cytori
3020 Callan Road, San Diego, CA 92121
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INVESTIGATOR INITIATED STUDY (IIS) PROGRAM

SUBMISSION FORM

INVESTIGATOR AND SITE INFORMATION		
First Name:	Last Name:	Title:
Specialty:		Phone: Email:
Hospital/Clinic Name and Address:		
Facility Type:	☐ Public Hospital ☐ Private Hospital ☐ University Hospital ☐ Clinic ☐ Other – please specify: _____	
Name of IRB and/or Ethics Committee:	Frequency/Schedule of IRB meetings:	
Submission deadlines:	Estimated review time:	

STUDY OVERIVEW INFORMATION	
Study Type: ☐ Clinical ☐ Preclinical ☐ Other – specify: _____	Indication/Area of Interest:

NATURE OF REQUEST TO CYTORI
Support Requested: ☐ Medical/Scientific Information ☐ Treatment Protocol Template ☐ Product ☐ Data Collection Support ☐ Publication Support ☐ Other – please specify _____

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Study Project Description *(including hypothesis and objectives, study title, phase of research (i.e. pre-clinical, clinical within current indication, clinical in unapproved indication), population to be studied (number of subjects, inclusion/exclusion criteria) treatment regimen, endpoints, enrolment and approximate study dates). Please use additional pages if needed. Description should be less than 5 pages.*

Study Title:

Background and Rationale:

Hypothesis:

Objectives:

Study Design (i.e. open-label, controlled, blinded, cohort, randomized):

Study Population (number of subjects, inclusion/exclusion criteria):

Endpoints:

Data Analysis:

Timeline:

References:

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REQUIRED DOCUMENTS CHECK-LIST **(Please provide the following documents)**
☐ Submission Form (i.e. this application) ☐ Submission Agreement ☐ Curriculum Vitae/Resume of Investigator (Note: curriculum vitae of co-investigators or staff who will participate in the study may be submitted but are not required) *If the following are available, they may be submitted:* ☐ IRB/Ethics Committee Approval Letter ☐ Draft Informed Consent (if clinical study)

Thank you for taking your time to complete this form.
Please return form via email to: iis@cytori.com or fax to: 858-458-0900
Allow 4-6 weeks for Cytori's Scientific Review Committee to review your submission.

Completed by: _____

(Print name)

_____ Date_____

(Signature) **(dd/mm/yyyy)**