TransCelerate BIOPHARMA INC.

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.

1. COMPLETED BY:

Full Name: Tuyoshi Kojima

Date Completed: 01Dec2015 **Role:** Center for Clinical Reearch

Investigator Name:

2. SITE DETAIL:

Institution Name: Kumamoto University Hospital

Address (Location): 1-1-1 Honjo , Chuo-ku ,

City: Kumamoto **State/Region/Province:** Kumamoto

Country: Japan **Postal Code:** 860-8556

Type: Academic

Therapeutic Area: ☒ Auto immune ☒ Cardiovascular ☒ Critical Care ☒ Dermatology ☒ Infectious Disease ☒ Men's Health ☒ Metabolic/ Endocrine ☒ Musculoskeletal ☒ Neuroscience ☒ Oncology ☒ Osteoporosis ☒ Pain ☒ Pediatrics ☒ Psychiatry ☒ Respiratory ☒ Vaccines ☒ Virology ☒ Women's health

Other:

Trial phase capabilities: ☒ I ☒ II ☒ III ☒ IV **other areas of expertise:**

Do you have affiliated research sites or satellite sites/clinics? ☐ Yes ☐ No

Which different sponsor type(s) do you have research experience? ☒ Industry ☐ Academic ☒ Investigator Initiated ☐ None

Ethnicity of patient population - please break down your population by % of ethnicity

99% Japanese , 1% other

Demographics of patient population: ☒ Pediatric ☒ Adult **Other comments:**

Is your site affiliated with a government agency or part of a government funded health service? ☒ Yes ☐ No
If Yes, please specify the affiliation

National University Corporation

Site Contacts: ***Primary site contact for clinical trials***

First Name: Tuyoshi **Phone:** +81-96-373-5842 **Fax:** +81-96-373-5809

Surname: Kojima **Email:** chiken-kuh@fc.kuh.kumamoto-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: Kumamoto University Hospital IRB

Address: 1-1-1 Honjo , Chuo-ku

City: Kumamoto

State/Region/ Province: Kumamoto

Country: Japan

Postal Code: 860-^8556

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?

- IRB/ERB/ Ethics committee(s) meeting schedule/frequency : once a month(recess in August),almost 4th Monday
- Amount of time in advance of an IRB/ERB/ Ethics committee meeting that all documentation must be submitted : 2 weeks before IRB
- Amount of time following an IRB/ERB/Ethics committee review you receive written confirmation of approval : 2 week
- 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? : No

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.**

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. Japanese

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: Kumamoto University Hospital Department of Clinical laboratry examination

Phone: NA **Fax:** NA **Email:** NA

Local lab accreditation ☐ GLP ☐ CLIA ☒ CAP ☒ ISO ☒ other Japan Medical Association , JAMT

Does the study staff that prepares or transports dangerous goods have training that meets the IATA International Air Transport Association (US) or other countr ies 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:
Internet Explore ver.11 , Adobe Reder 9

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: 1-1-1 Honjo , Chuo-ku , Kumamoto , 860-8556 , JAPAN

Primary Contact: Tuyoshi Kojima **Phone:** +81-96-373-5842

Email: chiken-kuh@fc.kuh.kumamoto-u.ac.jp **Fax:** +81-96-373-5809

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.

Max/Min is recorded once a day , and temperature is recorded every 60 mins.

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

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 Datatrak

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: