**RESEARCH PROTOCOL SUMMARY**

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| --- | --- |
| **PRINCIPAL INVESTIGATOR:** |  |
| **CO-INVESTIGATOR:** |  |

**PROTOCOL SUMMARY**

|  |  |
| --- | --- |
| **STUDY TITLE:** |  |
| **STUDY NUMBER:** |  |
| **PROTOCOL DATE/VERSION:** |  |
| Drug or Device/Generic and Trade Name/Manufacturer: |  |
| Study Population (inclusion/exclusion criteria): |  |
|  |  |
| Study Objectives(s): |  |
|  |  |
| Current standard of care and/or alternatives: |  |
|  |  |
| Risks and benefits of the study treatment: |  |
|  |  |
| Drug Dosage/route/rate/schedule: |  |
|  |  |
| Drug Information:  | **[ ]** Internal Device [ ]  External Device |
| Side Effects: |  |
|  |  |
| Treatment Modification: |  |
|  |  |
| Schedule of study related tests/procedures: |  |
|  |  |
| Study Design: | **[ ]** Randomized double blind – number of arms      [ ]  Open label |
|  | **[ ]** Other: |  |
| How long will subjects participate in the treatment phase and follow-up phase? |  |
|  |  |
| How many subjects are to be enrolled at this site? |  |

Signature:       Date: