FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
Okayama University Hospital	Hospital or Medical Center	2-5-1 Shikatacho, Okayama, Okayama, Japan, 700-8558

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Kuroda, Satoshi	kuroda-s@cc.okayama-u.ac.jp	Facility Profile Manager
No	Sato, Asami	yamada-a@cc.okayama-u.ac.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)

Therapeutic Area	Sub-Therapeutic Area
Male Urogenital Diseases	
Hemic and Lymphatic Diseases	
Digestive System Diseases	
Bacterial Infections and Mycoses	
Eye Diseases	
Endocrine System Diseases	
Disorders of Environmental Origin	
Congenital, Hereditary, and Neonatal Diseases and Abnormalities	
Cardiovascular Diseases	
Chemically-induced Disorders	
Mental disorders	
Musculoskeletal Diseases	
Neoplasms	
Nervous System Diseases	
Nutritional and Metabolic Diseases	
Occupational Diseases	
Otorhinolaryngologic Diseases	
Parasitic Diseases	
Respiratory Tract Diseases	
Skin and Connective Tissue Diseases	
Stomatognathic Diseases	
Virus Diseases	
Wounds and Injuries	
Female Urogenital Diseases and Pregnancy Complications	
Immune System Diseases	

Other Areas of Expertise

Study Phase Capabilities

Phase I; Phase II; Phase III; Phase IV

Other Facility Details

Do you have Affiliated Research Sites or Satellite Sites/Clinics? A Satellite Site is a secondary location where the investigator sees clinical trial subjects, usually this is the same investigator who sees subjects at the primary site location.	No
What study types does your Facility have experience with?	Industry; Investigator Initiated
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes

Patient Population

Patient Population Demographics	Pediatrics - Less than or equal to 17; Adults - Ages 18-64; Geriatrics - Greater than or equal to 65

Patient Population Comments

IRB/ERB/ETHICS COMMITTEE

General Questions

What is the average time (in days) to start a study once you have received the regulatory package?	30-60
Does your facility perform IRB/ERB/Ethics Committee submissions?	Yes
Does your facility have a dedicated department or group to perform IRB/ERB/Ethics Committee submissions?	Yes
Department Contact Name	Division of
Department Contact Phone Number	+81-86-235-7991
Department Contact Email Address	chiken@okayama-u.ac.jp
Is your facility able to initiate study activities prior to IRB/ERB/Ethics Committee protocol approval?	No
What types of IRB/ERB/Ethics Committee does your Facility use?	Local
Does your institution and/or local regulation mandate the distribution of safety reports [e.g., Development SafetyUpdate Report (DSUR), suspected unexpected serious adverse reaction (SUSAR)] to a local Review only IRB/ERB/Ethics Committee?	Yes
Are there any other steps that the Sponsor should be aware of for your IRB/ERB/ Ethics Committee review and submission?	No
Other Steps Explain	

OTHER REVIEW BOARDS

Does your facility have Other Review Boards that need to approve the study prior to IRB/ERB/Ethics Committee submission? For example, scientific, radiation safety committees, or others.	Yes

Review Board Name	Meeting Frequency
Preliminary screening committee (For a Protocol of Ancillary research)	Other - As needed

Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: Okayama University Hospital Clinical Laboratory	
Lab Name	Okayama University Hospital Clinical Laboratory
Lab Contact First Name	Division of Clinical Research of New Drugs and Therapeutics, Center Of Innovative Clinical Medicine
Lab Contact Last Name	
Address	2-5-1, Shikata-cho, Kita-ku, Okayama, Okayama, Japan
Phone Number	+81-86-235-7991
Fax Number	+81-86-235-7795
Email Address	chiken@okayama-u.ac.jp
Local Lab Accreditation	ISO; Others
Other Local Lab Accreditation	JAMT

CONSENT & TRAINING

Consent	
Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for Pediatric Populations?	No
Does your Facility have a written SOP/Policy/Procedure for: Other Vulnerable Populations?	No
Will your Facility require language translations for consents?	No
Select the required languages	
If located in the US, has your Facility used or are you able to use the informed consent short form?	
Training	
Does your Facility have a training program for the research staff?	Yes
Does the course content include GCP?	Yes
Does your Facility use an external program to conduct research training?	No
Please provide program course name.	

Do you have a process or program in place to retrain research staff when a protocol is amended?	No
Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countries hazardous training requirements for shipping dangerous goods?	No

FACILITY & EQUIPMENT

Facility Capabilities	
Can your Facility support patient visits on weekends?	Yes
Can your Facility support in-patient admissions for research studies?	Yes
Does your study staff have sufficient English knowledge to understand communications in English?	Yes
Does your Facility have access to translators and translation support for trial conduct (e.g. consent, trial specific instruction)?	NA
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Does your Facility have the ability to collect and store PK/PD specimens?	Yes
Does your Facility have the ability to collect PK/PD samples beyond normal business hours?	Yes
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	Yes
Equipment	
Identify the Diagnostic Equipment available at or near the Facility to support Research studies?	Computerized Tomography Scan; Dual-Energy X-ray Absorptiometry or Bone Densitometry; Magnetic Resonance Imaging; Fluoroscopy; Positron Emission Tomography Scan; X-Radiation; Magnetic Resonance Angiography; Magnetic Resonance Spectroscopy; Mammography; Nuclear Medicine (e.g.Bone scan,Thyroid scan,Thallium cardiac stress test); Electrocardiogram
General Equipment	
Does your Facility have an SOP or process that ensures routine calibration and maintenance of general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphymomanomer, etc.?	Yes
Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?	Yes
Equipment Available At The Facility To Support Research Studies	
Identify the equipment available at the Facility to support Research studies?	Refrigerated Centrifuge; Centrifuge; Refrigerator (2 to 8 Degrees C); Freezer (-20 to -30 Degrees C); Freezer (-70 to -80 Degrees C)
Equipment Capabilities: Refrigerator (2 to 8 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Not Applicable
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	Yes
Do you have an SOP which supports calibration of this equipment?	Yes
Equipment Capabilities: Freezer (-20 to -30 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Not Applicable
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	Yes
Do you have an SOP which supports calibration of this equipment?	Yes

Equipment Capabilities: Refrigerator (-70 to -80 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	No
Does this equipment provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Not Applicable
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	Yes
Do you have an SOP which supports calibration of this equipment?	Yes
Computer Capabilities	
Does your Facility have computers which are dedicated to research studies?	Yes
What type of computer operating system(s) does your institution use to support studies?	Windows (Windows XP, Windows 7, Windows 8, etc.)
What type of internet access does your Facility have?	Cable or DSL
Does your Facility limit or prohibit access and use of external web-based tools or sites for clinical research? (e.g. web portals to submit documents to sponsors or CROs)	Yes
Does the Facility have access to local IT support?	Yes

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Investigational Product Shipping Details	
IP Recipient Name	Yoichi Kawasaki
Address	2-5-1, Shikata-cho, Kita-ku, Okayama, Okayama, Japan
Email Address:	
Phone Number:	
Fax Number:	
Investigational Product Storage Location	
IP Storage Location Name	Investigational Product Management Department, Division of Clinical Research of New Drugs and Therapeutics, Center for Innovative Clinical Medicine
Address	2-5-1, Shikata-cho, Kita-ku, Okayama, Okayama, Japan
Email Address:	
Phone Number:	
Fax Number:	
Investigational Product Storage Equipment	
Identify the Investigational Product Storage Equipment at your Facility	Refrigerator (2 to 8 Degrees C); Freezer (-20 to -30 Degrees C); Freezer (-70 to -80 Degrees C)
Equipment Capabilities: Refrigerator (2 to 8 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Does this equipment provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	By Minute
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	Yes
Do you have an SOP which supports calibration of this equipment?	Yes
Equipment Capabilities: Freezer (-20 to -30 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Does this equipment have Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	By Minute
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	Yes
Do you have an SOP which supports calibration of this equipment?	Yes
Equipment Capabilities: Refrigerator (-70 to -80 Degrees C)	
Do you have the ability to generate a temperature monitoring log for this equipment?	Yes
Does this equipment provide Min/Max Temperature Monitoring?	Yes

How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	By Minute
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	Yes
Do you have an SOP which supports calibration of this equipment?	Yes
Investigational Product Storage And Handling	
Is the Investigational Product Storage Room secured with controlled access?	Yes
Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?	Yes
Does the Investigational Product Storage Room provide Min/Max temperature monitoring?	Yes
Does the Investigational Product Storage Room have back-up power?	Yes
Does the Investigational Product Storage Room have a temperature alarm?	Yes
Do you have an SOP which supports calibration of the temperature monitoring equipment?	
Does your Facility have the ability to manage on-site or off-site destruction of Investigational Product?	Yes
Does your Facility have a written SOP/Policy/Procedure for destruction of Investigational Product?	Yes
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	No
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	No
Describe additional Investigational Product Storage & Handling Capabilities	
Preparation and Administration Of Investigational Product	
Identify the Investigational Product preparation capabilities at your Facility	Vertical laminar flow hood (chemo/ hazardous drugs); Horizontal laminar flow hood (non-hazardous drug preparation)
Is your Facility capable of administering infusions?	Yes
Is your Facility adequately staffed to support studies with both blinded and un-blinded Investigational Product?	Yes
Controlled Substances	
Does the Facility have the required licenses or registrations to receive, store, dispense and return controlled substances as required by local law?	Yes
Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?	Yes
Does the Facility have the ability to handle radio-labelled Investigational Product?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	Yes
Attachments	

Document Type	Document Name	Description
No Records		

SOURCE DOCUMENTATION

Source Documents	
What type of source documents will be used?	Electronic
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	Yes
Provide Location name and address of any offsite archives	
Electronic Medical Records (EMR)/Electronic Health Records (EHR)	
Do you have Electronic Health Records (EHR)/ Electronic Medical Records (EMR)?	Yes
What EMR/EHR system do you use?	In-house system
For Facilities with satellite sites, where is the monitor required to access source documents?	Main Facility Only
Please list any access limitations/requirements for the Electronic Medical Records.	
Monitoring	
Check all equipment that will be available to Monitors:	Phone; Fax; Copy Machines; Internet Access
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	Oracle Inform; Medidata Rave; Oracle RDC Remote Data Capture

ADDITIONAL LOCATIONS

Additional Locations					
Add any addresses you wish to be available in the Study Site Profile. These addresses will be available for selection in the following sections of the Study Site Profile - Additional Study Locations - These addresses can be added to your FDA Form 1572, if applicable.					
Location Name	Contact Name	Address	Phone Number	Fax Number	E-mail Address
No Records					

ADDITIONAL INFORMATION & ATTACHMENTS

Additional Information
Please provide additional information not captured in other sections of the Facility Profile that you feel is important for Sponsors to know about your Facility. Please reference the section name if applicable.

Facility Attachments		
Document Type	Document Name	Document Description
No Records		

ORGANIZATION AFFILIATIONS

Organization Affiliations			
The Organization (s) that requested Affiliation with your Facility/Department are listed below with Affiliation Status			
Organization Name and Address	Organization Affiliation Type	Organization Affiliation Status	Status Date
No Records			