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Factors in Determining the Feasibility of Conducting a Company-Sponsored Clinical Trial

As a clinical faculty member of Mount Sinai School of Medicine, at some point in your career, you may be interested in or approached by a for-profit company to perform a clinical trial. The following information is intended to assist you in making the decision whether or not to participate.

1. Patient Population:

The number one concern of the sponsor will be quick enrollment of eligible patients. It is important before accepting a trial that you carefully review the enrollment criteria to ensure that you have the appropriate patient population. Do not assume that any patient who is eligible will agree to participate. Poor enrollment performance will count against you in the placement of future clinical trials so carefully review your access to patients who meet all inclusion/exclusion criteria.

2. Financial Viability:

Is the company providing adequate reimbursement for the expenses of the study? Study procedures may not be billable to private or government insurers, and it is imperative that you be able to cover all third party study expenses. The worksheet located at: http://www.mssm.edu/grants/files/trials_cost_analysis.xls can assist you in determining the financial viability of conducting an industry sponsored clinical trial. This useful financial tool provides a cost benefit analysis by comparing contract value with projected expenses for both full and partial enrollment of patients. Furthermore, you should avoid doing business with companies that are financially unstable. If a company goes out of business, you may not be able to recoup your expenses.

3. Space:

Do you have dedicated space for research? You will need space to see patients and also to keep patient files in locked cabinets in a secure location. If you do not have space to see patients, it may be possible to conduct your study in the General Clinical Research Center (GCRC). Contact the IRB (212) 659-8980 for more information.

4. Staffing:

Studies vary considerably in the amount of time required to conduct them. Even something as simple as a physical and history could vary between 5 minutes and an hour and a half in different studies. The case report forms will offer you the best idea of the time required, so request to see them. In most cases, it makes sense to hire a research coordinator rather than rely entirely on physician time and effort. If you do not have a coordinator, your department may be able to assist you. If physician time will still be extensive, review whether the loss to other revenue streams such as private clinical practice is acceptable. Also, the GCRC offers Nurse Practitioner (NOT coordinator) time to studies run through their facility.

5. Training:

At a minimum, all staff doing human subjects research need to be certified by the Institutional Review Board (IRB). Contact the IRB at (212) 659-8980 to arrange for certification. You should also be familiar with Good Clinical Practices. Also contact the IRB if you or your staff would like to pursue continuing education.

6. Access to Investigational Products and Cutting Edge Technologies:

Industry sponsored clinical trials generally offer access to medications or devices not yet on the market. These studies might represent an otherwise unavailable opportunity to provide treatment for your patients. Many

studies offer compassionate use extensions, wherein all patients, even the placebo control group, receive free medication after the study is over. Be sure to inquire if your patients will be eligible for an extension.

7. Networking:

Performing an industry sponsored clinical trial will establish a professional relationship with a drug/device company that may lead to future studies or collaborations. Also, you will have the opportunity to meet colleagues at the company sponsored investigator meetings.

8. Career Advancement for your Staff:

A nurse who is also a trained study coordinator will have more career opportunities than nurses who are not coordinators. Your staff may enjoy working on a clinical trial and you may be able to fund underutilized, but valued, employees through your clinical trial participation.

Other sources of information: The following sites may be useful tools when performing clinical trials:

<http://www.fda.gov/> outlines drug and device regulations and registration information.

<http://www.mssm.edu/irb/> provides internal Mount Sinai School of Medicine human subject policy and forms.

<http://ohrp.osophs.dhhs.gov/index.htm> is the site of the federal Office of Human Subjects Protection.

If you have additional questions about participating in a particular trial or would like to provide feedback about the above, please contact Jessica Moise at (212) 659-8970.