KC IRB
Protocol #: 1812779814
Investigator: Waltz, Amy Catherine
Summary Printed 01/17/2019

KC IRB
Protocol Summary

Protocol Number: 1812779814
Title: Randomized Controlled Trial of XYZ Drug
Status: Submitted to IRB
Expiration Date:
Last Approval Date:
Investigator: Waltz, Amy Catherine

Protocol Details
Type: Expedited
Application Date: 01/17/2019
IU or Investigator held IND/IDE?
FDA Application No:

Organizations

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Funding Source

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Subjects

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Areas of Research

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Personnel

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<td>Waltz, Amy Catherine</td>
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## Personnel

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## Questionnaires

**Label**

- A - Level of Review Assessment
- B - Lay Summary & Research Design
- C - Sites & Collaborations
- D - Recruitment Methods
- E - Risks, Benefits, Protections
- F - Data Safety Monitoring
- G1 - Children
- H - Informed Consent Process
- J - Child Assent & Parental Consent Process
- K - HIPAA
- L - VA Research
- M - ClinicalTrials.gov
- Conflicts of Interest
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IRB APPROVAL

This research project, including all noted attachments, has been reviewed and approved by the Indiana University IRB.

☐ Exempt Category(ies), if applicable:

☒ Expedited Category(ies), if applicable: (2) (4) (5) (7)

☒ Study meets the criteria of approval for a period of: ☒ one (1) year ☐ other, __________________

☐ Study meets the criteria of approval and per IU HRPP Policy, renewal is not required for this protocol.

Reviewing IRB Committee: IRB-02
Level of Review: Expedited

Authorized IRB Signature: ___________________________ IRB Approval Date: 1/17/2019

Printed Name of IRB Member: Avril Pitt