



FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Kanazawa Medical Center	Hospital or Medical Center	1-1 Shimoishibikimachi, Clinical Research Department / Clinical Trial Management Office, Kanazawa, Ishikawa, Japan, 920-8650

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Tabuchi, Katsunori	katuta3456789@gmail.com	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	Sub-Therapeutic Area
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
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
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
Nutritional and Metabolic Diseases	Metabolic Diseases
Nutritional and Metabolic Diseases	Nutrition Disorders
Virus Diseases	Viremia
Bone	Bone
Bone	Osteoporosis
Cardiovascular Diseases	Kidney Diseases
Cardiovascular Diseases	Metabolic
Digestive System Diseases	Inflammatory Bowel Disease
Hemic and Lymphatic Diseases	Anemia
Hemic and Lymphatic Diseases	Hemophilia
Infectious Diseases	Infectious Diseases
Inflammation	Inflammation
Internal Medicine	Internal Medicine
Musculoskeletal Diseases	Arthritis
Nephrology	Nephrology
Neuroscience	Neuroscience
Ob-Gyn	Ob-Gyn
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
Oncology	Skin
Oncology	Uterine
Orthopedics	Orthopedics
Pediatrics	Pediatrics
Vaccines	Vaccines
Women's Health	Women's Health
Allergy	Allergy
Pain	Pain
Oncology	Carcinoma
Oncology	Sarcoma
Bacterial Infections and Mycoses	Bacterial Infections
Bacterial Infections and Mycoses	Central Nervous System Infections
Bacterial Infections and Mycoses	Infection
Bacterial Infections and Mycoses	Mycoses
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
Virus Diseases	Sexually Transmitted Diseases
Virus Diseases	Skin Diseases, Viral
Virus Diseases	Slow Virus Diseases
Virus Diseases	Tumor Virus Infections
Virus Diseases	Zoonoses
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	Mesomycetozoa Infections
Parasitic Diseases	Opportunistic Infections
Parasitic Diseases	Parasitemia
Parasitic Diseases	Pregnancy Complications, Parasitic
Parasitic Diseases	Protozoan Infections
Parasitic Diseases	Skin Diseases, Parasitic
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
Musculoskeletal Diseases	Bone Diseases
Musculoskeletal Diseases	Cartilage Diseases
Musculoskeletal Diseases	Fasciitis
Musculoskeletal Diseases	Foot Diseases
Musculoskeletal Diseases	Hand Deformities
Musculoskeletal Diseases	Joint Diseases
Musculoskeletal Diseases	Rheumatic Diseases
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
Digestive System Diseases	Liver Diseases
Digestive System Diseases	Pancreatic Diseases
Digestive System Diseases	Peritoneal Diseases
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
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
Otorhinolaryngologic Diseases	Ciliary Motility Disorders
Otorhinolaryngologic Diseases	Ear Diseases
Otorhinolaryngologic Diseases	Laryngeal Diseases
Otorhinolaryngologic Diseases	Nose Diseases
Otorhinolaryngologic Diseases	Otorhinolaryngologic Neoplasms
Otorhinolaryngologic Diseases	Pharyngeal Diseases
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
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
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	Eyelid Diseases
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
Male Urogenital Diseases	Genital Diseases, Male
Male Urogenital Diseases	Pelvic Floor Disorders
Male Urogenital Diseases	Tuberculosis, Urogenital
Male Urogenital Diseases	Urogenital Neoplasms
Male Urogenital Diseases	Urologic Diseases
Female Urogenital Diseases and Pregnancy Complications	Female Urogenital Diseases
Female Urogenital Diseases and Pregnancy Complications	Pregnancy Complications
Cardiovascular Diseases	Cardiovascular Abnormalities
Cardiovascular Diseases	Cardiovascular Infections
Cardiovascular Diseases	Heart Diseases
Cardiovascular Diseases	Pregnancy Complications, Cardiovascular
Cardiovascular Diseases	Vascular Diseases
Hemic and Lymphatic Diseases	Hematologic Diseases
Hemic and Lymphatic Diseases	Lymphatic Diseases
Congenital, Hereditary, and Neonatal Diseases and Abnormalities	Infant, Newborn, Diseases
Skin and Connective Tissue Diseases	Connective Tissue Diseases
Skin and Connective Tissue Diseases	Skin Diseases
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



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
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
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
Chemically-induced Disorders	Drug-Related Side Effects and Adverse Reactions
Chemically-induced Disorders	Poisoning
Chemically-induced Disorders	Substance-Related Disorders
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	Pediatrics - Less than or equal to 17; Adults - Ages 18-64; Geriatrics - Greater than or equal to 65
Patient Population Comments	
Japanese 95%, Asian 3%, other 2%	

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 dedicated department or group to perform IRB/ERB/Ethics Committee submissions?	Yes
Department Contact Name	Clinical
Department Contact Phone Number	+81-76-262-4161
Department Contact Email Address	302-kanazawaCR@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?	Yes
Other Steps Explain	1,NHO Kanazawa Medical Center, Institutional Review Board E-mail : 302-kanazawaCR@mail.hosp.go.jpPhone number : 076-203-45202,NHOCRB/National Hospital Organization Central Review Board3,Pediatric Clinical Trials Network Central Review Board

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: NHO Kanazawa Medical Center Institutional Review Board	
IRB/ERB/Ethics Committee Name	NHO Kanazawa Medical Center Institutional Review Board
Address	1-1 shimoishibikimachi kanazawa Ishikawa 920-8650, Japan, Clinical Research Department / Clinical Trial Management Office, 1-1 shimoishibikimachi, Kanazawa, Ishikawa, Japan, 920-8650
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

Registration#	Registering Body
N/A	N/A

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.	Yes
---	-----

Review Board Name	Meeting Frequency
Pediatric Clinical Trials Network Central Review Board	Monthly
NHOCRB/National Hospital Organization Central Review Board	Monthly

Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: Kanazawa Medical Center Clinical Laboratory	
Lab Name	Kanazawa Medical Center Clinical Laboratory
Lab Contact First Name	
Lab Contact Last Name	
Address	1-1 shimoishibikimachi kanazawa Ishikawa,920-8650,Japan, Clinical Laboratory, 1-1 shimoishibikimachi, kanazawa, Ishikawa, Japan, 920-8650
Phone Number	+81-76-262-4161
Fax Number	N/A
Email Address	
Local Lab Accreditation	None



CONSENT & TRAINING

Consent	
Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?	No
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?	Yes
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
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.	Less than 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?	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?	
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Less than 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?	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.	Less than 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?	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?	Yes

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Investigational Product Shipping Details	
IP Recipient Name	NHO Kanazawa Medical Center Clinical Trial Management Office
Address	1-1 shimoishibikimachi, Clinical Research Department / Clinical Trial Management Office, Kanazawa, Ishikawa, Japan, 920-8650
Email Address:	302- kanazawaCR@mail.hosp.go.jp
Phone Number:	+81-76-203-4520
Fax Number:	+81-76-262-4191
Investigational Product Storage Location	
IP Storage Location Name	NHO Kanazawa Medical Center yakuzaibu
Address	1-1 shimoishibikimachi, Clinical Research Department / Clinical Trial Management Office, Kanazawa, Ishikawa, Japan, 920-8650
Email Address:	302- kanazawaCR@mail.hosp.go.jp
Phone Number:	+81-76-203-4520
Fax Number:	+81-76-262-4191
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.	Less than 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?	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 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?	No	
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); Horizontal laminar flow hood (non-hazardous drug preparation)	
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?	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		
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; Other	
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.	To log in to an electronic medical record, an ID and password	



must be assigned. In addition, the monitors can only access the medical records of patients who participated in the clinical trial.

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 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 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			