

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: | <input type="text"/> |
| Date Completed: | <input type="text"/> Role: <input type="text"/> |
| Investigator Name: | <input type="text"/> |
| 2. SITE DETAIL: | |
| Institution Name: | <input type="text"/> |
| Address (Location): | <input type="text"/> |
| City: | <input type="text"/> State/Region/Province: <input type="text"/> |
| Country: | <input type="text"/> Postal Code: <input type="text"/> |
| Type: | <input type="text"/> |
| Therapeutic Area: | <input type="checkbox"/> Auto immune <input type="checkbox"/> Cardiovascular <input type="checkbox"/> Critical Care <input type="checkbox"/> Dermatology <input type="checkbox"/> Infectious Disease <input type="checkbox"/> Men's Health <input type="checkbox"/> Metabolic/ Endocrine <input type="checkbox"/> Musculoskeletal <input type="checkbox"/> Neuroscience <input type="checkbox"/> Oncology <input type="checkbox"/> Osteoporosis <input type="checkbox"/> Pain <input type="checkbox"/> Pediatrics <input type="checkbox"/> Psychiatry <input type="checkbox"/> Respiratory <input type="checkbox"/> Vaccines <input type="checkbox"/> Virology <input type="checkbox"/> Women's health |
| Other: | <input type="text"/> |
| Trial phase capabilities: | <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV other areas of expertise: <input type="text"/> |
| Do you have affiliated research sites or satellite sites/clinics? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| Which different sponsor type(s) do you have research experience? | <input type="checkbox"/> Industry <input type="checkbox"/> Academic <input type="checkbox"/> Investigator Initiated <input type="checkbox"/> None |
| Ethnicity of patient population - please break down your population by % of ethnicity | |
| <input type="text"/> | |
| Demographics of patient population: | <input type="checkbox"/> Pediatric <input type="checkbox"/> Adult Other comments: <input type="text"/> |
| Is your site affiliated with a government agency or part of a government funded health service? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| If Yes, please specify the affiliation | |
| <input type="text"/> | |
| Site Contacts: <i>Primary site contact for clinical trials</i> | |
| First Name: | <input type="text"/> Phone: <input type="text"/> Fax: <input type="text"/> |
| Surname: | <input type="text"/> Email: <input type="text"/> |

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:

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

Email:

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?

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.

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:

Phone: Fax: Email:

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 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:

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:

Primary

Contact:

Phone:

Email:

Fax:

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.

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

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: