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FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Chiba Medical Center 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 Trial Office
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

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: NHO Chiba Medica Center Chibahigashi National Hospital Institutional Review Board	
IRB/ERB/Ethics Committee Name	NHO Chiba Medica Center Chibahigashi National Hospital Institutional Review Board
Address	673 Nitona-Cho,Chuo-ku, Chiba, Chiba, Japan, 260-8712
Registration#	**Registering Body**
NA	
What is the meeting frequency of your Local 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?	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

Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: National Hospital Organization Chiba Medical Center Chibahigashi National Hospital clinical inspection department	
Lab Name	National Hospital Organization Chiba Medical Center 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

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Local Lab Accreditation	Others
Other Local Lab Accreditation	Quality Assurance Facility CertificateCertificate 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?	No
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	品質保証施設認証書20240601-20260531_28-Jun-2025_05-03-30_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
What types of eConsent platforms does your Facility use? (Select all that apply)	
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 study conduct (e.g. consent, study 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, sphymomanomer, etc.?	Yes
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.	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 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
Does your Facility have antivirus software on all these electronic devices?	Yes
Does your Facility continuously update the anti-virus software to the most recent version?	Yes
Does your Facility have an SOP or process that documents both physical and firewall security measures that are used for electronic systems?	No
Does your Facility perform periodic system reviews to ensure they remain in a validated state?	Yes
Does your Facility have an SOP or process that documents user management processes that are used for electronic systems?	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
What type of internet browser(s) does your institution use to support studies? (Check all that apply)	Chrome, Edge
Is access to the internet secured against unauthorized use?	Yes
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 your institution allow the download of information from an external portal ?(e.g. eDC system)	Yes
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)?	Yes
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	Phone Number	Fax Number	Email Address	Site Specific Requirements
National Hospital Organization Chibahigashi National Hospital	673 Nitona-Cho,Chuo-Ku, Chiba, Chiba, Japan, 260-8712	+81432615171	+81432643139		

Investigational Product Storage Location

IP Storage Location Name	Address	Phone Number	Fax Number	Email Address
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	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.	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?	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

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Do all of the Facility's systems/technology used to store and manage source data conform with international system standards (e.g. ICH/GCP/EU)?	Yes
Does your Facility have secure storage for patient records?	Yes
Does your Facility have patient record archiving on-site?	Yes
Does your Facility have an SOP or process that documents how to limit access and prevent the premature destruction of the Facility's files?	Yes
What type of investigator site file/regulatory binder used (select all that apply)	Paper
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
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?	
Are monitors able to access EHR/EMR while off site?	No
Does your Facility require Sponsor representative to sign any local form (paper or electronic) for access, or any other purpose?	
Does your Facility utilize any additional electronic systems to capture source data outside of the EMR/EHR?	
Does your Facility utilize any additional electronic systems or paper-based systems to access patient medical history?	
Do the systems used for clinical trial data entry and management have audit trail functionality?	

Bring Your Own Device	
Can your Facility support the use of bring your own device (BYOD) technologies to conduct Clinical Trials?	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
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

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.

SIP Registered Locations

Location Name	Address
No Records	

SIP Non-Registered Locations

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	**User Role**	**Request Affiliation Date**	**Affiliation Status change Date**	**Affiliation Status**
Gunji,Mitsuhiro	Clinical Research User	05-Jul-2023	05-Jul-2023	Confirmed
Fujita,Takanori	Clinical Research User	13-Apr-2023	13-Apr-2023	Confirmed
Ito,Mone	Clinical Research User	10-Mar-2023	10-Mar-2023	Confirmed
Tsukada,Emi	Clinical Research User	06-Apr-2023	06-Apr-2023	Confirmed
saito,saki	Clinical Research User	15-Mar-2023	15-Mar-2023	Confirmed
oosawa,teruyo	Clinical Research User	13-Apr-2023	13-Apr-2023	Confirmed
Tamano,Ayumi	Clinical Research User	09-Mar-2023	09-Mar-2023	Confirmed
Ishii,Fumie	Clinical Research User	30-Apr-2021	30-Apr-2021	Confirmed
Matsumura,Ryutaro	Investigator	20-Jul-2021	20-Jul-2021	Confirmed
Toba,Mutsumi	Clinical Research User	26-Aug-2021	26-Aug-2021	Confirmed
Ishino,Yusuke	Clinical Research User	14-Dec-2021	14-Dec-2021	Confirmed
Futami,Hidekazu	Investigator	10-Feb-2022	10-Feb-2022	Confirmed
Ito,Chihiro	Clinical Research User	03-Feb-2022	03-Feb-2022	Confirmed
Nakazawa,Takuya	Investigator	10-Feb-2022	10-Feb-2022	Confirmed
Oya,Yoshihiro	Investigator	25-Jan-2022	25-Jan-2022	Confirmed
Inaba,Yoko	Clinical Research User	07-Mar-2022	07-Mar-2022	Confirmed
Wakabayashi,Yutaka	Investigator	23-Feb-2022	23-Feb-2022	Confirmed
kasuya,tadamichi	Investigator	03-Jun-2022	03-Jun-2022	Confirmed
hirayama,shin	Clinical Research User	12-Mar-2025	12-Mar-2025	Confirmed
Sato,Masanobu	Clinical Research User	05-Mar-2025	05-Mar-2025	Confirmed
Sugisaki,Kazuki	Clinical Research User	10-Apr-2025	10-Apr-2025	Confirmed
Ishii,Yuri	Clinical Research User	10-Apr-2025	10-Apr-2025	Confirmed
Oshiga,Mitsunori	Clinical Research User	28-Feb-2025	28-Feb-2025	Confirmed
Ogawa,Minami	Clinical Research User	12-May-2025	12-May-2025	Confirmed
Saito,Masaru	Clinical Research User	05-Aug-2024	05-Aug-2024	Confirmed
Onozato,Mai	Clinical Research User	02-Oct-2024	02-Oct-2024	Confirmed
Nomura,Rie	Clinical Research User	10-Jan-2025	10-Jan-2025	Confirmed
Ito,Katsuya	Clinical Research User	05-Apr-2024	05-Apr-2024	Confirmed

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Name	User Role	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Urasaki,Kayoko	Clinical Research User	02-May-2024	02-May-2024	Confirmed
Hara,Hikari	Clinical Research User	10-Jun-2024	10-Jun-2024	Confirmed
Toda,Yosuke	Investigator	15-May-2024	15-May-2024	Confirmed
Sakurai,Sawa	Clinical Research User	12-Nov-2025	12-Nov-2025	Confirmed
Suzuki,Kohei	Clinical Research User	05-Mar-2026	05-Mar-2026	Confirmed
Oiwa,Sakurako	Clinical Research User	16-Feb-2026	16-Feb-2026	Confirmed
HIDAKA,MIZUHO	Clinical Research User	10-Jun-2026	10-Jun-2026	Confirmed