

Investigator Initiated Study (IIS) Request Form

Requestor Contact Information

Name: _____

Organization/Hospital Affiliation: _____

Email Address: _____ Phone Number: _____

Principal Investigator Contact Information

Name: _____

Organization/Hospital Affiliation: _____

Email Address: _____ Phone Number: _____

General Research Information

Date Submitted: _____

Grant Request:

Funding Hemanext One® RBC Storage System Both
 Other (*Specify*) _____

Study/Protocol Title: _____

Research Setting:

Single Center Study Multi-Center Study
 Other (*Specify*) _____

Study Type:

Prospective Retrospective
 Case Series Other (*Specify*) _____

Randomization:

Yes No

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Outside Resources (if applicable): _____

Site(s): _____

Target Enrollment: _____

Project Dates: _____

Entire Proposed Project Period Start Date: _____ End Date: _____

Research Objectives & Detail Information

Objective:

- *Describe the purpose or objectives of the study.*
- *State the research question or hypotheses to be tested.*

Expectations / Publication Plans:

- *White papers, posters, podium presentations*
- *At what time points*

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Rationale:

- *Explain the significance of the study in terms of why this is important and how will it add to existing knowledge.*
- *Provide rationale for conducting the study. Include references to support the information provided.*
- *Describe any relevant preliminary data.*

Inclusion and Exclusion Criteria:

- *Describe the criteria that define who will be included or excluded in the final study sample.*

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Study Endpoints:

- *Describe the primary and secondary study endpoints.*

Include justification for clinical sample size and primary hypothesis testing.

Budget:

- *Describe or attach if available.*

Submission – Please carefully review your responses.

Please download and save this form. Once you have filled out the form in its entirety, please email to Medinfo@hemanext.com, along with