



## **NXSTAGE RESEARCH GRANT REQUEST FORM**

**Please provide all information and send this form and required attachments to Kristen Sheppard/ Legal Department via fax to 978-687-4805 or via email to [ksheppard@nxstage.com](mailto:ksheppard@nxstage.com). A formal notification of the status of your request will be sent to you once a decision is reached. If your request is approved, the Legal Department will provide you with an research grant agreement for execution. If you have any questions about the NxStage Research Grant Program or your request, please call Kristen Sheppard at 978-332-5923. Please note that NxStage will not consider incomplete grant requests.**

### **Requestor Information**

Name of Principal Investigator for this Research Grant	
Name of Affiliation/ Institution Requesting Funding	
Request Date	
Amount Requested	
Affiliation/ Institution Tax ID Number	
National Provider ID Number	
Checks Payable To	
Name of Principal Contact at Affiliation/ Institution	
Contact Phone Number	
Contact Fax Number	
Contact E-mail Address	

### **Research Activity Information**

Title of Research Activity	
Projected Start Date	
Projected End Date	
<b>Device(s):</b> <i>What devices do you intend to use for this study?</i>	
<b>Study Objective/Research Question:</b> <i>What is the goal of the study?</i>	
<b>Study Rationale:</b> <i>Provide background information including previous studies as applicable.</i>	

<p><b>Study Design:</b></p> <ul style="list-style-type: none"> <li>- Examples include prospective, retrospective, randomized, observational, crossover, etc.</li> <li>- Must include specific details of treatment and/or therapy.</li> </ul>	
<p><b>Enrollment Size:</b></p> <ul style="list-style-type: none"> <li>- Number of patients to be enrolled</li> <li>- Provide statistical rationale for sample size if sufficiently powered to answer the research question, or provide rationale for sample size if not statistically powered.</li> <li>- Target number of per-protocol/ as-treated patients</li> </ul>	
<p><b>Number of Study Sites:</b></p> <ul style="list-style-type: none"> <li>- Provide number of collaborating sites if study is to be performed at more than one location.</li> <li>- Provide contact information for each additional location involved, including local Investigator and name and address of facility(ies).</li> </ul>	
<p><b>Patient Population:</b></p> <p>What is the general description of patients in the study? Consider disease state, age, gender, etc.</p>	
<p><b>Primary Endpoint(s):</b></p> <p>What hypothesis is the research attempting to investigate and how do you define success or failure of the study/ treatment?</p>	
<p><b>Secondary Endpoint(s):</b></p> <p>Are there additional items you intend to study?</p>	
<p><b>Inclusion/ Exclusion Criteria:</b></p> <p>What are the major criteria to define if a patient can be enrolled in the study?</p>	
<p><b>Discontinuation Criteria:</b></p> <p>What are the criteria to define if a patient would be removed from the study?</p>	
<p><b>Statistical Methods:</b></p> <p>What will serve as your primary analysis population – Intent-to-Treat or Per-Protocol? Provide rationale.</p>	



**Please attach the following: (Required)**

- 1) Detailed budget showing all costs of conducting the study; including staffing resources, materials and lab costs, which will not otherwise be reimbursed by insurance as part of standard patient care.

**Other Support:**

- 1) Has Investigator or Affiliation/ Institution previously received an Educational or Research Grant from NxStage?  YES  NO
- 2) Will Investigator or Affiliation/ Institution seek or receive support for the current research activity from other sources?  YES  NO

If YES to either of the questions above, please provide the amount of support, a description of each activity funded, and whether the activity is completed or ongoing: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

- 3) Is Investigator or Affiliation/ Institution associated with NxStage?  YES  NO

If YES, please explain: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Requestor Certification**

**In making this request I certify that: (1) all information provided on this form and attachments is accurate and complete; (2) I have all requisite institutional authority to submit this Research Grant request and to arrange for performance of the indicated activities; (3) the attached budget reflects fair-market value for the items and services described and does not include funds to compensate for any activities other than those described in the grant request; (4) no part of any item or service described in the attached budget will be billed to a federal healthcare program or any third-party payer or individual; and (5) I understand that consideration of this Research Grant request is not conditioned on prescribing, purchasing, or recommending products or services of NxStage.**

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_ Title: \_\_\_\_\_