

First Name – Las	t Name:						
Office Address:							
Contact Number:	Office:						
	Mobile:						
	Fax:						
Email:							
Preferred Contac							
Best Time Contac	Day:(Mon – Fri) Time:						
	Time						
Study Title:							
Research Type:	☐ Observational Study						
	☐ Descriptive Study: ☐ Cross-Sectional Study ☐ Longitudinal Study ☐ Retrospective Study						
	☐ Analytical Study: ☐ Cross-Sectional Study ☐ Cohort Study ☐ Case-control Study						
	☐ Experimental Study						
	Clinical Research: Phase I Phase II Phase III Phase III Phase III Phase III						
	Randomization: Randomization Non-Randomization						
	Blinding: Opened-label Single-Blind Double-Blind						
Funding/Grant:	Domestic Grant; please specify						
9	Industry-Sponsored						
Sample Size:	Recruitment Target						
Sample Size:	% Screening Failure Not Applicable						
G. 1							
Study Timelines:	Total Study Duration = Weeks/ Months/ Years						
	Recruitment Period = Weeks/ Months/ Years						
	Expected date of First Patient First Visit =						
	Expected date of Data Base Locked =						
Investigational Product:	Oral: Tablet Capsule Powder						
Troduct.	Injection: Intravenous (IV) Intramuscular (IM) Subcutaneous (SC) Intradermal (ID)						
	Locally Acting Product: Skin Topical Products (Cream/ Gel/ Ointments/ Lotions)						
	☐ Transdermal Pad ☐ Nasal Spray						
	☐ Inhaler ☐ Ophthalmology products						



Nursing Services N/A						
	Subject Recruitment Assistant		Make study appointments and follow up with the subjects			
	Vital Signs (BP, Pulse, Temperature)		Body Measurements			
	Questionnaire, Interviews, Surveys**		Subject Education and/or Subject Training			
	ECG (Test only, no reading)		Blood Draw (minimal or no processing)			
	PK-PD Sampling		Urine Collection			
	Serum Pregnancy Test		Urine Pregnancy Test			
	PO, SQ, IM Medication Administration		IV administration for Invasive Medication or Toxic agents			
	IV Administration for Non-Invasive Medication☐ Infusion Pump☐ Syringe Pump		Other			
Othe	r anticipated Nursing Services, Please specify:					



Phai	rmacy Services N/A						
	Investigational Product (IP) Storage – Room Temperature (15-25 °C)		Investigational Product Storage – Refrigerated Temperature (2-8 °C)				
	IP Dispensing / Counseling		IP accountability				
	IP Order and Return/Destruction		Monitoring IP Storage Conditions Temperature range°C Humidity range%				
	IP Randomization - IVRS		IP Randomization - manually				
	IV preparations for non-invasive IP		IV preparations for invasive IP e.g. Chemotherapy preparation				
	Other anticipated Pharmacy Services, Please specify:						
Faci	lities/Space Services						
	Outpatient Clinic - Number of examination room per visit = - Number of patients per visit (expected) =		PK Clinic Day timehours Overnight at CRC				
	Bed for study subject - OPD Day timehours Overnight at CRC		In-Patient at King Chulalongkorn Memorial Hospital; Admission for days				
	Meeting room (Study team meeting, teleconference) Frequency ☐ weekly ☐ monthly ☐other,	-	Study equipment storage				
	Document storage		Laboratory kits storage				
	Fax, Telephone for study related activities						
Othe	er anticipated Facilities/Space Services, Please specify:						
l							



Bloc	od Sample Processing	/ Anal	ysis N/A				
	СВС		GLUCOSE		BUN		CREATININE
	CHOLESTEROL		TRIGLYCERIDE		HDL CHOLESTEROL		LDL CHOLESTEROL
	URIC ACID		TOTAL PROTEIN		ALBUMIN		BILIRUBIN (TOTAL&DIRECT)
	AST		ALT		LDH		СРК
	LACTATE		CALCIUM		MAGNESIUM		SODIUM
	CALCIUM		POTASSIUM		CHLORIDE		CO ₂
	PHOSPHORUS		CREATININE		TSH		PBMC
	Other, (please specify)					
Urin	nalysis N/A						
	Urine Protein		Urine Creatinine		Urine Pregnancy Test		
Frozen Samples Storage							
	Blood Sample				Urine Sample		
Tem	perature:	0 ° C	Specific temper	rature	° C		
Tota	l Number of Sample Tu	ibes:	Blood Samples =	tul	oes / subject Total	tı	ibes for subjects
			Urine Samples =	tul	oes / subject Total	t	ubes for subjects
Stora	age Period:		Days/ Weeks/ Months/	Years	3		
Other Storage Requirements (please specify)							
Ship	oment Process for Sam	ple	□ N/A				
Cou	rier:						
Cou	rier Contact Detail:						
Shipping Address:							



	nration Phase Design data management plan						
		T					
	Design data management plan						
			Develop plan for data analysis				
Imple	CRF Design - Paper		CRF Design – Electronic (stand-alone system)				
	Implementation Phase						
1) Da	ata Management						
	CRF Processing/Filing		Coding of medical data (only Items to be code)				
	Data entry and verification		Audit (Source document vs. CRF vs. Queries vs. Database)				
	Data validation and query generation		Data cleaning & data base close-up				
	Query Management (running validation routine, errors resolutions)		Web-based Routine data monitoring report in a standard format				
2) Sta	atistical Analysis						
Р	Prepare a data file for statistical analysis		Perform the analysis and write the RESULTS section of the report				
□ P	Prepare a batch file for statistical analysis		Quality control for statistical analysis				
	Write statistical method in the METHODS section of the report		Write statistics-related issues in the DISCUSSIONS section of report				
□ P	Programming for reporting template (on request)		Consulting only				



I hereby confirm that the information mentioned in this checklist is true to best of my knowledge and would like to request the most accurate cost estimate for all services and facilities at ChulaCRC.				
Investigator name:				
Investigator Signature:	Date:			
Please return the completed checklist and kindly attach the Protocol or Syn Chulalongkorn University, 7 th Floor, Aor.Por.Ror. Building, Rama IV Road	1 33 . 3 3			
Draft budget will be proposed within 5-10 working days after received com 3547 or 02-251 6704.	pleted checklist. For more information please contact			