JEFFERSON—Office of Human Research

# SUMMARY OF INTERVENTIONAL HUMAN SUBJECTS RESEARCH

**Version Date – FOR OHR USE: 11/11/21**

Please address all applicable points to create a complete and succinct synopsis of the protocol. If a point does not apply to your study, please state “NA.” Use language, insofar as is possible, that can be understood by a layperson, and provide meanings for all acronyms used.Please maintain all questions in the body of the text. For non-interventional research (questionnaires, surveys, and all sociobehavioral research), use form OHR-2B. **Form must be typewritten.**

**PART A - SUMMARY OF STUDY**

1. Brief Summary

1. Provide a brief (2-3 sentences) lay language synopsis of the study. Include an explanatory sentence about the study article *(e.g., product X is a compound that increases excretion of salt and therefore may be of use in the treatment of high blood pressure)*
2. Provide the following information about the study article(s):

Class of drug (anti-hypertensive, purgative, etc.) or type of device (stent, glucose sensor, etc.):

Mechanism of action (if drug or biologic):

***NOTE: If this submission is for an extension study of an IRB approved protocol, please provide a copy of the most recent IRB-approved OHR-9 form in addition to a short (one-paragraph) lay-language synopsis of the original study plan and a review of any efficacy information obtained in the parent trial.***

2. Objectives and Significance

a. State the primary objective(s) of the study.

b. State the secondary objectives(s) of the study.

c. What benefit or knowledge will be gained?

d. State hypothesis you are testing.

3. Briefly describe the background and rationale for the research in lay language. Please limit response to one paragraph. State the perceived problem and why it is being investigated. *(Do not include references and please do not cut and paste grant application or review articles. “See investigator brochure” is not an acceptable response.)*

4. Briefly describe the research design. ***(Use charts and flow diagrams if applicable****. “See protocol” is not an acceptable response.)*

* 1. Subjects: State inclusion and exclusion criteria.
  2. Procedures: Provide study visit details. *(Study team standard operating procedures should not be addressed here. Use diagrams or flow charts when appropriate. For an investigator initiated study, this form should NOT substitute for a separately drafted protocol which should be included in the IRB packet as a separate document)*
  3. Data analysis: (*Provide statistical design* ***for primary endpoint only.*** *Please indicate* ***how the study is powered*** *and what statistical tool(s) will be applied. Please do not cut and paste entire statistical section from the sponsor protocol. Pilot studies* ***do not******require*** *a statistical plan but need to outline how the results will be used to power future studies.)*
  4. If the protocol involves sending tissue to a commercial entity, please certify that the following criteria are met (see TJU policy #110.17, “Collection, storage, use and distribution of tissue for research purposes”). Also, please provide a copy of the sponsor contract/agreement or an e-mail from ORA certifying same. The PI certifies that he or she (check applicable statements):

Will have significant input into the study design and/or conduct of the study.

Will receive experimental data and participate in data analysis.

Has established the right to be a co-author on any publications related to this protocol.

Certifies that Jefferson ORA is negotiating a sponsored research agreement, to be signed prior to work commencing.

5. Delineate procedures that are standard of care from those that are being performed specifically for the research. *Delete examples and add additional rows to table as appropriate. Provide the information to the best of your ability.*

|  |  |  |
| --- | --- | --- |
| **Procedure** | **Research** | **Standard of Care** |
| EXAMPLE 1: CT Abdomen visits 1 and 6 |  | X |
| EXAMPLE 2: CT Abdomen visit 8 | X |  |
| EXAMPLE 3: Pregnancy test each visit | X |  |
|  |  |  |
|  |  |  |

6. Describe the Data and Safety Monitoring Plan (DSMP) for this protocol. See OHR Policy G 616 for guidance.

\_\_\_ Study is minimal risk and does not require a DSMP. Accuracy of data will be confirmed by PI before study is locked.

* For Investigator Initiated Treatment Trials:

Will the study be overseen by the KCC Data Safety Monitoring Committee?

\_\_\_\_\_\_ YES \_\_\_\_\_\_\_ NO

If NO, please provide information regarding a DSMP or independent study monitor

Who is the monitor or describe the expertise of the DSM Committee:

What will be monitored:

Stopping rules:

Frequency of monitoring reports:

* For commercially sponsored research:

Is there a DSMP or DSMC? \_\_\_\_\_\_\_ YES \_\_\_\_\_\_\_NO

If NO, please provide sponsor rationale and indicate how the site will receive information about study-wide adverse events or unanticipated problems involving risk to subjects or others?

* For NIH-sponsored studies:

Is this a National Clinical Trial Network (NCTN) study? \_\_\_\_\_\_\_ YES \_\_\_\_\_\_\_ NO

If NO, please provide information regarding a DSMP or independent study monitor

Who is the monitor or describe the expertise of the DSM Committee:

What will be monitored:

Stopping rules:

Frequency of monitoring reports:

If Jefferson is a subcontracted site of a multi-center NIH-sponsored trial, how often and by what mechanism will safety or other reports be received from the coordinating center?

7. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data.

8. The following steps must be taken to ensure that identifiable data remains confidential and secure. Please check each box to confirm your understanding. There are fields below to provide explanations and to describe deviations as well as additional measures.

1. A separate research chart must be maintained apart from the medical record/chart of the subject.
2. There are 18 identifiers described in 45 CFR 164.514 that make data identifiable. To be considered de-identified, data must not contain any of the identifiers (also see OHR-5 for list of identifiers).
3. When not in use, identifiable data should be stored in a locked cabinet or desk in a locked room.
4. Access to the data should be limited. Only the individuals who need the data should have access.
5. If hardcopies of identifiable data must be taken to another building, a locked container such as a banker bag should be used. The container should be marked with instructions for returning the container if misplaced.
6. If hardcopies of identifiable data must be mailed, there must be a contract in place which specifies the method of doing this. The data should be placed in one envelope inside of another envelope. Both envelopes should have tamper-evident seals and should be addressed to the specific recipient. Signatures should be required for receipt, or lockable mailboxes should be used.
7. If research data is stored on your work computer, encryption software must be installed on the computer. Contact IS&T if you are not sure if the encryption software is installed.
8. PHI may be emailed between Jefferson email addresses. Jefferson email must not be sent from or forwarded to a non-Jefferson email address such as your personal email.
9. Research data and PHI should not be stored on portable devices including laptops. If research data must be stored on a portable device, contact IS&T.
10. External monitors will only be given access to subjects’ medical records as specified in the signed consent form.
11. Research data and PHI must be maintained per Jefferson policies.

If you have any explanations for, or deviations to the items listed above, please describe them:

If applicable, please describe any additional measures that will be taken:

9. Will the subjects bear any costs that are not part of routine clinical care? \_\_\_\_Yes \_\_\_\_No

a.) If yes, please list the relevant tests, procedures, hospitalizations, etc., for which they would be liable.

b.) Are there means of subsidizing these extra costs for subjects who cannot afford them? If yes, please explain.

10. How will the cost of reasonably foreseeable medical care in the event of a research-related injury be covered? This information can be found in, and must be consistent with, the contract. Contact your contracts specialist with any questions.

\_\_\_\_Covered by the Commercial Sponsor

\_\_\_\_Covered by the Subject

\_\_\_\_Covered by Jefferson, Government, Philanthropy or other grant (Please identify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**PART B- SUBJECTS AND FACILITIES**

1. What is the expected number of subjects to be enrolled?

|  |  |  |  |
| --- | --- | --- | --- |
| **No. subjects per year** | **Total No. subjects** | **No. Subjects Nationally or Internationally (if applicable)** | **No. subjects at collaborating Institutions (if applicable)** |
| Up to: | Up to: |  |  |

2. Identify where the research will be conducted and describe the adequacy of facilities.

3. Please identify any facilities to be used for research other than those assigned to Department or division.

4. Describe provisions to protect the privacy of participants during the course of the study. (Privacy can be defined as the participant’s desire to control the ways in which s/he is approached and/or the ways in which his/her private information is shared with others.)

5. How has the research staff been trained regarding study protocol and their duties related to the protocol (in-service, investigator meeting, etc.)?

6. Within the study population, are the following groups eligible to be subjects in this study?

|  |  |  |
| --- | --- | --- |
|  | **Yes** | **No** |
| \*Women of reproductive potential |  |  |
| Pregnant women/fetuses/neonates (*if yes, and study is interventional or targets pregnant women, include OHR-27 as an addendum to the OHR-2*) |  |  |
| Men of reproductive potential |  |  |
| Vulnerable Populations (Please see list below) |  |  |
| Individuals with impaired decision-making capacity (check yes *only if research targets and could benefit this population)* Note: If yes, please also review and complete the information in this form for decisionally –impaired subjects. |  |  |
| \*Minorities |  |  |
| Prisoners (*if yes, notify the IRB in advance of the meeting*) |  |  |
| \*Economically or educationally disadvantaged persons |  |  |
| Students/employees |  |  |

7. If applicable, what additional protective mechanisms are in place to protect the rights and welfare of vulnerable populations?

8. If one of the populations with an (\*) in the table above are excluded, provide the reason.

Note: NIH policy requires that minorities and women be adequately represented as research subjects. If this is an NIH-funded study and you will be excluding either of these populations, you must provide a scientific reason for such exclusion.

**PART C- DRUGS AND DEVICES**

**I. General Information**

1. Identify all investigational drugs and/or devices to be used in this study and provide related information: *(please note that an approved drug is investigational if it is a test article/comparator in a research study)*

NA – No Investigational Drugs or Devices Used in this Study

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Drug or Device** | **IND# / IDE# / HDE#** | **Organization / Person Holding IND / IDE / HDE** | **FDA Approved** | **Not Being Used for Intended Indication** |
| Drug – Specify: | IND #: | Jeff - Specify:  Other - Specify: |  |  |
| Device – Specify: | IDE  HDE  #: | Jeff - Specify:  Other - Specify: |  |  |
| Drug – Specify: | IND #: | Jeff - Specify:  Other - Specify: |  |  |
| Device – Specify: | IDE  HDE  #: | Jeff - Specify:  Other - Specify: |  |  |

If research involves an investigational drug or device, the Principal Investigator (PI) will confirm that the IND/IDE/HDE numbers are valid by providing the IRB with one of the following:

* The sponsor protocol imprinted with the IND/IDE/HDE number
* A written communication from the sponsor documenting the IND/IDE/HDE number
* A written communication from the FDA documenting the IND/IDE/HDE number (required if an investigator listed on the protocol holds the IND/IDE/HDE)

2. When the investigator or Jefferson holds the IND/IDE/HDE, the Investigator/Jefferson becomes the “sponsor” of the research and assumes responsibility to ensure that all FDA regulatory criteria for sponsors are met. Please provide your plan for meeting FDA regulatory criteria for sponsors.

For example:

* Investigator who holds an IND/IDE/HDE will assign some or all responsibilities to meet FDA sponsor requirements to a contract research organization (CRO).
* Investigator will undergo an audit by a CRO to ensure that procedures are in place so that all FDA regulatory requirements of sponsors will be met.
* Investigator will assign responsibility of compliance with some FDA regulatory requirements to a CRO and investigator will obtain an audit from a CRO to ensure that procedures are in place so that all other FDA regulatory requirements of sponsors will be met.

NOTE: If you intend to use someone who is in-house and who has expertise on sponsor requirements, please justify that that person has equivalent expertise to a CRO.

3. Identify all non-investigational medications and/or devices specified in the protocol that the subject will receive while on this study. *This refers to drugs or devices that the subject will receive but are not being tested as part of this study.*

### II. Drugs

**Does study involve drugs?** YES \_\_\_\_\_ NO \_\_\_\_\_If no, delete the REST of this Drugs section.

1. Will the study drug(s) be dispensed by the Investigational Drug Service (IDS)? \_\_Yes \_\_ No

NOTE: The IDS must receive, track, and dispense drugs for all in-patient clinical trials. If this is an out-patient study and the IDS is not dispensing the study drug, please provide answers to each of the following questions and include a copy of the form you will use for documenting investigational drug receipt, storage and dispensing.

1. Where will drug be stored?
2. Who will have access to drug?
3. Who will maintain drug accountability logs, and dispense drug?
4. What measures to maintain security of drug storage and access are in place?

2. If sponsor is not supplying test article, where will it be obtained and who will pay for it?

3. Please briefly summarize relevant human clinical data related to the study drug. Also take note of the following:

* Standard of care drugs should be addressed only if they are part of randomized design in this study *(i.e., they are part of the research)*.
* Do not describe pre-clinical testing results unless they are relevant to a phase I study.
* Description of animal data should be very brief, such as: “Studies in mice revealed kidney damage (protein in urine) in very high doses in X% of animals.”
* For Phase II studies, briefly indicate the maximum tolerated dose and adverse effects found in phase I studies.

4. Please list the known side effects for each study drug.

5. Does this study include an off-label use of an FDA-approved drug? If yes, please explain.

6. If the investigational product does not have an IND#, please certify that its intended use meets at least one of the following FDA categories for IND exemption (21 CFR 312.2) by checking applicable statement(s). If none of the following categories apply, the sponsor must obtain an IND# or IND exemption letter from the FDA.

1. **Exemption Category 1** [21 CFR 312.2(b)(1)] – **All criteria for this category must apply**

\_\_\_ The drug product is lawfully marketed in the United States.

\_\_\_ It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;

\_\_\_ It is not intended to support a significant change in the advertising for the product;

\_\_\_ It does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

\_\_\_ It is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively]; and

\_\_\_ It is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7].

1. **In Vitro Diagnostic Biological Product** [21 CFR 312.2(b)(2)]

\_\_\_ The study is a clinical investigation involving a (a) blood grouping serum; (b) reagent red blood cells; and/or (c) anti-human globulin and the product is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure and it is shipped in compliance with Sec. 312.160.

1. **In Vitro and Animal Testing** [21 CFR 312.2(b)(3)]

**\_\_\_** A drug intended solely for tests in vitro or in laboratory research animals is exempt from the requirements of this part if shipped in accordance with Sec. 312.160.

1. **Use of Placebo** [21 CFR 312.2(b)(5)]

**\_\_\_** A clinical investigation involving use of a placebo is exempt from IND requirements if the investigation does not otherwise require submission of an IND.

7. Do you intend to invoke the exception from informed consent requirements for emergency research [21 CFR 50.24]? If so, investigational drug requires IND.

NOTE: The FDA reviews IND applications and makes a decision (exempt or requires an IND) within 30 days of receipt of the application. You may submit your proposal to the FDA and to the IRB for review simultaneously, but you may not initiate any research procedure(s) prior to meeting the IND requirements and obtaining IRB approval.

### III. Devices

1. **Does study involve a device?** YES \_\_\_\_\_ NO \_\_\_\_\_ If no, delete the REST of this Device section.

***If YES, please submit OHR-25 Investigational Device Worksheet.***

2. Does the study involve an in vitro diagnostic device? YES \_\_\_\_\_ NO \_\_\_\_\_

***If YES, please submit OHR-28 In Vitro Diagnostic Device Worksheet.***

3. Will the investigational device be purchased, stored and tracked via Supply Chain Management (Jefferson) or AJH Purchasing (Abington)? \_\_\_ Yes \_\_\_No

4. If no, please address the following:

1. Where will the device be stored?
2. What security measures are in place to prevent the device from being used in a patient who is not enrolled in the research study or by a physician not involved in the study?
3. Provide details as to how device will be tracked (logged in, stored, assigned to subject, implanted, etc.)

5. Who will teach investigators how to use the device and who will determine competence?

6. For Device Studies, certify below that you will meet the responsibility requirements for investigators found at 21 CFR 812 subpart E:

Study will be performed according to the signed agreement with the sponsor.

Study will not be initiated until FDA and IRB approval is obtained.

Informed consent will be obtained from all subjects after FDA and IRB approval is obtained.

Any financial conflicts of interest will be disclosed prior to starting the study and updated as appropriate during the conduct of the study.

Device will be disposed of as per sponsor directions and any remaining unused devices will be returned to the sponsor.

7. Please briefly summarize relevant human clinical data for the study device.

8. Please list the known or potential side effects for the device.

**PART D - RISKS, BENEFITS, AND ALTERNATIVES**

1. What are the risks of the research? *[Please note: this is not the same as the description of the known side effects of the test article(s). Examples include: time commitment requirements that impinge on daily activities, study drug ineffective, unpredicted adverse effects or drug interactions, anxiety about questionnaires, etc.]*

2. Discuss how the study design minimizes risks and maximizes benefits associated with this study. *(Consider number of subjects required to answer the research question, frequency of tests for adverse events, specific exclusion criteria, etc.)*

3. What are the potential benefits of participation?

4. Explain how the risks of the research are justified by potential benefit to the subject or society.

5. How would you treat this patient in a non-investigational setting? Please describe the treatment that is considered standard of care, as well as any alternative procedures or drugs or other courses of therapy that might be used, if such alternatives exist (include palliative care).

6. How do the risks and side effects of the standard therapies compare to those associated with the study therapy?

7. If this is a placebo-controlled trial, please provide rationale for use of placebo.

8. If subjects will not receive standard of care, provide rationale for this and address risks of not receiving standard of care.

9. Please address any risks associated with a “washout” period if applicable.

**PART E - CHILDREN**

1. Will this study involve children (age 17 or under)?

**\_\_\_ YES –** Complete form OHR-26, “Research Involving Children” and submit as an addendum to the OHR-2.

**\_\_\_ NO –** Delete the REST of this Children section and skip to Part F.

2. Discuss your plan for recruitment of children.

3. Describe standard of care related to this research for children (if relevant, i.e., what is the standard treatment of the condition being investigated in the age group to be studied)

4. Justify the age range of children to be enrolled.

5. Indicate the expertise of the research team with regard to children.

6. Describe the facilities to be used for children in this study.

7. Describe how the parental permission and child assent process (for 7-17 year olds) will be carried out.

**PART F – RECRUITMENT, EQUITABLE SELECTION, AND CONSENT PROCESS**

1. Discuss the recruitment plan and describe recruitment methods and materials (e.g., physician referral, newspaper ad, radio, TV spot, e-mail, etc.). *Please attach all relevant materials for IRB review and approval.*

Use of the University logo is dictated by University Policy. Guidelines regarding the logo’s use are described on the Creative Services website. Any variation from the standards requires approval according to the policy. Misuse of the University Logo may result in disciplinary action.

2. Will all qualified subject populations have adequate access to recruitment materials? Please explain.

3. Is the location and cultural setting of the research equally accessible to all qualified subject populations? If not, what can be done to make the location and setting more accessible?

4. Are non-English speaking participants anticipated?

(Please note that in general, non-English speaking subjects should not be excluded from studies with possible therapeutic benefit unless there is a valid scientific, ethical, or logistical reason.)

Please do one of the following:

1. Provide the rationale for excluding non-English speaking participants.

-OR-

1. The following steps will be taken if non-English speaking subjects are anticipated:

* A translated full consent form, in the subject’s language, will be IRB approved prior study initiation.
* All translated documents must be included with the IRB submission, along with proof of translation (certification from agency or name and qualifications of individual). Please note that this includes consent forms, recruitment materials, and all relevant patient-facing documents.
* At the time of the consent discussion, a translator will need to be present (in-person or via telephone interpreter service). The translator must be an adult who is fluent in both languages.
* All parties will sign the translated consent form.

-OR-

1. If the above process will not be used, please describe the process that will be used if non-English speaking subjects are anticipated:

Note: For additional information, including information about unexpected non-English speaking subjects, please see OHR Policy IC 705.

5. If you are requesting a waiver of written consent, describe the information that will be provided to participants.

6. Who will conduct the consent interview?

7. Who will provide consent or permission (e.g., subject, legally authorized representative, parent, caregiver, etc.)?

8. Where will the consent interview take place?

9. Provide a step-by-step description of the consent process.

10. Describe your plan to assess a person’s capacity to consent.

11. Will you seek assent from decisionally-impaired individuals? If so, describe your plan for obtaining assent. Note: If decisionally-impaired subjects will be included and are not capable of consenting themselves, the OHR-8 consent template must be submitted along with a simplified consent form (e.g., OHR-8C) and/or the surrogate consent form (OHR-8B).

12. Will the potential subject be informed of the research or be provided a copy of the consent to review prior to the actual time of consent? If so, how much time in advance? How much time will be available for the consent process?

13. What provisions will be made if the potential subject does not wish to proceed with the consent interview at the first encounter?

14. Is surrogate consent involved? YES \_\_\_\_\_\_ NO \_\_\_\_\_\_

15. Will subjects be paid or receive any other inducements for participating? If yes, please explain. *Please note that payment of subjects must be on a pro-rated basis unless there are compelling reasons not to prorate. There cannot be a requirement to finish all visits in order for subjects to be paid, as this is considered coercive.*

16. Describe any steps taken to minimize the possibility of coercion or undue influence.

17. The following list of procedures (referred to as MCARE procedures) is used to determine which investigator signature line option should be used in the consent form.

None - The study does not involve any of these procedures -OR- Check All that Apply:

1. Administration of anesthesia (local, general, conscious sedation, etc.)
2. Performance of surgical procedures
3. Administration of chemotherapy and therapeutic radiation
4. Administration of blood and/or human source products
5. Refusal to allow transfusion of blood and/or human source products
6. Insertion of a surgical device or appliance
7. Performance of abortion
8. Performance of sterilization
9. Performance of any HIV-related testing (See Policy #113.58, HIV Testing, for specific documentation requirements)
10. Performance of ECT
11. Administration of an experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner or the removal of bone, fluids or tissue for use in research or in the manufacture of a product. Experimental procedures and consent forms must be approved by the Institutional Review Board (“IRB”).
12. Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization
13. Performance of vaginal delivery/cesarean section

18. Based on the answer above, select the appropriate option for the investigator signature line. The option you choose must match the option in the consent form.

Include for studies involving MCARE procedures.

By signing below, you the physician investigator, certify that you and/or a qualified practitioner who is also a co-investigator or key personnel, reviewed the purpose, procedures, risks, benefits, and alternatives to participation with the study participant. The other elements of consent may be provided by properly trained and qualified key personnel.

Include for all other studies.

By signing below, you the investigator, certify that you, a co-investigator, or other properly trained and qualified key personnel, reviewed the elements of consent with the study participant.

19. If your study involves MCARE procedures, but you do not intend to have a physician investigator or a qualified practitioner who is also a co-investigator or key personnel review the purpose, procedures, risks, benefits, and alternatives to participation with the study participant, please provide the rationale.

20. A copy of the signed and dated consent form must be given to the subject and this must be documented. How will it be documented that subjects are given a copy of the signed and dated consent form? Check All that Apply:

Checkbox on the consent form

Consent Checklist

Progress Note

EPIC

Screening and enrollment log

A log indicating that each subject received or declined the consent form

Other (Indicate Method):

**PART G - STANDARD / EXPERIMENTAL RADIATION USE**

1. Does this study involve the use of radioactive material or radiation source?

**YES \_\_\_\_\_ NO \_\_\_\_\_**  If no, skip to Part H.

2. a.) Will the subject receive radiation greater than normally received in the course of standard therapy or diagnostic procedures? \_\_\_\_ Yes \_\_\_\_No

If YES, complete the OHR-32 and submit as indicated in the form.

b.) If yes, indicate what type of radiation the patient will be receiving:

\_\_\_\_\_\_ Diagnostic \_\_\_\_\_\_ Therapeutic \_\_\_\_\_\_ Both. If both please explain.

3. Is any radiation modality experimental? \_\_\_\_ Yes \_\_\_\_No

If yes, what are the risks associated with the experimental modality?

Please provide a copy of the approval letter from the Radiation Safety Committee when received.

**PART H - LOCATION/COLLABORATION**

1. This study involves research to be performed at/in/with *(check ALL appropriate entries)*:

Abington-Jefferson Health

East Falls (Philadelphia University)

Jefferson-Northeast

Jefferson Health-New Jersey

Jefferson-Center City

Jefferson as part of a multi-center, commercially sponsored study

Jefferson as part of an NCTN study

JKCCN sites (specify sites):

Rothman Institute (specify sites):

Methodist

Jefferson and Other Institution(s) *Please name institutions only for investigator-initiated and federally funded studies where data will be shared between institutions. Please provide copy of collaborating institution IRB approval letter if applicable. The OHR will effect IRB Authorization Agreements with collaborating institutions as required. Please name institutions:*

Collaboration with City Services *(City of Philadelphia IRB must approve study. For more information, go to* [*http://www.phila.gov/health/irb/*](http://www.phila.gov/health/irb/)*.) Please list collaborating city services:*

Unaffiliated Investigators. *Each will need to complete an unaffiliated investigator agreement available on the OHR website.* Please specify by name and role in study:

2. This question is not applicable if research is a commercially sponsored multi-center trial.

Will research be conducted in states other than Pennsylvania?  YES  NO

If YES, does research involve subjects age 17 or younger?  YES  NO

If YES to either or both, in what state(s) will research be conducted? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Below please (a) verify the age at which participants in such state(s) have the ability to consent to participation in research, including any medical treatments or procedures, if applicable and/or (b) verify the requirements for determining who may serve as a Legally Authorized Representative, including a guardian for a child to participate in research.  You must also provide information on any state specific regulations on privacy requirements and genetic research if applicable.  Please contact the Privacy Office for information, as needed.

Age at which participants have the ability to consent to participate in research: \_\_\_\_\_\_

State specific requirements: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

3. If the investigator is the lead investigator or Jefferson is the lead site in a multi-site study, please address the following:

1. Where is the repository for adverse events and unanticipated problems and how will information be disseminated to other sites?
2. Who will tabulate and disseminate interim results?
3. Who will provide information to other sites concerning protocol modifications?
4. Describe how information that is relevant to participant safety will be managed (i.e., notifying site investigators of SAEs and Unanticipated Problems Involving Risks to Subjects or Others, communicating DSMB or Interim Reports, etc.)
5. Is this study part of a cooperative single IRB submission?  YES  NO
   1. If yes, please attach documentation of approval by the Federal department or agency supporting or conducting the research or lead institution as part of your submission. IRB approval will NOT be issued until documentation has been received.
   2. List all institutions submitted as part of the cooperative single IRB submission:

**Collaborative Studies:** For investigator-initiated studies that are collaborative or multi-center, or for federally funded studies where Jefferson is the lead site, please provide documentation of approval by the Federal department or agency supporting or conducting the research or lead institution. If the collaborating institution does not have its own IRB, then the institution must first obtain a Federal-Wide Assurance (FWA) from the Office of Human Research Protection (OHRP). This registers the institution with the federal government for conducting human subjects research.

Unaffiliated investigators involved with this study should fill out an Unaffiliated Investigator Agreement, also available at the above Website address.

**PART I - CERTIFICATION**

Federal Regulations require the following responsibilities of the Principal Investigator. Please check those items to which you have conformed, and sign.

As Principal Investigator, I certify that: *(check appropriate boxes)*

I understand the federally-mandated responsibilities of a research investigator in conducting a clinical protocol.

I will conduct this clinical protocol in accordance with these responsibilities.

I will consent all subjects with an IRB-approved consent form, if applicable to the project, and store the consent forms in a safe repository.

I will provide all subjects with a copy of their signed and dated consent form.

All personnel have been appropriately trained for their assigned roles in this research.

If this study utilizes an investigational agent(s), the dose(s) of the agent(s) cited in the IRB internal forms and the consent form agrees with the dose(s) cited in the protocol.

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### Signature of Principal Investigator Date