

WORKING WITH INDUSTRY

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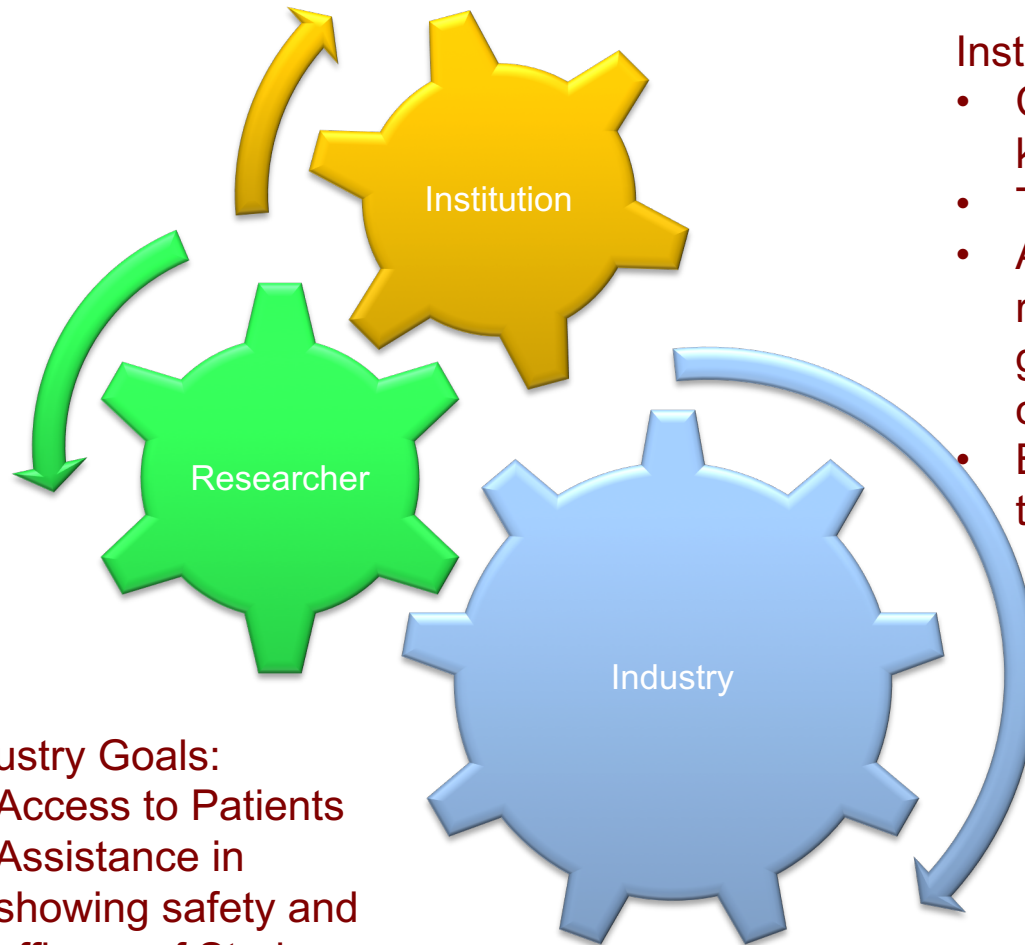
Working With Industry

- I. Goals of Working with Industry**
- II. Types of Contractual Agreements**
- III. Who do I contact to work with Industry?**
- IV. Systems to track agreements w/in Penn**
- V. Things to consider**
- VI. Sample Scenarios**

I. Goals of Institution, Industry, and Researcher

Researcher Goals:

- Receive funding for research
- Ability to publish findings
- Improve Patient Care
- Access to tools/materials/data and/or Study Drugs/Devices



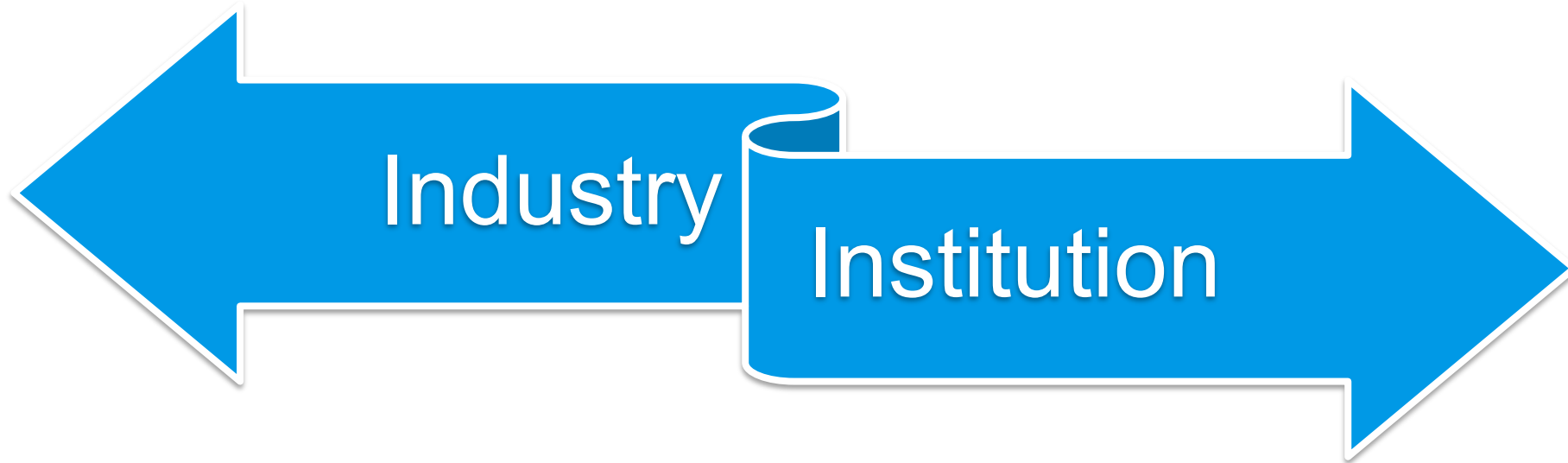
Institution Goals:

- Contribute to the body of knowledge
- Training/Education
- Additional source of research funding besides government, Institution, or foundations
- Bring or develop latest treatments to patients

Industry Goals:

- Access to Patients
- Assistance in showing safety and efficacy of Study Drugs/Devices
- IP Generation
- Access to Data

I. Where Goals Diverge



Industry:

- For-profit company
- Competitive Advantage
- Exclusivity
- IP Ownership and Use
- Data Ownership and Use
- Protect Confidential Information
- Limit publication of unfavorable results

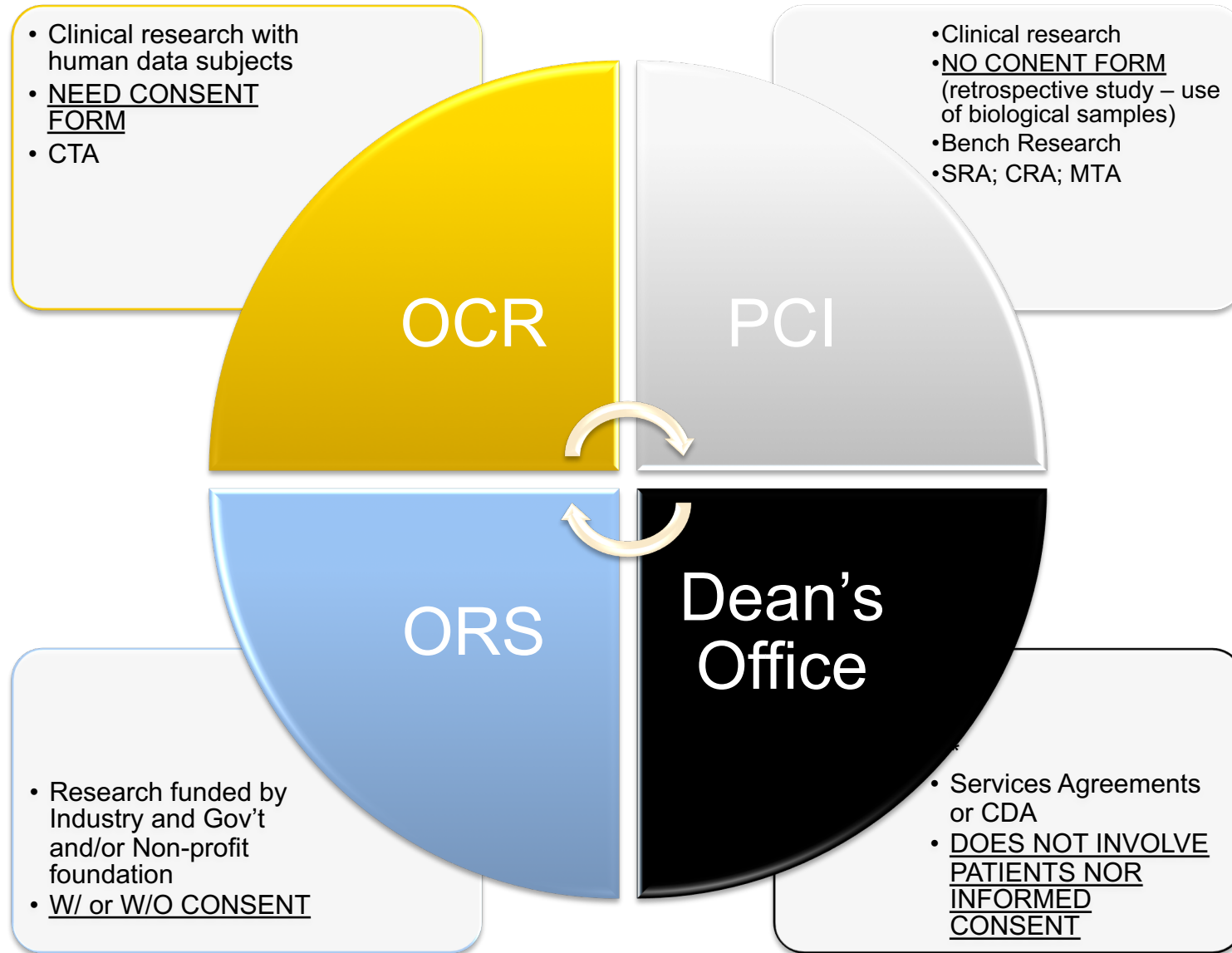
Institution:

- Non-profit entity
- Contributing to the body of knowledge
- Publication of Data and results without restriction
- Ability to license to other entities
- Retain use of IP for publication, research, education, patient care

II. Types of Agreements

Agreement	Description
Clinical Trial Agreement (CTA)	A clinical trial agreement is the instrument that enables Penn's participation as a site in a clinical trial. The clinical trial could either be industry-initiated or investigator-initiated.
Sponsored Research Agreement (SRA)	Agreements used when a company provides funding to Penn for a particular researcher or researchers to pursue a specific area of research during a defined timeframe.
Collaborative Research Agreement (CRA)	A binding agreement between organizations that are cooperating in the conduct of a research program which defines the obligations each party has to the others participating in the collaborative research effort.
Confidential Disclosure Agreement (CDA)	Agreements that govern the exchange of confidential information between two or more parties for certain evaluation purposes.
Service Agreement	A written contract to engage an outside party to perform routine testing, standardized procedures, or services where the outcomes are not likely to result in the addition of new knowledge or publishable information.
Material Transfer Agreement (MTA)	Agreements that govern the transfer of research material between organizations.
Data Use Agreement (DUA)	Generally, these are agreements that govern the transfer and use of data between organizations, where the data is nonpublic or otherwise subject to some restrictions of its use.

III. Who do I contact to work with Industry?



IV.

MTA – CDA - CRA

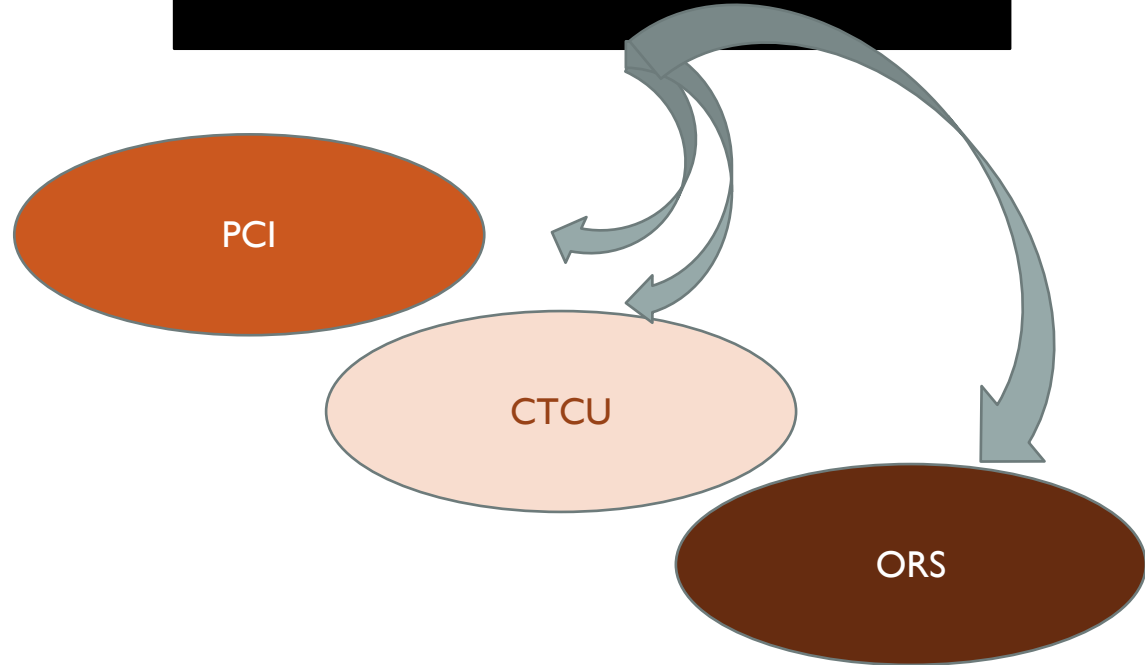
Non-Monetary

Penn RIS

PCI

CTCU

ORS



CTA – SRA

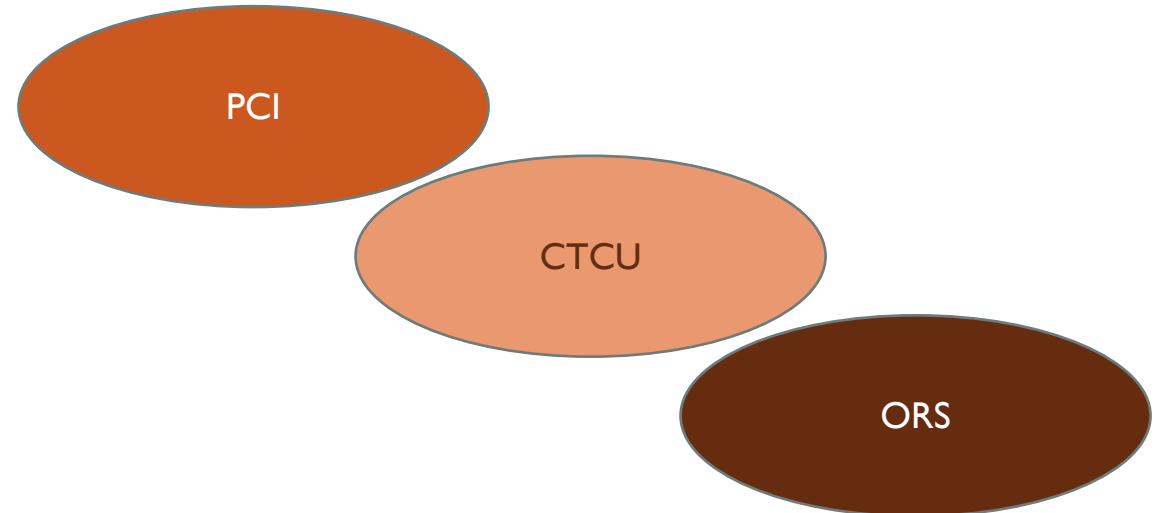
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IV.

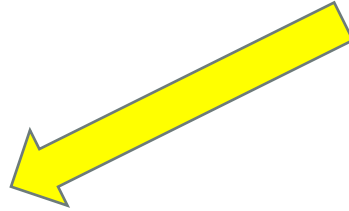
Services Agreements

Non-Monetary

Monetary

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Penn ERA



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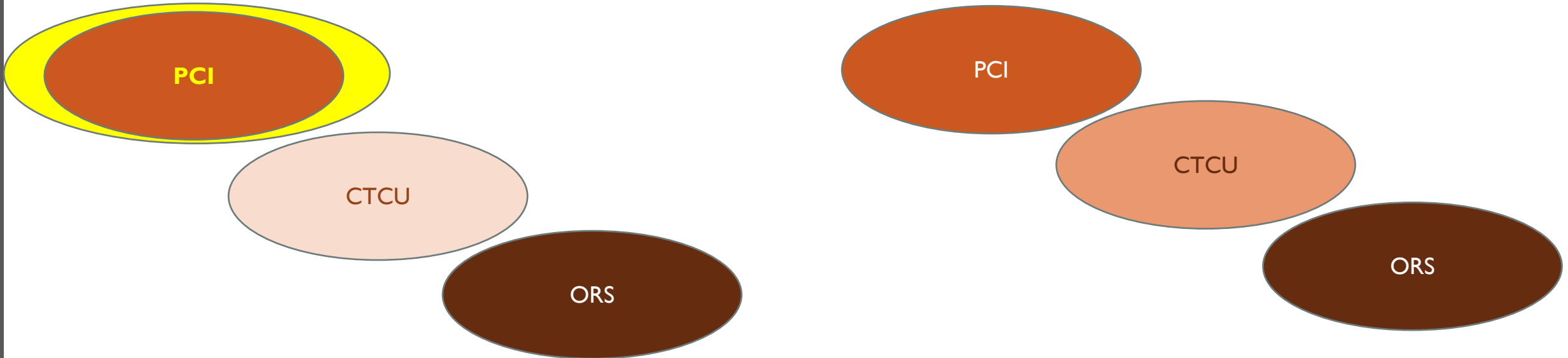
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V. CDA: Things to Consider

Before getting into any substantive discussion with a Company, enter into a **Confidentiality Disclosure Agreement (CDA)**

- What does a CDA do? Protect the confidential information (CI) disclosed between the parties
- CDA – Mutual (both parties disclose) vs. One-way (only 1 party discloses)
- Obligations: No use or disclosure of CI to 3rd parties during CDA term plus 1-5 years thereafter
- Risk – track what CI is shared or received to avoid claims that confidential information is Company's vs. Institution
- BEST PRACTICE: Consult PCI to see if any information shared can be protected in a patent filing before sharing information

VI. MTA: Things to Consider

Bench Research - requesting the Company's compound or sending the Company samples for them to analyze

- **Data Ownership and Use**
- **Intellectual Property**
 - Ownership
 - Inventorship
 - Option to obtain a license
- **Publication**
 - Pre-review for removal of sponsor confidential information
 - Additional 30/60 days delay for IP filing
 - Penn has editorial Control

VII. RA: Things to Consider

Research to test a hypothesis that is of interest to both the Researcher and the Company

- **Publication**
 - Delay for protection of Company Confidential Information and/or IP filing
 - Editorial Control hold by Penn
- **Data Ownership and Use**
 - Ownership and Control of Data
- **Intellectual Property**
 - Ownership
 - Inventorship
 - Retention of Rights
 - Company access to the IP generated

VIII. DUA: Things to Consider

Company wants to access or use data set

- **Data Ownership and Use**
- **Informed Consent**
 - Does the ICF permit the described use
 - Any restrictions in the ICF
- **Publication**
 - Does Company provide any of its data analysis to Institution?

IX. Service Agreement: Things to Consider

Company requests Researcher to perform a service

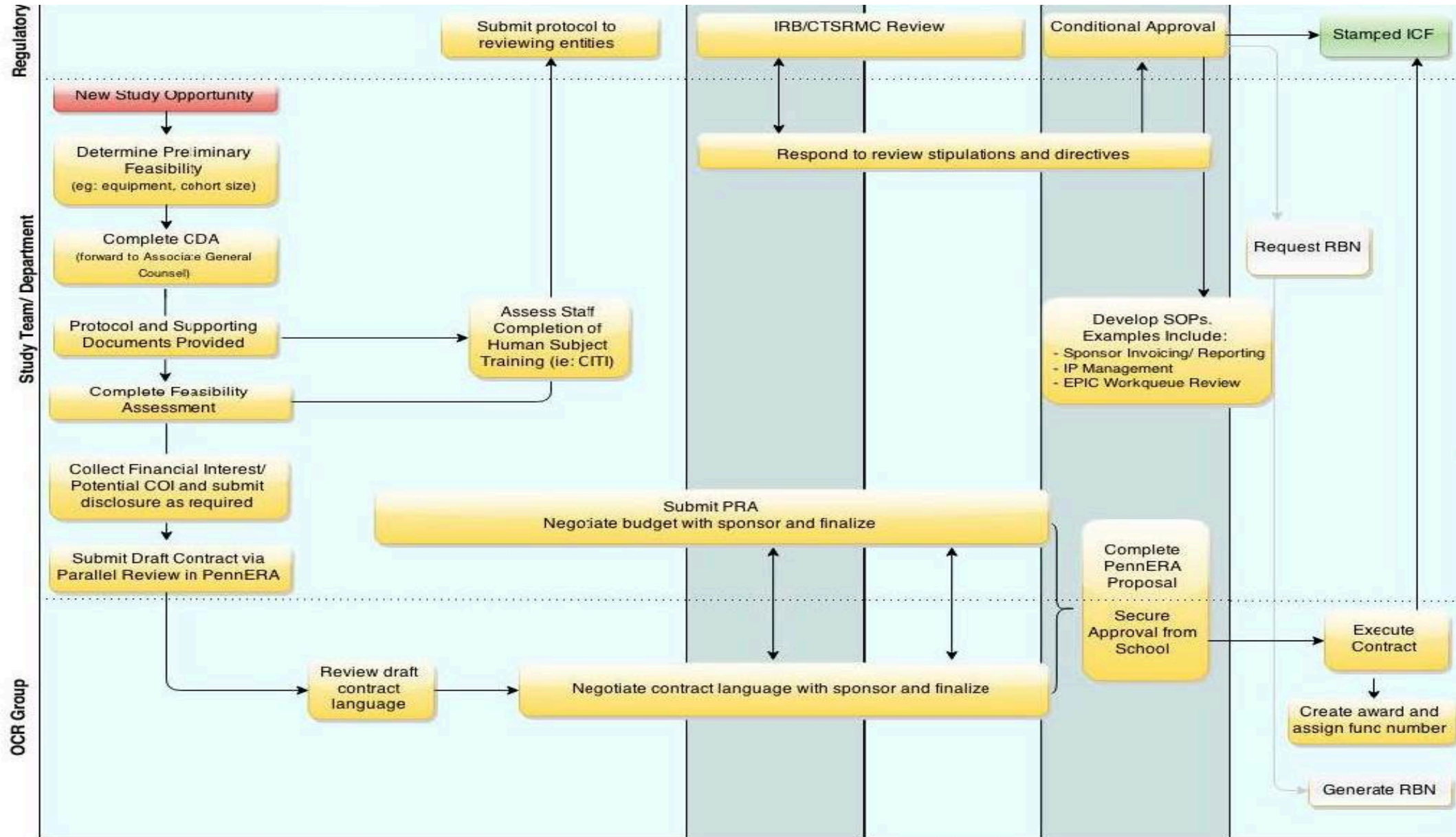
- **Rare**
- **Institution:**
 - No rights to use the data for further research or grant application
 - No Publication rights
- **Company:**
 - Owns the data & controls the data
 - Owns the Intellectual Property generated if any

V. CTA: Things to Consider

Research on Study Drug or Device to determine its safety and efficacy

- **Publication**
 - Delay for protection of Sponsor Confidential Information and/or IP filing
 - Editorial Control
- **Data Ownership and Use**
 - Ownership and Control of Data
- **Intellectual Property Related to Study Drug or Study Device**
 - Difference if Researcher (Investigator Initiated (II)) or Company (Sponsor Initiated (SI)) Protocol
 - Limit scope to Study, requirement to include Study Drug/Device
 - Ownership
 - Inventorship
 - Retention of Rights
- **Regulatory**
 - Between Researcher and Industry, who submits IND or IDE?
 - Who submits on clinicaltrial.gov website?

V. Parallel Review Process for CTA



VI. Scenario #1

Researcher presents a talk on his/her current research at an academic conference. A Company Representative reaches out to the Researcher and wants to know his/her thoughts on likelihood of research outcomes.

VI. Scenario #1 Researcher Response

- Direct the Company Representative to any peer-reviewed publications on the topic and not provide any prospective statements on research outcomes
- Do not publicly state inferences about research that you would not state in a peer-reviewed journal
- If there are further discussions, request separate meeting and a mutual CDA
- NOTE: Before presentation or publication or discussions with third parties please consult PCI to see if IP protection can/should be obtained

VI. Scenario #2

Company is funding a clinical trial or sponsored research at the Institution and wants Researcher to publish only data that it approves of in advance.

VI. Scenario #2 Researcher Response

- Freedom to publish is a core academic value at Penn
- Timely publication and dissemination of research results, whether perceived to be positive, negative, neutral, or unclear for the Company, are important principles behind the academic freedom afforded to Penn's and your reputation
- Further, Penn's mission as a non-profit, academic research is premised on the independent and unbiased conduct of research and assessment of data
- While Researcher can provide Company advance drafts of presentation or publication to remove Company's CI and/or obtain patent protection of any inventions contained therein, deletions are not allowable if it causes the presentation or publication to be incomplete, inaccurate, or misleading
- Delays in publication should not be extensive (e.g., less than 30-60 days) nor block eventual publication
- Company should NEVER have editorial control over Researcher's publication

VI. Scenario #3

Company wants to own all data and results associated with bio-samples that were obtained in a clinical trial (CTA) or sponsored research agreement (SRA) without accounting to Penn.

VI. Scenario #3 Researcher Response

- Address on a case-by-case basis (e.g., Penn as sole site for II trial vs. Penn as one of 20 sites in an international trial sponsored by a for-profit)
- Penn needs to retain at least a right to use data and results for non-commercial research, educational purposes, health care operations, clinical care, and/or regulatory purposes
- Researchers need to retain rights to use data and results to advance their careers, either at Penn or elsewhere, including in later research funded by the government
- Is the CTA or SRA II?
 - Does Penn hold the IND/IDE?
 - If Penn holds IND or IDE, Penn needs to own and be able to use the data for regulatory purposes
- What does the ICF say for the patient data that is the subject of the agreement? Are there any restrictions imposed on the data use or its transfer to third parties, whether for-profit or not-for-profit?
- Is Company's use aligned with Penn's core mission of advancing the body of knowledge?

VI. Scenario #3 Researcher Response (cont'd)

- **NOTE: There are also circumstances in which the Company wants to own the bio-samples themselves, which is problematic for many reasons, the most obvious being that Penn and Investigators should not be in a position to secure rights to patient samples and deliver those rights to a Company (also, the IRB perhaps would not be likely to approve an ICF providing sponsors an ownership interest in the bio-samples themselves)**
 - However, under an MTA, CTA, or other contractual instrument, Penn may be able to provide Sponsors with the right to use bio-samples, provided the ICF allowed for this use

VI. Scenario #4

Company is a start-up and in order to increase interest by its prospective shareholders/financiers wants to publish quotes by the Researcher on study data before its publication.

VI. Scenario #4 Researcher Response

- Standard agreement terms requires that Company obtains written permission of Penn in advance of publication
- Company should TIMELY (e.g., within 3-5 business days before publication) contact Penn Medicine Communications to ensure that any quotes/references to Penn or its Researchers are acceptable
- Consider any perceptions of conflict of interest
- NOTE: Quotes and statements should not express or infer positive, negative, or neutral research results unless or until all of the data has been collected and analyzed by the Penn researcher(s) and publication/presentation has occurred

Conclusion

THANK YOU.....



DO YOU HAVE ANY QUESTIONS ?