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 Maizuru Medical Center

THERAPEUTIC AREAS AND PATIENT POPULATION

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

- Nervous System Diseases
- Cardiovascular Diseases
- Congenital, Hereditary, and Neonatal Diseases and Abnormalities
- Digestive System Diseases
- Endocrine System Diseases
- Eye Diseases
- Female Urogenital Diseases and Pregnancy Complications
- Immune System Diseases
- Male Urogenital Diseases
- Mental disorders

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 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%

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 Office
Department Contact Phone Number	+81-773-62-2680
Department Contact Email Address	406-chiken@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	National Hospital Organization Maizuru Medical Center Institutional Review Board
Street Name and Number	2410 Azayukinaga
Building/Floor/Room/Suite	
Additional Address Info	
Country	Japan
State/Province/Region	Kyoto
City	Maizuru
Zip/Postal Code	625-8502

Registration No.	Registering Body
NA	NA

What is the meeting frequency of your Local IRB/ERB/Ethics Committee?

- ○ Weekly
- ○ Twice a Month
- ○ Monthly
- ○ Quarterly
- ◉ Other: Once every two months

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	
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	
Lab Contact First Name	
Lab Contact Last Name	
Street Name and Number	
Building/Floor/Room/Suite	
Additional Address Info	
Country	- Select Country -
State/Province/Region	- Select State -
City	
Zip/Postal Code	
Phone Number	
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:	eAprin	
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
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, 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

☑ **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?

- [x] 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? I don't know

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	National Hospital Organization Maizuru Medical Center
Street Name and Number	2410 Azayukinaga
Building/Floor/Room/Suite	
Additional Address Info	
Country	Japan
State/Province/Region	Kyoto
City	Maizuru
Zip/Postal Code	625-8502
Phone Number	+81-773-62-2680
Fax Number	+81-773-62-2776
Email Address	406-chiken@mail.hosp.go.jp

INVESTIGATIONAL PRODUCT STORAGE LOCATION

IP Storage Location Name	
Street Name and Number	
Building/Floor/Room/Suite	
Additional Address Info	
Country	- Select Country -
State/Province/Region	- Select State -
City	
Zip/Postal Code	
Phone Number	
Fax Number	
Email Address	

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:

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	( ) 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? Select

Please list any access limitations/requirements for the Electronic Medical Records:

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.*