Clinical Site Details (IRB222815)

Protocol Information

Question 1

Are you submitting this protocol for the first time?

Answer

Yes

Question 2

Has this study been disapproved or withdrawn from another IRB?

Answer

N/A

N/A

Question 3

Are you transferring oversight from another IRB?

Answer

N/A

N/A

Question 4

Title of Protocol

Answer

test

Question 5

Protocol Number

Answer

test

Question 6

Study Duration

Answer

test

Question 7

Sponsor

Answer

test

Question 8

Funding Source

Answer

Industry

No Documents Uploaded

Investigator Information

Question 1

Investigator Name

Answer

test

Question 2

Investigator Email

Answer

test

Question 3

Sub Investigator Name

Answer

test

Question 4

Sub Investigator Email

Answer

test

Question 5

Primary point of contact if different from above

Answer

test

Question 6

Primary point of contact email address

Answer

test

Question 7

Has the investigator ever had an FDA audit?

Answer

No
N/A

Question 8

How long has the investigator been involved in research?

Answer

1-5 years

Question 9

What is the investigator's NPI if applicable

Answer

test

What training in the field of human subjects protection has the investigator completed?

- [x] OHRP Human Subject Assurance Training

Explanation

test

- [x] CITI Program Training

Explanation

test

- [ ] Certified Physician Investigator Training

Explanation

test

- [ ] ACRP training (CCRC, CCRA)

Explanation

test

- [ ] SOCRA (CCRP)

Explanation

test

- [ ] Graduate or undergraduate research studies or degrees

Explanation

test

- [ ] Academy of Physicians in Clinical Research

Explanation

test

☑ Other

Explanation

test

Question 11

What is the current number of research studies supervised by the investigator?

Answer

test

Question 12

Do you have any pending or active restrictions related to research or the practice of medicine?

Answer

Yes

Explanation

test

Question 13

Does your site have an FWA?

Answer

No

Question 14

Please provide FWA number

Answer

N/A

No Documents Uploaded

No Documents Uploaded

No Documents Uploaded

Study Information

Question 1

What type of research is being conducted?

Answer

Device
N/A

No Documents Uploaded

Informed Consent Form

What type of consent is required for this study?

- [x] No consent (requesting waiver of consent)

Explanation

gedg

- [x] undefined

Explanation

gedg

- [ ] Written, signed consent by subject

Explanation

gedg

- [x] Written, signed consent by legally authorized representative

Explanation

gedg

- [ ] Written, signed assent by minor

Explanation

gedg

- [ ] HIPAA authorization agreement

Explanation

gedg

- [ ] Waiver of HIPAA agreement

Explanation

gedg

- [ ] Online/website/electronic signature consent

Explanation

gedg

Question 2

Will HIPAA authorization language be included in the ICF (informed consent form)?

Answer

N/A

Question 3

Will the participants be compensated for participation in the study?

Answer

Yes

Question 4

Will the consent forms be offered in languages other than English?

Answer

No

Question 5

Have the dcument been translated by a professional translator?

Answer

N/A

N/A

No Documents Uploaded

The informed consent process is a continuous process and the IRB expects that proper subject consent is ensured by the investigator throughout the research study. To comply with the terms set forth by this IRB, the investigator must ensure that:

- No study procedures shall be conducted prior to completion of the informed consent forms which include subject or legally authorized representative (LAR) signatures and date, investigator or person obtaining consent signature and date, and providing a copy of the signed consent to the study participant.
- The identified research participant is given plenty of time to consider their participation in the study and all questions are answered. The identified research participant must be told that their participation in the study is voluntary and that they are under no obligation to participate. The potential participant must voice understanding before proceeding.
- The consent discussion must be in language understandable to the potential research participant's comprehension level.
- The informed consent discussion must be performed in a private setting free from other people who may overhear the discussion, such as a private exam room or other closed-door setting.
- Only the most current, IRB-approved consent forms may be used for enrollment.
- All efforts must be taken to ensure participant anonymity including:
    - Safe storage of subject identifiers-all subject identifiers must be coded and de-identified
    - Safe storage of subject identifiers-all subject identifiers must be coded and de-identified
    - All paper-based records will be stored in a double-locked area such as a locking filing cabinet inside of a locking door and only accessible to authorized staff.
    - All electronic-based records will only be accessed by authorized staff using secure login credentials.

☐ Your initials below signify that you have read the terms and agree with them:

Protocol Procedures

Which subject populations will be enrolled in the study?

- [ ] Adults

N/A

- [ ] Children (17 years and under)

N/A

- [ ] Blind/Visually Impaired

N/A

- [ ] Deaf/Hard of Hearing (including sign language communicators)

N/A

- [ ] Individuals with impaired decision-making (requiring a LAR, including those with impaired or diminished mental capacity, dementia, and those suffering from mental health disorders)

N/A

- [ ] Educationally Disadvantaged/Impaired or no reading skills

N/A

- [ ] Economically disadvantaged

N/A

- [ ] Healthy individuals

N/A

- [ ] Terminally ill individuals

N/A

- [ ] HIV positive

N/A

- [ ] Hospitalized

N/A

- [ ] Institutionalized (including nursing home, LTAC, assisted living, residential facility, mental hospital)

N/A

- [ ] Prisoners

N/A

- [ ] Military Personnel

N/A

- [ ] Pregnant women

N/A

- [ ] Human fetuses/neonates

N/A

- [ ] Non-English speakers

N/A

- [ ] Women only

N/A

- [ ] Men only

N/A

- [ ] Other

N/A

Which race and ethnic groups will be enrolled in the study?

- [ ] White, not of Hispanic origin

N/A

- [ ] White, of Hispanic origin

N/A

- [ ] Black, not of Hispanic origin

N/A

- [ ] Black, of Hispanic origin

N/A

- [ ] American Indian/Alaskan Native

N/A
- [ ] Asian

N/A
- [ ] Native Hawaiian/Pacific Islander

N/A
- [ ] Multiracial

N/A
- [ ] Other

N/A

Question 1

Will any subject populations be excluded from the study?

Answer

N/A

N/A

Question 2

How many subjects will be enrolled in the study?

Answer

N/A

What recruitment methods will be used in the study?

- [ ] In-person conversation during routine office visits

N/A
- [ ] Recruiting participants from previous research studies

N/A
- [ ] Mass print advertisements such as a newspaper, magazine, or billboard

N/A
- [ ] Flyer, poster, or bulletin board in office

N/A
- [ ] Radio or television ads

N/A
- [ ] Direct mail to potential subjects

N/A
- [ ] Internet including social media recruiting

N/A
- [ ] Chart review

N/A
- [ ] Telephone screening

N/A
- [ ] Other

N/A

Question 3

What is the location(s) name and address where the research procedures will take place?

Answer

N/A

Question 4

Will any samples or data collected in this study be retained for future research?

Answer

N/A

Please explain how the data and/or samples will be stored, secured, and de-identified. Include information on how the data and/or samples might be used for future research *

N/A

No Documents Uploaded

☐ Your initials below signify that you have read the terms and agree with them:

Submission Form

By submitting this application you attest to the following:

- Research will not commence prior to receiving the IRB approval letter.
- The principal investigator will personally supervise and/or conduct the study.
- The principal investigator ensures that all persons involved in conducting the study are trained and have proper credentialing for conducting research.
- Only the most current IRB-approved consent form will be used to enroll subjects.
- No changes will be made to the research protocol, consents forms, and all patient-facing materials without the approval of the IRB
- The study procedures will comply with all applicable laws and regulations regarding the conduct of research
- All findings from the study that directly affect subject safety will be communicated to subjects and to this IRB
- All serious adverse events (SAEs), whether related to the study procedures or not, will be reported to this IRB within 2 business days of the investigator becoming aware of the event for IRB safety review
- The sponsor agrees to submit and provide payment to this IRB for annual review yearly

☐ Your initials below signify that you have read and agree to the terms listed above