Continuin Review Details (IRB578940)

Risk Assessment

Question 1

Since the date of the last approval, has any regulatory agency including, but not limited to, the sponsor, statistical agency, medical monitor, data safety monitoring board (DSMB), or a data monitoring committee (DMC) provided any correspondence that has not yet been reported to the IRB?

Answer

Yes

Explanation

Since the date of the last approval, has any regulatory agency including, but not limited to, the sponsor, statistical agency, medical monitor, data safety monitoring board (DSMB), or a data monitoring committee (DMC) provided any correspondence that has not yet been reported to the IRB?

Uploaded supporting documents

1725004316210-651-1705563391376-ReferredTo (2).pdf

Question 2

Since the date of the last approval, have you encountered any unanticipated problems? Unanticipated problems involve risks to subjects or others and include any incident, experience, or outcome that meets all of the following criteria:

- 1. is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied:
- 2. is related or possibly related to a subject's participation in the research; and
- 3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

Answer

Yes

Explanation

Since the date of the last approval, have you encountered any unanticipated problems? Unanticipated problems involve risks to subjects or others and include any incident, experience, or outcome that meets all of the following criteria: 1. is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied: 2. is related or possibly related to a subject's participation in the research; and 3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

Informed Consent Process

Question 1

Which version of the ICF are you currently using?

Answer

Test2

Uploaded the most recent ICF

1725005718206-519-1705328092698-ReferredTo.pdf

Question 2

Who is performing the informed consent at your site?

Answer

Test2

Question 3

Have there been any challenges faced to the consenting process?

Answer

Yes

Explanation

Test2

Question 4

Have there been any changes to the consent form that have not been reported to the IRB?

Answer

Yes

Explanation

Test2

Question 5

Are you ensuring that:

- 1. The participants are made aware that their participation is voluntary and that they may choose to withdraw at any time?
- 2. The participants are provided with a copy of the informed consent form to take home?
- 3. The participants are provided with the most up-to-date contact information for study staff?
- 4. The investigator is providing the most current information regarding the study that may affect the participants' willingness to participate in the study?

- 5. All participants have been consented or re-consented, where necessary, with the most current approved informed consent form?

Answer

Yes

Explanation

Test2

Uploaded new informed consent form

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Investigator and Institution Information

Question 1

Have there been any changes in the investigator’s situation or qualifications?

Answer

Yes

Mark all that apply

- [x] suspension of hospital privileges
- [x] change in medical license status
- [x] increase in number of research studies conducted by the investigator
- [ ] expired or updated human research protections training

Uploaded supporting documents here

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Question 2

Have there been any investigation of or complaints related to the investigator’s conduct of research?

Answer

Yes

Explanation

sdfdsfsdf

Uploaded supporting documents here

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Question 3

Have there been any changes in the facility’s ability to adequately support the research protocol?

Answer

Yes

Mark all that apply

- [x] Personnel changes
- [x] Financial resource changes
- [x] Change in facility address
- [x] Change in facility resources (ie: loss of laboratory space or licensure, loss of adequate storage space, structural damage or changes to the physical facility)
- [x] Other

Please describe the changes and explain in as much detail as possible. Please provide any solutions, whether temporary or permanent, work-arounds, and/or protocol adjustments

N/A

Uploaded supporting documents here if applicable (ie: new informed consent with facility address change, updated protocol to reflect facility changes, updated delegation of authority log, etc.)

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Have these changes been reported to the IRB?

N/A

Question 4

Have there been any changes in facility regulations, standard operating procedures, or standards of professional conduct?

Answer

Yes

Explanation

Have there been any changes in facility regulations, standard operating procedures, or standards of professional conduct?

Uploaded supporting documents here

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Question 5

Have there been any changes to state or local law regarding research that affects the conduct of research?

Answer

Yes

Explanation

Have there been any changes to state or local law regarding research that affects the conduct of research

Research Progress

Question 1

Total Subjects Enrolled

Answer

weqwewqe

Question 2

How many subjects have discontinued their participation?

Answer

wqewqewq

Out of that number, how many subjects withdrew of their own accord

N/A

Describe the reasons for withdrawal

N/A

how many subjects were terminated before completion of the protocol by the decision of the PI, Sponsor, or other contracted research personnel

N/A

Describe the reasons for termination

N/A

Question 3

How many adverse events have occurred since the last approval?

Answer

qweqwewq

Have these events been reported to the IRB?

N/A

What was the reason the adverse events were not reported to the IRB?

N/A

Please describe the adverse events including what occurred, the timeline in which it occurred, and the time at which the study personnel became aware of the adverse event

N/A

Uploaded any supporting documents

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Question 4

How many subject have completed the study per protocol?

Answer

qwewqewqewq

Question 5

Have there been any updates/changes to the protocol since the last approval?

Answer

Yes

Have these changes been reported to the IRB?

N/A

Explanation

qweqweqwewqewqe