

## Feasibility Checklist

	<b>Validating Enrollment Potential</b>
	<p>If unsure of the potential subject population, contact KMSF or VAMC to determine the number of patients seen by a designated physician or clinic with a specific diagnosis code:</p> <p style="text-align: center;">KMSF contact: Kathryn Cox 257-7910 ext 301 <a href="mailto:kacox0@uky.edu">kacox0@uky.edu</a></p> <p style="text-align: center;">VAMC contact: Carol Ward (859) 233-4511 ext 5138 <a href="mailto:Carol.Ward@med.va.gov">Carol.Ward@med.va.gov</a></p>
	Review and evaluate the inclusion and exclusion criteria to see if realistic. Treatment naïve population?
	Determine if the trial requires too much of the study patients or volunteers – in time or cost – i.e. Some cancer studies leave expense to subject for standard of care (SOC) or rescue medications
	Are there extenuating circumstances that would adversely affect recruitment- i.e. Traditional treatment becoming approved over the counter (OTC).
	What is the expected screen failure ratio and will sponsor pay for unlimited screen fails?
	Are you or other investigators at the site doing a similar or competing protocol that could affect any of the above?
	Will a patient stipend be in the sponsor's budget to cover subject cost to participate (mileage, parking, etc)?
	Are vulnerable populations involved (children, prisoners, decisionally challenged) that may required additional IRB and recruitment protections.
	<b>Protocol Considerations</b>
	Do you have previous experience with the sponsor (or CRO)? Good-bad?
	Do you have experience in the therapeutic area under investigation.
	Are the procedures consistent with the site's standards of care? Are they realistic or too frequent?
	Does the PI feel the study is safe, ethically acceptable, scientifically sound, and appropriate in regard to risk-benefit ratio? (Placebo or wash out?)
	Is study drug dosing complex? Do you expect compliance issues?
	Are follow-up visits reasonable and are the visit windows acceptable and/or flexible?
	<b>Draft Budget</b> (UKCRO can assist with this if needed).
	Does the sponsor's preliminary budget seem adequate?
	Does the budget include costs for administrative start-up; IRB services; drafting the informed consent and preparing the IRB submission?
	Will the sponsor pay the required 26% overhead?

	Will the sponsor pay for items/events that are difficult to budget for in advance? i.e. adverse event reporting; protocol amendments; re-consenting subjects; unanticipated monitoring or sponsor audits, screen-fails, long-term storage, unplanned or re-scheduled missed visits, etc.
	Is payment schedule reasonable?
	<b>Staff Requirements</b>
	Dissect the protocol and use the event schematic and <a href="#">UKCRO staff calculator</a> to evaluate all tasks evolved. Is it feasible in light of current work load (consider real start time)?
	Do you have qualified and 'dedicated' research staff to coordinate the trial? Will UKCRO operations services be needed?
	Do you have training needs?
	Review study case reports forms (CRF) and patient questionnaires if available and assess time required to complete.
	Does the PI have adequate time and scheduling availability to devote to the overall supervision of the trial?
	Will it involve call time or coming in off hours for enrollment?
	Are there adequate sub-investigators to assist PI with the trial?
	How often will the monitor visit and do they expect the study will be either sponsor or FDA audited?
	Consider ancillary or specialty staff needs– (Investigational Drug Service, labs, diagnostics, etc) for example will after hours drug formulation require extra pharmacy staff?
	<b>Facility Considerations</b>
	Is adequate clinic and office space available? Will the UKCRO research clinic be needed?
	Will coordination with other departments or services be required?
	Is any special equipment required – sponsor may want to have standardized type of equipment among sites?
	Is access to emergency rescue equipment necessary?
	<b>Supplies</b>
	What will sponsor supply (Case Report Forms (CRF), source documents, electronic consent template, packaged lab kits, etc.)?
	Will electronic or remote data capture be used? If so, will sponsor provide hardware and training?