## Principal Investigator and Department Information

<table>
<thead>
<tr>
<th>Name:</th>
<th>Phone Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>School:</td>
<td>Dept:</td>
</tr>
<tr>
<td>Email:</td>
<td>PIC #:</td>
</tr>
</tbody>
</table>

## Clinical Research Coordinator Information

<table>
<thead>
<tr>
<th>Name:</th>
<th>Phone Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email:</td>
<td>Fax Number:</td>
</tr>
</tbody>
</table>

## Research Administrator Information (with Clinical Trials Functions)

<table>
<thead>
<tr>
<th>Name:</th>
<th>Phone Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Email:</td>
<td></td>
</tr>
</tbody>
</table>

## Primary Department Contact For Questions

- [ ] PI
- [ ] Coordinator
- [ ] Other

| Name: | Email: | Phone: |

## Additional Budget / MCA contacts

Specify the name and email address of other individuals besides others listed above who also need to receive a copy of the completed budget and MCA.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Email Address:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Email Address:</td>
</tr>
</tbody>
</table>

## Agreement Type

- [ ] Industry-initiated CTA
- [ ] Investigator initiated CTA
- [ ] Study Order under Master CTA
- [ ] Incoming subcontract from another institution
- [ ] Other (Specify): |

## Study Information

<table>
<thead>
<tr>
<th>Sponsor:</th>
<th>Protocol Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study acronym/short title:</td>
<td></td>
</tr>
<tr>
<td>Official Protocol Title: (as it appears on the Protocol)</td>
<td></td>
</tr>
<tr>
<td>Primary Objective(s) of Trial:</td>
<td></td>
</tr>
<tr>
<td>Is therapeutic intent a primary objective of the trial? [ ] Yes [ ] No</td>
<td></td>
</tr>
<tr>
<td>Estimated number of Emory subjects:</td>
<td></td>
</tr>
<tr>
<td>Estimated start date (month/year)</td>
<td>Length of study: [ ] Month(s) or [ ] Year(s)</td>
</tr>
</tbody>
</table>

## Type of Study (check all that apply):

- [ ] Drug(s) [ ] If Yes IND #
- [ ] Device(s) [ ] If Yes IDE # [ ] IDE Exempt
- [ ] Data registry (no intervention)
- [ ] Behavioral intervention
- [ ] Investigator initiated [ ] If Yes, registered with ClinicalTrials.gov? [ ] Yes [ ] No
- [ ] Other (Specify): |

## Trial funded by:

Specify funding type:
| AHRQ | Discretionary Fund | Industry Sponsor | Not Funded |
| CDC | DOD | Internal, Departmental | VA |
| CMS | Foundation | NIH | Other (Specify): |

Have you submitted to the study for IRB approval?
- Yes
- If Yes, Status: Yes
- No
- If No, Date application will be submitted: /

Specify the primary Emory site where subjects will be seen:

| Specify all other collaborating locations where subjects will also be seen. Check all that apply |
| Academic Medical Center | Grady Clinic |
| CHOA Egleston | Grady Memorial Hospital (GMH) |
| CHOA Scottish Rite | Hope Clinic |
| Emory Crawford Long Hospital (ECLH) | Ponce de Leon Clinic |
| Emory Children’s Center (ECC) | Veterans Administration Medical Center (VAMC) |
| Emory Children’s Clinic | Wesley Woods (WW) |
| Emory Clinic (TEC) | Other: |
| Emory University Hospital (EUH) | Other: |

Will subcontracts be required?
- Yes
- No
- If yes, Sub 1 name:
- Sub 2 name: |
- Sub 3 name: |
- Sub 4 name: |

For Drug/Device trials only, please complete the following:

<table>
<thead>
<tr>
<th>Drug Trial Phase</th>
<th>Device Category</th>
<th>Provided free by Sponsor?</th>
<th>FDA Approved?</th>
<th>Approved for this indication?</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>A</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>II</td>
<td>B</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>I/II</td>
<td></td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>III</td>
<td></td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>IV</td>
<td></td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
</tbody>
</table>

Effective November 1, 2007, Phase III Industry Initiated, Industry Sponsor, and Industry Funded clinical trials are routed through Western Institutional Review Board (WIRB). Will this trial go to (WIRB)?
- Yes
- No

Sponsor Information

<table>
<thead>
<tr>
<th>Sponsor Contract Contact:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sponsor Contract Address:</td>
</tr>
<tr>
<td>Sponsor Contract Email:</td>
</tr>
<tr>
<td>Sponsor Contract Phone Number:</td>
</tr>
</tbody>
</table>

FedEx # to send contract: Acct# is for [ ] Sponsor [ ] CRO [ ] Depart.
Is the Sponsor the Primary Contact for Budget Work? [ ] Yes [ ] No
If Yes, Sponsor Budget Contact Name: |
If Yes, Sponsor Budget Contact Mailing Address: |
If Yes, Sponsor Budget Contact Email: |
If Yes, Sponsor Budget Contact Phone Number: |

Contract Research Organization (CRO) Information

<table>
<thead>
<tr>
<th>Name of CRO:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRO Contract Contact:</td>
</tr>
<tr>
<td>CRO Contract Address:</td>
</tr>
<tr>
<td>CRO Contract Email:</td>
</tr>
<tr>
<td>CRO Contract Phone Number:</td>
</tr>
</tbody>
</table>

Is the CRO the Primary Contact for Budget Work? [ ] Yes [ ] No
If Yes, CRO Budget Contact Name:
If Yes, CRO Budget Contact Mailing Address:
If Yes, CRO Budget Contact Email:
If Yes, CRO Budget Contact Phone Number:

Certification Information

Intellectual Property / Data Use Concerns:
Did the PI develop or assist in the development of this protocol? □ Yes □ No
Do you anticipate an invention resulting from this study? □ Yes □ No
If yes, please explain:
Do you intend to use the data from this study for other purposes (i.e. future grant submission or studies)? □ Yes □ No

Certification Information

Conflict / Restriction Concerns:
Is the PI, any employee or student involved in this project debarred, suspended or otherwise excluded from participation in federal or healthcare programs/activities? □ Yes □ No
Are you doing any related research for another party including another private company or government sponsor that would conflict with this study? □ Yes □ No

Attachment Checklist Requirements
Email all appropriate attachments listed below as a package to ClinicalTrials@Emory.edu

☐ Protocol
☐ Study Schema Schedule of Events – List of all procedures to be performed & included
☐ Clinical Trial Agreement
☐ Investigator Effort Calculations Report
☐ Draft Budget
☐ IND Approval Letter or IND Exempt Letter
☐ Informed Consent – Sponsor Draft ☐ Informed Consent – Emory Draft
☐ Most recent FDA Communications (Ex: IND Letter, IDE Category Assignment Letter, Study Specific Correspondence from FDA)

The following must also be delivered to the Clinical Trials Office before any work can begin. Please deliver to 1599 Clifton Road NE., 5th Floor. Attention: Pre-Award Program.
☐ Signed SPAF ☐ Signed “Blue Sheet”

OSP Internal Use Only

UPN# Reference #