

Managing, Drafting and Negotiating Industry Subcontracts

Proactive Solutions and Potential Roadblocks



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ALABAMA AT BIRMINGHAM

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



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

IF AT FIRST YOU DON'T SUCCEED...



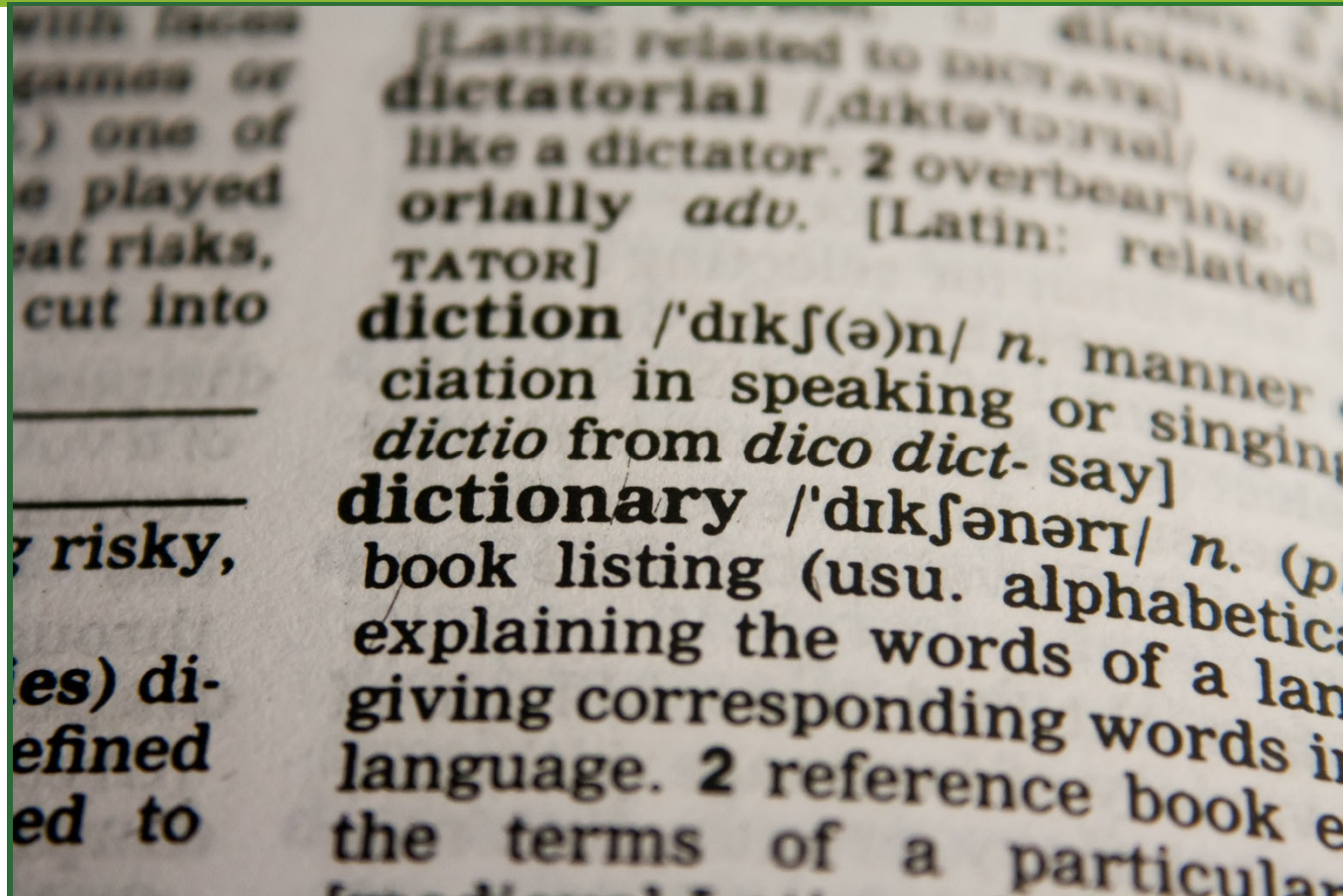
Everything I Have
Learned Has Come
From My Own
Mistakes.

Set the Expectations
Early

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COMMON TERMS AND ASSUMPTIONS FOR TODAY



Industry Sponsored
Investigator Initiated

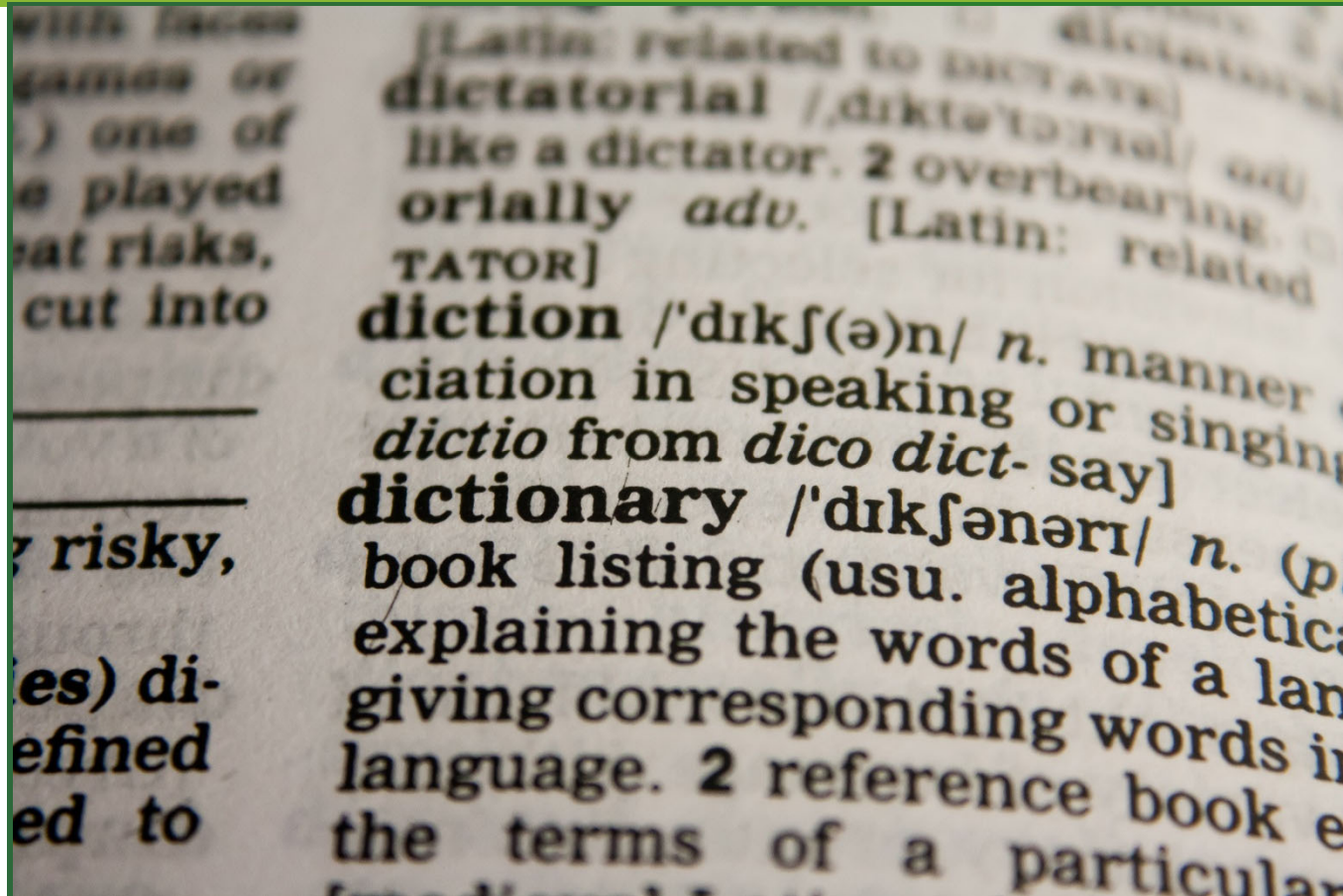
Terms:

Prime – The contract
between Institution
and the industry
partner

Sponsor – The
industry partner

-Cont.-

COMMON TERMS AND ASSUMPTIONS FOR TODAY



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



1 + 1 = 3

Substantially
Similar

3rd Party
Beneficiary

Regulatory Audit
and Inspection

[illegible]

Too Soon?

TIME TO SUBCONTRACT



Drafting The
Subcontract

Negotiating The
Subcontract

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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

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QUESTIONS?



Frequently
asked
Questions

IF I CAN EVER BE OF ANY HELP

- Thank you all for your time and attention.

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