

### Site Profile Form

**Purpose of Site Profile form:** The intent of the Site Profile form is to capture site capabilities that are collected during site qualification and not to replace current individual pre-study activities. The intent is to reduce the administrative burden on sites associated with completing multiple forms requesting the same or similar information. The form is not intended to capture study specific or therapeutic specific information.

The form will be in an electronic format, with drop down or check boxes to keep the form simple and easy to use. There will be free text input boxes for providing any necessary explanations. Site should keep a copy of the completed form on file.

If additional text is needed in any of responses, use an asterisk and enter at the bottom of the form.

<b>1. COMPLETED BY:</b>	
Full Name:	Takeshi Ioroi
Date Completed:	Jul 25, 2017
Role:	CRC / Pharmacist
Investigator Name:	
<b>2. SITE DETAIL:</b>	
Institution Name:	Kobe University Hospital
Address (Location):	7-5-2, Kusunoki-cho, Chuo-ku
City:	Kobe
State/Region/Province:	Hyogo
Country:	Japan
Postal Code:	650-0017
Type:	University Hospital
Therapeutic Area:	<input checked="" type="checkbox"/> Auto immune <input checked="" type="checkbox"/> Cardiovascular <input checked="" type="checkbox"/> Critical Care <input checked="" type="checkbox"/> Dermatology <input checked="" type="checkbox"/> Infectious Disease <input checked="" type="checkbox"/> Men's Health <input checked="" type="checkbox"/> Metabolic/ Endocrine <input checked="" type="checkbox"/> Musculoskeletal <input checked="" type="checkbox"/> Neuroscience <input checked="" type="checkbox"/> Oncology <input checked="" type="checkbox"/> Osteoporosis <input checked="" type="checkbox"/> Pain <input checked="" type="checkbox"/> Pediatrics <input checked="" type="checkbox"/> Psychiatry <input checked="" type="checkbox"/> Respiratory <input checked="" type="checkbox"/> Vaccines <input checked="" type="checkbox"/> Virology <input checked="" type="checkbox"/> Women's health
Other:	Refer to the additional information column.
Trial phase capabilities:	<input checked="" type="checkbox"/> I <input checked="" type="checkbox"/> II <input checked="" type="checkbox"/> III <input checked="" type="checkbox"/> IV other areas of expertise:
Do you have affiliated research sites or satellite sites/clinics?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Which different sponsor type(s) do you have research experience?	<input checked="" type="checkbox"/> Industry <input checked="" type="checkbox"/> Academic <input checked="" type="checkbox"/> Investigator Initiated <input type="checkbox"/> None
Ethnicity of patient population - please break down your population by % of ethnicity	
Japanese : almost 100 %	
Demographics of patient population:	<input checked="" type="checkbox"/> Pediatric <input checked="" type="checkbox"/> Adult    Other comments:
Is your site affiliated with a government agency or part of a government funded health service? If Yes, please specify the affiliation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Site Contacts: <i>Primary site contact for clinical trials</i>	
First Name:	Takeshi
Phone:	+81-78-382-6669
Fax:	+81-78-382-6690
Surname:	Ioroi
Email:	chiken@med.kobe-u.ac.jp

**3. ETHICAL COMMITTEE REVIEW PROCESS**

**PART A - This section is only applicable if the site is directly responsible for performing the ethics committee submission.**

**IRB/ERB/Ethics committee**

Name:

Address:

City:

State/Region/Province:

Country:

Postal Code:

**IRB/ERB/Ethics committee registration number (if applicable)**

**IRB/ERB/Ethics committee type:**

Central  Local  Central/acts as local

Name:

Phone:

Email:

Does your site have a separate department that handles IRB/ERB/Ethics committee Submissions?  Yes  No

If yes, please provide contact information for this department to the right of the form

Please provide a general outline of the steps required to obtain approval for a study at your institution/site, including whether any steps are dependent on one another, and/or if they can be completed in parallel or in sequence. Please ensure that the following steps are covered, in addition to any other applicable administrative steps required at your site (example – contract/budget approval, scientific review committees, etc.)

- IRB/ERB/ Ethics committee(s) meeting schedule/frequency
- Amount of time in advance of an IRB/ERB/ Ethics committee meeting that all documentation must be submitted
- Amount of time following an IRB/ERB/Ethics committee review you receive written confirmation of approval
- Does your local IRB/ERB/Ethics committee require payment of any fees ahead of submission or prior to the release of the final approval documents?

Schedule : once a month. ( Every third Wednesday at 10:30 AM. )  
 Submission : 4 weeks before IRB [initial application], 2 weeks before IRB [change application]

**PART B- this section is only applicable if the site is NOT responsible for directly performing ethics committee submissions.**

Please provide a general outline of the steps required to obtain approval for a study at your institution/site, including whether any steps are dependent on one another, and/or if they can be completed in parallel or in sequence (example- contract/budget approval, scientific review committees, or other, but excluding ethical committee or health-authority submissions handled directly by the sponsor/CRO  N/A or please, explain.

NA

**4. INFORMED CONSENT**

Does your site have a written SOP, policy/procedure for Informed Consent? .....  Yes  No

Minor Assent for pediatric populations?.....  Yes  No

Other vulnerable populations?.....  Yes  No

Will your site require language translations for consents .....  Yes  No

If so, what languages will be required? Please list.

**5. SITE QUALIFICATIONS/TRAINING**

Does your site have a training program for the research staff? .....  Yes  No

Does the course content include GCP? .....  Yes  No

Does your site use an external program to conduct research training? If yes, please provide program course name:  Yes  No

Does your program have a provision for training staff when updates to protocols occur?.....  Yes  No

**6. FACILITIES AND EQUIPMENT**

**LOCAL LAB:**

Name/Details: Kobe University Hospital Clinical Laboratory

Phone: +81-78-382-6314

Fax: +81-78-382-6348

Email: kensa@med.kobe-u.ac.jp

Local lab accreditation  GLP  CLIA  CAP  ISO  other JMA, JAMT

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  N/A

**EQUIPMENT:**

Is Calibration of equipment done routinely? .....

Yes  No

Are records and calibration frequency available?.....

yes  No

Do you have non-frost-free freezers for biological sample storage?.....

-20  -70  N/A

Do you have refrigerators for biological sample storage?.....

Yes  No

Is there temperature monitoring for refrigerators? .....

Yes  No

Is there temperature monitoring for freezers? .....

Yes  No

Are records maintained and available?.....

Yes  No

Is there a back-up plan for a power outage of refrigerators and freezers?.....

Yes  No

Is the system alarmed if the equipment is out of range for refrigerators and freezers?.....

Yes  No

Do you have access to an ECG? .....

Yes  No

Do you have  External phone lines  International phone lines

Do you have a centrifuge for process lab samples? .....

Yes  No

Do you have refrigerated centrifuge for processing lab samples? .....

Yes  No

**COMPUTER CAPABILITY:**

Does your site have dedicated computers for the research studies?.....

Yes  No

What is your current browser and adobe version? Please list:

Browser : IE11.1007.10586.0, Microsoft Edge 25.10586.672.0, FireFox 54.0.1, Google Chrome 59.0.3071.115, Adobe : X

Does your site have internal firewalls? .....

Yes  No

Does your site have high speed internet access? .....

Yes  No

Does your site have wireless internet capabilities?.....

Yes  No

**OTHER:**

PK/PD capability? .....

Yes  No

Lab hours to accommodate PK/PD studies beyond (8-5, M-F)? .....

Yes  No

Is your site open on weekends? .....

Yes  No

Are you able to admit research subjects to an in-patient setting for research purposes?.....

Yes  No

**DIGITAL DIAGNOSTIC CAPABILITIES:**

CT  MRI  PET  X-ray  DXA  Other (please list) \_\_\_\_\_

**STORAGE FACILITIES:**

Is the onsite patient record storage secured to protect patient privacy? .....

Yes  No

Are the archiving facilities on site?  Yes  No, if offsite provide name and location information.

Is there storage area on site for study related materials, ex. Lab kits or other items?.....

Yes  No

**7. INVESTIGATIONAL PRODUCT (IP)**

Ship to address: 7-5-2, Kusunoki-cho, Chuo-ku

Primary

Contact: Takeshi Ioroi

Phone: +81-78-382-6669

Email: chicken@med.kobe-u.ac.jp

Fax: +81-78-382-6690

Storage location the same as the shipping address? (if study specific skip)  Yes  No

Infusion capability? .....  Yes  No

**IP-STORAGE AND HANDLING**

Is the IP storage area secured with controlled access? .....  Yes  No

Is the temperature monitoring available for the following?  Room temp  Refrigerator  Freezer

Please detail temperature device capabilities (for example –min/max), frequency for monitoring.

Temperature : Min / Max. Frequency : Every working day.

Is the temperature monitoring alarmed in the event that there is an excursion? .....  Yes  No

Is there backup plan in the event of a power outage or equipment failure? .....  Yes  No

Is your site adequately staffed to perform both blinded and un-blinded roles, in case un-blinded drug monitoring is required? .....  Yes  No

**8. QUESTIONS SPECIFIC TO DESTRUCTION OF IP**

Does your site have the capability to destroy IP on site/arranged directly via sub-contractor?.....  Yes  No  N/A

Does your site have a written SOP/policy/procedure for IP destruction? .....  Yes  No  N/A

**IP – SATELLITE SITE (S)**

Will the satellite site(s) have a dedicated inventory?  Yes  No  N/A

Do you have a drug transportation procedure for satellite sites?  Yes  No  N/A

**9. QUESTION SPECIFIC TO CONTROLLED SUBSTANCES**

Does the site have the regulatory required licenses or registrations to receive, store, dispense and return controlled substances as required by local law? .....  Yes  No  N/A

The storage facility for controlled substances is securely constructed with restricted access to prevent theft or diversion? .....  Yes  No  N/A

Radio labeled IP capability? .....  Yes  No  N/A

Does your site have the capability to destroy IP on site for controlled substances?  Yes  No  N/A

**10. SOURCE DOCUMENTATION/CRFS/SITE MONITORING**

Source documents: Are site source documents  Paper  Electronic  Both

Please list any access limitations/requirements for the electronic medical records

Only viewing [The sponsor view the electronic medical records by directly observing the CRC viewing only required patient data.]

Will monitors have access to  Phone  Fax  Copy machines  Internet access

CRFs

What electronic data systems has your staff used for clinical trials?  Inform  Medidata Rave  Oracle

Other, please list Viedoc, DDworks

Please provide any additional information not captured elsewhere on this form, that you feel is important that we should know about your site. Please reference section number if applicable:

2. SITE DETAIL:

[Other therapeutic Area]

General Internal Medicine / Cardiovascular Medicine / Nephrology / Rheumatology and Clinical Immunology / Gastroenterology /  
Neurology / Medical Oncology and Hematology / Infectious Diseases / Radiology / Radiation Oncology /  
Palliative and Supportive Care / Gastrointestinal Surgery / Hepato-Biliary-Pancreatic Surgery / Breast Surgery /  
Cardiovascular Surgery / Physical Medicine and Rehabilitation / Neurosurgery / Ophthalmology /  
Otolaryngology-Head and Neck Surgery / Urology / Obstetrics and Gynecology / Plastic Surgery / Aesthetic Surgery /  
Oral & Maxillofacial Surgery / Diagnostic Pathology / Kampo Internal Medicine / Department of Clinical Genetics