

FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Chibahigashi National Hospital	Hospital or Medical Center	673 Nitona Chuo-ku, Chiba, Chiba, Japan, 260-8712

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Ishii, Fumie	ishii.fumie.nz@mail.hosp.go.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	Sub Therapeutic Area
Allergy	
Digestive System Diseases	
Endocrine System Diseases	
Eye Diseases	
Immune System Diseases	
Nephrology	
Nervous System Diseases	
Musculoskeletal Diseases	
Pediatrics	
Vaccines	
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; Academic
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 Facility or group to perform IRB/ERB/Ethics Committee submissions?	Yes
Department Contact Name	Clinical
Department Contact Phone Number	80432615171
Department Contact Email Address	ishii.fumie.nz@mail.hosp.go.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; 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	

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: National Hospital Organization Chibahigashi National Hospital Institutional Review Board	
IRB/ERB/Ethics Committee Name	National Hospital Organization Chibahigashi National Hospital Institutional Review Board
Address	672 Nitara Cho Chiba-ku Chiba, NA Japan 260-8740
Registration#	Registering Body
NA	
What is the meeting frequency of the IRB/ERB/Ethics Committee?	Monthly
Other	
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?	Yes

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
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Local Lab

Is your Facility using a Local Lab?		Yes
Local Lab: National Hospital Organization Chibahigashi National Hospital clinical inspection department		
Lab Name		National Hospital Organization Chibahigashi National Hospital clinical inspection department
Lab Contact First Name		
Lab Contact Last Name		
Address		673 Nitona-Cho,Chuo-Ku, Chiba, Chiba, Japan, 260-8712
Phone Number		+81432615171
Fax Number		+81432643139
Email Address		ishii.fumie.nz@mail.hosp.go.jp
Local Lab Accreditation		Others
Other Local Lab Accreditation		Certificate of Accuracy Assurance Facility JMA
Additional Questions		
Does your Facility have a SOP/written procedure for documenting bio-specimen (Sample) processing steps/chain of custody?		
Do your written procedures ensures that study-specific temperature bio-specimen storage requirements are known to responsible staff to ensure compliance?		
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
Lab Certification or Accreditation	JAMT 日本臨床衛生技師会精度管理調査 20210825_12-Sep-2022_11-29-12_GMT.pdf	
Lab Certification or Accreditation	JAMT 臨床検査精度管理調査2022年度20220825_17-Jun-2023_09-49-51_GMT.pdf	
Lab Certification or Accreditation	JMA 日本医師会検査精度管理調査 20220218_12-Sep-2022_11-30-10_GMT.pdf	
Lab Certification or Accreditation	JMA 日本医師会臨床検査精度管理調査令和4年度 20230217_17-Jun-2023_09-50-11_GMT.pdf	
Lab Certification or Accreditation	千葉県臨床検査技師会精度管理 20220201_12-Sep-2022_11-30-24_GMT.pdf	
Lab Certification or Accreditation	精度保証施設認証書20200401-20220331_06-May-2021_03-39-07_GMT.pdf	

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?	Yes
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)?	Yes
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; X-Radiation; Magnetic Resonance Angiography; 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

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: 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
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.); Apple/Mac (OS X Snow Leopard, Mountain Lion, El Capitan, etc.)
What type of internet access does your Facility have?	Cable or DSL; Wi-Fi

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?	No	
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
National Hospital Organization Chibahigashi National Hospital	673 Nitona-Cho, Chuo-Ku, Chiba, Chiba, Japan, 260-8712		+81432615171	+81432643139

Investigational Product Storage Location				
IP Recipient Name	Address	Email Address	Phone Number	Fax Number
Pharmacy Department	673 Nitona-Cho, Chuo-Ku, Chiba, Chiba, Japan, 260-8712		81432615171	81432643139

Investigational Product Storage Equipment	
Identify the Investigational Product Storage Equipment at your Facility	

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?	Yes
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 And 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 (non-vented)
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?	No
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	Document Description
Investigational Product Storage SOP	薬剤部内治験薬保管庫の温度管理に関する手順書 第5版 _pdf_17-Jun-2023_09-10-29_GMT.pdf	
Investigational Product Storage SOP	薬剤部内治験薬保管庫の温度管理に関する手順書 _20180601_01-May-2021_07-38-51_GMT.pdf	

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
Provide Location name and address of any offsite archives	
What type of investigator site file/regulatory binder used (select all that apply)	Paper
What investigator site file (eISF) / eRegulatory system do you use?	
Are monitors able to access eISF/eReg while off-site?	
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)?	No
Monitoring	
Check all equipment that will be available to Monitors:	Copy Machines
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	Oracle Inform; Medidata Rave; Others : ClinTrac, Veeva,
Describe Other EDC Systems	ClinTrac, Veeva,
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring?	No
Which of the following capabilities are available to support remote source data verification? (Check all that apply)	

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					

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 site. 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 are listed below with Affiliation Status			
Organization Name and Address	Organization Affiliation Type	Organization Affiliation Status	Status Date
No Records			

ASSOCIATED SITE USERS

Associated Site Users



Once checked, this checkbox will enable the Approval/Rejection workflow for this Facility. Any site user requesting to associate with this Facility would require to send the affiliation requests and only once Approved, this Facility will be shown on User's Profile.

Site User Association Requests				
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
No Records				

Associated/Confirmed Site Users				
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Fujita, Takanori	fujita.takanori572@eps.co.jp	13-Apr-2023		Confirmed
Ito, Mone	mitou@chiba-cc.jp	10-Mar-2023		Confirmed
Tsukada, Emi	tsukada.emi.kt@mail.hosp.go.jp	06-Apr-2023		Confirmed
saito, saki	saito.saki615@eps.co.jp	15-Mar-2023		Confirmed
oosawa, teruyo	oosawa.teruyo.mq@mail.hosp.go.jp	13-Apr-2023		Confirmed
Tamano, Ayumi	tamano.ayumi993@eps.co.jp	09-Mar-2023	09-Mar-2023	Confirmed
Ishii, Fumie	ishii.fumie.nz@mail.hosp.go.jp	30-Apr-2021	30-Apr-2021	Confirmed
Matsumura, Ryutaro	matsumura.ryutaro.hm@mail.hosp.go.jp	20-Jul-2021		Confirmed
Toba, Mutsumi	toba.mutsumi.sa@mail.hosp.go.jp	26-Aug-2021		Confirmed
Ishino, Yusuke	ishino.yusuke.cz@mail.hosp.go.jp	14-Dec-2021		Confirmed
Futami, Hidekazu	futami.hidekazu.re@mail.hosp.go.jp	10-Feb-2022		Confirmed
Ito, Chihiro	ito.chihiro.ut@mail.hosp.go.jp	03-Feb-2022		Confirmed
Nakazawa, Takuya	nakazawa.takuya.te@mail.hosp.go.jp	10-Feb-2022		Confirmed
Oya, Yoshihiro	ooya.yoshihiro.cw@mail.hosp.go.jp	25-Jan-2022		Confirmed
Inaba, Yoko	inaba.yoko.ev@mail.hosp.go.jp	07-Mar-2022		Confirmed
Wakabayashi, Yutaka	wakabayashi.yutaka.sp@mail.hosp.go.jp	23-Feb-2022		Confirmed
kasuya, tadamichi	kasuya.tadamichi.ya@mail.hosp.go.jp	03-Jun-2022		Confirmed