

# 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:

|  |   |
|--|---|
| Cardiovascular Diseases                                | ▼ |
| Digestive System Diseases                              | ▼ |
| Endocrine System Diseases                              | ▼ |
| Female Urogenital Diseases and Pregnancy Complications | ▼ |
| Hemic and Lymphatic Diseases                           | ▼ |
| Male Urogenital Diseases                               | ▼ |
| Mental disorders                                       | ▼ |
| Musculoskeletal Diseases                               | ▼ |
| Neoplasms  | ▼ |
| Nervous System Diseases                                | ▼ |

Sub-Therapeutic Areas:

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

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.  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:

# 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

Clinical trial management room

Department Contact Phone Number

+81-83-241-1199

Department Contact Email Address

511-KanmonChicken@mail.hosp.go.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.

# SIP Facility Profile Form

## Local IRB/ERB/Ethics Committee

### IRB/ERB/Ethics Committee Name

Street Name and Number

Building/Floor/Room/Suite

Additional Address Info

Country

State/Province/Region

City

Zip/Postal Code

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"/> |

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

|                                      |   |
|--------------------------------------|---|
| <b>IRB/ERB/Ethics Committee Name</b> | <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

Clinical trial management room

Lab Contact Last Name

Kanmon Medical Center

Street Name and Number

1-1, Chofusotoura-cho

Building/Floor/Room/Suite

Additional Address Info

Country

Japan

State/Province/Region

Yamaguchi

City

Shimonoseki

Zip/Postal Code

752-8510

Phone Number

+81-83-241-1199

Fax Number

+81-83-241-1317

Email Address

511-KanmonChiken@mail.hosp.go.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.

## 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:

CAVI ABI

## 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.

- 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

## 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         | Kanmon Medical Center            |
| Street Name and Number    | 1-1, Chofusotoura-cho            |
| Building/Floor/Room/Suite | Clinical trial management room   |
| Additional Address Info   |                                  |
| Country                   | Japan                            |
| State/Province/Region     | Yamaguchi                        |
| City                      | Shimonoseki                      |
| Zip/Postal Code           | 752-8510                         |
| Phone Number              | +81-83-241-1199                  |
| Fax Number                | +81-83-241-1317                  |
| Email Address             | 511-KanmonChiken@mail.hosp.go.jp |

## INVESTIGATIONAL PRODUCT STORAGE LOCATION

|                           |                                   |
|---------------------------|-----------------------------------|
| IP Storage Location Name  | Kanmon Medical Center             |
| Street Name and Number    | 1-1, Chofusotoura-cho             |
| Building/Floor/Room/Suite | Pharmaceutical department         |
| Additional Address Info   |                                   |
| Country                   | Japan                             |
| State/Province/Region     | Yamaguchi                         |
| City                      | shimonoseki                       |
| Zip/Postal Code           | 752-8510                          |
| Phone Number              | +81-83-241-1199                   |
| Fax Number                | +81-83-241-1317                   |
| Email Address             | 511-KanmonChicken@mail.hosp.go.jp |

**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.

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.

- 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

# 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  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.

# SIP Facility Profile Form

## **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:*

ID.PW



## 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.