

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

National Hospital Organization Higashi-ohmi General Medical Center

THERAPEUTIC AREAS AND PATIENT POPULATION

THERAPEUTIC AREA(S) Provide the list of Therapeutic Areas for your Facility:

Cardiovascular Diseases
Digestive System Diseases
Endocrine System Diseases
Eye Diseases
Male Urogenital Diseases
Musculoskeletal Diseases
Otorhinolaryngologic Diseases
Respiratory Tract Diseases
Stomatognathic Diseases
Nervous System Diseases

Sub-Therapeutic Areas:

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

Other Areas of Expertise:

- Radiology
- Anesthesiology
- Skin and Connective Tissue Diseases

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
 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:

Japanese;99% Brazilian;1%

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 61-90
 91-120 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

Department Contact Phone Number

Department Contact Email Address

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.

SIP Facility Profile Form

Local IRB/ERB/Ethics Committee

IRB/ERB/Ethics Committee Name

institutional Review Board

Street Name and Number

255

Building/Floor/Room/Suite

National Hospital Organization Higashi-ohmi General Medical Center

Additional Address Info

Gochi-cho

Country

Japan

State/Province/Region

Shiga

City

Higashiomi-shi

Zip/Postal Code

527-8505

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.

SIP Facility Profile Form

REVIEW ONLY IRB/ERB/ETHICS COMMITTEE

IRB/ERB/Ethics Committee Name	<input type="text"/>
Street Name and Number	<input type="text"/>
Building/Floor/Room/Suite	<input type="text"/>
Additional Address Info	<input type="text"/>
Country	<input type="text" value="- Select Country -"/>
State/Province/Region	<input type="text" value="- Select State -"/>
City	<input type="text"/>
Zip/Postal Code	<input type="text"/>
Registration No.	Registering Body
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

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? Yes No

For example, scientific, radiation safety committees, or others.

Review Board Name	Meeting Frequency		
<input type="text"/>	<input type="radio"/> Weekly	<input type="radio"/> Twice a Month	<input type="radio"/> Monthly
	<input type="radio"/> Quarterly	<input type="radio"/> Other <input type="text"/>	
<input type="text"/>	<input type="radio"/> Weekly	<input type="radio"/> Twice a Month	<input type="radio"/> Monthly
	<input type="radio"/> Quarterly	<input type="radio"/> Other <input type="text"/>	

SIP Facility Profile Form

LOCAL LAB

Is your Facility using a local lab?

Yes No

Lab Name

Department of clinical laboratory

Lab Contact First Name

Satoshi

Lab Contact Last Name

Kurokawa

Street Name and Number

255

Building/Floor/Room/Suite

National Hospital Organization Higashi-ohmi General Medical Center

Additional Address Info

Gochi-cho

Country

Japan

State/Province/Region

Shiga

City

Higashiomi-shi

Zip/Postal Code

527-8505

Phone Number

+81-748-22-3030

Fax Number

Email Address

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.

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: Other vulnerable populations? Yes No

Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for pediatric 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 No
 Don't Know
 Not Applicable

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:

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 No
 Not Applicable
- Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)? 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 normal business 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
- CT Scan Computerized Tomography Scan
- DXA Dual-Energy X-ray Absorptiometry or Bone Densitometry
- ECG/EKG Electrocardiogram
- FLRO Fluoroscopy
- MRI Magnetic Resonance Imaging
- MRA Magnetic Resonance Angiography (MRA)
- MRS Magnetic Resonance Spectroscopy (MRS)
- MAMMO Mammography
- NMED Nuclear medicine (e.g. Bone scan, thyroid scan, thallium cardiac stress test)
- PET Positron Emission Tomography Scan
- 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, sphygmomanometer, 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

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 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 (-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

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?

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

What type of internet access does your Facility have?

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)?

Does the Facility have access to local IT support?

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

INVESTIGATIONAL PRODUCT SHIPPING DETAILS

IP Recipient Name	Department of pharmacy
Street Name and Number	255
Building/Floor/Room/Suite	National Hospital Organization Higashi-ohmi General Medical Center
Additional Address Info	Gochi-cho
Country	Japan
State/Province/Region	Shiga
City	Higashiomi-shi
Zip/Postal Code	527-8505
Phone Number	+81-748-22-3030
Fax Number	+81-748-22-3033
Email Address	402-chiken.255@mail.hosp.go.jp

INVESTIGATIONAL PRODUCT STORAGE LOCATION

IP Storage Location Name	<input type="text"/>
Street Name and Number	<input type="text"/>
Building/Floor/Room/Suite	<input type="text"/>
Additional Address Info	<input type="text"/>
Country	<input type="text" value="- Select Country -"/>
State/Province/Region	<input type="text" value="- Select State -"/>
City	<input type="text"/>
Zip/Postal Code	<input type="text"/>
Phone Number	<input type="text"/>
Fax Number	<input type="text"/>
Email Address	<input type="text"/>

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

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 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 (-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.

- 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

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.

- 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

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

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 No Not Applicable
- Do you provide your Satellite Site(s) with a dedicated inventory of Investigational Product? Yes No 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)? Yes No Not Applicable

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:

- Extemporaneous Preparation
- Vertical laminar flow hood (chemo/hazardous drugs)
- Glove box (non-vented)
- 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 No
 Not Applicable

Is the storage area for controlled substances securely constructed with restricted access in accordance with local law?

Yes No
 Not Applicable

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 No
 Not Applicable

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

SOURCE DOCUMENTS

What type of source documents will be used? (Select all that apply):

Paper

Electronic

Does your Facility have secure storage for patient records?

Yes

No

Does your Facility have patient record archiving on-site?

Yes

No

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

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:

A person is given personal ID and password.

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:

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.