Ascension

This document includes all questions in the eIRB SmartForm application.

All questions are visible here, but the electronic form includes branching, based on the study so when you are completing the form, you may or may not see each question.

Basic Study Information

1. * **Title of study:**

2. * **Short title:**

3. * **Brief description:**

4. * **What kind of study is this?**

5. * **Will an external IRB act as the IRB of record for this study?**
   ○ Yes ○ No

6. * **Local principal investigator:**
   Jackie Kirchen

7. * **Does the local principal investigator have a financial interest related to this research?**
   ○ Yes ○ No

8. **Which IRB should oversee this study?**

9. * **Attach the protocol:**

Document	Category	Date Modified	Document History
There are no items to display			

View: SF: Study Funding Sources (not integrated with Grants)

Study Funding Sources

1. * **Identify each organization supplying funding for the study:**

Funding Source	Sponsor's Funding ID	Grants Office ID	Attachments

There are no items to display

View: SF: Local Study Team Members

Local Study Team Members

1. **Identify each additional person involved in the design, conduct, or reporting of the research:**

   Name Roles Financial Interest Involved in Consent E-mail Phone

   There are no items to display

2. **External team member information:**

   Name Description

   There are no items to display

View: SF: Study Scope

Study Scope

1. * **Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?**
   ○ Yes ○ No

2. * **Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?**
   ○ Yes ○ No

View: asc_SF: Local Research Locations

Local Research Locations

1. **Identify research locations where research activities will be conducted or overseen by the local investigator:**

Location	Contact	Phone	Email
There are no items to display			

View: SF: Local Site Documents

Local Site Documents

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable)

   Document Category Date Modified Document History

   There are no items to display

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

   Document Category Date Modified Document History

   There are no items to display

3. **Other attachments:**

   Document Category Date Modified Document History

   There are no items to display

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

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Date: Thursday, October 14, 2021 3:28:47 PM Print Close

View: SF: Drugs

Drugs

1. * **List all drugs, biologics, foods, and dietary supplements to be used in the study:**

Generic Name	Brand Name	Attachment Name
caffeine	Cafcit	

2. * **Will the study be conducted under any IND numbers?**

● **Yes** ○ No

3. * **Identify each IND:**

IND Number	IND Holder	Other Holder
XXX123	Sponsor	

4. **Attach files:** (such as IND or other information that was not attached for a specific drug)

Document	Category	Date Modified	Document History
There are no items to display			

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View: SF: Devices

Devices

1. * **Select each device the study will use as an HUD or evaluate for safety or effectiveness:**

Device	Humanitarian Use Device	Attachment Name
There are no items to display		

2. * **Device exemptions applicable to this study:** IDE

3. * **Identify each IDE or HDE number:**

IDE / HDE Number	IDE / HDE Holder	Other Holder
There are no items to display		

4. **Attach files:** (such as IDE, HDE, or other information that was not attached for a specific device)

Document	Category	Date Modified	Document History
There are no items to display			

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View: SF: Study-Related Documents

Study-Related Documents

1. **Consent form templates:** (include an HHS-approved sample consent document, if applicable)

   Document Category Date Modified Document History

   There are no items to display

2. **Recruitment material templates:** (add templates for all material to be seen or heard by subjects, including ads)

   Document Category Date Modified Document History

   There are no items to display

3. **Other attachments:**

   Document Category Date Modified Document History

   There are no items to display

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other study-related documents not attached on previous forms

Ascension

Date: Thursday, October 14, 2021 3:08:00 PM Print Close

View: Copy of asc_ SF: sv_Subject Population

Subject Population

1. **State the number of subjects to be recruited both locally and nationally and number of research study sites (if multi-center study). List total as a single number, rather than a range:**

   * Recruitment Target Total for Local Site:

   If multi-center study:

   Number of Study Sites:

   Recruitment Target Total for All Sites:

2. * **Check all categories of Vulnerable Populations that are likely to be comprise the target population for this study:**

   There are no items to display

3. **Are there any demographic exclusions (i.e., gender, age race, ethnicity, language, etc.):**

Yes

Explain why this population is excluded:

Ascension

Date: Thursday, October 14, 2021 3:18:54 PM Print Close

View: Copy of asc_SF: sv_Vulnerable Population - Children

Vulnerable Population - Children

*** 1. Explain why it is necessary to involve children in this research:**

*** 2. Indicate your assessment of the risk level this study presents to children subjects:**

Greater than minimal risk to children subjects AND presents the prospect of direct benefit to the individual subjects.

Greater than minimal risk to subjects but does NOT present the prospect of direct benefit to the individual subjects.

The study does not fall into one of the 3 categories above but presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Select all that are applicable:

There are no items to display

Select all that are applicable:

There are no items to display

3. Check all safeguard options below that are relevant for the inclusion of children:

There are no items to display

Enter a brief summary for each safeguard checked above:

*** 4. Indicate how permission of parents or guardians will be addressed, select all applicable:**

Permission will be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Permission will be obtained from one parent only.

Waiver of parent permission will be sought.

*** Describe the rationale for seeking permission of only one parent:**

5. Indicate how assent of child subjects will be addressed:

(choose 1 only)

Assent will be obtained from all children.
Assent will be obtained from some of the children.
Assent will NOT be obtained from any of the children.

Briefly Describe Assent Process:

Briefly describe the rationale for not obtaining assent from some or all child subjects:

There are no items to display

6. Will this research involve wards of the state or any other agency, institution, or entity?

● **Yes** ○ No

Check each of the following that is true for your study:

There are no items to display

Provide detailed information about the proposed permission/assent process, as well as the identity and authority of the individuals who will provide permission for the Ward subjects.

Ascension

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View: Copy of SF: sv_Vulnerable Population - Pregnant Women and/or Fetuses

Vulnerable Population – Pregnant Women and/or fetuses

*** 1. Explain why it is necessary to include pregnant women and/or fetuses in this research:**

*** 2. Indicate your assessment of the risk level of the research for Pregnant Women and/or fetuses:**

Not greater than minimal risk and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means

Greater than minimal risk and the risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus

*** 3. Expected benefit of this research to the pregnant woman and/or fetus (mark all that apply)**

Research holds out the prospect of a direct benefit both to the pregnant woman and the fetus

Research holds out the prospect of a direct benefit to the pregnant woman.

There is no prospect of direct benefit for the woman or the fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

This research holds out the prospect of a direct benefit solely to the fetus.

This research will involve participants who are pregnant and meet the definition of "children" as defined in the federal regulations (45 CFR 46.402).

*** 4. Check all opinions below that are relevant for the inclusion of pregnant women and/or fetuses:**

Where scientifically appropriate, preclinical studies have been conducted and provide data for assessing potential risks to pregnant women and fetuses

Consent will be obtained.

Each individual providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate

No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

Individuals engaged in the research will have no part in determining the viability of a neonate nor in any decisions relative to termination of a pregnancy.

Select all that are applicable:

The pregnant woman

Both the pregnant woman and the fetus’ father (except that the father’s consent need NOT be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest).

Ascension

Date: Thursday, October 14, 2021 3:23:46 PM Print Close

View: Copy of SF: sv_Vulnerable Population – Cognitively or Decisionally Impaired Adults

Vulnerable Population – Cognitively or Decisionally Impaired Adults

*** 1. Explain why it is necessary to involve adults with cognitive or decisional impairment in this research.**

*** 2. Indicate your assessment of the level of risk this study presents to cognitively or decisionally impaired adult subjects.**

No greater than minimal risk to the participants.

The intervention or procedure presents an increase over minimal risk to participants AND offers the potential for direct individual benefit to the participant and is available only in the context of the research study.

The intervention is an increase over minimal risk which does NOT have the potential for direct individual benefit, but the knowledge sought has direct relevance for understanding participants' disorder or condition.

*** 3. Check all opinions below that are relevant for the inclusion of cognitively or decisionally impaired adults:**

A plan for assessing the capability of the subject has been developed and is fully described in the protocol or documents included with this IRB submission.

Verbal explanation of the research will be provided in lay language and to the extent of compatibility with the subject's understanding.

Extra time will be available to answer questions from the subject and/or caregiver during the consent process and throughout the study.

At the potential study participant's request, family members/significant others can participate in informed consent process.

If capable, the subject will personally sign and date the informed consent document.

Caregiver to assist with medications and identifying adverse events.

Subjects will be withdrawn if they appear to be unduly distressed.

Assent will be obtained from: (One of the following must be checked).

Extra Monitoring

Other

Assent obtained from -- Check One:

All subjects

Some subjects
None of the subjects

Describe "Some Subjects":

Describe "Extra Monitoring":

Describe "Other":

Ascension

Date: Thursday, October 14, 2021 3:24:26 PM Print Close

View: Copy of SF: sv_Vulnerable Population – Prisoners

Vulnerable Population – Prisoners

* 1. Explain why it is necessary to involve prisoners in this research:

* 2. Check all options below that are relevant for the inclusion of prisoners:

Verbal explanation of the research will be provided in lay language which is understandable to the subject population.

Procedures for selection of subjects within the prison will be immune from arbitrary intervention by prison authorities or prisoners.

Any advantages to the Prisoner through participation in the research, will not be of such a magnitude that his/her ability to weigh the research risks against the value of such advantages in the limited choice prison environment is impaired.

The risks involved in the research are commensurate with risks that would be accepted by non-Prisoner volunteers.

Assurance has been obtained that parole boards will not consider a Prisoner's research participation in making parole decisions, and each Prisoner will be clearly informed in advance that research participation will have no effect on his/ parole.

A provision has been made for examination or care of subjects after the end of their participation, taking into account the varying lengths of individual Prisoners' sentences, and for informing subjects of this fact.

Other

Describe "Other":

Ascension

Date: Thursday, October 14, 2021 3:28:31 PM Print Close

View: SF: sv_Non English Speaking Subjects

Non-English Speaking Subjects

1. Explain why it is necessary to include Non-English Speaking subjects in your study:

v

2. Describe what changes to study materials and communication will be used to ensure subjects are informed about their participation:

(Check all that apply)

Study consent form translated by a certified medical translator/ Ascension Translation Services.
Use of Ascension Interpreter services during the consent process and each visit/interaction.
Study team member is a certified medical interpreter.
Study materials, brochures, etc. will be available in applicable language(s).
Other (describe below)

Describe Other:

3. Describe any additional safeguards in place for protecting this population.

Ascension

Date: Thursday, October 14, 2021 3:25:15 PM Print Close

View: SF: sv:Other Vulnerable Populations

Other Vulnerable Populations

1. What other vulnerable populations do you plan to include in your study?

Physical Impairment
Life-Threatening Condition/Seriously Debilitating Illness
Economically Disadvantaged
Educationally Disadvantaged
Employees
Students/Residents/Fellows
Nursing Home Residents
Other

Describe "Other":

2. Explain why it is necessary to include any of these populations in your study:

3. Describe any safeguards you will use for protecting the vulnerable population(s).

Ascension

Date: Thursday, October 14, 2021 3:25:40 PM Print Close

View: Copy of SF: sv_Confidentiality

Confidentiality

1. * **Will you be accessing, recording, or using any individually identifiable data as part of this study?**
   (This includes data collected on tracking or enrollment logs):
   ○ Yes ○ No

Ascension

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View: Copy of SF: sv_Confidentiality Details

Confidentiality Details

Check the items below to explain how confidentiality and privacy of individually identifiable data collected for this study will be protected.
Members of the research team should only gather or share the minimum amount of Private Health Information (PHI) needed for the study.

* 1. Data Source

(please check all that apply):

Treatment or Test Results, Medical and/or Dental Records, etc.
Interviews
Survey or Questionnaire
Other – for example: audio, video, photographs (describe below)

Describe "Other":

* 2. Data Recording / Collection Method

(please check all that apply)**:**

Computer, Laptop, Smart Phone (or other similar device)
Paper (e.g., Notes, Case Report Form, etc.)
Other – for example: audio, video, photographs (describe below)

Describe "Other"

* 3. Describe all those who will have access to any individually identifiable information/data

(for example: PI, research coordinator, biostatistician, external collaborators, etc.)?

4. Describe the measures you will take to safeguard the information/data.

The collection of information will be limited to the minimum amount necessary to achieve the aims of the research.

Paper-based records will be kept in a secure location within an Ascension facility, will not be removed from the facility, and will only be accessible to study personnel.

Computer-based files will be stored ONLY on an Ascension server or other secure Ascension-owned, -affiliated or -approved location and ONLY made available to personnel involved in the study through the use of access privileges and passwords.

NO Removable media (such as CDs, thumb drives, etc...) will be used (if removable media must be used, please contact your IRB Office for further guidance)

Ascension's REDCap software will be used to gather and store the study data.

Regular back-ups of electronic data to a secure Ascension-owned location.

Records (data and biospecimens) will include ONLY indirect identifiers (unique code/key which could be used by the study team to identify a subject)

Prior to access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of identifiable information.

As soon as feasible, identifiers will be removed from study-related information.

A Certificate of Confidentiality has been obtained from the NIH.

Audio and/or video recordings of subjects will be transcribed then destroyed to eliminate the ability to identify subjects.

For FDA-regulated research: Electronic source data will be captured, reviewed & retained in accordance with FDA Guidance on Electronic Source Data in Clinical Investigations.

Other (describe below)

Describe "Other":

* **5. How long will you retain the data before discarding?**

(Note: Regulations require that Non-Health Data be retained for at least 3 years; and, Health Data must be retained for at least 6 years from the date the study participant signs the HIPAA Authorization Agreement. The retention period for FDA-regulated research is at least 2 years after the drug/device has received FDA approval. Sponsors and grantors may require different data retention periods. Other Federal, State, and local laws may impact this as well. Please check with your IRB Office if you are unsure how long your study data must be retained)

* **6. How will you discard the data?**

Ascension

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View: Copy of SF: sv_Sharing Data or Tissue

Sharing Data or Tissue

For this purpose, sharing may include releasing, transmitting or providing access to research and health data and/or tissue specimens within the research team, to research sponsors, etc. You must use reasonable safeguards when sharing any form of research data and/or tissue specimens.

*** 1. As a part of this study, will you share identifiable health data with anyone not listed as a sub-investigator or sponsor?**

○ Yes ○ No

*** 2. Do you plan, or does your sponsor's protocol require, banking tissue or other specimens locally for future use?**

○ Yes ○ No

Ascension

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View: Copy of SF: sv_Sharing Data

Sharing Data

*** 1. List the individuals or entities with which you will share identifiable health data as part of this study.**

(including those doing bio statistical or other data analysis for the study)**:**

.

*** 2. Please describe the methods of transmission which will be used to share this identifiable health data**:

Secure web site
Encrypted email
Fax in a secured area
Shared drive with password protection
US Postal Service or other trackable courier service
Private telephone conversation to authorized personnel
Other: (describe below)

Describe "Other":

.

Ascension

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View: Copy of SF: sv_Sharing Tissue

Sharing Tissue

*** 1. List the individuals or entities with which you will share the tissues or other sepcimans:**

.

*** 2. Describe where you will store the tissue or other specimens, how long they will be stored,**
how the specimens will be accessed, and who will have access to the specimens:

.

*** 3. List the data to be stored or associated with each specimen banked locally:**

.

*** 4. Describe the procedures you will follow to release locally banked data or specimens, including:**
the process to request a release, approvals required for release, who can obtain data or specimens,
and the data you will provide with the specimens:

.

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View: Copy of SF: sv_Recruitment

Recruitment

* **1. Provide a justification for the recruitment goal.**
(e.g. statistical justification)

* **2. Describe the reasonableness of recruiting the required number of suitable subjects with the agreed recruitment period.**
(i.e. number of potential subjects do you have access to, percentage of those potential subjects do you need to recruit)

* **3. Are there other active studies at your recruitment site that have overlapping eligibility criteria that might generate competition in recruiting subjects?**
● **Yes** ○ No

Describe the rationale for the overlap and any processes to address this.

* **4. How will potential subjects be identified?**
Databases
Medical Records
Advertisements
Newsletters
Physician Referral
Self Referral
Clinics/Offices
Other

Describe "Other":

* **5. Describe where recruitment materials will be posted, published or distributed or any other relevant details about how the materials will be used.**

* **6. Does the protocol include any activities that would need to meet institutional guidelines for marketing/communications.**
(i.e. recruitment material that is part of a news story or video recording done in a hospital)?
● **Yes** ○ No

*** 7. Will a study team member contact potential subjects directly for recruitment purposes?**

● **Yes** ○ No

Describe how you will obtain access to the potential subject's contact information.

How will identified potential subjects be contacted?

Letter (must be approved by IRB)
Phone Call (Script must be approved by IRB)
Face-to-Face
Other (describe below)

Describe "Other":

Who will be contacting the potential subjects?

Principal Investigator
Sub-Investigator/Co-Investigator
Research Coordinator/Research Nurse
Other

Describe "Other":

8. Before a potential subject signs a consent document, are there any screening questions that you need to directly ask the individual to determine eligibility for the study?

● **Yes** ○ No

Describe the questions that need to be asked, why, and whether any information is recorded

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View: Copy of SF: sv_Economic Burden

Costs and Compensation

* **1. Will the subjects bear any costs which are not part of the standard of care?**

● **Yes** ○ No

Describe the exams, tests, and/or procedures that subjects or their insurance are expected to pay for which are required for the study and are NOT part of routine care.

Provide justification for additional financial burden on subjects as a requirement for participation in this study.

2. If applicable, describe the available compensation in the event of research related injury.

This is required if the research involves more than Minimal Risk to Subjects.

* **3. Will subjects be compensated for participation in the study** (e.g., payment, free services, gifts, course credit, including extra credit)?

● **Yes** ○ No

Ascension

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View: Copy of SF: sv_Economic Burden Compensation

Subject Compensation Details

1. * **Explain the compensation arrangements**
   (e.g., amount and timing of compensation and the proposed method of disbursement), including reimbursement of expenses:

2. * **Justify the proposed compensation arrangements**
   (e.g., how this proposed compensation arrangement is not considered to be coercive):

3. **Explain if there will be any partial compensation if the subject fails screening or otherwise withdraws prior to completion of the study:**

* NOTE: Upload documents which detail the compensation arrangements, including any draft or final sponsor contracts, budgets and / or billing grids under "Other Attachments" on the "Local Site Documents" SmartForm

Ascension

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View: Copy of Informed Consent and HIPAA Auth

Informed Consent and HIPAA Authorization

*** 1. Do you want to request a waiver of consent, alteration of consent, or waiver of HIPAA Authorization for your study?**

○ Yes ○ No

Ascension

Date: Thursday, October 14, 2021 4:23:55 PM Print Close

View: Copy of Request for Waiver or Alteration

Request for Waiver or Alteration of Informed Consent and/or Waiver of HIPAA Authorization

* **1. Does this project utilize FDA regulated device or drug:**
● **Yes** ○ No

* **2. Are you requesting a Waiver of Informed Consent Procedures?**
● **Yes** ○ No

Does this request apply to the entire Subject population?
○ Yes ○ No

* **3. Are you requesting an Alteration of Informed Consent Procedures?**
● **Yes** ○ No

Does this request apply to the entire subject population?
○ Yes ○ No

Describe how the alteration deviates from normal consent procedures.

4. Describe why research involves no more that minimal risk to the individual.

5. Describe why the research will not adversely affect the rights and welfare of subjects.

6. Describe why the research would not be possible to conduct without a waiver or alteration of consent.

7. Describe if information will be provided to the subject once the research is complete, when appropriate.

* **8. Are you requesting a Waiver of Documentation of Informed Consent?**

● **Yes** ○ No

Check which of the following apply:
(Select 1 choice only)

The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.
The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

Describe the process. Note, if a written summary will be provided to the subjects, it must be reviewed and approved by the IRB.

* **9. Are you requesting a Waiver of HIPAA Authorization?** Note, this should be marked "Yes" if you will be accessing, using or disclosing PHI for research before signed HIPAA Authorization is obtained.

● **Yes** ○ No

Describe why there is minimal risk to the privacy of the subject.

The information will not be disclosed unless it is stripped of all identifiers
Data will be encrypted prior to any disclosure
Only the minimum necessary data in order to achieve the goals of the research will be sued
Access to the information will be limited within the study team
The study team will not re-use or disclose PHI to any other person or entity, except as required by law, research oversight
Other

Describe "Other"

Describe when identifiers will be destroyed.

Identifiers must be destroyed at the earliest opportunity consistent with conduct of research unless otherwise justified.

Upon completion of data collection
Upon completion of data analysis
Upon completion of specimen processing
Identifiers will be retained indefinitely
Other

Describe "OTHER"

Explain why identifiers will be retained indefinitely.

There are no items to display

Describe why the research cannot practicably be conducted without access to the PHI.

PHI is needed to identify subject eligibility
PHI is needed to answer the research question
Other

Explain the choice(s) above:

Summarize what protected health information (PHI) is needed

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View: Copy of SF: sv_Other Questions

Other Questions

* **1. Is this a Resident, Fellow, or Other Student project?**

○ Yes ○ No

If yes, provide the name(s) of the involved residents/fellows/students

First Name	Last Name	Email
There are no items to display		

2. If the study involves the use of gene therapy or recombinant DNA, at an Ascension facility, please provide a description of biomedical materials involved and the need for Institutional Biosafety Committee (IBC) review approval:

3. If the study involves exposure to radiation (including extra images) that are specifically done as part of the research (not considered standard care) please provide a description of radiation involved and the safeguards you will use:

* **4. Is this study interventional in nature** (e.g. drug or device trial; comparative effectiveness trial; etc.)?

○ Yes ○ No

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View: Copy of SF: sv_Research Resources

Research Resources

* **1. How many actively accruing research studies does the PI listed for this study have open?**
(including studies reviewed by IRBs other than your Ascension Ministry Market IRB)?

* **2. How many study participants are currently receiving study intervention for studies on which you are the PI**
(including studies reviewed by IRBs other than the Ascension IRB)?

* **3. How many research staff are supporting the PI in conducting the studies identified above?**
(research nurses/coordinators, data analysts, other)

First Name	Last Name	Role	FTE
There are no items to display			

* **4. Describe the average amount of time per month that you, as the PI, will devote to conducting**
and completing the research (your response should be in the form of hours/month)**:**