



*An Early Feasibility Study Playbook Resource*

# Site Feasibility and Qualification Information

February 2026

**MDIC**

Medical Device  
Innovation Consortium

# [Site Name]

## Site Feasibility and Qualification Information

This document supports site qualification and feasibility. Sponsors and CROs should use this information to populate feasibility forms or surveys and avoid duplicating requests. Any information not included here can be provided upon request.

**All study start-up communications & documents should be directed to the following distribution list:**

Site Overview & General Capability		
<i>List Names and Emails</i>  <b>SITE INFORMATION</b>	Department	
	Street Address	
	Building	
	City, State, Zip	
	Phone	
	Website	
	<b>REGULATORY &amp; IRB CONTACT</b> Oversees regulatory Process. Should be included on all study specific and regulatory correspondence. Oversees all new study submissions, modification and maintenance of study protocols including renewals.	Name
Title		
Email		
<b>FINANCE CONTACT</b> Oversees Finance process. Primary liaison between sponsor and Clinical Trials Office. Should be included on all study specific correspondences.	Name	
	Title	
	Email	
<b>OPERATIONS CONTACT</b> Oversees all research operations and compliance	Name	
	Title	
	Email	
	Cell Phone	
<b>REGULATORY DOCUMENTS CONTACT</b> Primarily responsible for regulatory start up documents (CVs, ML, FDFs) pre SIV.	Name	
	Title	
	Email	
	Phone	
<b>CLINICAL RESEARCH MANAGER</b> Handles all activities from the SIV forward. Oversees the research coordinators. Should be included on all study specific correspondences	Name	
	Title	
	Email	
	Phone	
<b>PRINCIPAL INVESTIGATOR</b> Primarily responsible for regulatory start up documents (CVs, ML, FDFs) pre SIV.	Name	
	Title	
	Phone	

PRIMARY RESEARCH COORDINATOR WILL BE ASSIGNED PRIOR TO THE SIV

**Confidential Disclosure or  
NON-Disclosure Agreement  
(CDA/NDA):**

*EXAMPLE: Please send via email a word version of the CDA/NDA. The Start-up team will forward the CDA/NDA to our clinical trials office for review and execution. The Clinical Trials Office will reach out to you directly with redlines if necessary*

### Start-Up FAQs

*What documents are required to begin start-up activities at your site?*

*EXAMPLE: Provide the final protocol, informed consent document(s), instructions for use and/or investigational brochure, case report forms, FDA approval or FDA conditional approval letter, a final or draft version of the CEC and/or DSMB charters as well as any imaging manuals if applicable. Once CMS approval has been received, we will need a copy of the CMS approval letter. In addition, we will need the NCT trial number published on Clinicaltrials.gov.*

*Are any internal committee reviews required in addition to IRB submission and approval?*

*EXAMPLE: Joint Radiation Safety Committee (JRSC) Approval for protocols that involve any form of radiation (cath lab procedure, x-ray or nuclear imaging, etc.)  
Submission to JRSC will be completed concurrently with the IRB Submission.*

*Does your site use an electronic system for management of regulatory documents?*

*EXAMPLE: We use a remote, centralized storage platform, Lab Archives, to provide direct access to standard regulatory documents including CAP/CLIA, lab normal, CVs & medical licenses*

*Can your site enroll subjects prior to receiving CMS approval for IDE studies?*

*What is the process to schedule Site Initiation Visit?*

*What is the address that study supplies should be shipped to?*

## Contracts/Budgets

<b>LEGAL NAME &amp; ADDRESS OF INSTITUTION</b>	Institution/Site Name:	
	Street Address:	
	City, State, Zip:	
	Tax ID:	
<b>CONTRACT NEGOTIATION INFORMATION</b>		
<b>PAYMENT ADDRESS</b>	Payable to:	
	Attn:	
	Street Address:	
	City, State, Zip:	
	Email:	
<b>F&amp;A RATES</b> (Institution Overhead)	Federally Funded Trials:	%
	Industry-Sponsored Clinical Trials:	%
<i>How long on average does the contract and budget review /approval process take?</i> <i>Brief description of the process:</i>		<i>EXAMPLE: 6-8 weeks</i>
<i>How would the site and/or Institution name appear on the contract?</i>		
<i>Can the contract be executed prior to IRB approval?</i>		
<i>Are any other agreements needed at your institution?</i>		

## Local IRB Information

<b>IRB Name:</b>	
<b>Director:</b>	
<b>Street Address:</b>	
<b>IRB City, State, Zip:</b>	
<b>Email Address:</b>	
<b>Contact Telephone:</b>	
<b>Website:</b>	
<b>Federal-Wide Assurance (FWA)#:</b>	
<b>IRB Fees</b> <i>(Effective 2025)</i>	Initial IRB Review:
	Continuing Review:
<i>Can your site use a Central IRB?</i>	<i>Only with NIH Funded Research</i>
<i>How often does your IRB meet?</i>	<i>EXAMPLE: The IRB schedule is attached or provide link if available online</i>
<i>How far in advance do IRB submissions need to be submitted prior to the meeting date?</i>	
<i>On average once all documents are submitted, how long does it take to receive IRB approval?</i>	<i>EXAMPLE: 6-8 Weeks</i> <i>Once we receive the full start up packet as described in item 4, we will begin the IRB application</i>
<i>From the IRB meeting date, what is the period of time expected for the IRB to provide approval documents?</i>	<i>EXAMPLE: 2-4 Weeks</i>
<i>Does your IRB require an executed Clinical Trial Agreement and Budget prior to IRB review or approval?</i>	<i>EXAMPLE: No but CTA cannot be executed until IRB approval</i>
<i>Can you provide a copy of the IRB rosters?</i>	<i>EXAMPLE: All rosters are available in Lab Archives Central Regulatory Folder</i>

### Investigational Product-Drug Trials

<b>RESEARCH PHARMACY</b>	Contact:		
	Street Address:		
	Floor/Room:		
	City, State, Zip:		
	Phone:		
	Email:		
	Website:		

<b>PHARMACY FEES</b> <i>(EFFECTIVE Date)</i>	<b>INDUSTRY SPONSORED</b>		
	Start up \$ _____	Monthly Maintenance Fee \$____/Month	Dispensing Fees \$ _____ depending on route of administration

### Investigational Product-Device Trials

<b>Does the site require a No Charge PO to receive product?</b>	<input type="checkbox"/> Yes, the site needs a No Charge PO per shipment. <input type="checkbox"/> Yes, use blanket study PO: <input type="checkbox"/> No
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<b>Delivery Address</b>	Attention Line:		
	Street Address:		
	Floor/Room:		
	City, State, Zip:		
	Phone:		
	Email:		

<b>Device Storage Location:</b> <i>Brief Description</i>	
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<b>Vendor Credentialing Process:</b> <i>Brief description</i>	<i>EXAMPLE: Temperature-controlled and access-restricted storage if required. Separation from commercial devices to prevent mix-ups</i>
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## General Site FAQs

<i>What is the size of your study team?</i>	
<i>How many studies does a research coordinator typically have?</i>	
<i>When is a research study coordinator assigned?</i>	
<i>Does your site have high speed internet access?</i>	
<i>What is your site's approach to Monitoring Process? (onsite, remote, both)</i>	
<i>Will monitors have direct access to the EMR?</i>	
<i>Does your site have an established record retention and archiving practices?</i>	
<i>Do you have the ability to upload/redact source documents for remote monitoring</i>	
<i>Do you have a secure location to maintain study-related clinical materials (e.g., study binders, kits, research samples)?</i>	
<i>Can you process and ship samples to the core lab?</i>	
<i>Do you have access to a Centrifuge?</i>	
<i>Do you have access to a Freezer?</i>	
<i>Do you have access to a Refrigerator?</i>	
<i>Does your site have experience with web-based EDC?</i>	
<i>Can your site enroll subjects prior to receiving CMS approval for IDE studies?</i>	
<i>Has the FDA or any other governing body inspected this department?</i>	<i>FDA inspections and findings are publicly accessible. Please refer to: <a href="https://datadashboard.fda.gov/ora/cd/inspections.htm">https://datadashboard.fda.gov/ora/cd/inspections.htm</a> for up to date information.</i>
<p><i>Does your site require any language translations? documents related to</i></p> <ul style="list-style-type: none"> <li>• <i>Informed Consent</i></li> <li>• <i>Retention</i></li> <li>• <i>Adverse Events</i></li> <li>• <i>Monitoring</i></li> </ul>	<i>EXAMPLE: We serve a large number of Spanish-speaking patients. Therefore, the informed consent and HIPAA authorization, and any other patient facing research materials must be translated to Spanish. We have a local translation center approved by the IRB to complete this task.</i>

## Protocol-Specific Questions

### Experience With Similar Studies

<p><b>Key similarities or relevant prior experience</b> Experience with studies of similar design, indication, or risk profile (IDE, EFS, Clinical indication)</p>	<p><i>Previous participating in clinical trials are publicly accessible on <a href="https://clinicaltrials.gov">clinical trial.gov</a> or search using MDIC EFS Explorer</i></p>
<p><b>Number of ongoing studies and trial phases</b> (study start up, enrollment, long term follow-up)</p>	

### Patient Population & Recruitment Feasibility

<p><i>Does the site have access to the target patient population?</i></p>	
<p><i>Estimated number of potentially eligible patients per month/year</i></p>	
<p><i>Anticipated enrollment rate for this study</i></p>	
<p><i>Competing trials or standard-of-care limitations that may affect recruitment</i></p>	
<p><i>Key inclusion/exclusion criteria that may limit enrollment at your site</i></p>	
<p><i>Ability to support screening, longitudinal follow-up, and retention</i></p>	

### Study-Specific Timeline Expectations

<p><i>Expected time to first patient enrolled</i></p>	
<p><i>The main factors that could realistically delay study startup, activation, or enrollment at your site for this specific protocol.</i></p>	
<p><i>Sponsor responsibilities that most impact this study's timeline:</i></p>	
<p><i>Site position on expedited startup requests for this protocol:</i></p>	