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FACILITY NAME & ADDRESS

Facility Name	Facility Type	Facility Address
National Hospital Organization Takasaki General Medical Centar		36 Takamatsucho, Takasaki, Gunma, Japan, 370-0829

FACILITY CONTACTS

Primary FPM?	Name	Email Address	Roles
Yes	Masui, Kazumi	masui.kazumi.un@mail.hosp.go.jp	Facility Profile Manager; Budget/Financial Contact; Clinical Research Manager; Contingency Contact - Business; Contract Manager; Delegation Manager; Facility Clinical Trial Contact; Head of Facility; Regulatory Contact (Facility/Department)
No	Hagiwara, Ayumi	hagiwara-ayumi@iromgp.com	Facility Profile Manager
No	Hagiwara, Yui	hagiwara-yui@iromgp.com	Facility Profile Manager

THERAPEUTIC AREAS & PATIENT POPULATION

Therapeutic Area(s)	
Therapeutic Area	Sub Therapeutic Area
Cardiovascular Diseases	
Allergy	
Digestive System Diseases	
Endocrine System Diseases	
Female Urogenital Diseases and Pregnancy Complications	
Fertility	
Inflammation	
Male Urogenital Diseases	
Nervous System Diseases	
Nutritional and Metabolic Diseases	
Neoplasms	
Nephrology	
Oncology	
Pediatrics	
Respiratory Tract Diseases	
Skin and Connective Tissue Diseases	
Vaccines	

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Therapeutic Area	Sub Therapeutic Area
Women's Health	

Other Areas of Expertise

Study Phase Capabilities
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

IRB/ERB/ETHICS COMMITTEE

General Questions	
What is the average time (in days) to start a study once you have received the regulatory package?	30-60
Does your Facility perform IRB/ERB/Ethics Committee submissions?	Yes
Does your Facility have a Facility or group to perform IRB/ERB/Ethics Committee submissions?	Yes
Department Contact Name	Clinical trial office
Department Contact Phone Number	+81273225901
Department Contact Email Address	masui.kazumi.un@mail.hosp.go.jp
Is your Facility able to initiate study activities prior to IRB/ERB/Ethics Committee protocol approval?	No
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?	No
Other Steps Explain	

LOCAL IRB/ERB/ETHICS COMMITTEE

Local IRB/ERB/Ethics Committee: National Hospital Organization Takasaki General Medical Center Institutional Review Board	
IRB/ERB/Ethics Committee Name	National Hospital Organization Takasaki General Medical Center Institutional Review Board
Address	36,Takamatsu-cho, Takasaki-shi, Gunma, Japan, 370-0829

Registration#	Registering Body
No Records	

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What is the meeting frequency of the IRB/ERB/Ethics Committee?	Monthly
Other	
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?	Yes

LOCAL IRB/ERB/ETHICS COMMITTEE ATTACHMENTS

Document Type	Document Name	Document Description
No Records		

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.	

Local Lab

Is your Facility using a Local Lab?	Yes
Local Lab: Laboratory of National Hospital Organization Takasaki General Medical Center	
Lab Name	Laboratory of National Hospital Organization Takasaki General Medical Center
Lab Contact First Name	Mai
Lab Contact Last Name	Okayama
Address	36,Takamatsu-cho, Takasaki-shi, Gunma, Japan, 370-0829
Phone Number	0273225901
Fax Number	
Email Address	
Local Lab Accreditation	Others
Other Local Lab Accreditation	Japanese Association of Medical Technologists, Japan Medical Association and Gunma Association of Medical Technologists.
Additional Questions	
Does your Facility have a SOP/written procedure for documenting bio-specimen (Sample) processing steps/chain of custody?	
Do your written procedures ensures that study-specific temperature bio-specimen storage requirements are known to responsible staff to ensure compliance?	
What is the system or tool that the site currently has or utilizes to document Bio-specimen (Sample) Processing Steps/ Chain of Custody?	
Please indicate tissue collection and processing capabilities at your site?	
Does your Facility has established processes to oversee staff compliance with study-specific lab manual instructions for bio-specimen processing?	
What are your Facility’s capabilities for tissue collection and/or processing (embedding)?	
Are LOINC codes available for the Local Lab? (If Yes, you can upload the relevant LOINC list as an attachment in Lab Documentation)	

Attachments

Document Type	Document Name	Document Description
No Records		

CONSENT & TRAINING

Consent	
Does your Facility have a written SOP/Policy/Procedure for: Informed Consent?	Yes
Does your Facility have a written SOP/Policy/Procedure for: Minor Assent for Pediatric Populations?	Yes
Does your Facility have a written SOP/Policy/Procedure for: Other Vulnerable Populations?	Yes
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.	APRIN
Do you have a process or program in place to retrain research staff when a protocol is amended?	Yes
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?	No
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)?	No
Does the Facility have storage space for Study-Related materials (e.g. Lab Kits, Patient Materials, etc.)?	Yes
Is the lab kit storage space able to support early phase studies which may require an increased number of kits?	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; Positron Emission Tomography Scan; 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 maintenancof general equipment? Examples of general equipment include: scale, pulse oximeter, stadiometer, sphymomanomer, etc.?	Yes
Does your Facility have the necessary equipment to treat medical emergencies (ie. code cart)?	Yes

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.	
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?	Other
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
Does your Facility prohibit the use of an external USB device (e.g. to download and send data from a temperature monitoring device)?	Yes
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?	No

Attach Your BCP or SOP

Document Type	Document Name	Document Description
No Records		

INVESTIGATIONAL PRODUCT & CONTROLLED SUBSTANCES

Investigational Product Shipping Details

IP Recipient Name	Address	Email Address	Phone Number	Fax Number
kazumi masui	36,Takamatsu-cho, Clinical trial office, 1F, Takasaki-shi, Gunma, Japan, 370-0829	kazumi.masui.un@mail.hosp.go.jp	0273225901	

Investigational Product Storage Location

IP Recipient Name	Address	Email Address	Phone Number	Fax Number
National Hospital Organization Takasaki General Medical Center	36,Takamatsu-cho, Investigational product storage room, Takasaki-shi, Gunma, Japan, 370-0829	ishida.fumiya.gc@mail.hosp.go.jp	81273225901	81273220161

Investigational Product Storage Equipment	
Identify the Investigational Product Storage Equipment at your Facility	Refrigerator (2 to 8 Degrees C); Freezer (-20 to -30 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.	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?	Yes
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?	Yes
How frequently can temperature measurement occur? Check the most frequent measurement your equipment can support.	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?	Yes
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 this equipment?	Yes
Does your Facility have the ability to manage on-site or off-site destruction of Investigational Product?	No
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?	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)?	Not Applicable
Describe additional Investigational Product Storage And Handling Capabilities	The temperature alarm is not in the thermometer, but in the storage.
Preparation and Administration Of Investigational Product	
Identify the Investigational Product preparation capabilities at your Facility	Extemporaneous Preparation; Vertical laminar flow hood (chemo/hazardous drugs)
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?	No
Does your Facility have the ability to manage on-site or off-site destruction of controlled substances when appropriate?	No

Attachments		
Document Type	Document Name	Document Description
No Records		

SOURCE DOCUMENTATION & REMOTE MONITORING

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	
What type of investigator site file/regulatory binder used (select all that apply)	Paper
What investigator site file (eISF) / eRegulatory system do you use?	
Are monitors able to access eISF/eReg while off-site?	
Please list any access limitations/ requirements for eISF/eReg	NA
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
For Facilities with satellite sites, where is the monitor required to access source documents?	
Please list any access limitations/requirements for the Electronic Medical Records.	
Do you work with a vendor that can electronically exchange data for clinical research from the EHR/EMR?	No
Do you have institutional approval to export data from the EHR/EMR for the clinical research?	Yes
Are monitors able to access EHR/EMR while off site?	No
Does your Facility require Sponsor representative to sign any local form (paper or electronic) for access, or any other purpose?	Yes
Provide details of information requested	A pledge concerning the use of the medical information system is required.
Monitoring	
Check all equipment that will be available to Monitors:	
What Electronic Data Capture (EDC) systems has your staff used for clinical trials?	
Describe Other EDC Systems	
Does your site/institution and/or local regulations allow remote source data verification of study participant data to support remote monitoring?	No
Which of the following capabilities are available to support remote source data verification? (Check all that apply)	

Attachments		
Document Type	Document Name	Document Description
No Records		

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 site. 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 are listed below with Affiliation Status			
Organization Name and Address	Organization Affiliation Type	Organization Affiliation Status	Status Date
No Records			

ASSOCIATED SITE USERS

Associated Site Users

☐ Once checked, this checkbox will enable the Approval/Rejection workflow for this Facility. Any site user requesting to associate with this Facility would require to send the affiliation requests and only once Approved, this Facility will be shown on User's Profile.

Site User Association Requests				
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Tokuda,Shoko	chiken.tokuda@gmail.com	12-Dec-2022		Pending
Koibuchi,Yukio	chiken.koibuti@gmail.com	12-Dec-2022		Pending
Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Takasaki,Investigational Product Administrator	chiken.yakuzaibutyo@gmail.com	14-Dec-2022		Confirmed
Tokuda,Shoko	chiken.tokuda@gmail.com	12-Dec-2022		Confirmed
Koibuchi,Yukio	chiken.koibuti@gmail.com	12-Dec-2022		Confirmed
Uchiumi,Noriko	uchiumi.noriko.hz@mail.hosp.go.jp	01-Dec-2022		Confirmed
Narusawa,Eriko	chiken.enarusawa@gmail.com	11-Jan-2023		Confirmed
Tomizawa,Nao	tomizawa.nao.un@mail.hosp.go.jp	01-Dec-2022		Confirmed
Sano,Nozomi	chiken.nsano@gmail.com	28-Jun-2022		Confirmed
Hagiwara,Ayumi	hagiwara-ayumi@iromgp.com	01-Aug-2022	08-Dec-2022	Confirmed
Uehara,Sanae	chiken.uehara@gmail.com	26-Jul-2022		Confirmed
Tomaru,Shota	chiken.stomaru@gmail.com	28-Jun-2022		Confirmed

Name	E-mail Address	Request Affiliation Date	Affiliation Status change Date	Affiliation Status
Ishibashi,Yohei	yishibashi.oct13@gmail.com	22-Jun-2023		Confirmed
Seta,Hiroki	hirohiro-s-1209@outlook.jp	22-Jun-2023		Confirmed
Mogi,Ayaka	ayaka-mogi@iromgroup.co.jp	15-Feb-2023		Confirmed
Negishi,Rika	rika-negishi@iromgroup.co.jp	16-Feb-2023		Confirmed
Hatori,Naoki	nhatori1203@gmail.com	15-Feb-2023		Confirmed
Imai,Nana	nana-imai@iromgroup.co.jp	21-Feb-2023		Confirmed
Ota,Masaki	ota.masaki.qk@mail.hosp.go.jp	15-Feb-2023		Confirmed
Murata,Tomoyuki	nqi30132@yahoo.co.jp	27-Jan-2023		Confirmed
Kobayashi,Hiroo	hrkb00-circle@yahoo.co.jp	01-Feb-2023		Confirmed
Takahashi,Yosuke	yosuke.19950222@gmail.com	15-Feb-2023		Confirmed
Okoma,Naoya	m13201026@gunma-u.ac.jp	02-Feb-2023		Confirmed
Higuchi,Takaho	takaho-higuchi@iromgroup.co.jp	28-Feb-2023		Confirmed
Takahashi,Shinya	takahashi.shinya.tp@mail.hosp.go.jp	15-Feb-2023		Confirmed
Chigira,Ayaka	chigira_ayaka@yahoo.co.jp	15-Feb-2023		Confirmed
Hiroi,Shitoshi	chiken.hiroi@gmail.com	09-Mar-2023		Confirmed
Takase,Ayaka	takase.ayaka.he@mail.hosp.go.jp	24-Apr-2023	01-May-2023	Confirmed
Hagiwara,Yui	hagiwara-yui@iromgp.com	26-Apr-2021	04-Jun-2024	Confirmed
Masuda,Tomoyuki	chiken.tmasuda@gmail.com	02-Dec-2021		Confirmed
Ishida,Fumiya	ishida.fumiya.gc@mail.hosp.go.jp	30-Nov-2022		Confirmed
Takata,Daisuke	gaotadafu@gmail.com	17-Nov-2022	17-Nov-2022	Confirmed
Fukuda,Nobuaki	fukuda.nobuaki.cw@mail.hosp.go.jp	22-Aug-2022		Confirmed
Kudo,Tomohiro	chiken.kudo@gmail.com	04-Aug-2022		Confirmed
Funada,Yukari	funada.yukari.zx@mail.hosp.go.jp	10-Jan-2024		Confirmed
Seki,Risa	seki.risa.bv@mail.hosp.go.jp	09-Jan-2024		Confirmed
Nakagawa,Junichi	nakagawa.jiyunichi.za@mail.hosp.go.jp	14-Jun-2024		Confirmed
Honda,Chikako	kanno.chikako.ej@mail.hosp.go.jp	07-Jun-2024		Confirmed
Masui,Kazumi	masui.kazumi.un@mail.hosp.go.jp	29-May-2024	04-Jun-2024	Confirmed