**The “SPICI” Investigator Initiated**

**Clinical Trial Agreement Clauses**

**You Must Understand**

An Investigator Initiated Clinical Trial Agreement or an IIT is an agreement for a clinical trial that is designed and conducted by a sponsor-investigator. Sponsor-Investigator is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug/device is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a sponsor-investigator in 21 CFR Part 312 include both those applicable to an investigator and a sponsor. We can separate out these terms to get a better understanding of the expectations. An Investigator is an individual who actually conducts a clinical investigation. A Sponsor is a person who takes regulatory responsibility for and initiates the clinical investigation.

There are so many clinical trials available from industry partners. Let’s look at why one would want to participate in an IIT. For the investigator, IITs promote the ability to pursue a study that an industry partner may not be interested in. IITs can add to academic achievement for an investigator. IITs can also provide the investigator with the opportunity to own and sell data or intellectual property. For industry partners, IITs allow the ability to fund a study with interest in the high-level results or which meet an unmet medical need. Industry partners may also obtain some rights to data or intellectual property with limited investment.

It is important to recognize that the preview of agreements from a typical clinical trial agreement (“CTA”) to an IIT is really a spectrum of options that will be negotiated by the parties. A typical IIT involves the sponsor-investigator taking all the risk, developing the protocol, being the regulatory sponsor and has full independent financial support. A typical CTA has the industry partner assuming all the risk, being the regulatory sponsor, providing all the drugs/devices and funding the entire study. In between those two differing perspectives are many different options for the agreements. An agreement similar to an IIT might have the industry partner providing the drug/device and some funding in exchange for having some rights to the data. An agreement that is getting closer to a traditional CTA could have an investigator develop the protocol, but the industry partner is the regulatory sponsor and provides all the funding.

Let’s dive into those five critical clauses for an IIT. They are subject injury, publication, indemnification, , confidentiality, and intellectual property “SPICI". The goal of the parties to a IIT should be achieving the best way to balance these provisions in a way that is fair for both parties.

**Indemnification**

Indemnification in a traditional CTA will have the Industry Partner indemnifying the investigator for (a) use of the study drug/device; (b) the performance of a procedure required by the protocol; (c) their use of the study data; and (d) intellectual property claims related to the drug/device. Because an IIT involves a protocol that was drafted by the investigator, the risk will shift in an IIT. An indemnification provision in an IIT would involve the investigator (or her/his employer) indemnifying the industry partner for its negligence or wrongful acts, violation of laws or breach of a warranty in the agreement. Occasionally in an IIT, an industry partner may indemnify the investigator for the industry partner’s use of the study data.

**Subject Injury**

Subject Injury language in a traditional CTA will require the industry partner to pay for the diagnosis and treatment of subject injuries for study subjects. Not surprising, but in an IIT, there is typically no subject injury provision. This is understandable because the investigator, not the industry partner, developed the protocol and is responsible for the regulatory requirements.

**Publication**

In a CTA publication language will include a complex system to delay or wait for a multicenter publication and various reviews of the publication by the industry sponsor. Because IITs may be at one site or more than one-site.. When one site is involved, there is no need to delay an initial publication for a multisite study. Also, if there are initial findings that can be published during the study then the option is available. For instance, an investigator may want to publish on successful recruitment strategies for a disease group that is historically hard to enroll. However, the industry partner will want similar reviews of the publication to look for its confidential information and any intellectual property protections.

**Confidential Information**

Industry partner confidential information language is most critical in a CTA. While there may be some protection of the investigator’s (or its employer’s) confidential information in a CTA, the industry partners want to protect all their intellectual property for their drug/device and protocol which they developed. In an IIT, the sponsor-investigator developed the protocol, so the protections will shift to protect their protocol but will continue to protect the industry partner’s intellectual property.

**Intellectual Property and Study Data**

Intellectual property language in the spectrum of contracts from an IIT to a CTA could vary dramatically. It will depend on the amount of funding, the type of drug/device, the protocol and other factors. One constant term is the source documentation, such as medical records. The original medical records from the participating site will always be owned by the site in both CTAs and IITs. In a CTA, the industry partner will own all the intellectual property that comes from the study. In an IIT, the investigator (or its employer) may grant to the industry partner a non-exclusive, sub-licensable, transferable, royalty-free license for drug/device related inventions. In addition, the investigator (or its employer) will provide the industry partner with the first right to negotiate an exclusive license with full rights to the inventions.

Study data is owned by the industry partner in a CTA and they typically provide the investigator with a non-exclusive license to use the data for its own internal non-commercial, quality and educational purposes. In an IIT, depending on funding and the agreement of the parties, the investigator (or its employer) will own the study data. They will also provide a non-exclusive license to the industry partner to use, reproduce and transmit the study data.

While the breadth of options in an agreement for a clinical trial, from an IIT to a CTA can vary broadly, it is important to take special note of the five terms described herein. These terms are of critical importance to all parties. Having an appropriate balance of these terms will lead to beneficial research benefiting all parties and society, as well.