# Managing, Drafting and Negotiating Industry Subcontracts

**Proactive Solutions and Potential Roadblocks** 





#### INTRODUCTION



Who am I?

Why am I here?

What are we talking about today?



# SUBCONTRACTING OVERVIEW



Organization

Attention to Detail

Utilize Technology

It's not easy but it doesn't have to be hard.

# OUR ROADMAP



- Negotiating the Prime Agreement
- 2. Drafting the Subcontract
- 3. Negotiating the Subcontract
- 4. Troubleshooting
- 5. Questions

# IF AT FIRST YOU DON'T SUCCEED...



Everything I Have Learned Has Come From My Own Mistakes.

Set the Expectations Early



#### COMMON TERMS AND ASSUMPTIONS FOR TODAY

m: related to Dic like a dictator. 2 overbear orially adv. [Latin: TATOR diction /'dikf(a)n/ n. manner ciation in speaking or singing dictio from dico dict- say] dictionary /'diksənəri/ n. (p) book listing (usu. alphabetica risky, explaining the words of a lan giving corresponding words in es) dilanguage. 2 reference book e efined ed to

Industry Sponsored Investigator Initiated

#### Terms:

Prime – The contract between Institution and the industry partner

Sponsor – The industry partner

-Cont.-

#### COMMON TERMS AND ASSUMPTIONS FOR TODAY

a: related to but orially adv. [Latin: TATOR diction /'dikf(a)n/ n. manner ciation in speaking or singing dictio from dico dict- say] dictionary /'diksənəri/ n. (p) book listing (usu. alphabetica risky, explaining the words of a lan giving corresponding words in es) dilanguage. 2 reference book e efined ed to

Institution – The party contracting with the industry partner

Subsite – The party receiving the subcontract from Institution

Subcontract – The contract between Institution and Subsite

#### NEGOTIATING THE PRIME CONTRACT

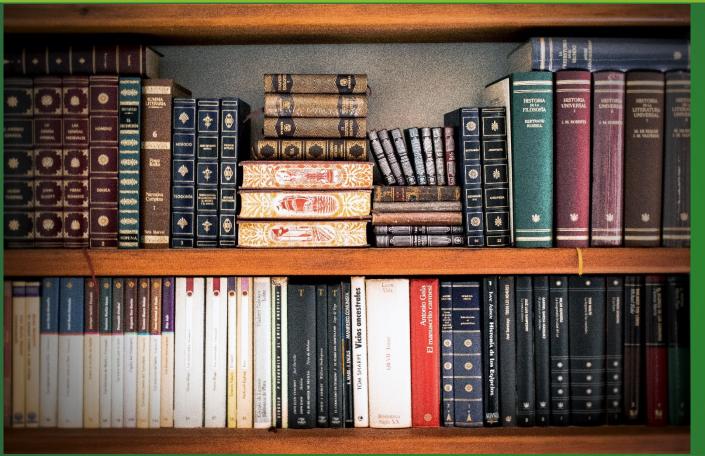


Stay Vague and General

Fight A Little Harder



#### CHOICE OF LAW AND INDEMNIFICATION



Silence Is Golden

State v. Private

The Enforcer?

Who Is Responsible?

LOI's



# SUBJECT MEDICAL INJURY



Specific To Your **Internal Policies** 

Know Your Drug

# INTELLECTUAL PROPERTY



Patentable

Tangible

Hereby Assigns

If You Are Going to Grant It You Have To Retain It



#### BIOLOGICAL SAMPLES AND ADDITIONAL RESEARCH



Protocol Required Only

Study Drug Related Only



# IDENTICAL VS. SIMILAR AND MISCELLANY



Substantially Similar

3<sup>rd</sup> Party Beneficiary

Regulatory Audit and Inspection



#### **FU GDPR**

```
y),+function(a){"use strict";function b(b){return this.each(function(){v
le[b]()})}var c=function(b){this.element=a(b)};c.VERSION="3.3.7",c.TRANSITION_DURATION=150,c.prot
 одомл-menu)"),d=b.data("target");if(d||(d=b.attr("href"),d=d&&d.replace(/.*(?=#[^\s]*$)/,"")),!
ropdown-menu)"),d=b.data("target");1f(d||(d=b.attr( ||| tr /) d data("show.bs.tab",{relatedTarget:e[0] Too Soon?
faultPrevented()){var h=a(d);this.activate(b.closest("li"),c),this.activate(h,h.parent(),functio
rigger({type:"shown.bs.tab",relatedTarget:e[0]})})}}},c.prototype.activate=function(b,d,e){func
active").removeClass("active").end().find('[data-toggle="tab"]').attr("aria-expanded",!1),
 ia-expanded",!0),h?(b[0].offsetWidth,b.addClass("in")):b.removeClass("fade"),b.parent(".dropdou
().find('[data-toggle="tab"]').attr("aria-expanded",!0),e&&e()}var g=d.find("> .active"),h=e&&
/e")||!!d.find("> .fade").length);g.length&&h?g.one("bsTransitionEnd",f).emulateTransitionEnd
;var d=a.fn.tab;a.fn.tab=b,a.fn.tab.Constructor=c,a.fn.tab.noConflict=function(){return a.fn.t
"show")};a(document).on("click.bs.tab.data-api",'[data-toggle="tab"]',e).on("click.bs.tab.data
se strict";function b(b){return this.each(function(){var d=a(this),e=d.data("bs.affix"),f="ob
etypeof b&&e[b]()})}var c=function(b,d){this.options=a.extend({},c.DEFAULTS,d),this.$target=a
",a.proxy(this.checkPosition,this)).on("click.bs.affix.data-api",a.proxy(this.checkPositionWi
null,this.pinnedOffset=null,this.checkPosition()};c.VERSION="3.3.7",c.RESET="affix affix-top
State=function(a,b,c,d){var e=this.$target.scrollTop(),f=this.$element.offset(),g=this.$target
"bottom"==this.affixed)return null!=c?!(e+this.unpin<=f.top)&&"bottom":!(e+g<=a-d)&&"bottom"
l!=c&&e<=c?"top":null!=d&&i+j>=a-d&&"bottom"},c.prototype.getPinnedOffset=function(){if(this
RESET).addClass("affix");var a=this.$target.scrollTop(),b=this.$element.offset();return
WithEventLoop=function(){setTimeout(a.proxy(this.checkPosition,this) 1)}
```



# TIME TO SUBCONTRACT



Drafting The Subcontract

Negotiating The Subcontract



# DRAFTING THE SUBCONTRACT



Template v. The Prime

Federal Template Use

Prime As An Exhibit



# NEGOTIATING THE SUBCONTRACT



Setting
Expectations Early

Cannot Place Your Institution In Breach



# SAY NO!



You Will Never Make Everyone Happy

Be Firm

Be Direct

Be Nice...They Are Coming Your Way Soon



# TROUBLESHOOTING

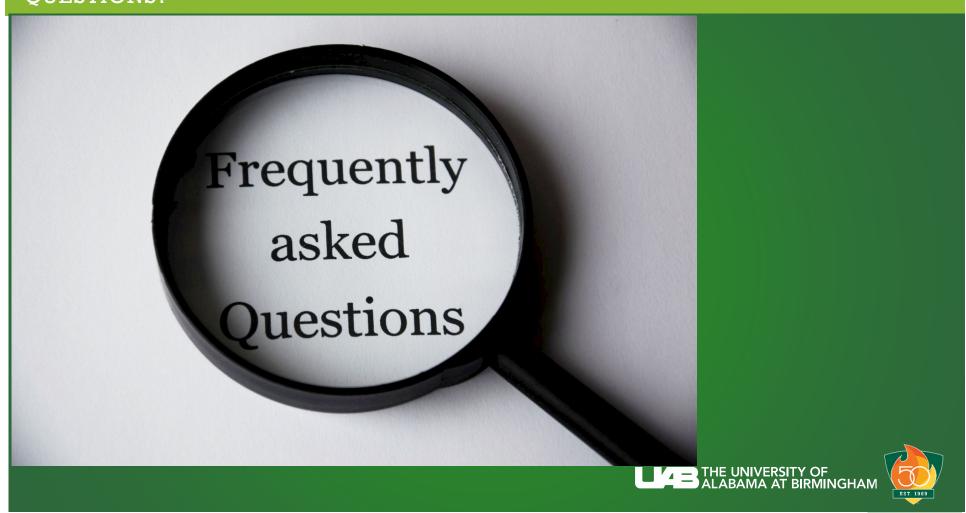


Back To The Drawing Board

Investigator Help



# **QUESTIONS?**



#### IF I CAN EVER BE OF ANY HELP

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