PCRT Site Evaluation Form

Name of Site: **Today's Date:**	
Site Address:	
Person completing this information: Name: Title: Address: ☐ **Same as PI**	Phone: Fax: Email:
Name and contact information of Principal Investigator:	
Name: Address: PI Specialty:	PI Phone: PI Fax: PI E-mail:
Name(s) and contact information for other site research personnel:	
Sub-Investigator(s)	
Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail:	Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail:

PCRT Site Evaluation Form

Research Nurse(s)	
Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail	Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail
Study Coordinator(s)	
Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail:	Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail
Data Manager(s)	
Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail	Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail
Pharmacists(s)	
Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail	Name: Title: Address: ☐ **Same as PI** Phone: Fax: E-mail

PCRT Site Evaluation Form

Criteria for Investigators		
Are you **board certified** in Oncology?	☐**yes**	☐**no**
Are one or two sub-investigator(s) available to support 24 hour calls?	☐**yes**	☐**no**
Do your clinical research coordinators have at least two years experiences?	☐**yes**	☐**no**
Are your clinical research nurses **certified** in Clinical Research?	☐**yes**	☐**no**
Are your clinical research coordinators **certified** in Clinical Research?	☐**yes**	☐**no**

Study Specific Information
Number of Oncology trials conducted as a Principal Investigator?
Number of Pancreatic Cancer trials conducted and/or participated in as an Investigator?
Have you had experience using the RECIST (Response Evaluation Criteria in Solid Tumors) guidelines in clinical trials? ☐**yes** ☐**no**

	Phase (I – IV)	No. of Patients Enrolled	Approximate Date of First Patient Enrolled	Duration of Study
Please give brief information regarding **Current** pancreatic cancer studies conducted:				

	Phase (I – IV)	No. of Patients Enrolled	Length of Study Enrollment Period	Duration of Study
Please give brief information regarding **Past** pancreatic cancer studies conducted:				

PCRT Site Evaluation Form

Patient Population Information
Number of newly diagnosed Pancreatic Cancer Patients you see per year in your practice?
% of patients considered “non-resectable?”
% of patients from your practice/institution?
% of patients referred from Family Practitioners/Internists?
% of patients referred from Other Specialists? (Please Specify)
% of patients referred from Advertising?
% of patients from non-local referrals?
Do you have a formal process in place for Patient Recruitment? ☐**yes** ☐**no** If yes, which of these do you use: ☐Data/Record Mining ☐Internal Advertising ☐Referrals ☐External Advertising ☐Patient Data Base ☐Public Advertising ☐Web Posting ☐Recruitment Center ☐Other, please describe: _____
Investigator Information
Are you able to demonstrate adequate subject availability based on chart review? ☐**yes** ☐**no**
Are your medical records paper or electronic? ☐paper ☐electronic
Can your records be easily retrieved? ☐**yes** ☐**no**
Does your site provide human subjects training for all study personnel? ☐**yes** ☐**no**
IRB / Regulatory Information
How are regulatory documents collected and supplied?
Responsible person and contact information: Name: Address: City, State, Zip: Telephone: Fax: Email:
Will you be able to use a Central IRB for initial approval of studies? ☐**yes** ☐**no**

If yes, please give provide the name and contact information for the **Central IRB:** Name Address: City, State, Zip: Telephone: Email: **If no**, please give the name and address of the **Local Institutional Review Board:** Name Address: City, State, Zip: Telephone: Email:
Are there any special requirements for IRB submission? ☐**yes** ☐**no** **If yes**, please comment.
How often does the IRB meet/date of next meeting?
How far in advance of a meeting, is submission required?
Will additional approvals be required for submission (e.g. scientific review committee, fiscal review, committee, etc.)? ☐**yes** ☐**no** If yes, can approval be done in parallel? ☐**yes** ☐**no** Please describe your review process:
What is the approximate time it would take from receiving the protocol to IRB approval?
How soon after IEC/IRB approvals do you typically receive written notification of approval?
Is a fee required for use of your IEC/IRB? ☐**yes** ☐**no** If yes, please indicate the cost.
Does your informed consent form (ICF) need to be translated? ☐**yes** ☐**no**

PCRT Site Evaluation Form

If yes, please indicate from which language the ICF needs to be translated from and to which language the ICF needs to be translated to and any cost, if known.	
Does your IEC/IRB require a signed/ approved **contract** before reviewing a protocol? ☐**yes** ☐**no** Does your IEC/IRB require a signed/ approved **budget** before reviewing a protocol? ☐**yes** ☐**no**	
Contract/Budget Information	
Do you have a separate department to handle **contracts** and/or **budgets**? ☐**yes** ☐**no**	
If yes, please provide contact information for <u>Contracts:</u> Name: Address: City, State, Zip: Phone: Fax: Email:	If yes, please provide contact information <u>for budgets</u>: Name: Address: City, State, Zip: Phone: Fax: Email:
If no, who is responsible for <u>site contracts</u>? Name: Address: Phone: Fax: Email:	If no, who is responsible for <u>site budgets?</u> Name: Address: Phone: Fax: Email:
Site Information	
Patient/Staff Facilities – please comment on availability of the following:	
Patient exam rooms (location, number, type suitable for study drug administration)	
Inpatient facility: availability, telemetry, 24 hour monitoring	
Outpatient facility: hours of operation, resources available, EKG'S, late PK draws	
Do you have a Gastroenterology oncology suite with emergency capabilities on-site? ☐**yes** ☐**no**	

If no, is a nearby clinic or hospital available?	☐**yes**	☐**no**
Pharmacy/Drug Storage and Dispensing		
Who will be responsible for drug dispensing and accountability?		
Is there a separate IDS pharmacy/storage area? If yes, is there fee? If yes, how much?	☐**yes** ☐**yes**	☐**no** ☐**no**
Are there refrigerators/freezers with temperature logs/backup generators?	☐**yes**	☐**no**
Are standard operating procedures in place for handling investigational drugs?	☐**yes**	☐**no**
Are standard operating procedures in place for destroying investigational drugs?	☐**yes**	☐**no**
Access to Equipment		
ECG (12-lead)	☐yes on-site	☐yes off-site
Centrifuge	☐yes on-site	☐yes off-site
MRI	☐yes on-site	☐yes off-site
X-Ray	☐yes on-site	☐yes off-site
Spiral CT	☐yes on-site	☐yes off-site
PET Scanner	☐yes on-site	☐yes off-site
-20 C Freezer	☐yes on-site	☐yes off-site
-70 C Freezer	☐yes on-site	☐yes off-site
Radiology		
Can you get a designated physician to read scans for studies/consistency?	☐**yes**	☐**no**
Can you get copies of films if needed to submit to the sponsor?	☐**yes**	☐**no**
Can you get electronic submission of scans if required?	☐**yes**	☐**no**
Laboratory		
Do you utilize an on-site lab or send specimens off-site for processing?	☐**on-site**	☐**off-site**
Who will be responsible for drawing labs/PK samples? Who or what organization processes the samples? Name: Address: City, State, Zip: Telephone:		
Is there access to dry ice for shipping?	☐**yes**	☐**no**