



FIEVE CLINICAL RESEARCH

SITE FEASIBILITY INFORMATION

Research Staff		Yes	No	Comments
1.	Are the PI/Sub-I and research staff CVs and other qualifications available for review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Available upon request.
2.	Has the research staff conducted controlled blinded studies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	See Study History Log for previous studies conducted by FCR.
3.	Is the research staff knowledgeable of the current regulatory requirements (i.e., GCPs, ICH)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Research staff is trained annually and provided with regulatory updates, as they are made available thru the regulatory authorities.
4.	Has a regulatory agency (e.g., FDA or local health authorities) performed an audit of your studies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A copy or a description of the inspection outcome (i.e., FDA 483, etc.) is available upon request.
5.	Is the research staff willing to commit adequate time and resources to conduct the study (including monitoring, sponsor auditing and regulatory agency inspection)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The research staff is dedicated to meeting the needs of the sponsor and most importantly the studies that are awarded to us.
6.	Does the research staff understand the importance of the ongoing data review?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The research staff is trained to work closely with the monitor and sponsor representatives to assure that clean and accurate data is collected and entered into the database appropriately.
7.	Is the study coordinator a full or part time employee? Is this his/her primary responsibility?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The study coordinating team comprises of full-time Study Coordinators who's primary responsibility is to assure that the research staff adheres to the protocol procedures, supports the PI/Sub-I, assures enrollment goals are met and is the primary contact for the monitors.
8.	Will there be adequate back-up personnel to support study activities? How will vacations/sick time of study personnel be handled?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	A back-up Study Coordinator is always signed to a study in the event the primary Study Coordinator is not available.

SITE FEASIBILITY INFORMATION (cont.)

Research Staff		Yes	No	Comments
9.	Are training, qualification and CVs of facility staff tracked and monitored?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	All research staff CVs are maintained on an annual basis along with licenses and certification renewals. Upon hire each research staff member is trained on the company SOPs, GCP/ICH guidelines and fundamentals of clinical trial research. Staff is re-trained as updated information is made available.
10.	Will the research staff provide Financial Disclosure?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Available upon request.
11.	What emergency procedures does the site have available?	Many of our employees are CPR and/or BLS certified. We also have access to 911.		

Facility		Yes	No	Comments
1.	Is access to the facility restricted? What are the security measures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The building security requires all guests to register prior to entry to the office area. Main office suite is secured with limited access. All office guests are greeted by the receptionist and required to sign in.
2.	What are your hours of operation?	Monday and Friday from 9:00 AM to 5:00 PM Tuesday, Wednesday, Thursday 8:30 AM to 7:00 PM		
3.	Does the facility have disaster prevention plan (i.e., in event of power outage, fire, flood, etc.)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Available upon request.
4.	Does the site have documented processes (i.e., SOPs) for conducting clinical trials at the site?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Table of Contents are available upon request.
5.	Does the site have adequate space for the storage of study related materials (i.e., source documents, CRF, drug/clinical supplies, etc.)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The facility has adequate storage space for all study related materials. We maintain an organized and neat working environment. Any study related materials meeting criteria for archiving are sent to an off-site storage facility (Iron Mountain), which can be retrieved as needed.
6.	Are there any security measures in place for the storage of investigational product?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Investigational Products are stored in a secured temperature monitored storage area that has limited access to research staff.
7.	Does the site have a -20 °C and -70 °C freezer for study sample storage?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	We have a -30°C freezer dedicated for study sample storage.

SITE FEASIBILITY INFORMATION (cont.)

Facility		Yes	No	Comments
8.	Is there a temperature log for the freezers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Research staff checks and records the temperature daily.
9.	Are freezer(s) and other laboratory equipment calibrated and maintained with documentation in place (i.e., equipment service logs)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Calibration and maintenance logs are available upon request.
10.	Does the site have access to dry ice? Is the site familiar with IATA shipping guidelines, and have a trained person?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
11.	Does the site have adequate lab facilities and treatment areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	We have a CLI-waived lab that has full capabilities for processing and packaging lab specimens.
12.	Does the site have a centrifuge?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
13.	How far is the nearest hospital?	New York University Medical Center and Bellevue Hospital Center are within 1.0 mile from FCR.		

Recruitment Capabilities		Yes	No	Comments
1.	Describe the recruitment structures for the clinic?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Primarily use the database followed by print, radio, and occasionally TV
2.	Does the site have a patient database?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.	Does the site use advertisements for the recruitment of patients?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Yes, we have capabilities to create study specific ads or utilize ads provided by the Sponsor

Data Collection/Entry		Yes	No	Comments
1.	Do study personnel have experience with EDC (i.e., InForm)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<ul style="list-style-type: none"> • Medidata Rave • Inform • PhaseForward • TrialMaster
2.	What other types of data collection systems does the study staff have experience with?	<ul style="list-style-type: none"> • Clintara Pen • IVRS • Electronic Diaries • MedAvante-Centralized Rating • Study specific cognitive batteries 		
3.	Who will be performing the data entry for EDC?	Data-entry is completed by the dedicated data entry staff.		
4.	Will study personnel be able to perform data entry within five business days from subject visit?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	FCR SOPs require data to be entered within 72 hours of data collection.
5.	What will happen to study files when the study is completed and archived?	All study related documents are archived at Iron Mountain within 90 days of study close-out.		

SITE FEASIBILITY INFORMATION (cont.)

Data Collection/Entry		Yes	No	Comments
6.	How long will the site keep study related files on archive?			As requested by the sponsor or in accordance to regulation whichever is longer.

Monitoring Activities		Yes	No	Comments
1.	Was a clinical study conducted at the site within the last twelve months?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	See Study History Log
2.	Do you have a dedicated space for monitors when they visit?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Yes, there is office space dedicated to monitors that gives them access to a phone, fax/printer/scanner/copier, and high-speed internet.
3.	How much notice do you require before scheduling monitoring visits?			We usually request that monitors schedule their first visit within 2 to 4 weeks of the first patient first visit and follow-up visits at least two weeks prior to the scheduled visit.

Documentation, Regulatory and Accountability		Yes	No	Comments
1.	Who will be responsible for completing the CRFs?			PI/Sub-I and CRC are responsible for completing source documents and CRFs as appropriate.
2.	Does the research staff have an SAE reporting process in place?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
3.	Who is responsible for evaluating severity and causality of each AE?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	PI or qualified Sub-I is responsible for evaluating severity and causality of each AE.
4.	How does the site keep track of patients' visits and schedules?			Site maintains patient visit log that tracks scheduled and actual visit dates.
5.	Who will be responsible for regulatory documents at the site?			The CRC or qualified designee is responsible for maintaining and tracking study regulatory documents.
6.	What is the typical turn-around time to negotiate a signed protocol agreement?			2-4 weeks, depending on sponsor/client review times
7.	Is the PI/ Sub-I familiar with the FDA 1572 form?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

SITE FEASIBILITY INFORMATION (cont.)

	Informed Consent Form & IRB/IEC	Yes	No	Comments
1.	Will the site use a central IRB/IEC?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	We have worked with many central IRBs mostly with: <ul style="list-style-type: none"> • Copernicus • Quorum <ul style="list-style-type: none"> • Shulman • Chesapeake • WIRB
2.	Does the research staff understand the informed consent process and the required elements?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The research staff is trained of GCP/ICH Guidelines, as well as the company SOPs for Informed Consent
3.	Will the site require an ICF in another language?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	We only require ICFs in English.

For questions and additional information, please contact:

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