# Site CV

**Site Name: XXX**

**Opening Statement:**

**Years of experience, # of industry-sponsored trials conducted (# in the last 5 years), TA expertise, % of total studies conducted where you met/exceeded enrollment, IRB type, Average days from activation to FPI.**

# **1 Site Contact & Location**

Site location:

Contact Information:

Phone:

Fax:

Email:

Website:

Social Media:

# **2 General**

*Site Introduction – “elevator pitch”*

* *Total # of sites & location*
* *Photos of building*
* *Expertise & general capabilities*
* *What makes you stand out & unique*

**[Site Name]** is a leading clinical research site with **[#] locations** across **[City/Region/Country]**, specializing in **[therapeutic areas]**. With **[#] years of experience**, we have successfully conducted **[#] trials** and enrolled **[#] participants**, achieving an **[X]% retention rate** and meeting/exceeding diversity enrollment benchmarks by **[X]%**. Our site stands out due to **[unique differentiator, e.g., strong community partnerships, multilingual staff, specialized recruitment strategies].**

# **3 Investigators**

Investigator Name:

Specialty:

Years of Clinical Experience:

Years of Research Experience:

Bio:

Investigator Name:

Specialty:

Years of Experience:

Years of Research Experience:

Bio:

# **4 Study Staff**

Name:

Credentials:

Certifications:

Role:

Name:

Credentials:

Certifications:

Role:

Ancillary Staff Available: ie. Raters, Pharmacists, Registered Dietitians

# **5 Organization Structure**

# **6 Training**

* Describe the process for onboarding?
* Describe the process for general training?
* Describe the process for study specific training?
* List SOP TOCs
* Describe your Quality Management Systems process?

# **7 Audit**

* Previous Regulatory Inspections:

# **8 Capabilities**

* Do you have any special therapeutic area of expertise? If yes, specify:

* Number of trials conducted per year:
  + Phase 1
  + Phase 2
  + Phase 3
  + Phase 4
* Publications, presentations, other:

9 Patient Access & Volunteer Database

* *Total Number*
* *Highlights of Special Populations/Medical Diagnosis/Medications*
* *Patient Engagement Initiatives*
* *Census Data of Region re: Race & Ethnicity*
* *Recruitment Capabilites ie. Marketing, Query Capability, Pre-Screening*

# **10 Informed Consent Process**

# Do you perform pre-screening, with a dedicated generic REB approved ICF? If yes, explain the process?

* Describe study specific ICF process:

# **11 Facilities**

# Equipment List:

# Number of Exam Rooms:

# Available Diagnostics:

(on site):

(off site):

# Local Lab:

# CTMS:

# Paperless Regulatory:

# Paperless Source:

# Other:

# List of EDC Experience:

# Ability to manage long visit days, daycare/eldercare, observation periods and/or overnights

# **12 Ethics Committee**

* Can you use central ethics? Yes / No
* If not, describe your ethics process requirements.

* Do you have a dedicated regulatory person? If yes, provide contact information.

# 13 Contract & Budget

* How long is contract turn around?
* How long is budget turn around?

* Do you have a dedicated contracts/budgets person? If yes, provide contact information.

# **14 Archiving**

* Does your site have a short term archiving process that differs from long-term archiving?
* Where are the study documents stored for long term retention?

Location: