**Summary Checklist**

*Enter the required information for each item listed below. If not applicable, please state so.*

1. **Protocol IRB submission date and last approval.**
2. **Accrual to date**
3. **Remaining accrual**
4. **IND agents or IDE devices and when issued**
5. **Sources of investigational agents or devices (with letter of support, provide letter under the IND/IDE section)**
6. **If amending protocol to address new question, date of amendment and accrual time frame for new cohort**
7. **Other sources of funding. Please explain in budget justification how there is no overlap**