Cytori Therapeutics K.K.
Otemachi Park Building 7F
1-1-1 Otemachi, Chiyoda-ku, Tokyo 100-0004 Japan
TEL: +81.3.6860.5700 FAX: +81.3.6860.5705

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 OVERVIEW INFORMATION	
Study Type: ☐ Clinical ☐ Preclinical ☐ Other – please 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 CHECKLIST
(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: contactjp@cytori-jp.com.

Allow 4-6 weeks for Cytori's Scientific Review Committee to review your submission.

Completed by: _____

(Print name)

_____ **Date:** _____

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