What is a *Feasibility Assessment*?

In research, a feasibility assessment is an analysis or evaluation of a proposed study to provide an overview of the primary issues related to the research to identify any "make or break" issues that would prevent the successful completion of the study. In other words, a good feasibility assessment determines whether carrying out the study makes sense in the context of your individual/department/center and/or institutional goals and capacity.

Why should you do a *Feasibility Assessment*?

Setting up and conducting a research study takes manpower, money and time. This includes your time along with time from institutional offices such as the Grants and Contracts office, the IRB and other ancillary committees. Data from 2014-2015 has shown that up to 30% of studies at UVa are closed prior to completion of which almost 20% had no subjects enrolled. Time spent deciding the feasibility of conducting the study in the beginning may help you better coordinate and direct your valuable limited resources, and prevent a great deal of frustration in the long run!

What is the process for doing a *Feasibility* Assessment in my department/ center?

Every department/center follows a required process and related form(s) that must be completed as part of the *Feasibility Assessment.* You are encouraged to check with research support within your department/ center to determine the required process.

What items should be considered when doing a *Feasibility Assessment*?

1. Sponsor Considerations:
    - Current relationship with this sponsor:
        - Is this a new sponsor with whom you/your department want to develop a relationship?
        - Is this an existing sponsor with whom you/your department have had difficulty?
        - Is this an existing sponsor with whom you/your department work regularly and have established positive relationship?
    - Is there a Clinical Research Organization (CRO) overseeing the study?
        - Is it a CRO you/your department have worked with before and have established a positive relationship?
    - Does UVa have a master agreement with the sponsor?

- Does the funding source fill a need in your department?
    - NIH funded
    - Investigator-initiated
    - Sponsored (industry or cooperative group)
- How/why was UVa/PI selected as a site for this study?

2. Scientific and Faculty Considerations
    - Is the study related to research goals of the institution/ department / investigator?
    - Issues about the proposed PI at UVa:
        - Senior faculty member
            - How does the study fit with his/her current portfolio?
            - Does s/he have adequate time to devote to this study?
        - Junior faculty
            - Does this further his/her start-up goals for their research?
            - Does the study provide academic potential for the junior faculty member?
            - Does the study provide pilot data potential, therefore provide future grant potential?
            - Does the study provide "learning" potential (opportunity to learn the role of clinical investigator, etc.)?
    - How many other studies does the study team have open? Are they able to handle the workload in the allotted time?
    - Is the study scientifically sound? Will you be able to answer the research questions / hypotheses?
    - Will the outcomes of the study provide important knowledge to society?
    - Do you have the subject/patient population at UVa to meet the enrollment goals?
    - Are the study procedures significantly different from our current clinical routine?
    - Will the study require input from referring services/departments?

3. Subject/Patient Considerations
    - Does the study offer some important potential clinical treatment options for subjects/patients which they would not have access to outside of the study?
    - Does the study address an unmet clinical need for subjects/patients at UVA?
    - Will the inclusion/exclusion criteria make the study difficult to enroll?
    - Will the frequency of visits impact study completion?

- Will the study place difficult burdens on the subjects/patients which might affect dropout rate (e.g. frequent visits/ invasive procedures)?
- Will the time required to screen for the study be higher than usual (e.g., will it take longer to identify eligible subjects/patients)?

4. Budget Considerations
    - Is there a budget proposed?
    - Does the budget adequately cover costs? If not, are there funds from other resources available?
    - What are the costs for conducting this study? Please note, the largest cost associated with conducting clinical research studies is generally personnel, specifically clinical research coordinator effort and investigator effort. However, you must also consider subject/patient costs, costs of study procedures and/or treatments which are not billed to the subject/patient/insurance, and other direct costs.

5. Practical issues:
    - Is the protocol well written/clear/understandable? Do you have the ability to make modifications?
    - Do you have adequate subjects/patients to participate?
        - Referral potential?
        - Recruitment planning?
        - Consider a specific search for eligible subjects/patients through the CDR, EPIC or other existing clinical database.
    - Is there any overlap with other current clinical study commitments?
    - Do you have adequate infrastructure (facilities, equipment) to participate?

Who should I contact if I do not know how to answer some of the questions above?

The answer to this question may be different depending on the department/ center. If it is not clear to whom you should talk to in your department you are encouraged to ask your supervisor, department chair or the SOM Clinical Trials Office.