SIP Facility Profile Form

***Note:** Invalid phone numbers and email address if entered in text fields in the form shall not be populated in SIP.*

Facility Name

Therapeutic Areas And Patient Population

Therapeutic Area(s): Provide the list of Therapeutic Areas for your Facility

- Neoplasms
- Hemic and Lymphatic Diseases
- Male Urogenital Diseases
- Mental Disorders
- Nervous System Diseases
- Respiratory Tract Diseases
- Skin and Connective Tissue Diseases
- Cardiovascular Diseases
- Female Urogenital Diseases and Pregnancy Complications
- Wounds and Injuries

Sub-Therapeutic Areas:

***Note:** Sub-Therapeutic Areas can be selected online from the Facility Profile in SIP.*

Other Areas of Expertise:

Oncology, Hematologic Malignancy, Eye Diseases, Otorhinolaryngologic disease, Digestive system disease, Endocrine system disease, Musculoskeletal disease

Study Phase Capabilities

☑ Phase I ☑ Phase II ☑ Phase III ☑ Phase IV

Other Facility Details

Do you have Affiliated Research Sites or Satellite Sites/Clinics? A Satellite Site is a secondary location where the investigator sees clinical trial subjects. Usually this is the same investigator who sees subjects at the primary site location. ○ Yes ◉ No

What study types does your Facility have experience with?

☑ Academic ☑ Industry ☑ Investigator Initiated ☑ Government ☐ Other

Is your Facility affiliated with a government agency or part of a government funded health service? ○ Yes ◉ No ○ Not Applicable

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:

100% Japanese

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SIP Facility Profile Form

IRB/ERB/Ethics Committee

What is the average time (in days) to start a study once you have received the regulatory package? ○ Less than 30 ◉ 30-60 ○ 90 ○ 91-120 ○ 61-Greater than 120

Does your Facility perform IRB/ERB/Ethics Committee submissions? ◉ Yes ○ No

Does your Facility have a dedicated department or group to perform IRB/ERB/Ethics Committee submissions? ◉ Yes ○ No

Department Contact Name: Yasuhiro Kidera

Department Contact Phone Number: +81-72-366-0221

Department Contact Email Address: ck-jimu@med.kindai.ac.jp

Is your Facility able to initiate study activities prior to IRB/ERB/ Ethics Committee protocol approval? ○ Yes ◉ No

What types of IRB/ERB/Ethics Committee does your Facility use? (Select all that apply.) ☑ Local ☐ Central Acting as Local ☐ Sponsor Provided Central

Does your institution and/or local regulation mandate the distribution of safety reports [e.g., development Safety Update report (DSUR), suspected unexpected serious adverse reaction (SUSAR) to a local Review Only IRB/ERB/Ethics Committee? ◉ Yes ○ No

Are there any other steps that the Sponsor should be aware of for your IRB/ERB/Ethics Committee review and submission? ◉ Yes ○ No

If Yes, provide details about the role various committees play in your site's review and submission process. If you have multiple local IRBs, explain what drives the decision on which IRB to use.

Clinical trials initiated by October 2022 that involve protocols including gene analysis require approval from the Ethics Committee.

SIP Facility Profile Form

Local IRB/ERB/Ethics Committee

IRB/ERB/Ethics Committee Name	Kindai University Hospital Institutional Review B
Street Name and Number	377-2 Ohnohigashi
Building/Floor/Room/Suite	Kindai University Hospital
Additional Address Info	
Country	Japan
State/Province/Region	Osaka
City	Osaka-Sayama
Zip/Postal Code	589-8511

Registration No.	Registering Body

What is the meeting frequency of your Local IRB/ERB/Ethics Committee?
○ Weekly ○ Twice a Month ◉ Monthly ○ Quarterly ○ Other

How long before IRB/ERB/Ethics Committee review is the Submission Packet required?
○ 1 week ○ 2 weeks ◉ Greater than 2 weeks

Does the IRB/ERB/Ethics Committee require payment prior to release of final approval documents?
○ Yes ◉ No

Does the IRB/ERB/Ethics Committee require contract/budget approval prior to release of final approval documents?
○ Yes ◉ No

***Note:** Attachments can be uploaded online from the Facility Profile in SIP.*

***Note:** Additional Local IRB/ERB/Ethics Committees can be added online from the Facility Profile in SIP.*

Central Acting as Local IRB/ERB/Ethics Committee

***Note:** Central Acting as Local IRB/ERB/Ethics Committee can be selected online from the Facility Profile in SIP.*

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SIP Facility Profile Form

Review Only IRB/ERB/Ethics Committee

IRB/ERB/Ethics Committee Name	
Street Name and Number	
Building/Floor/Room/Suite	
Additional Address Info	
Country	- Select Country -
State/Province/Region	- Select State -
City	
Zip/Postal Code	

Registration No.	Registering Body

***Note:** Additional Review Only IRB/ERB/Ethics Committees can be added online from the Facility Profile in SIP.*

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 ○ No

Review Board Name	Meeting Frequency
	○ Weekly ○ Twice a Month ○ Monthly ○ Quarterly ○ Other
	○ Weekly ○ Twice a Month ○ Monthly ○ Quarterly ○ Other

SIP Facility Profile Form

Local Lab

Is your Facility using a local lab? (●) Yes ( ) No

Lab Name	Department of Central Clinical Laboratory
Lab Contact First Name	Mayumi
Lab Contact Last Name	Ohtani
Street Name and Number	377-2 Ohnohigashi
Building/Floor/Room/Suite	Kindai University Hospital
Additional Address Info	
Country	Japan
State/Province/Region	Osaka
City	Osaka-Sayama
Zip/Postal Code	589-8511
Phone Number	+81-72-366-0221
Fax Number	+81-00-0000-0000
Email Address	kensabu-tiken@med.kindai.ac.jp

Local Lab Accreditation (Select all that apply)

☐ None ☐ GLP ☐ CLIA ☐ CAP ☑ ISO ☑ Others

***Note:** Attachments can be uploaded online from the Facility Profile in SIP.*
***Note:** Additional Local Labs can be added online from the Facility Profile in SIP.*

Does your Facility have a SOP/written procedure for documenting bio-specimen (sample) processing steps/chain of custody? (●) Yes ( ) No

Do your written procedures ensure that study-specific temperature bio-specimen storage requirements are known to responsible staff to ensure compliance? (●) Yes ( ) No

What is the system or tool that the Site currently has or utilizes to document Biospecimen (Sample) Processing Steps/Chain of Custody?

( ) Internal Electronic System (LIMS)
( ) Manual Log (e.g. Excel based tool)
(●) Prefer to use Sponsor-provided system/tool
( ) Other

Please indicate tissue collection and processing capabilities at your Site?

(●) On-site collection and processing
( ) Site utilizes a sub-contractor for collection and/or processing
( ) Other

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SIP Facility Profile Form

Local Lab

Does your Facility have established processes to oversee staff compliance with study-specific lab manual instructions for bio-specimen processing? (●) Yes ( ) No

What are your Facility's capabilities for tissue collection and/or processing (embedding)?

Are LOINC codes available for the lab? ( ) Yes (●) No

Consent And Training

Consent

Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?	(•) Yes	( ) No
Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for pediatric populations?	(•) Yes	( ) No
Does your Facility have a written SOP/Policy/Procedure for: Other vulnerable populations?	(•) Yes	( ) No
Will your Facility require language translations for consents?	(•) Yes	( ) No

***Note:** Languages can be selected online from the Facility Profile in SIP.*

If located in the US, has your Facility used or are you able to use the informed consent short form?	( ) Yes ( ) Don't Know ( ) Not Applicable	(•) No

Training

Does your Facility have a training program for the research staff?	(•) Yes	( ) No
Does the course content include GCP?	(•) Yes	( ) No
Does your Facility use an external program to conduct research training?	(•) Yes	( ) No
Please provide program course name:	CITI Japan	
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes	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?	(•) Yes	( ) No

Facility And Equipment

Facility Capabilities

Can your Facility support patient visits on weekends?	(•) Yes	( ) No
Can your Facility support in-patient admissions for research studies?	(•) Yes	( ) No
Does your study staff have sufficient English knowledge to understand communications in English?	( ) Yes	(•) No
Does your Facility have access to translators and translation support for study conduct (e.g. consent, study specific instruction)?	( ) Yes (•) Not Applicable	( ) No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	(•) Yes	( ) No
Is the lab kit storage space able to support early phase studies which may require an increased number of kits?	(•) Yes	( ) No
Does your Facility have the ability to collect and store PK/PD specimens?	(•) Yes	( ) No
Does your Facility have the ability to collect PK/PD samples beyond normalbusiness hours?	(•) Yes	( ) No
Does your Facility typically allow the collection of Pharmacogenomic (PGX) samples for research purposes?	( ) Yes	(•) No

Equipment

Identify the Diagnostic Equipment available at or near the Facility to support Research studies? (Check all that apply.)

- [ ] NA — Not Applicable
- [x] CT Scan — Computerized Tomography Scan
- [x] DXA — Dual-Energy X-ray Absorptiometry or Bone Densitometry
- [ ] ECG/EKG — Electrocardiogram
- [x] FLRO — Fluoroscopy
- [x] MRI — Magnetic Resonance Imaging
- [x] MRA — Magnetic Resonance Angiography
- [x] MRS — Magnetic Resonance Spectroscopy
- [x] MAMMO — Mammography
- [x] NMED — Nuclear medicine (e.g. Bone scan, Thyroid scan, Thallium cardiac stress test)
- [x] PET — Positron Emission Tomography Scan
- [x] X-ray — X-Radiation
- [ ] Other — Other

Describe any additional equipment relevant to Clinical Trials:

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 ( ) No

Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)? (●) Yes ( ) No

Identify the equipment available at the Facility to support Research studies

Centrifuge

Refrigerated Centrifuge

- [x] **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? Does this equipment provide Min/Max Temperature Monitoring?	(●) Yes ( ) No; (●) Yes ( ) No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
Does this equipment have back-up power?	(●) Yes ( ) No
Does this equipment have a temperature alarm?	( ) Yes (●) No
Do you have an SOP which supports calibration of this equipment?	Yes No

- [x] **Freezer (-20 to -30 Degrees C)**

Equipment Capabilities: Freezer (-20 to -30 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	(●) Yes ( ) No
Does this equipment provide Min/Max Temperature Monitoring?	(●) Yes ( ) No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
Does this equipment have back-up power?	(●) Yes ( ) No
Does this equipment have a temperature alarm?	( ) Yes (●) No
Do you have an SOP which supports calibration of this equipment?	( ) Yes (●) No

- [x] **Freezer (-70 to -80 Degrees C)**

Equipment Capabilities: Freezer (-70 to -80 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	(●) Yes ( ) No
Does this equipment provide Min/Max Temperature Monitoring?	(●) Yes ( ) No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	Daily
Does this equipment have back-up power?	(●) Yes ( ) No
Does this equipment have a temperature alarm?	( ) Yes (●) No
Do you have an SOP which supports calibration of this equipment?	( ) Yes (●) No

- [ ] **Freezer (Liquid Nitrogen -135 Degrees C)**

Equipment Capabilities: Freezer (Liquid Nitrogen -135 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment?	( ) Yes ( ) No
Does this equipment provide Min/Max Temperature Monitoring?	( ) Yes ( ) No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	- Select -
Does this equipment have back-up power?	( ) Yes ( ) No
Does this equipment have a temperature alarm?	( ) Yes ( ) No
Do you have an SOP which supports calibration of this equipment?	( ) Yes ( ) No

Computer Capabilities

Does your Facility have computers which are dedicated to research studies? (●) Yes ( ) No

What type of computer operating system(s) does your institution use to support studies?

- [ ] Apple/Mac (OS X Snow Leopard, Mountain Lion, El Captain, etc.)
- [ ] I don't know
- [ ] Other
- [ ] Unix/Linux (Solaris, Ubuntu, Redhat, etc.)
- [x] Windows (Windows XP, Windows 7, Windows 8, etc.)

What type of internet access does your Facility have? 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

Does your facility prohibit the use of an external USB device (e.g. to download and send data from a temperature monitoring device)? (●) Yes ( ) No ( ) I don't know

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? (●) Yes ( ) No

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SIP Facility Profile Form

Investigational Product & Controlled Substances

Investigational Product Shipping Details

IP Recipient Name	Department of Pharmacy
Street Name and Number	377-2 Ohnohigashi
Building/Floor/Room/Suite	Kindai University Hospital
Additional Address Info	
Country	Japan
State/Province/Region	Osaka
City	Osaka-Sayama
Zip/Postal Code	589-8511
Phone Number	+81-72-366-0221
Fax Number	+81-00-0000-0000
Email Address	crc@med.kindai.ac.jp

Note: Additional Investigational Product Shipping Details can be added online from the Facility Profile in SIP.

Investigational Product Storage Location

IP Storage Location Name	Department of Pharmacy
Street Name and Number	Department of Pharmacy
Building/Floor/Room/Suite	Kindai University Hospital
Additional Address Info	
Country	Japan
State/Province/Region	Osaka
City	Osaka-Sayama
Zip/Postal Code	589-8511
Phone Number	+81-72-366-0221
Fax Number	+81-00-0000-0000
Email Address	crc@med.kindai.ac.jp

***Note:** Additional Investigational Product Storage Locations can be added online from the Facility Profile in SIP .*

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SIP Facility Profile Form

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? Does this equipment provide Min/Max Temperature Monitoring?	◉ Yes ○ No ◉ Yes ○ No
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 ○ No
Does this equipment have a temperature alarm?	○ Yes ◉ No
Do you have an SOP which supports calibration of this equipment?	○ Yes ◉ No

☑ **Freezer (-20 to -30 Degrees C)**

Equipment Capabilities: Freezer (-20 to -30 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment? Does this equipment provide Min/Max Temperature Monitoring?	◉ Yes ○ No ◉ Yes ○ No
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 ○ No
Does this equipment have a temperature alarm?	○ Yes ◉ No
Do you have an SOP which supports calibration of this equipment?	○ Yes ◉ No

☑ **Freezer (-70 to -80 Degrees C)**

Equipment Capabilities: Freezer (-70 to -80 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment? Does this equipment provide Min/Max Temperature Monitoring?	◉ Yes ○ No ◉ Yes ○ No
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 ○ No
Does this equipment have a temperature alarm?	○ Yes ◉ No
Do you have an SOP which supports calibration of this equipment?	○ Yes ◉ No

☐ **Freezer (Liquid Nitrogen -135 Degrees C)**

Equipment Capabilities: Freezer (Liquid Nitrogen -135 Degrees C)

Do you have the ability to generate a temperature monitoring log for this equipment? Does this equipment provide Min/Max Temperature Monitoring?	○ Yes ○ No ○ Yes ○ No
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	- Select -
Does this equipment have back-up power?	○ Yes ○ No
Does this equipment have a temperature alarm?	○ Yes ○ No
Do you have an SOP which supports calibration of this equipment?	○ Yes ○ No

SIP Facility Profile Form

Investigational Product Storage & Handling

Is the Investigational Product Storage Room secured with controlled access?	(●) Yes	( ) No
Do you have the ability to generate a temperature monitoring log for this Investigational Product Storage Room?	(●) Yes	( ) No
Does the Investigational Product Storage Room provide Min/Max temperature monitoring?	(●) Yes	( ) No
Does the Investigational Product Storage Room have back-up power?	(●) Yes	( ) No
Does the Investigational Product Storage Room have a temperature alarm?	( ) Yes	(●) No
Do you have an SOP which supports calibration of the temperature monitoring equipment?	( ) Yes	(●) No
Does your Facility have the ability to manage on-site or off-site destruction of Investigational Product?	(●) Yes	( ) No
Does your Facility have a written SOP/Policy/Procedure for destruction of Investigational Product?	(●) Yes ( ) Not Applicable	( ) No
Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product?	( ) Yes (●) Not Applicable	( ) No
Does your Facility have a written SOP/Policy/Procedure to ensure that Investigational Product is appropriately maintained during transportation to Satellite Site(s)?	( ) Yes (●) Not Applicable	( ) No

Describe additional Investigational Product Storage & Handling Capabilities:

SIP Facility Profile Form

Preparation And Administration Of Investigational Product

Identify the Investigational Product preparation capabilities at your Facility

- [x] Extemporaneous Preparation
- [x] Vertical laminar flow hood (chemo/hazardous drugs)
- [ ] Glove box (non-vented)
- [x] Horizontal laminar flow hood (non-hazardous drug preparation)
- [ ] Glove box (vented to outside)

Preparation and Administration of Investigational Product

Is your Facility capable of administering infusions?	(●) Yes	( ) No
Is your Facility adequately staffed to support studies with both blinded and un-blinded Investigational Product?	(●) Yes	( ) No

Controlled Substances

Controlled Substances are defined as: A drug or chemical whose manufacture, possession, or use is regulated by a government, such as illicitly used drugs or prescription medications that are designated a Controlled Drug.

Does the Facility have the required licenses or registrations to receive, store, dispense and return controlled substances as required by local law?	(●) Yes ( ) Not Applicable	( ) No
Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?	(●) Yes ( ) Not Applicable	( ) No
Does the Facility have the ability to handle radio-labelled Investigational Product?	(●) Yes	( ) No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	(●) Yes ( ) Not Applicable	( ) No

Attachments

Upload relevant Investigational Product & Controlled Substances documentation including: relevant SOPs for managing or storing Investigational Product(s), IP storage equipment, or licenses/ registrations to receive, store, dispense and return controlled substances.

***Note:** Attachments can be uploaded online from the Facility Profile in SIP.*

Source Documentation & Remote Monitoring

Source Documents

What type of source documents will be used? (select all that apply) Does your Facility have secure storage for patient records? ☑ Paper ☑ Electronic / ◉ Yes ○ No

Does your Facility have patient record archiving on-site? ◉ Yes ○ No

Provide Location name and address of any offsite archives

What type of Investigator Site File/regulatory binder used? (select all that apply) ☑ Paper ☐ Electronic

What Investigator Site File(eISF)/eRegulatory system do you use? - Select -

Please specify.

Are monitors able to access eISF/eReg while off-site? ○ Yes ○ No

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 ○ No

What EMR/EHR system do you use? ☐ In-house system ☑ Others

***Note:** Please select other options for EMR/ EHR used at your Facility online.*

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:

The Electronic Medical System is capable of restricting the CRA's access to only the patient records of clinical trial participants.

Do you work with a vendor that can electronically exchange data for clinical research from the EHR/EMR? ○ Yes ◉ No

Please indicate the vendor used.

Please provide the name and e-mail for contact at Site who works with the vendor and sponsors

Do you have institutional approval to export data from the EHR/ EMR for the clinical research? ◉ Yes ○ No

Are monitors able to access EHR/EMR while off-site? ○ Yes ◉ No

Does your facility require Sponsor representative to sign any local form (paper or electronic) for access, or any other purpose? ○ Yes ◉ No

Provide details of information requested.

SIP Facility Profile Form

Monitoring

Check all equipment that will be available to Monitors:

☐ None ☑ Phone ☐ Fax ☑ Copy Machines ☑ Internet Access

What Electronic Data Capture (EDC) systems has your staff used for clinical trials?

☐ None ☐ Oracle Inform ☑ Medidata Rave ☑ Oracle Remote Data Capture (RDC) ☑ Others

Describe Other EDC Systems:

TAO, cubCDMS, Data Labs, Viedoc, eClinical

Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring? ◉ Yes ○ No

Which of the following capabilities are available to support remote source data verification? (check all that apply)

☑ Video Conferencing
☐ Screen Sharing
☑ Systems or platforms for source document upload
☐ EHR/EMR access by monitor
☐ Can send pseudo anonymized certified source documents via secure transfer

Additional Information And 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

Upload any non-study specific Facility documents that have not been included in other sections of the profile. Lab, IRB/ERB/Ethics Committee, Investigational Product and Controlled Substance documentation should be included in those sections. The document type drop-down list provides examples of the type of documentation to be included in this section.

***Note:** Attachments can be uploaded online from the Facility Profile in SIP.*

変更履歴

2018/11/12: 初版

2020/7/7：

①LOCAL LAB “Others”に「Japanese Association of Medical Technologists」を追記。

②Investigational Product Storage Equipment “Freezer(-70 to -80 Degrees C)”に新たにチェックを加える。

2024.08.28：新しく Form に追加された質問への回答を追記。