



INVESTIGATOR-INITIATED TRIALS

APPENDIX 1: EXAMPLE INVESTIGATOR-INITIATED TRIAL CONCEPT FORM

Investigator-Initiated Trial Concept Form	
<p>This Investigator-Initiated Trial (IIT) Concept Submission Form must be completed for your IIT to be considered for evaluation. The following required documentation must be submitted for your request to be considered:</p> <ul style="list-style-type: none"> Documentation of GCP training Curriculum Vitae License of the Sponsor-investigator <p>Send the completed IIT Concept Submission Form and supporting documentation via email to InvestigatorIT@herontx.com</p>	
<p>For Heron use only IIT Reference Number: _____ - _____</p>	
1. General Information	
<i>Date of Request</i>	
<i>Name of requestor</i>	
<i>Email</i>	
<i>Phone #</i>	
<i>Affiliation/Institution</i>	
<i>Type of Study</i>	<input type="checkbox"/> <i>Clinical</i> <input type="checkbox"/> <i>Non-clinical</i>
<i>Therapeutic Area of Project</i>	
2. Primary Sponsor-Investigator	
<i>Prefix</i>	
<i>First Name</i>	
<i>Last Name</i>	
<i>Suffix</i>	
<i>Degree / Credentials</i>	
<i>Institution Name</i>	
<i>Institution Type</i>	
<i>Address 1</i>	
<i>Address 2</i>	
<i>City</i>	



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Investigator-Initiated Trial Concept Form	
<i>Country*</i>	
<i>State</i>	
<i>Postal Code</i>	
3. Primary Institution Information	
<i>Institution Name</i>	
<i>Institution Type</i>	
<i>Primary Contact Person</i>	
<i>Address 1 (No PO Boxes)</i>	
<i>Address 2</i>	
<i>City</i>	
<i>Country*</i>	
<i>State</i>	
<i>Postal Code</i>	
<i>Phone Number</i>	
4. Concept of Study	
<i>Summary of Concept (i.e. study design, objectives, endpoints, comparator, sample size, statistical power)</i>	
<i>Please attach additional page if necessary</i>	
<i>Are there Additional Countries for this Project?</i>	
<i>Is this a single center or multicenter?</i>	
<i>Estimated Duration</i>	
5. Support	
<i>Concept Support Type</i>	
<i>Describe Support (please attach additional page if necessary)</i>	

****At this time, Heron Therapeutics can only accept study applications from institutions located within the United States.***