

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