



WE'LL EARN YOUR APPROVAL.

FAIR SHAKE™

## A 4-Point Training Program to Navigate Through Regulations

Even with great improvements in clinical research education in the last decade, we're still falling short. As an industry, we have the knowledge, but we're lacking the application; we continue to routinely violate regulations as evidenced by a continuous stream of warning letters flowing out of the various offices of the FDA.

The FAIR Shake™ technique takes an otherwise complicated maze of requirements and breaks them down into four simple areas that can be applied to clinical research questions. Are you in compliance with:

<b>F</b>	<b>Federal regulations</b>
<b>A</b>	<b>Agreements</b> (FDA Form 1572 - drugs / Investigator Agreements - devices)
<b>I</b>	<b>Investigational Plan (protocol)</b>
<b>R</b>	<b>Requirements of the IRB</b>

The goal is to foster a pattern of thinking that will allow you to navigate through the complexity of the regulatory framework in a very simple way that is based in regulatory fact as opposed to popular opinion. This technique will position you to raise the bar on your own study teams as you gain confidence in your ability to wage an educated debate when potential areas of non-compliance are raised.



Giving Your Studies a  
**fair** ((shake))™

To learn more, contact John E. Lehmann, Director of Business Development **440.801.1540**

## Benefits of the Fair Shake™ technique:

- Boil research down to four key areas
- Easily navigate through the regulations
- Learn how to apply the knowledge
- Simplify your decision-making process

Because some elements of the Fair Shake™ are variable, the key to “application” lies in understanding the following:

A decision about regulatory compliance made at **one site for one study** may not be the right decision at **another site for the same study** or at the **same site for another study**.



## The regulations that govern clinical research are there for a very important reason -

to protect the human subjects that are on the other side of that consent form, the human subjects that together make up that target enrollment number sites strive to reach, the human subjects whose stories are told inside all of those binders.

## As clinical research professionals:

it is our responsibility to not only know the regulations, but to know how to apply them in various situations. Training is essential. Accurate application is essential. Adopting this FAIR Shake™ technique into your daily practice will help you bridge the two.



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