the study and the overall anticipated duration of the project**.

|  |
| --- |
|  |

**K. Describe other information about the research** *(e.g. manipulations of the environment, etc)* that is not covered above

|  |
| --- |
|  |

**L. LOCATION of Research Activities:**

**1. Indicate the geographical locations where research procedures will be performed and data will**

**be collected:**

|  |  |
| --- | --- |
|  | Illinois |
|  | Other US states/territories - *specify*: |
|  | International locations – *specify*: |

**2. Indicate all of the specific locations where research procedures will be performed and data will be collected:**

|  |  |
| --- | --- |
|  | RFUMS campus - *specify location*: |
|  | Online research |
|  | Hospital(s) - *specify location*: |
|  | Community clinic(s) - *specify location*: |
|  | Participant’s homes |
|  | Primary or secondary school(s) - *specify location*: |
|  | Nursing home(s) - *specify location*: |
|  | Other location(s) not listed above – *specify location*: |

**3. If there are multiple sites where research activities will occur, specify/describe the activities/roles of each site**

|  |
| --- |
|  |

**4. If some of the research activities will be conducted outside of the RFUMS campus**, please identify any site-specific regulations affecting your project and discuss any approvals or permissions that will be needed prior to beginning the research (e.g. school, senior living community)

|  |
| --- |
|  |

***\*If a community location (school, clinic etc) is checked, appropriate documentation of approval***

***from the entity must be submitted before final approval will be granted.***

**Part III: Participants, Recruitment & Compensation**

**A. What is the maximum number of participants requested for this study?**

|  |
| --- |
|  |

**B. Describe the population from which you will be recruiting with respect to gender identity and race/ethnicity.**

|  |
| --- |
|  |

**Are you excluding any gender identities?** No  Yes

*If YES, describe the rationale for exclusion.*

|  |
| --- |
|  |

**Are you excluding any racial or ethnic groups?** No  Yes

*If YES, describe the rationale for exclusion.*

|  |
| --- |
|  |

**C. What is the age range of the participants?**

|  |
| --- |
|  |

**D. Select all categories of participants that will be included in your study:**

|  |  |
| --- | --- |
|  | **Healthy adult volunteers** |
|  | \*RFUMS students |
|  | \*RFUMS employees |
|  | \*People with cognitive impairment |
|  | \*People with limited literacy |
|  | \*People who speak a language other than English |
|  | \*Patients of healthcare provider if provider is part of the research team |
|  | \*People who are economically disadvantaged |
|  | Children (participants under age 18) *Complete and submit Appendix V:D (Vulnerable Populations: Children)* |
|  | Peoplewho are incarcerated,or under detention or on probation *Complete and submit Appendix V:C (Vulnerable Populations: Participants who are incarcerated))* |
|  | Pregnant or nursing individuals *Complete and submit Appendix V:B (Vulnerable Populations: Pregnant People, Fetuses, Neonates)* |
|  | \*Other category of participants with diminished capacity or voluntariness not listed above |
|  | None of the above (explain): |

*\****For these participant categories potential vulnerability for coercion or diminished capacity affecting voluntariness may exist. Describe how your study procedures provide additional safeguards to avoid this.** *(e.g. PI will not recruit personally recruit his/her own patients or students). (Do not include discussion of provisions for protected vulnerable populations (red font above) for which you have attached Appendix V:B, V:C or V:D for Vulnerable Populations here)*

|  |
| --- |
|  |

**E. Describe the inclusion or exclusion criteria for participants.**

|  |
| --- |
|  |

**F. Recruitment: Select which statement accurately applies to your research project:**

|  |  |
| --- | --- |
|  | **Statement A**: Potential subjects will self-identify based on response to an advertisement, flyer, presentation or respondent driven sampling. |
|  | **Statement B**: Potential subjects will be recruited based on information contained in private/protected records (medical records, student records). This also includes subjects who will be recruited from the PI or Co-I’s patient population. |

***If ONLY statement A is selected, skip to section III.G below***

***If statement B is selected, answer questions 1-3 below:***

**1. Explain how the researcher has legitimate access to these records.**

|  |
| --- |
|  |

**2. Identify who will make initial contact with potential subjects.**

|  |
| --- |
|  |

**3. Will the records include MEDICAL (HIPAA protected) records?**

|  |  |
| --- | --- |
|  | **No** |
|  | **\*Yes** |

***\*You must attach Appendix P “Use of Protected Health Information” along with additional documentation referenced in Appendix P.***

**G. Select all of the Methods/Tools that will be used to recruit participants:**

|  |  |  |
| --- | --- | --- |
|  | Type of Method/Tool | Required Materials for submission |
|  | Flyers/Notices | *Submit copy with application* |
|  | Mailers (U.S. Post) | *Submit copy with application* |
|  | Newspaper ads | *Submit draft of ad with application* |
|  | Radio or TV ads | *Submit script with application* |
|  | Internet /social networking sites | *Text, page mockup of posting (including images)*  *Indicate site(s):* |
|  | Letters or emails | *Submit letter or email with application* |
|  | Phone call | *Submit phone script with application* |
|  | Presentations at meetings | *Submit script with application* |
|  | Face to face public intercept | *Submit script with application* |
|  | Participant pool (web-based) recruiting methods | *Specify*: |
|  | Other method not described above | *Describe*: |

**H. Briefly describe each recruitment method** **checked above.**

|  |
| --- |
|  |

**I. Describe the expertise your team has to recruit a representative sample from your intended population of interest (e.g. fluent in Spanish, members of the community, etc.).** If applicable, discuss the specific strategies you will use to recruit participants from under-resourced populations.

|  |
| --- |
|  |

**J. Financial Compensation:**

|  |  |
| --- | --- |
| Yes | No |
|  |  |

**1. Will participants be compensated for their participation?**

**2. If yes, describe the type and amount of financial compensation** (money, gift cards etc.) and whether compensation will be prorated if there are multiple research activities, or if a participant withdraws early from the study.

|  |
| --- |
|  |

**3. Describe any costs that participants may incur because of participation in the research.**

|  |
| --- |
|  |

**Part IV: Risks and Benefits**

**A. Risks.** From the list below, select ALL of the reasonably foreseeable risks, discomforts, hazards, or inconveniences related the participants’ participation in the research.

|  |  |
| --- | --- |
|  | Collection oruse of private records (e.g. educational or medical records) |
|  | Manipulation of psychological or social state such as sensory deprivation, social isolation, psychological stress |
|  | Probing for personal or sensitive information in surveys or interviews (e.g. private  behaviors, employer assessments) |
|  | Collection of potentially sensitive data with identifiers |
|  | Presentation of materials which some participants may consider sensitive, offensive,  threatening or degrading |
|  | Use of deceptive techniques |
|  | Possible invasion of privacy of subject or subject’s family |
|  | Social or economic risk (reputational, cultural, employability, etc.) |
|  | Identification of child, spousal, or elder abuse |
|  | Possible risks to others who are not participants |
|  | Identification of illegal activity |
|  | Risk of injury or bodily harm |
|  | Placebo Use (if standard treatment will be withheld) |
|  | Treatment will be withheld/altered or subjects will discontinue current treatment (a washout period is included) |
|  | Administration of physical stimuli |
|  | Major changes in diet, exercise or sleep |
|  | Other *(specify here)*: |
|  | *There are no risks of any kind to any participants enrolled in this study. This option is valid only if none of the risks above are selected.* |

**B. Describe the nature of the risks** indicated above, indicating the probability, magnitude, duration, and reversibility of the risks. *(All of the risks/harms must be also disclosed in the informed consent form/process).*

|  |
| --- |
|  |

**C. Describe the steps that will be taken to minimize risks or harms and to protect the welfare of**

**participants.** Be sure to include a description of how you will handle an adverse or unexpected outcome that could be potentially harmful (e.g., suicidal ideation). *If the study will include protected vulnerable populations, include the appropriate Appendix V from the IRB website and indicate that here and do not reiterate that information here.*

|  |
| --- |
|  |

**D. Benefits\*.** Describe any benefits that individuals may reasonably expect from participation.

If there are none, state "None."

|  |
| --- |
|  |

\**Note: participation in the research itself and compensation from participating in the research are not considered benefits. Also, do not include potential benefits to society or others.*

**Part V: Privacy and Confidentiality**

*Privacy refers to having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally or intellectually) with others. Confidentiality refers to how the subject’s identifiable data will be handled, managed, stored, and, if applicable, disseminated.*

**A. Personal Identifiers.** Will you or any member of your research team collect or have access to any of the personal identifiers listed below? *Select all that apply:*

|  |  |
| --- | --- |
|  | Name |
|  | Date of birth |
|  | Mailing or email address |
|  | Phone or fax numbers |
|  | Social Security number |
|  | Medical records |
|  | License, certificate or Vehicle ID |
|  | IP address |
|  | Biometric identifiers |
|  | Photos/images/audio or video recording |
|  | Signatures, handwriting samples |
|  | Any unique identifier not mentioned above *(specify here*): |
|  | No member of the research team (including PI) will have access to any personal identifiers *(This option is valid only if none of the other options are selected)* |

**B. Protection of the Privacy Interests of Participants, Confidentiality and Data Management:**

1. **Describe the steps that will be taken to protect participants’ privacy interests throughout the research activities**. Include a discussion of the conditions under which interaction with subjects will occur (e.g., consent discussion occurs in a private room).

|  |
| --- |
|  |

**2. Describe steps that will be taken secure the data study-wide.** (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data) during use, transmission and storage.

|  |
| --- |
|  |

**3. Describe where and how will data (or specimens) be stored;** how long will the data or specimens be stored and who will have access to stored data or specimens:

|  |
| --- |
|  |

**4. Even if direct identifiers are not recorded or maintained, are there potential ethical or legal circumstances when it would be necessary to break confidentiality** (e.g. requirements for mandated reporting)? If yes, explain below:

|  |
| --- |
|  |

**5. Will you be returning *individual or group* research results to participants?**

\*Yes, individual results

\*Yes, group (i.e., aggregated) results

No

\***If *Yes*, please describe the process by which results will be returned to participants** *(Who will provide results to participants, what information will participants receive, where will participants receive the information, do participants have the option not to receive results…)*

|  |  |
| --- | --- |
|  |  |

**C. Withdrawal of Participants:**

1. **Describe circumstances under which participants will be withdrawn from the research**

**without their consent.**

|  |
| --- |
|  |

1. **Describe procedures that will be followed when participants withdraw from the research, including use or treatment of data after withdrawal.**

|  |
| --- |
|  |

**Part VI: Informed Consent Processes**

**A. Indicate the informed consent process(es) and/or documents to be used in the study.**

|  |  |
| --- | --- |
|  | **Not Applicable** (using pre-existing data or specimens only) |
|  | |
|  | **Informed Consent form** *(attach the consent form to be used to this application)* |
|  | \*Modified consent: oral script/online/unsigned consent *(submit the script/text to be used with Appendix Form W)* |
|  | \*No, I am seeking a waiver of written informed consent *(submit Appendix Form W)* |
|  | **Assent form for participants under age 18** *(attach the assent form to be used to this application)* |
|  | \*Modified Assent: oral script/online/unsigned assent for participants under age 18 *(submit script/text to be used with Appendix Form W)* |
|  | \*No, I am seeking a waiver of assent for participants under age 18 *(attach* *Appendix W)* |
|  | **Parental/guardian permission form for participants under age 18** *(submit the permission form to be used to this application)* |
|  | \*Modified Parental/guardian permission: oral script/online/unsigned permission for participants under age 18 to be used *(submit script/text to be used with Appendix W)* |
|  | \*No, I am seeking a waiver of parental/guardian permission for participants under age 18 *(attach* *Appendix Form W)* |

*\*If any of the “NO” or “Modified” boxes above are checked you must submit Appendix W.*

**B. Briefly describe when and where the informed consent process will be done and discuss how privacy will be insured during the process.**

|  |
| --- |
|  |

**C. Documentation of Informed Consent**

|  |  |
| --- | --- |
|  | Not applicable |
|  | Yes |
|  | \*No, I am seeking a waiver of written informed consent |

*\*If \*No” is checked, you must submit Appendix Form W*

**D. Broad consent:** Broad consent refers to an (optional) alternative consent process for use **only** for the storage, maintenance, and secondary use of [**identifiable private information**](https://www.safecomputing.umich.edu/dataguide/?q=node/65) **or identifiable biospecimens** for future, yet-to-be-specified, research.

|  |  |
| --- | --- |
|  | Not applicable |
|  | Yes, I am using broad consent |
|  | No, I am not using broad consent |

**If yes, please complete the following *and ensure that D1 and D3 are conveyed in the consent***

***form*:**

**1. Describe the types of research that may be conducted with the data/biospecimens.**

|  |
| --- |
|  |

**2. Describe your system for recording and tracking who has agreed to or refused broad consent.**

|  |
| --- |
|  |

**3. Describe the terms of the broad consent to** determine whether proposed future secondary research use falls within the scope of the identified types of research. ***Ensure that this information is conveyed in the consent form.***

|  |
| --- |
|  |

**Part VII: Research Collaborations and Other Approvals**

**A. Does this research project involve collaborations with any personnel or sites outside of Rosalind Franklin University?** If yes\*, briefly describe the collaboration (with whom and for what purpose):

|  |
| --- |
|  |

**B. Is this research proposal being reviewed by any other institution’s IRB (dual review)?** If yes, please provide information below:

|  |
| --- |
|  |

*\*Additional requirements for ensuring appropriate IRB oversight may apply. These requirements are often dependent on whether or not the site/personnel is considered “engaged” in human subjects research according to federal definitions. For example, the IRB may require a signed individual investigator agreement (IIA) or an institutional authorization agreement (IAA) with the collaborators. These forms are available on the IRB website. Contact the IRB office (irb@rosalindfranklin.edu) to determine how IRB oversight of the research activity with the external site/personnel should be addressed.*

**C. Does this project require use of a single IRB model (i.e. a study involving both federal funding and multiple research centers)?**

|  |  |
| --- | --- |
|  | No |
|  | Yes, and I completed the necessary registration in the SMART IRB portal for RFUMS to serve as the reviewing IRB |
|  | Yes, I intend to have RFUMS serve as the reviewing IRB, but I have not registered this study using the SMART IRB portal |
|  | Other, describe below |

|  |
| --- |
|  |

**D. Does this research proposal require approvals from any other committee at RFUMS (for example,** Biosafety, Conflict of Interest, OSR) or any other outside entity (for example a site requiring a data use agreement or a certificate of confidentiality)?If yes, please specify below and provide documentation.

|  |
| --- |
|  |

**Part VIII: Conflict of Interest (COI) Disclosure**

Rosalind Franklin University Policy requires that personnel conducting research involving human participants at Rosalind Franklin University disclose any significant personal conflict of interest that would reasonably appear to be affected by, or potentially influence the research project. A ***personal interest*** is any interest held by the individual that is not associated with employment or affiliation with the University (e.g. salary from this University is not a personal interest). Although the scope of the term is extensive, the most common types of personal interests are: financial, familial, and institutional:

* *Financial interest* is the receipt or expectation of receiving a thing of monetary value *of any amount*(e.g., stock, patent, partnership, gift, income, reimbursements, and honoraria, but does not include a publicly traded mutual fund).
* *Familial Interest* is an existing or expected relationship with a particular person by blood, marriage, or adoption (or substantially similar relationship).
* *Organizational Interest* is a current, recent, or expected status as member, employee, officer, director, trustee, consultant, or agent of an entity.

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| Do you, your spouse and/or your dependent children have any personal interests (defined above): | | |
| * That could reasonably appear to be affected by the results of this research project? |  |  |
| * With the external sponsor of this research project? |  |  |
| * With any other entity whose financial interests could reasonably appear to be affected by this research project? |  |  |
| * That creates an actual or apparent bias or improper influence upon your judgment relating to this research project? |  |  |
| * In the experimental item of this research project? |  |  |
| Does this protocol include research that overlaps with any patent you are part of? |  |  |
| Does any member of your research team have a situation where that person would answer “yes” to any of the subparts of the questions above? |  |  |
| Is this project the subject of a Conflict of Interest (COI) committee management plan that you have included with this application? |  |  |

*If you answered “Yes” to any of the questions, contact Rosalind Franklin University’s COI office for guidance on next steps regarding disclosure, review of the financial interest and resolution or management of any real or apparent conflict of interest. The IRB is not able to approve this project until it has been determined by the COI office that no investigator or personnel involved in this research activity has a conflict of interest related to this research.*

**Part IX: Assurances and Signatures**

*Before submitting an electronic copy of this application, “X” or otherwise clearly mark the attestation box and type your name and* ***today’s date****.*

**As Principal Investigator of this study, I assure the IRB that the following statements are true**:

• I acknowledge that the information provided and that I have the duty and responsibility to protect the rights and welfare of the human participants as well as the scientific and ethical integrity of this research project

• I have determined I have the resources necessary to protect participants, such as appropriately trained research staff, necessary facilities and equipment and funds needed to accomplish the objectives.

• I will seek and obtain prior written approval from the IRB for any substantive modifications in the proposal, including changes in procedures, co-investigators, funding agencies, etc.

• I will promptly report any unexpected or otherwise significant adverse events or unanticipated problems or incidents that may occur in the course of this study.

• I will report in writing any significant new findings which develop during the course of this study that may affect the risks and benefits to participants.

• I will not begin my research until I have received written notification of final IRB approval.

• I will comply with all IRB requests to report on the status of the study.

• I will maintain records of this research according to IRB guidelines.

• If these conditions are not met, I understand that approval of this research could be suspended or terminated.

Attestation of Principal Investigator

**Name/Signature of PI Date**