

FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Shibukawa Medical Center	Hospital or Medical Center	383 Shiroy, Shibukawa, Gunma, Japan, 377-0280

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Naoi, Takahiro	naoi.takahiro.cu@mail.hosp.go.jp	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	Sub Therapeutic Area
Bacterial Infections and Mycoses	Bacterial Infections
Bacterial Infections and Mycoses	Central Nervous System Infections
Bacterial Infections and Mycoses	Infection
Bacterial Infections and Mycoses	Mycoses
Bacterial Infections and Mycoses	Zoonoses
Cardiovascular Diseases	Kidney Diseases
Cardiovascular Diseases	Metabolic
Cardiovascular Diseases	Cardiovascular Abnormalities
Cardiovascular Diseases	Cardiovascular Infections
Cardiovascular Diseases	Heart Diseases
Cardiovascular Diseases	Pregnancy Complications, Cardiovascular
Cardiovascular Diseases	Vascular Diseases
Chemically-induced Disorders	Drug-Related Side Effects and Adverse Reactions
Chemically-induced Disorders	Poisoning
Chemically-induced Disorders	Substance-Related Disorders
Digestive System Diseases	Inflammatory Bowel Disease
Digestive System Diseases	Biliary Tract Diseases
Digestive System Diseases	Digestive System Abnormalities
Digestive System Diseases	Digestive System Fistula
Digestive System Diseases	Digestive System Neoplasms
Digestive System Diseases	Gastrointestinal Diseases

Therapeutic Area	Sub Therapeutic Area
Digestive System Diseases	Liver Diseases
Digestive System Diseases	Pancreatic Diseases
Digestive System Diseases	Peritoneal Diseases
Disorders of Environmental Origin	Environmental Illness
Disorders of Environmental Origin	Preconception Injuries
Endocrine System Diseases	Adrenal Gland Diseases
Endocrine System Diseases	Bone Diseases, Endocrine
Endocrine System Diseases	Diabetes Mellitus
Endocrine System Diseases	Dwarfism
Endocrine System Diseases	Endocrine Gland Neoplasms
Endocrine System Diseases	Female Athlete Triad Syndrome
Endocrine System Diseases	Gonadal Disorders
Endocrine System Diseases	Parathyroid Diseases
Endocrine System Diseases	Pituitary Diseases
Endocrine System Diseases	Polyendocrinopathies, Autoimmune
Endocrine System Diseases	Thyroid Diseases
Endocrine System Diseases	Tuberculosis, Endocrine
Eye Diseases	Asthenopia
Eye Diseases	Cogan Syndrome
Eye Diseases	Conjunctival Diseases
Eye Diseases	Corneal Diseases
Eye Diseases	Eye Abnormalities
Eye Diseases	Eye Diseases, Hereditary
Eye Diseases	Eye Hemorrhage
Eye Diseases	Eye Infections
Eye Diseases	Eye Injuries
Eye Diseases	Eye Manifestations
Eye Diseases	Eye Neoplasms
Eye Diseases	Eyelid Diseases

Therapeutic Area	Sub Therapeutic Area
Eye Diseases	Lacrimal Apparatus Diseases
Eye Diseases	Lens Diseases
Eye Diseases	Ocular Hypertension
Eye Diseases	Ocular Hypotension
Eye Diseases	Ocular Motility Disorders
Eye Diseases	Optic Nerve Diseases
Eye Diseases	Orbital Diseases
Eye Diseases	Pupil Disorders
Eye Diseases	Refractive Errors
Eye Diseases	Retinal Diseases
Eye Diseases	Scleral Diseases
Eye Diseases	Uveal Diseases
Eye Diseases	Vision Disorders
Eye Diseases	Vitreous Detachment
Female Urogenital Diseases and Pregnancy Complications	Female Urogenital Diseases
Hemic and Lymphatic Diseases	Anemia
Hemic and Lymphatic Diseases	Hemophilia
Hemic and Lymphatic Diseases	Hematologic Diseases
Hemic and Lymphatic Diseases	Lymphatic Diseases
Immune System Diseases	Autoimmune Diseases
Immune System Diseases	Erythroblastosis, Fetal
Immune System Diseases	Glomerulonephritis, Membranoproliferative
Immune System Diseases	Graft vs Host Disease
Immune System Diseases	Hypersensitivity
Immune System Diseases	Immune Reconstitution Inflammatory Syndrome
Immune System Diseases	Immunologic Deficiency Syndromes
Immune System Diseases	Immunoproliferative Disorders
Immune System Diseases	Purpura, Thrombocytopenic
Immune System Diseases	Transfusion Reaction

Therapeutic Area	Sub Therapeutic Area
Male Urogenital Diseases	Genital Diseases, Male
Male Urogenital Diseases	Pelvic Floor Disorders
Male Urogenital Diseases	Tuberculosis, Urogenital
Male Urogenital Diseases	Urogenital Abnormalities
Male Urogenital Diseases	Urogenital Neoplasms
Male Urogenital Diseases	Urologic Diseases
Mental disorders	Anxiety Disorders
Mental disorders	Bipolar and Related Disorders
Mental disorders	Disruptive, Impulse Control, and Conduct Disorders
Mental disorders	Dissociative Disorders
Mental disorders	Elimination Disorders
Mental disorders	Feeding and Eating Disorders
Mental disorders	Mood Disorders
Mental disorders	Motor Disorders
Mental disorders	Neurocognitive Disorders
Mental disorders	Neurodevelopmental Disorders
Mental disorders	Neurotic Disorders
Mental disorders	Paraphilic Disorders
Mental disorders	Personality Disorders
Mental disorders	Schizophrenia Spectrum and Other Psychotic Disorders
Mental disorders	Sexual Dysfunctions, Psychological
Mental disorders	Sleep Wake Disorders
Mental disorders	Somatoform Disorders
Mental disorders	Substance-Related Disorders
Mental disorders	Trauma and Stressor Related Disorders
Musculoskeletal Diseases	Arthritis
Musculoskeletal Diseases	Bone Diseases
Musculoskeletal Diseases	Cartilage Diseases
Musculoskeletal Diseases	Fasciitis

Therapeutic Area	Sub Therapeutic Area
Musculoskeletal Diseases	Foot Deformities
Musculoskeletal Diseases	Foot Diseases
Musculoskeletal Diseases	Hand Deformities
Musculoskeletal Diseases	Jaw Diseases
Musculoskeletal Diseases	Joint Diseases
Musculoskeletal Diseases	Muscular Diseases
Musculoskeletal Diseases	Musculoskeletal Abnormalities
Musculoskeletal Diseases	Rheumatic Diseases
Neoplasms	Cysts
Neoplasms	Hamartoma
Neoplasms	Neoplasms by Histologic Type
Neoplasms	Neoplasms by Site
Neoplasms	Neoplasms, Experimental
Neoplasms	Neoplasms, Hormone-Dependent
Neoplasms	Neoplasms, Multiple Primary
Neoplasms	Neoplasms, Post-Traumatic
Neoplasms	Neoplasms, Radiation-Induced
Neoplasms	Neoplasms, Second Primary
Neoplasms	Neoplastic Processes
Neoplasms	Neoplastic Syndromes, Hereditary
Neoplasms	Paraneoplastic Syndromes
Neoplasms	Precancerous Conditions
Neoplasms	Pregnancy Complications, Neoplastic
Nervous System Diseases	Autoimmune Diseases of the Nervous System
Nervous System Diseases	Autonomic Nervous System Diseases
Nervous System Diseases	Central Nervous System Diseases
Nervous System Diseases	Chronobiology Disorders
Nervous System Diseases	Cranial Nerve Diseases
Nervous System Diseases	Demyelinating Diseases

Therapeutic Area	Sub Therapeutic Area
Nervous System Diseases	Nervous System Malformations
Nervous System Diseases	Nervous System Neoplasms
Nervous System Diseases	Neurocutaneous Syndromes
Nervous System Diseases	Neurodegenerative Diseases
Nervous System Diseases	Neurologic Manifestations
Nervous System Diseases	Neuromuscular Diseases
Nervous System Diseases	Neurotoxicity Syndromes
Nervous System Diseases	Restless Legs Syndrome
Nervous System Diseases	Sleep Wake Disorders
Nervous System Diseases	Trauma, Nervous System
Nutritional and Metabolic Diseases	Metabolic Diseases
Nutritional and Metabolic Diseases	Nutrition Disorders
Occupational Diseases	Agricultural Workers' Diseases
Occupational Diseases	Asthma, Occupational
Occupational Diseases	Bird Fancier's Lung
Occupational Diseases	Burnout, Professional
Occupational Diseases	Dermatitis, Occupational
Occupational Diseases	Hand-Arm Vibration Syndrome
Occupational Diseases	High Pressure Neurological Syndrome
Occupational Diseases	Inert Gas Narcosis
Occupational Diseases	Laboratory Infection
Occupational Diseases	Persian Gulf Syndrome
Occupational Diseases	Pneumoconiosis
Occupational Diseases	Sleep Disorders, Circadian Rhythm
Otorhinolaryngologic Diseases	Ciliary Motility Disorders
Otorhinolaryngologic Diseases	Ear Diseases
Otorhinolaryngologic Diseases	Laryngeal Diseases
Otorhinolaryngologic Diseases	Nose Diseases
Otorhinolaryngologic Diseases	Otorhinolaryngologic Neoplasms

Therapeutic Area	Sub Therapeutic Area
Otorhinolaryngologic Diseases	Pharyngeal Diseases
Parasitic Diseases	Central Nervous System Parasitic Infections
Parasitic Diseases	Coinfection
Parasitic Diseases	Eye Infections, Parasitic
Parasitic Diseases	Helminthiasis
Parasitic Diseases	Intestinal Diseases, Parasitic
Parasitic Diseases	Liver Diseases, Parasitic
Parasitic Diseases	Lung Diseases, Parasitic
Parasitic Diseases	Mesomycetozoea Infections
Parasitic Diseases	Opportunistic Infections
Parasitic Diseases	Parasitemia
Parasitic Diseases	Parasitic Diseases, Animal
Parasitic Diseases	Pregnancy Complications, Parasitic
Parasitic Diseases	Protozoan Infections
Parasitic Diseases	Skin Diseases, Parasitic
Parasitic Diseases	Zoonoses
Pathological Conditions, Signs and Symptoms	Morphological and Microscopic Findings
Pathological Conditions, Signs and Symptoms	Pathological Conditions, Anatomical
Pathological Conditions, Signs and Symptoms	Pathologic Processes
Pathological Conditions, Signs and Symptoms	Signs and Symptoms
Respiratory Tract Diseases	Bronchial Diseases
Respiratory Tract Diseases	Ciliary Motility Disorders
Respiratory Tract Diseases	Granuloma, Respiratory Tract
Respiratory Tract Diseases	Laryngeal Diseases
Respiratory Tract Diseases	Lung Diseases
Respiratory Tract Diseases	Nose Diseases
Respiratory Tract Diseases	Pleural Diseases
Respiratory Tract Diseases	Respiration Disorders
Respiratory Tract Diseases	Respiratory Hypersensitivity

Therapeutic Area	Sub Therapeutic Area
Respiratory Tract Diseases	Respiratory System Abnormalities
Respiratory Tract Diseases	Respiratory Tract Fistula
Respiratory Tract Diseases	Respiratory Tract Infections
Respiratory Tract Diseases	Respiratory Tract Neoplasms
Respiratory Tract Diseases	Thoracic Diseases
Respiratory Tract Diseases	Tracheal Diseases
Skin and Connective Tissue Diseases	Connective Tissue Diseases
Skin and Connective Tissue Diseases	Skin Diseases
Stomatognathic Diseases	Ankyloglossia
Stomatognathic Diseases	Jaw Diseases
Stomatognathic Diseases	Mouth Diseases
Stomatognathic Diseases	Pharyngeal Diseases
Stomatognathic Diseases	Stomatognathic System Abnormalities
Stomatognathic Diseases	Temporomandibular Joint Disorders
Stomatognathic Diseases	Tooth Diseases
Virus Diseases	Viremia
Virus Diseases	Arbovirus Infections
Virus Diseases	Bronchiolitis, Viral
Virus Diseases	Central Nervous System Viral Diseases
Virus Diseases	Coinfection
Virus Diseases	DNA Virus Infections
Virus Diseases	Encephalitis, Viral
Virus Diseases	Eye Infections, Viral
Virus Diseases	Fatigue Syndrome, Chronic
Virus Diseases	Hepatitis, Viral, Animal
Virus Diseases	Hepatitis, Viral, Human
Virus Diseases	Opportunistic Infections
Virus Diseases	Pneumonia, Viral
Virus Diseases	RNA Virus Infections

Therapeutic Area	Sub Therapeutic Area
Virus Diseases	Sexually Transmitted Diseases
Virus Diseases	Skin Diseases, Viral
Virus Diseases	Slow Virus Diseases
Virus Diseases	Tumor Virus Infections
Virus Diseases	Zoonoses
Wounds and Injuries	Abdominal Injuries
Wounds and Injuries	Amputation, Traumatic
Wounds and Injuries	Arm Injuries
Wounds and Injuries	Asphyxia
Wounds and Injuries	Athletic Injuries
Wounds and Injuries	Back Injuries
Wounds and Injuries	Barotrauma
Wounds and Injuries	Battered Child Syndrome
Wounds and Injuries	Birth Injuries
Wounds and Injuries	Bites and Stings
Wounds and Injuries	Burns
Wounds and Injuries	Cold Injury
Wounds and Injuries	Contrecoup Injury
Wounds and Injuries	Crush Injuries
Wounds and Injuries	Joint Dislocations
Wounds and Injuries	Drowning
Wounds and Injuries	Electric Injuries
Wounds and Injuries	Esophageal Perforation
Wounds and Injuries	Extravasation of Diagnostic and Therapeutic Materials
Wounds and Injuries	Foreign Bodies
Wounds and Injuries	Fractures, Bone
Wounds and Injuries	Fractures, Cartilage
Wounds and Injuries	Frostbite
Wounds and Injuries	Hand Injuries

Therapeutic Area	Sub Therapeutic Area
Wounds and Injuries	Heat Stress Disorders
Wounds and Injuries	Hip Injuries
Wounds and Injuries	Lacerations
Wounds and Injuries	Leg Injuries
Wounds and Injuries	Microtrauma, Physical
Wounds and Injuries	Multiple Trauma
Wounds and Injuries	Nasal Septal Perforation
Wounds and Injuries	Neck Injuries
Wounds and Injuries	Occupational Injuries
Wounds and Injuries	Radiation Injuries
Wounds and Injuries	Retropneumoperitoneum
Wounds and Injuries	Rupture
Wounds and Injuries	Self Mutilation
Wounds and Injuries	Shock, Traumatic
Wounds and Injuries	Shoulder Injuries
Wounds and Injuries	Soft Tissue Injuries
Wounds and Injuries	Spinal Cord Injuries
Wounds and Injuries	Sprains and Strains
Wounds and Injuries	Surgical Wound
Wounds and Injuries	Tendon Injuries
Wounds and Injuries	Thoracic Injuries
Wounds and Injuries	Tooth Injuries
Wounds and Injuries	Trauma, Nervous System
Wounds and Injuries	Tympanic Membrane Perforation
Wounds and Injuries	Vascular System Injuries
Wounds and Injuries	War-Related Injuries
Wounds and Injuries	Wounds, Nonpenetrating
Wounds and Injuries	Wounds, Penetrating
Bone	Bone

Therapeutic Area	Sub Therapeutic Area
Bone	Osteoporosis
Infectious Diseases	Infectious Diseases
Inflammation	Inflammation
Internal Medicine	Internal Medicine
Nephrology	Nephrology
Neuroscience	Neuroscience
Oncology	Brain
Oncology	Breast
Oncology	Central Nervous System
Oncology	Cervical
Oncology	Esophagael
Oncology	Gastric
Oncology	Bladder
Oncology	Colorectal
Oncology	Gastrointestinal
Oncology	Genitourinary
Oncology	Head and Neck
Oncology	Hematologic Malignancies
Oncology	Hepatocellular Carcinoma
Oncology	Leukemia
Oncology	Lung
Oncology	Lymphoma
Oncology	Melanoma
Oncology	Multiple Myeloma
Oncology	Ovarian
Oncology	Pediatrics
Oncology	Prostate
Oncology	Radiation Oncology
Oncology	Renal

Therapeutic Area	Sub Therapeutic Area
Oncology	Skin
Oncology	Uterine
Oncology	Carcinoma
Oncology	Sarcoma
Vaccines	Vaccines
Women's Health	Women's Health
Allergy	Allergy
Pain	Pain
Device	Device

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; Government
Is your Facility affiliated with a government agency or part of a government funded health service?	Yes

Patient Population

Patient Population Demographics	Adults - Ages 18-64; Geriatrics - Greater than or equal to 65
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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?	Less than 30
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	Department
Department Contact Phone Number	0279231010
Department Contact Email Address	207-chiken_mbx@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; Sponsor Provided Central
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: Institutional Review Board of National Hospital Organization Shibukawa Medical Center	
IRB/ERB/Ethics Committee Name	Institutional Review Board of National Hospital Organization Shibukawa Medical Center
Address	282 Shiroi, Shibukawa-shi, Gunma, Japan, 3770200
Registration#	Registering Body
NA	NA
What is the meeting frequency of the IRB/ERB/Ethics Committee?	Other
Other	every two month
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.	
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Local Lab

Is your Facility using a Local Lab?	Yes
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Local Lab: Clinical Trial Management Office		
Lab Name	Clinical Trial Management Office	
Lab Contact First Name	Takahiro	
Lab Contact Last Name	Naoi	
Address	383 Shiroi, Shibukawa-shi, Gunma, Japan, 3770280	
Phone Number	+81279231010	
Fax Number	+81279231011	
Email Address		
Local Lab Accreditation	Others	
Other Local Lab Accreditation	日本医師会臨床検査精度管理調査	
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
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?	Yes
Does your Facility use an external program to conduct research training?	Yes
Please provide program course name.	eAPRIN
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?	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; 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

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?	No
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?	No
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?	No
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?	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; Wi-Fi
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?		I don't Know
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?		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 Shibukawa Medical Center	383 Shiroi, Shibukawa-shi, Gunma, Japan, 3770280	Naoi.Takahiro.cu@mail.hosp.go.jp	0279231010	

Investigational Product Storage Location				
IP Recipient Name	Address	Email Address	Phone Number	Fax Number
National Hospital Organization Shibukawa Medical Center	383 Shiroi, Shibukawa-shi, Gunma, Japan, 3770280	207-chiken_mbx@mail.hosp.go.jp	0279231010	

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?	No
Does this equipment provide Min/Max Temperature Monitoring?	No
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?	No
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?	No
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?	No

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?	No
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?	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?	No
Does the Investigational Product Storage Room provide Min/Max temperature monitoring?	No
Does the Investigational Product Storage Room have back-up power?	Yes
Does the Investigational Product Storage Room have a temperature alarm?	No
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?	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 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)
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	Document Description
No Records		

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)	
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)?	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.	
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?	No
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; Others : Cerba Research,CENDUIT,FIRECREST,ALMAC,ERT
Describe Other EDC Systems	Cerba Research,CENDUIT,FIRECREST,ALMAC,ERT
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

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
Watanabe, Takafumi	watanabe.takafumi369@eps.co.jp	09-May-2023		Confirmed
Sawamura, Seigo	sawamura.seigo.yb@mail.hosp.go.jp	27-Mar-2019	19-Jun-2023	Confirmed
Hayashi, Haruko	hayashi.haruko.fv@mail.hosp.go.jp	17-Mar-2020		Confirmed
Fukasawa, Miwako	fukasawa.miwako.he@mail.hosp.go.jp	17-Mar-2020		Confirmed
Naoi, Takahiro	naoi.takahiro.cu@mail.hosp.go.jp	16-Sep-2020	20-Sep-2022	Confirmed
Saito, Akio	saito.akio.hf@mail.hosp.go.jp	22-Oct-2020		Confirmed
Iiai, Hitoshi	iiiai.hitoshi.mn@mail.hosp.go.jp	03-Dec-2020		Confirmed
Matsumoto, Morio	matsumoto.morio.zr@mail.hosp.go.jp	22-Jan-2021		Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Sawamura,Morio	morios8208@gmail.com	22-Jan-2021		Confirmed
Sakata,Konomi	sakata.konomi655@eps.co.jp	04-Apr-2022		Confirmed
Kamada,Rieko	kamada.rieko516@eps.co.jp	20-Apr-2022	20-Apr-2022	Confirmed