Closeout Report

Protocol Number: 1812779814
Submission Type: Request to Close
Title: Randomized Controlled Trial of XYZ Drug
Principal Investigator: Waltz, Amy Catherine
Report Printed: 01/17/2019

• ID #25320: Select the appropriate status of the study
  - Study will not be initiated
  - Study closed prior to completion
  - Study completed

  □ Study will not be initiated
  □ Study closed prior to completion
  ◼ Study completed

• ID #370: Since the beginning of the study, how many subjects have been consented?
  ◼ 25

• ID #371: Since the beginning of the study, how many subjects failed screening?
  ◼ 0

• ID #372: Since the beginning of the study, how many subjects have withdrawn from the study?
  ◼ 0

• ID #382: State the total number of VA subjects consented, or VA records or specimens reviewed or collected.
  ◼ 13

• ID #383: Select all of the additional categories in which the VA subjects, records, or specimens fall, and indicate the number of subjects in the box provided.
  ◼ Children

  □ Individuals Lacking Consent Capacity:
  □ Economically/Educationally Disadvantaged:
  □ Pregnant Women and Fetuses:
  □ Prisoners:
  □ Students of the Investigators:
  □ None of the Above

• ID #400: Since the last IRB review, did any events occur that required prompt reporting to the IU IRB?
  □ Yes
  ◼ No

• ID #404: Since the last IRB review, did any minor deviations or minor noncompliance occur at an IU-IRB approved performance site that did not require prompt reporting to the IRB?
  □ Yes
  ◼ No

• ID #25374: Since the last IRB review, did any adverse events occur at a greater frequency and/or severity than was previously expected based on the current protocol, informed consent document, and/or investigator's brochure?
  □ Yes
Closeout Report

☒ No

• ID #407: Is there a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) for this study?
  ☐ Yes
  ☒ No

  • ID #25325: Summarize the data safety monitoring findings since the last IRB review, explain why findings are not available, or indicate that a summary or report has been uploaded in the attachments section above.
        ☒ Test

  • ID #25326: Describe any observations and information about study results or trends.
        ☒ Test

  • ID #409: Have subjects experienced any direct benefit(s) from their participation in the study?
      ☒ Yes
      ☐ No

      • ID #410: Describe the direct benefit(s) to subjects.
          ☒ Test

  • ID #25327: Have any of the following occurred since the last IRB review? Choose all that apply.
    ☐ Literature publication which demonstrates a significant impact on the conduct of the study, or the well-being of subjects
    ☐ Audit from federal agencies which identified unanticipated problems involving risks to subjects or others or noncompliance
    ☐ Events which affected the validity of the data
    ☐ Increase in risk to subjects or others
    ☐ Investigator brochure update
    ☐ Change in the risk to benefit assessment
    ☒ None of the above

Authorized IRB Signature:  Clark Kent                   IRB Approval Date: 11/17/19

Printed Name of IRB Member:  Clark Kent