ClinicalTrials.gov
Protocol Registration System

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Create New Protocol Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. **Section 801 studies may only be registered by the Responsible Party.** If this is an applicable clinical trial as defined by US Public Law 110-85, Title VIII, Section 801, ensure that your organization is the Responsible Party as defined by the law before registering the study.
2. **IND/IDE studies may only be registered by the IND/IDE holder.** If the study is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE), ensure that your organization is the IND/IDE holder before registering the study.
3. **For NIH-funded studies, coordinate with the relevant Institute or Center.** If this is a US National Institutes of Health (NIH) funded study, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.
4. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the sponsor (primary organization that oversees implementation of study and is responsible for data analysis) or its designated principal investigator (PI).
5. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization, as sponsor or its designated PI, is registering the study.

Unique Protocol ID: *

Brief Title: *

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* Required by ClinicalTrials.gov
FDAAA Required to comply with US Public Law 110-85, Section 801
(FDAAA) May be required to comply with US Public Law 110-85, Section 801