Research Proposal Form

DOCTORS HOSPITAL AT RENAISSANCE
RESEARCH INSTITUTE

Applicant Information

Research Proposal Title: _____

Principal Investigator

Name: _____ Direct Phone: _____

Title: _____ Email: _____

Sub-Investigators: ☐ N/A

Name: _____ Email: _____

Name: _____ Email: _____

Vendor/Collaborator(s):

Name: _____ Direct Phone: _____

Title: _____ Email: _____

Resident:

Name: _____ Direct Phone: _____

PGY Training: _____ Email: _____

Mentor Name: _____ Direct Phone: _____

Mentor Title: _____ Email: _____

Program Director Name: _____ Direct Phone: _____

_____ _____

Conflict of Interest Disclosure

Facility & Personnel

Institution: *(where research will be conducted)*

Name of Institution: _____ Phone: _____

Address: _____ Fax: _____

Additional Locations: *(where research will be conducted)* ☐ N/A

Name of Institution: _____ Phone: _____

Address: _____ Fax: _____

Research Coordinator:

Name: _____ Direct Phone: _____

Title: _____ Email: _____

Research Assistant:

Name: _____ Direct Phone: _____

Title: _____ Email: _____

Device Description

Product Description:

Device: _____

Device: _____

Indication for Use: _____

Is this a Humanitarian Use Device (HUD): ☐ Yes ☐ No

Type of Research:

☐ **Inpatient** ☐ **Outpatient** ☐ **Both**

Non-Clinical ☐ Description: _____

Case Study/ Series ☐ Description: _____

Clinical Study ☐ Phase (1, 2, 3, 4):

☐ Prospective ☐ Retrospective

☐ Single Center ☐ Multi-Center

☐ Controlled ☐ Uncontrolled

☐ Randomized ☐ Non-Randomized

☐ Open ☐ Single Blind

Additional Information:

Will research involve off-label use of products listed? ☐ Yes ☐ No

Non-Clinical Research Plan:

Purpose:
Reason for the research

Hypothesis:

Primary Outcome:

Secondary Outcome(s):

Methods:
Detailed description of test methodology

Sample Size Rationale:
Provide statistical rationale

Statistical Analysis:
Specify how each outcome measure listed above will be analyzed

Clinical Significance:

Background / Summary of publication history on treatment of interest:

Estimated Start Date:

Estimated End Date:

Duration of Research:
(in months)

Estimated date of final deliverable:
(data analysis, written output, etc.)

Clinical Research Plan:

Purpose:
Reason for the research

Hypothesis:

IRB/EC Review Required::

Number of Subjects:

Sample Size Rationale:
Provide statistical rationale

Study Visit Schedule:
Describe each follow-up visit required

Is the visit schedule Standard of Care?

☐ Yes
☐ No, visits outside SOC are:

Primary Endpoint:
Describe clinical assessments, subject reported outcomes, image review, or other data proposed for collection.

Statistical Analysis:
Specify how each outcome measure listed above will be analyzed

Clinical Significance or Application:

Background / Summary of publication history on treatment of interest:

Estimated Start Date:

Estimated End Date:

Duration of Research:
(in months)

Estimated date of final deliverable:
(data analysis, written output, etc.)

Attachments

- Protocol / Study Plan ☐
- Budget Proposal ☐
- Lead Investigator CV ☐
- Subinvestigator CV ☐
- Medical License ☐
- Other: ☐ _____

SUBMIT

You must save this form to your computer before clicking submit.

If you have any questions about this form or the Doctors Hospital at Renaissance Research Institute, please contact:

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