I. Protocol Information

Protocol number: 12-N-3772
Z Number
Principal Investigator Name: Sridevi Sharvirala, D.O., Ph.D.
PI Contact Information:
Branch/Institute: CNS / NINDS
Office: 31 CENTER DR RM 8A27 BETHESDA MD 20892
Phone:
Email: sharviralas@mail.nih.gov

Protocol Title: protocol title sadfsdf

Precis: Precis qweqweqw

Accrual/Recruitment Status:
☐ No Recruitment Planned
☐ Not Yet Recruiting
☒ Recruiting
   ☒ Enrolling by Invitation
☐ Suspended
☐ No Longer Recruiting, subject follow-up only
☐ Open for Data Analysis

☐ If Expanded Access Study Update Status:
   ☐ Available: expanded access is currently available for this treatment.
   ☐ No longer available: expanded access was available for this treatment previously but is not currently available and will not be available in the future.
   ☐ Temporarily not available: expanded access is not currently available for this treatment, but is expected to be available in the future.
   ☐ Approved for marketing: this treatment has been approved for sale to the public.

Anticipated Date that the protocol will complete data 03/10/2014
Primary Completion 03/31/2014
II. Study Population

Are you currently recruiting?
- [x] Patients
- [ ] Healthy Volunteers
- [x] Other Volunteers
- [x] NIH Employees
- [x] Non-English Speaking
- [x] N/A

Does this research involve vulnerable or other special populations?
- [x] Children
- [x] Children who are wards of the state
- [x] Prisoners
- [x] Pregnant Women, Fetuses, or Neonates
- [ ] Adults who are or may be unable to consent
- [x] N/A

III. Enrollment Information

Summary of Protocol Enrollment:

<table>
<thead>
<tr>
<th>NIH/CC</th>
<th>Other Domestic Sites</th>
<th>Foreign Sites</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>4</td>
<td>12</td>
</tr>
</tbody>
</table>

If the protocol is open to accrual but there has been no subject accrual, or accrual was lower than expected during this past year, provide an explanation below:

sdasd

Has analysis by Sex/Gender, Racial, and/or Ethnic Subgroups for Phase III clinical trials been conducted and have significant differences been found?

- [x] Yes
  - a. Have analyses been reported? [ ] Yes [x] No
  - b. Have significant differences been [x] Yes [ ] No

- [ ] No
- [ ] N/A

If yes, please describe any differences found: dsfsdf
IV. Ionizing Radiation Use

- None
- Ionizing radiation exposure – medically indicated
- Ionizing radiation exposure – research indicated
  - Research usage HAS NOT changed
  - Research usage HAS changed

Radiation Safety Approval

V. Investigational New Drug/Device/Biologic/Tobacco Product

This protocol is/is not subject to US Food and Drug Administration regulations or under an Investigational New Drug (IND) Application, Investigational New Biologic (BB IND) Application, Investigational Device Exemption (IDE) or Investigational Tobacco Product

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Type</th>
<th>Number</th>
<th>Sponsor Name</th>
<th>Monitoring Entity</th>
</tr>
</thead>
<tbody>
<tr>
<td>46</td>
<td>4</td>
<td>DRUG</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Commercially approved products used to test the research hypothesis

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer(s)</th>
<th>Used as indicated</th>
<th>Off Label</th>
</tr>
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<tbody>
<tr>
<td>4</td>
<td>4</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Does the protocol involve a drug/device/product that may lead you or the NIH to receive payment or royalties? Yes No

VI. Will the protocol involve any Tech Transfer Agreements?

- Yes
  - CDA – Confidential Disclosure Agreement
  - CTA – Clinical Trials Agreement
  - CRADA – Cooperative Research and Development Agreement
  - MTA – Material Transfer Agreement/Human Material Transfer Agreement
  - MOU – Memorandum of Understanding
  - Other, hgljj

- No

VII. Conflict of Interest

Has the Personal Financial Holdings Form (PFH) form been completed and submitted to the Deputy Ethics Counselor? Yes No

Date submitted to 03/10/2014 Date cleared by 03/31/2014

VIII. Progress Information

**Description of protocol progress/findings from this research:**

Have any amendments been approved since the last continuing review? No Yes

Have any unanticipated problems (UPs) occurred since the Initial Review (IR) or last CR? No Yes

**Summary of unanticipated problems (UPs), reportable adverse events and deviations/violations as defined in the protocol since the last CR and in aggregate since the**
Have any subjects withdrawn from the study? ☐ No ☑ Yes

Is this study monitored by a DSMB/SMC? ☐ No ☑ Yes

If yes, date of the last DSMB/SMC review

Has any information appeared in the literature, or evolved from this or similar research (published/unpublished), that might affect the IRB’s evaluation of the risk/benefit analysis of human subjects involved in this protocol? ☐ No ☑ Yes

Risk/benefit assessment: 

Updated list of publications for this protocol for this reporting period: 

Provide a justification for continuation of the protocol: 

IX. Signatures

Principal Investigator Signature*  
Print Name  
Date

Accountable Investigator Signature  
Print Name  
Date

Branch Chief/CC Department Head Signature**  
Print Name  
Date

X. Approvals

IRB Chair Signature  
Print Name  
Date

Clinical Director Signature  
Print Name  
Date

XI. Concurrence

OPS Protocol Specialist Signature  
Print Name  
Date

* Signature signifies that investigators on this protocol have been informed that the collection and use of personally identifiable information at the NIH are maintained in a system of record governed under provisions of the Privacy Act of 1974. The information provided is mandatory for employees of the NIH to perform their assigned duties as related to the administration and reporting of intramural research protocols and used solely for those purposes. Questions may be addressed to the Protrak System Owner.

** I have reviewed this research project and considered the NIH Policy for Inclusion of Women and Minorities in Clinical Research. Taking into account the overall impact that the project could have on the research field involved, I feel the current plans adequately includes both sex/gender, minorities, children, and special populations, as appropriate. The current enrollment is in line with the planned enrollment report for inclusion of individuals on the basis of their sex/gender, race, and ethnicity and is appropriate and of scientific and technical merit.