

Critical Steps: Reviewing Protocols & Study Feasibility OVPR, Clinical Research – UMass Worcester

Not all sections of this template may apply to your potential study, but time spent reviewing feasibility is well worth the effort. It is critical to an adequate and accurate budget, and the first step in developing a practical plan for subject recruitment and retention.

Sponsor:

Have you had prior experience with this sponsor/CRO?

If so, do you anticipate contract or budget issues that need attention early on in the process?

Protocol Assessment:

Regarding the science, is the study valuable? Is the protocol well designed?

Is the study safe and ethically acceptable? Do you anticipate IRB issues/problems?

Is the protocol in its final form? Are you anticipating many changes or amendments before it is final?

Are the inclusion/exclusion criteria reasonable, given your potential research subjects? Are they overly restrictive?

Will this study require coordination with other divisions/departments?

Study Population:

Do you have access to the study population? Does this study compete with others for the same population? Will you be relying on other UMass depts. to identify potential subjects...how will you accomplish this? (e.g., will you need co-investigators?)

If study requires community recruitment aside from UMass, how will you accomplish this? Will the sponsor pay for advertising?

Are your enrollment estimates realistic? Is the enrollment period realistic?

Is the intensity and time required by the study appropriate for the population?

Do you anticipate recruitment of non-English speaking subjects? Do you have access to adequate translation services?

If protocol involves vulnerable subjects, be attentive to special recruitment and consent issues. Factor time & effort into your budget and recruitment/retention plan as needed.

If research includes subcontracts (i.e., PI as sponsor) there are special obligations as a coordinating center (budget/role definitions/regulatory oversight) that require planning and resources.

Site Resources: Staff

Does the PI have the time needed to devote to study?

Do you have adequate staff to conduct this study? Is the workload manageable for your present staff?

Who will coordinate the study, handle regulatory documents and day-to-day work of the study?

Is your research staff properly trained to perform study procedures as required by protocol? If not, will sponsor provide training?

If study requires inpatient stay, will non-study staff be involved? Who will in-service them? Who will be their resource?

If using hospital space, have you gathered correct study costs and clarified billing issues (see Clinical Research division in OVPR)?

Site Resources: Equipment and Facilities

Is there adequate space to conduct the study?

Do you have the equipment needed to conduct the study? If not, will sponsor provide or allow purchase (include in budget)?

Do you have adequate and secure record storage space?

Is data entry electronic/remote? If so, will sponsor provide staff with training?

- ☞ **Use a Budget Worksheet to draft a budget as you review the protocol for feasibility. Remember standard fees in budget, e.g., IRB fee, pharmacy start-up, pharmacy per patient costs and indirect rate (26% for industry)**
- ☞ **Involve OVPR, Clinical Research *early on* in the process to address any challenging contract issues; when you are sure you want to move ahead with the industry study, contact OVPR to begin contract negotiations**
- ☞ **Consult OVPR, Clinical Research if you want assistance with study feasibility review; budget evaluation must be reviewed as collaboration between PI/Dept and Contract Specialist in OVPR**
- ☞ **Remember, the success of your study depends upon a coordinated team effort and a realistic feasibility review – let us know if we can help**

Questions and follow-up needed:
