Session IV:

Managing Expectations and the Relationship

K-State Presenter:

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- Timelines
- Reporting Requirements
- Payments
- Publication Requirements
- Confidentiality Provisions
- Data



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Differences in Culture (University & Industry)

Differences in Institutional Missions

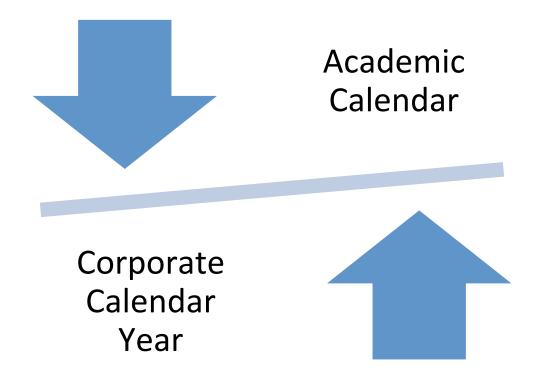








Differences in Culture (Calendar Reconciliation)





Differences in Culture - Timelines

Under Promise – Over Deliver

- Be Realistic
- Be Transparent
- Consider the Elasticity of Your Ability to be Flexible
- Anticipate Potential Hurdles
 - -Unforeseen Contingencies
 - -Student/Post Doc Recruitment and Hiring Delays
- Be Prepared To Consider Sponsor Deadlines Based On Their Budget Year
- Limit Time Extension Requests To The Pursuit Of New Mutually Agreeable Research Tracks



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Contractual Considerations

Reporting Requirements

- Apply Test Of Reasonableness With Due Consideration of Sponsor Needs
- Could Be Included In The Contract Terms Or As Part Of The Scope Of Work
- Considered Part of the "Deliverables"
- Reports Could Be Specified As a "Milestone" Event
- Submission Usually Effects Timely Payment Especially Final Payment
- Proactively Communicate Anticipated Delays
- Becomes Sponsor Owned Deliverables
- May Require Sponsor Format Or Investigator Initiated Format
 - ✓ Good Idea To Work This Out In Advance



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Contractual Considerations

Payments

- Payment Structure Requires Consideration of the SOP's of Both Parties
 - ✓ Cash Flow, Policies, Risk Adverseness, Previous Payment and Performance History
- Payment Can Be Set Up on Payment Schedule (Riskier In Some Cases)
 - ✓ Based on Task or Milestone Completion
 - ✓ Based on Specified Payment Dates, i.e. evenly spread over quarterly payments
 - ✓ Prefer a Portion of the Cost Paid in Advance, Especially for Reimbursement Payments
- Payment Can Be a Lump Sum Payment
 - ✓ \$X Paid Within Thirty Days of the Execution of the Agreement; Final Payment Within Thirty Days of the Receipt of the Final Report
- For Foreign Collaborations, Payments Should Be Made in USD



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Publication Requirements

Balancing of University-Industry Perspectives Freedom To Need For **Publish** Confidentiality



Publication Requirements

Sample Problematic Verbiage May Initially Appears as follows:

UNIVERSITY will not publish or otherwise release either to the public or to any third party any information resulting from the Research except in accordance with the following procedure and conditions:

- (a) Prior to the publication or release of any such information, UNIVERSITY will submit the information in writing to ____ for ____'s approval, and UNIVERSITY will be free to publish or release any such information if _____ does not object within ninety (90) days after receiving it.
- (b) ____ will have no right to object to the proposed publication or release of any such information except for reasons relating to the inclusion of Technical Information or the patenting of any invention resulting from the Research. In the event of an objection relating to inclusion of Technical Information, UNIVERSITY will not publish or release the information unless all Technical Information included therein has been deleted.



Publication Requirements

- Must preserve Publication Rights
 - ✓ Primary Component of K-State's Public Mission
 - ✓ Primary Component of K-State's IRS Status
 - ✓ Preserves the Right To Claim Certain Exemptions in Regards to Export Control Laws
 - ✓ One of the Main Components of Your Scholarship
- Must Avoid......
 - ✓ Granting External Veto Rights Over Your Ability To Freely Publish
 - ✓ Accepting "Company must approve" Verbiage ("thirty day right to review" is acceptable)
 - Must Carefully Review "Definition" and "Ownership" Sections of Contracts and Agreements, i.e. "Data" or "Results"
 - ✓ Including a Sponsor's Confidential Information in a Publication Without Express Prior Written Approval
- May Delay Publication Of Data From Site As Part Of Multi-Site Trial



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Confidentiality Provisions

Trust

- Parties Taking a Leap of Faith That Info Will Be Protected
- Must Have Deliberate Plan To Avoid Inadvertent Disclosure

Stewardship

- Requires Continuing Obligation Beyond Project Completion
- Requires Further Distribution Only On A Strict "Need To Know" Basis

Burden

- Must Be In Writing, Or At Least ID'd In Oral Disclosures
- Must Have A Reasonable Time Frame For Expiration Of Confidentiality
- Must Not Comingle With Own Information

Confidentiality Provisions

University Perspective

All information can be freely disseminated EXCEPT in limited clearly defined cases

K-State is subject to the Kansas Open Records Act ("KORA")

Industry Perspective

All information is confidential EXCEPT in limited clearly defined cases

Company approves release of data

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Data

- What is Data?
- How is it gathered?
- What laws and regulations apply?
- Where is it kept?
- Who Controls, "owns" it?
- Who wants to use it for what?
- How sensitive is it?
- Can it be protected?
- Does it have value?



Data

University Position

Separate types of "data"

Talk about use not ownership

Company Position

Combine types of "data"

Claim ownership

Data (cont'd)

University Position

Must define "data" if talking about ownership

"Institution agrees that all data generated during the course of the Study may be used by Company for any purpose including regulatory filings...."

Company Position

Must retain custodianship of all raw data

"Institution agrees that all data, inventions and discoveries generated during the course of the Study shall be the property of Company, and Institution shall execute any documents or undertake any further actions if requested by Company to evidence transfer of title thereto..."

Questions?

