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FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
Shinshu University Hospital		3-1-1 Asahi, Matsumoto, Nagano, Japan, 390-8621

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Shimizu, Sayo	shimizus@shinshu-u.ac.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	**Sub Therapeutic Area**
Respiratory Tract Diseases	
Cardiovascular Diseases	
Digestive System Diseases	
Immune System Diseases	
Endocrine System Diseases	
Mental disorders	
Nervous System Diseases	
Skin and Connective Tissue Diseases	
Musculoskeletal Diseases	
Stomatognathic Diseases	
Female Urogenital Diseases and Pregnancy Complications	
Male Urogenital Diseases	
Eye Diseases	
Otorhinolaryngologic Diseases	
Congenital, Hereditary, and Neonatal Diseases and Abnormalities	
Device	
Wounds and Injuries	
Pain	
Pediatrics	
Nutritional and Metabolic Diseases	
Orthopedics	

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Therapeutic Area	Sub Therapeutic Area
Nephrology	
Hemic and Lymphatic Diseases	
Oncology	

Other Areas of Expertise

Study Phase Capabilities
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; Academic
Is your Facility affiliated with a government agency or part of a government funded health service?	No

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?	61-90
Does your Facility perform IRB/ERB/Ethics Committee submissions?	Yes
Does your Facility have a Facility or group to perform IRB/ERB/Ethics Committee submissions?	Yes
Department Contact Name	Shinshu University Hospital, Center for Clinical Research
Department Contact Phone Number	+81-263-37-3389
Department Contact Email Address	chiken@shinshu-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

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: Shinshu University Hospital Institutional Review Board	
IRB/ERB/Ethics Committee Name	Shinshu University Hospital Institutional Review Board
Address	3-1-1 Asahi, Matsumoto, Nagano, Japan, 390-8621
Registration#	**Registering Body**
No Records	

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What is the meeting frequency of the IRB/ERB/Ethics Committee?	Monthly
How long before IRB/ERB/Ethics review is the Submission Packet required?	2 weeks
Does the IRB/ERB/Ethics Committee require payment prior to release of final approval documents?	No
Does the IRB/ERB/Ethics Committee require contract/budget approval prior to release of final approval documents?	No

LOCAL IRB/ERB/ETHICS COMMITTEE ATTACHMENTS

Document Type	Document Name	Document Description
No Records		

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.	No

Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: Laboratory Medicine	
Lab Name	Laboratory Medicine
Lab Contact First Name	
Lab Contact Last Name	
Address	3-1-1 Asahi, Matsumoto, Nagano, Japan, 390-8621
Phone Number	
Fax Number	
Email Address	
Local Lab Accreditation	CAP; ISO; Others
Other Local Lab Accreditation	JAMT, Japan Medical Association
Additional Questions	
Does your Facility have a SOP/written procedure for documenting bio-specimen (Sample) processing steps/chain of custody?	
What is the system or tool that the site currently has or utilizes to document Bio-specimen (Sample) Processing Steps/ Chain of Custody?	
Please indicate tissue collection and processing capabilities at your site?	
Does your Facility has established processes to oversee staff compliance with study-specific lab manual instructions for bio-specimen processing?	
What are your Facility’s capabilities for tissue collection and/or processing (embedding)?	
Are LOINC codes available for the Local Lab? (If Yes, you can upload the relevant LOINC list as an attachment in Lab Documentation)	

Attachments

Document Type	Document Name	Document Description
No Records		

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?	Yes
Select the required languages	Japanese
If located in the US, has your Facility used or are you able to use the informed consent short form?	Not Applicable
Training	
Does your Facility have a training program for the research staff?	Yes
Does the course content include GCP?	No
Does your Facility use an external program to conduct research training?	Yes
Please provide program course name.	APRIN
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?	No
Can your Facility support in-patient admissions for research studies?	Yes
Does your study staff have sufficient English knowledge to understand communications in English?	No
Does your Facility have access to translators and translation support for trial conduct (e.g. consent, trial specific instruction)?	No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Is the lab kit storage space able to support early phase studies which may require an increased number of kits?	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 maintenancof general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphymomanomer, etc.?	No
Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?	Yes
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?	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.	Hourly
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?	No
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 provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Hourly
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?	No
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.	Hourly
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?	No
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)	No
Does the Facility have access to local IT support?	Yes
Does your Facility prohibit the use of an external USB device (e.g. to download and send data from a temperature monitoring device)?	No
Business Continuity Plan	
Does your Facility have Business Continuity Plan (BCP) to protect essential business operations which describes how those processes will be performed during a crisis at your Facility?	Yes

Attach Your BCP or SOP

Document Type	Document Name	Document Description
No Records		

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Investigational Product Shipping Details

IP Recipient Name	Address	Email Address	Phone Number	Fax Number
Shinshu University Hospital	3-1-1 Asahi, Matsumoto, Nagano, Japan, 390-8621			

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Investigational Product Storage Location				
IP Storage Location Name	Address	Email Address	Phone Number	Fax Number
Shinshu University Hospital	3-1-1 Asahi, Matsumoto, Nagano, Japan, 390-8621			

Investigational Product Storage Equipment	
Identify the Investigational Product Storage Equipment at your Facility	Refrigerator (2 to 8 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.	Hourly
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?	No
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 this equipment?	No
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?	Not Applicable
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	Not Applicable
Describe additional Investigational Product Storage And Handling Capabilities	
Preparation and Administration Of Investigational Product	
Identify the Investigational Product preparation capabilities at your Facility	
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?	No

Attachments		
Document Type	**Document Name**	**Document Description**
No Records		

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SOURCE DOCUMENTATION & REMOTE MONITORING

Source Documents	
What type of source documents will be used?	Paper; Electronic
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	Yes
What type of investigator site file/regulatory binder used (select all that apply)	Paper; Electronic
What investigator site file (eISF) / eRegulatory system do you use?	Others: DDworks/Trial Site
Are monitors able to access eISF/eReg while off-site?	Yes
Please list any access limitations/ requirements for eISF/eReg	
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?	
Please list any access limitations/requirements for the Electronic Medical Records.	ID, Password
Do you work with a vendor that can electronically exchange data for clinical research from the EHR/EMR?	No
Do you have institutional approval to export data from the EHR/EMR for the clinical research?	No
Are monitors able to access EHR/EMR while off site?	Yes
Does your Facility require Sponsor representative to sign any local form (paper or electronic) for access, or any other purpose?	No

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; Others
Describe Other EDC Systems	DDworks 21, DATATRACK, Viedoc
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring?	Yes
Which of the following capabilities are available to support remote source data verification? (Check all that apply)	Video Conferencing; Can send pseudo anonymized certified source documents via secure transfer; EHR/EMR access by monitor; Systems or platforms for source document upload; Screen Sharing

Attachments

Document Type	Document Name	Document Description
No Records		

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					

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