

FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
Nihon University Itabashi Hospital		30-1 Oyaguchi Kamicho, Tokyo, Tokyo, Japan, 173-0032

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Enomoto, Yukiko	enomoto.yukiko@nihon-u.ac.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	Sub-Therapeutic Area
Bone	
Digestive System Diseases	
Device	
Bacterial Infections and Mycoses	
Allergy	
Eye Diseases	
Endocrine System Diseases	
Congenital, Hereditary, and Neonatal Diseases and Abnormalities	
Cardiovascular Diseases	
Chemically-induced Disorders	
Female Urogenital Diseases and Pregnancy Complications	
Hemic and Lymphatic Diseases	
Immune System Diseases	
Infectious Diseases	
Inflammation	
Internal Medicine	
Male Urogenital Diseases	
Fertility	
Mental disorders	
Musculoskeletal Diseases	
Neoplasms	
Nervous System Diseases	
Nutritional and Metabolic Diseases	
Ob-Gyn	
Occupational Diseases	
Oncology	
Orthopedics	
Otorhinolaryngologic Diseases	
Pathological Conditions, Signs and Symptoms	
Pediatrics	
Respiratory Tract Diseases	
Skin and Connective Tissue Diseases	
Stomatognathic Diseases	
Vaccines	
Virus Diseases	
Women's Health	
Wounds and Injuries	
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.	Yes



What study types does your Facility have experience with?	Industry; Investigator Initiated; Academic; Government
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?	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	Clinical Research Center
Department Contact Phone Number	+81-3-3972-8111
Department Contact Email Address	enomoto.yukiko@nihon-u.ac.jp
Is your facility able to initiate study activities prior to IRB/ERB/Ethics Committee protocol approval?	Yes
What types of IRB/ERB/Ethics Committee does your Facility use?	Central Acting as Local
Does your institution and/or local regulation mandate the distribution of safety reports [e.g., Development Safety Update 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	

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: Nihon University Hospitals' Joint Institutional Review Board	
IRB/ERB/Ethics Committee Name	Nihon University Hospitals' Joint Institutional Review Board
Address	30-1 Ohyaguchi, kami-cho, Itabashi-ku, Tokyo, Japan, 173-8610
What is the meeting frequency of the IRB/ERB/Ethics Committee?	Monthly
How long before IRB/ERB/Ethics review is the Submission Packet required?	Greater than 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
Registration#	Registering Body
-	

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
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Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: Clinical laboratory	
Lab Name	Clinical laboratory
Lab Contact First Name	
Lab Contact Last Name	
Address	
Phone Number	
Fax Number	



Email Address	
Local Lab Accreditation	CAP; ISO

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?	Yes
Does your Facility have a written SOP/Policy/Procedure for: Other Vulnerable Populations?	Yes
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?	Yes
Does your Facility use an external program to conduct research training?	Yes
Please provide program course name.	JMACCT
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
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; 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, sphygmomanometer, 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?	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.	Daily
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 provide Min/Max Temperature Monitoring?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
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?	No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
Does this equipment have back-up power?	Yes
Does this equipment have a temperature alarm?	No
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

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Investigational Product Shipping Details	
IP Recipient Name	Nihon University Itabashi Hospital
Address	30-1 Ohyaguchi kami-cho, Itabashi-ku, Tokyo, Japan, 173-8610
Email Address:	enomoto.yukiko@nihon-u.ac.jp
Phone Number:	+81-3-3972-8111 ex. 3007
Fax Number:	+81-3-3972-8179
Investigational Product Storage Location	
IP Storage Location Name	Nihon University Itabashi Hospital
Address	30-1 Ohyaguchi kami-cho, Itabashi-ku, Tokyo, Japan, 173-8610
Email Address:	enomoto.yukiko@nihon-u.ac.jp
Phone Number:	+81-3-3972-8111 ex. 3007
Fax Number:	+81-3-3972-8179
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.	Daily
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?	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?	No	
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 & Handling Capabilities		
Preparation and Administration Of Investigational Product		
Identify the Investigational Product preparation capabilities at your Facility	Extemporaneous Preparation; Vertical laminar flow hood (chemo/hazardous drugs); Glove box (vented to outside)	
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 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			