

What to Ask	Why This is Important to Determine?	Who To Ask?	How?	When?
<b>Best and worst case enrollment scenarios?</b>	Validate enrollment potential	Personnel involved in patient identification and recruitment (Investigator, CRC)	Interview: Enrollment forecasting techniques	Concept stage
<b>Potential barriers to enrollment and retention?</b>	Identify reasons for enrollment issues, develop recruitment plan	Personnel involved in patient identification and recruitment (Investigator, CRC)	Interview: Leaky Pipe Analysis & Enrollment Forecasting Techniques	Concept stage
<b>Access to the appropriate patient population</b>	Identify opportunities to amend I / E criteria and avoid protocol amendments; Identify if site will need to supplement potential patients from external sources; begin planning recruitment strategies	Investigator and Key Staff involved in	Interview: Leaky Pipe Analysis Enrollment & Forecasting Techniques	Concept Stage and Ongoing as Protocol is finalized
<b>Site Experience</b>	Identify training and resource support needs	Key staff involved in study conduct	Interview and/or Survey / Questionnaire (verify through review of CV)	Concept Stage (and ongoing as staff changes)
<b>Site Interest</b>	Determine level of commitment and engagement	The Investigator The key site staff	Just ask! Interview – open ended questions Consider MD to PI discussion	Concept Stage and Ongoing
<b>Site comfort with the research design?</b>	Identify potential issues and opportunities to improve design. Ensure site buy-in with the rationale	The Investigator The key site staff	Interview – open ended questions	Concept Stage and Ongoing

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<b>Site perception of risk to the subjects?</b>	Willingness and comfort exposing subject to risk and defending protocol to IRB / EC	The investigator	Interview – open ended questions	Concept Stage and Ongoing
<b>Likelihood of ethics approval and potential “non-negotiable” factors?</b>	Potential factors that will impact Ethics Committee approval of study	Investigator	Interview - open ended questions	Concept Stage and Ongoing as Protocol is finalized
<b>Opportunities to make the protocol more operationally efficient</b>	Identify opportunities to reduce delays and protocol amendments, enhance site comfort and compliance; identify resource needs early on	Personnel involved in study conduct	Interview	Concept stage and ongoing as site gains experience
<b>Site comfort level approaching patients and family about the study opportunity?</b>	Identify potential issues and opportunities to develop “important messages” and coaching tips for site personnel, patient educational materials and need for “mock” consent discussions training	Those involved in the consenting process	Interview – open ended questions	Draft / Final Protocol Stage and Ongoing
<b>Site perception of adequacy of the budget?</b>	Identify potential barriers to contract approval and site engagement; identify opportunities to develop and negotiate mutually acceptable budget	Investigator, Site director and other administrative personnel involved in financial planning	Interview – open ended questions	Draft protocol and ongoing as site gains experience
<b>Planned recruitment and retention approaches?</b>	Proactively plan recruitment / retention needs and approaches so that budgets and materials can be developed and	Personnel involved in subject recruitment and retention	Interview Survey / Questionnaire	Draft protocol and ongoing as site gains experience

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	approved in a timely fashion			
<b>Perceived site training needs?</b>	Create a study-specific training program and prioritize site training approach based on varied site learning needs	All staff involved in study conduct (don't forget ancillary staff – e.g., pharmacist, technicians)	Survey / Questionnaire	Draft Protocol and ongoing as site gains experience and/or staff changes
<b>Adequacy of site staff / resources?</b>	Identify additional resource support needs so that this can be factored into the budget development	Investigator Site Director All staff involved in study conduct	Survey / Questionnaire	Draft Protocol and ongoing as site gains experience and/or staff changes
<b>Site perception of administrative burdens associated with conducting the study?</b>	Identify aspects of study that will impact site resources and staff motivation; develop mitigation plan	Site Director or other administrative personnel	Interview (preferred) also Survey / Questionnaire	Draft protocol and ongoing as site gains experience with study conduct
<b>Access to appropriate equipment and facilities?</b>	Identify equipment needs so that this can be factored into the budget development	Site Director or other administrative personnel	Survey / Questionnaire with On-site inspection	Draft protocol or Final protocol (depending on your final site selection and budget development process)
<b>Expected ethics approval timelines?</b>	Project and plan for realistic site initiation date	Administrative staff (e.g., Clinical Research Coordinator)	Survey / Questionnaire	Final Protocol Stage

**CONSOLIDATED Version**

<b>Study Feasibility Questions to Address During:</b>		
<b>Concept Stage</b>	<b>Draft Protocol Stage</b>	<b>Final Protocol Stage</b>
Best and worst case enrollment scenarios?	Site comfort level approaching patients and family about the study opportunity?	Expected ethics approval timelines?
Potential barriers to enrollment and retention?	Site perception of adequacy of the budget?	
Access to the appropriate patient population	Planned recruitment and retention approaches?	
Site Experience	Perceived site training needs?	
Site Interest	Adequacy of site staff / resources?	
Site comfort with the research design?	Site perception of administrative burdens associated with conducting the study?	
Site perception of risk to the subjects?	Access to appropriate equipment and facilities?	
Likelihood of ethics approval and potential “non-negotiable” factors?		
Opportunities to make the protocol more operationally efficient		