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Informed Consent for New Investigators

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Author's note: *Too many new investigators conduct a clinical research study, realize what it means to be an investigator, and never do another study. A lot of time and effort by all parties can be saved if new investigators enter the industry with their eyes open.*

Thank you for your interest in serving as an investigator in our _____ clinical research study. Since you have not conducted clinical research before, we want to make you aware of the challenges you might face. Although these challenges might seem overwhelming, many current investigators have overcome them, and we will do our best to help you become a successful investigator in this study. Once you complete this study, you will be in a better position to decide whether to conduct additional studies.

Physicians conduct clinical studies for many reasons, including participation in cutting edge research, contribution to medical science, career advancement, intellectual curiosity, financial gain, reputation, interaction with key opinion leaders, and personal experience with an illness. Before proceeding, you should understand *your* reasons for participating and satisfy yourself that they justify the commitment.

As a new investigator, you might face the following challenges:

- Unless you are exceptionally savvy for a new investigator, your first study might not be as good as it appears to be.
- If you decide to continue in clinical research, you will have to secure a continuing stream of studies in competition with numerous other investigators, many of whom have established relationships with study sponsors.
- As a new investigator, you might not have the opportunity to participate in trials that are scientifically important, easy to fill with patients, financially rewarding, and low risk.
- You will have to find patients to participate in your studies. Many studies have stringent eligibility criteria and might not appeal to your patients.
- You will have to randomize patients to one of two (or more) study "arms," one of which will be, by definition, experimental (i.e., its safe and/or efficacy are unknown), and the other will likely be a placebo control. In other words, in most therapeutic areas, clinical research usually is not clinical care.
- Unless you intend to do all the work yourself, which generally is not advised, you will need support from a "study coordinator," who will also need training and compensation, regardless of whether there are studies to pay the bills. Your study coordinator will need to be a "jack of all trades" and handle a wide variety of responsibilities that are usually handled by specialists at large research sites.
- You and your study coordinator will have to be knowledgeable about numerous laws, regulations and guidelines for study conduct ("Good Clinical Practice" or "GCP"), protection of study participants, and billing compliance.
- You (or your study coordinator) will have to complete substantial amounts of patient, regulatory and other paperwork.
- You (or your study coordinator) will have to learn how to use a variety of data entry ("EDC") and other computer systems.

- At the beginning of a study, you are likely to invest time that will go largely uncompensated if you do not enroll enough patients in the study.
- You will need office space for your study coordinator(s) and storage space for study documents and materials. You will be responsible for storing the study records for many years, perhaps 15 or more.
- You might have to invest in expensive equipment, such as a centrifuge or deep freezer, and find space for it. Some of this equipment, e.g., EKG machines, might be study specific.
- You will probably want to negotiate better terms in the clinical trial agreement and budget than those offered by the study sponsor or contract research organization ("CRO"), which will require specialized expertise and possibly involvement by an attorney and/or other contract and financial specialists.
- You should not expect payment for your work for at least 90 days, and probably much longer.
- You will have to balance your clinical workload and that of your study coordinator with study activities that are inherently irregular and time sensitive.
- If your study coordinator leaves or otherwise becomes unavailable, you will probably have to do his or her work yourself until you can hire and train a replacement.
- If a study participant is injured during a study, perhaps due to an error by a staff member, you might be liable for financial and reputational damage.
- If you are working in a healthcare organization, support from executive management will be very helpful, if not essential.
- The time you spend on clinical research will not be available for your clinical practice or keeping up to date on your medical specialty.
- You will probably have to invest significant time and money in your clinical research program before the effort pays off financially, which may never occur.
- You should be prepared to weather the inevitable rough patches that most, if not all, investigators experience in clinical research.

Despite these challenges, thousands of physicians find clinical research personally and professionally rewarding. If you decide to proceed, we will be available to guide you through the process. In addition, you should also attempt to find an experienced investigator or study coordinator to serve as your mentor.

I, the undersigned, have carefully read this document. I have had the opportunity to ask questions about my responsibilities as an investigator in the study. My questions have been answered to my satisfaction. I wish to proceed as an investigator in the study.

_____	_____	_____
Printed Name	Signature	Date

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