Print Form

TransCelerate BIOPHARMA INC.
ACCELERATING THE DEVELOPMENT OF NEW MEDICINES

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: Cindy Quinnell, CCRC

Date Completed: Jan 3, 2023 **Role:** Clinical Research Program Coordinator

Investigator Name: Trusau; Hansen; Gala; Edgar; Kanneganti; Hutto; Metzler; Romandine-Kratz; Lace; Oldenburg

2. SITE DETAIL:

Institution Name: St. Vincent Hospital d/b/a Prevea Health

Address (Location): 1860 Shawano Avenue, 4th Floor

City: Green Bay **State/Region/Province:** WI

Country: USA **Postal Code:** 54303

Type: Other

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: Electrophysiology; Primary Care; Otolaryngology; Optometry; Plastics/Aesthetics; Neurosurgery; Allergy/Asthma; Neuropsych

Trial phase capabilities: ☐ I ☒ II ☒ III ☒ IV **other areas of expertise:** Device, Registry

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

Caucasian 89%, African American 3%, Native American/Alaska Native 4%, Asian American 3%, Native Hawaiian, etc. 0% Other 1%

Demographics of patient population: ☒ Pediatric ☒ Adult **Other comments:** Hispanic/Latino 10%;Not Hisp/Not Lat 90%

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

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

First Name: Cindy **Phone:** 920-272-1044 **Fax:** 920-272-1053

Surname: Quinnell **Email:** cindy.quinnell@prevea.com

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?

Site uses the central IRB whenever possible, and does not have a separate Scientific Review or Ethics committee. Local IRB is available if required by the study. Regulatory and IRB documents can completed at the site level in parallel with contract and budget negotiations, but the contract and budget must be finalized before Regulatory and IRB documents are actually submitted.

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.**

Site uses the central IRB whenever possible, and does not have a separate Scientific Review or Ethics committee. Please see above for the site process.

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**

Advarra ICH-GCP; Sponsor-specific; ACRP; CITI

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

6. FACILITIES AND EQUIPMENT

LOCAL LAB:

Name/Details: Prevea Health

Phone: 920-272-1044 **Fax:** 920-272-1053 **Email:** cindy.quinnell@prevea.com

Local lab accreditation ☐ GLP ☒ CLIA ☒ CAP ☐ ISO ☐ other

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:

Google Chrome Version 108.0.5359.125; Microsoft Edge Version 108.0.1462.54; Adobe Acrobat Pro Version 2022.003.20282

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) Nuclear Medicine, Ultrasound

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.

Prevea Health / 1727 Shawano Avenue / Green Bay, WI 54303

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: Prevea Health
1860 Shawano Avenue / 4th Floor Clinical Research / Green Bay, WI 54303

Primary Contact: Cindy Quinnell, CCRC **Phone:** 920-272-1044

Email: cindy.quinnell@prevea.com **Fax:** 920-272-1053

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.

Min/Max daily Monday-Friday (except holidays); continuous data logger on refrigerator

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

EPIC agreement needs to be signed by Sponsor prior to CRA receiving their own read-only access limited to that study's patients.

Will monitors have access to CRFs ☒ Phone ☒ Fax ☒ Copy machines ☒ Internet access

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

☒ Other, please list Study/Sponsor/CRO-specific EDC

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:

The Prevea Health Clinical Research Program is part of a large multi-specialty, multi-site health system which serves patients throughout eastern Wisconsin and Upper Michigan. The Prevea Health system has 175,000 patients in our database and provides access to more than 225 physicians and over 150 Advanced Practice Providers in more than 60 specialty areas. We are conducting or have conducted studies in Cardiology, Interventional Cardiology, Primary Care, Vascular Surgery, Type 1 Diabetes, Type II Diabetes, Metabolism/Obesity, Electrophysiology, Neurology, Neurosurgery, Pediatric Neurology, Gout, Sports Medicine; and Imaging. We have the potential to conduct studies in other areas as well, and are eager to expand. We have a number of experienced PIs and SubIs, and dedicated, full-time, experienced ACRP-certified (CCRC) study coordinators. We have access to the EMR for all of Prevea Health as well as several hospitals, so we are able to run searches for specific patient populations. We utilize the Complion electronic Regulatory system. We are also VirTrial-certified virtual capable, and a SCRS site.

We are a small, dedicated department within a very large health system. This allows us to give our studies and our patients the personal attention and flexibility that a small department can give, but also offer the robust patient population and amenities of a large system. We have had many compliments from study sponsors, auditors, and CRAs regarding our physical site, attention to detail, professionalism, competence, and proficiency.