SAMPLE PROTOCOL FEASIBILITY CHECKLIST

The feasibility study is used to provide a practical examination of the feasibility of each of the study elements required for success including:

- Likelihood of people agreeing to participate
- Recruitment rate
- Burden of the study
- Patients
- Staff expertise and availability
- Equipment requirements
    - Access to the right type
    - Availability
- Funding availability and adequacy

The following are factors to consider when you receive a new proposal or protocol.
Please note this list is not exhaustive.

1. Population

	Is the proposed enrollment goal realistic?
	Is the proposed enrollment period realistic?
	Will enrollment compete with other studies seeking the same patients?
	Are inclusion/exclusion criteria overly restrictive? (Consider the likely screen: screen failure ratio)
	Are vulnerable populations involved, e.g., children, impaired adults with special consent issues?
	Do you expect a significant number of adverse events? (How ill is this population?)

2. Protocol

	Is the protocol well designed?
	Is the protocol ethical? Will the HREC have problems with it?
	Is the study question important?
	Will the participants benefit from participating in the study?
	Is the protocol in final form? If not, how many amendments can be expected before it is in final form?
	Will coordination with other departments/services be required for study visits or procedures?
	Can other services (e.g., lab, radiology) meet the protocol requirements?
	Is necessary equipment available?
	Is the study unusually long in duration? (Drop-outs are more likely in long studies.)
	If an inpatient study, will floor staff need to be involved?

	Are participant compliance problems likely? If so, will it be necessary to monitor participants' compliance with time-consuming phone calls or postcards?
	Are case report forms complex?
	Is there a large number of case report forms per participant?
	Are drug or device storage/accountability requirements complicated?
	Will the drug be available for patients at the end of the study? (This can impact patient satisfaction.)

3. Procedures

	Are procedures frequent?
	Are procedures difficult, e.g., young patients asked to swallow pills?
	Are procedures painful?
	Are procedures inconvenient (causing participants to miss work or school)?
	Are participant diaries used? If so, does this require staff time for transcription or interpretation?
	Is the dosing schedule complex?

4. Staff

	Are qualified staff available?
	If needed, is training available?
	Is the workload manageable?
	Does the PI have adequate time to devote to the protocol?
	Are additional specialists needed?
	Are study visits complex, presenting possible scheduling difficulties, e.g., how many different study staff will participants encounter in a given visit?
	Is projected query turnaround time workable?
	Is adequate clinic and office space available?

5. Budgets

	Does the preliminary budget appear adequate?
	Does the funding cover events that are difficult to budget in advance, such as:
	• Protocol amendments (may require consent form revisions)?
	• Re-consenting participants?
	• Unanticipated monitoring visits?
	• Audits?
	• Unexpectedly high number of SAEs?
	Will funding cover screen failures?
	Will the proposed payment schedule allow you to keep afloat, e.g., adequate up-front payment; payments paced according to work required by protocol?
	If necessary to store study records off-site, is this funded?