**RESEARCH PROTOCOL SUMMARY**

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

**PROTOCOL SUMMARY**

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| **STUDY TITLE:** | | | |  | | | | | | | | | | | | |
| **STUDY NUMBER:** | | | | |  | | | | | | | | | | | |
| **PROTOCOL DATE/VERSION:** | | | | | | | | |  | | | | | | | |
| Drug or Device/Generic and Trade Name/Manufacturer: | | | | | | | | | | | | | | |  | |
| Study Population (inclusion/exclusion criteria): | | | | | | | | | | | | |  | | | |
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| Study Objectives(s): | | | | |  | | | | | | | | | | | |
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| Current standard of care and/or alternatives: | | | | | | | | | | | |  | | | | |
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| Risks and benefits of the study treatment: | | | | | | | | | |  | | | | | | |
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| Drug Dosage/route/rate/schedule: | | | | | | | |  | | | | | | | | |
|  |  | | | | | | | | | | | | | | | |
| Drug Information: | | | | Internal Device  External Device | | | | | | | | | | | | |
| Side Effects: | |  | | | | | | | | | | | | | | |
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| Treatment Modification: | | | | | |  | | | | | | | | | | |
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| Schedule of study related tests/procedures: | | | | | | | | | | |  | | | | | |
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| 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: