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

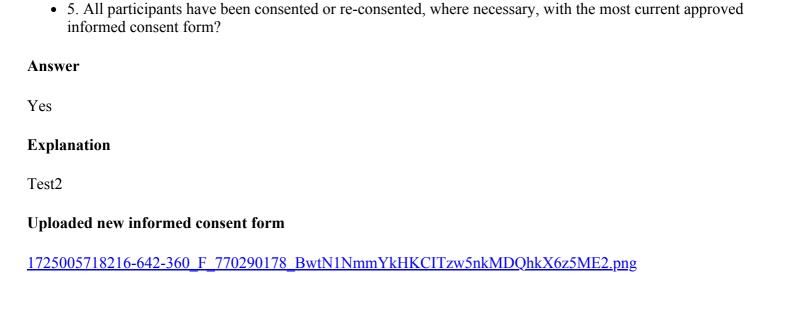
Since the date of the last approval, have you encountered any unanticipated problems? Unanticipated problems involve risks to subjects or others and include any incident, experience, or outcome that meets all of the following criteria: 1. is unexpected (in terms of nature, severity, or frequency) given (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 **Ouestion 2** Who is performing the informed consent at your site? Answer Test2 **Ouestion 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?

participants' willingness to participate in the study?

• 4. The investigator is providing the most current information regarding the study that may affect the



Investigator and Institution Information Question 1 Have there been any changes in the investigator's situation or qualifications? **Answer** Yes Mark all that apply ✓ suspension of hospital privileges ✓ change in medical license status ✓ increase in number of research studies conducted by the investigator expired or updated human research protections training Uploaded supporting documents here 1725006403773-331-360 F 770290178 BwtN1NmmYkHKCITzw5nkMDOhkX6z5ME2 2.png **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 <u>1725006403780-949-360 F 770290178 BwtN1NmmYkHKCITzw5nkMDQhkX6z5ME2-removebg-preview</u> (1).png **Question 3** Have there been any changes in the facility's ability to adequately support the research protocol?

Answer

Yes

Mark all that apply

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

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

Uploaded any supporting documents 1725006403794-968-360 F 770290178 BwtN1NmmYkHKCITzw5nkMDQhkX6z5ME2-removebg-preview.png 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

qweqwewqewqe