



SPEAKERS



Christopher Martin
JD
Contract Negotiator
Rutgers, The State University
Research Contract Services



Diana Boeglin
MS, MBA, CRA
Grants and Contracts Manager
The University of Chicago
Office of Research and National Laboratories



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Background of Data Use Agreement

“DUA” has multiple meanings:

- Technical definition
 - Healthcare purposes
 - HIPAA (45 CFR § 164.514)
 - BAA often required
- Generic definition
 - Research purposes – today’s focus
 - Human data most common
 - Many different regulations
 - BAA not appropriate



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Recent Proliferation of DUAs
FDP DTUA – emulates the UBMTA



Data vs. Materials



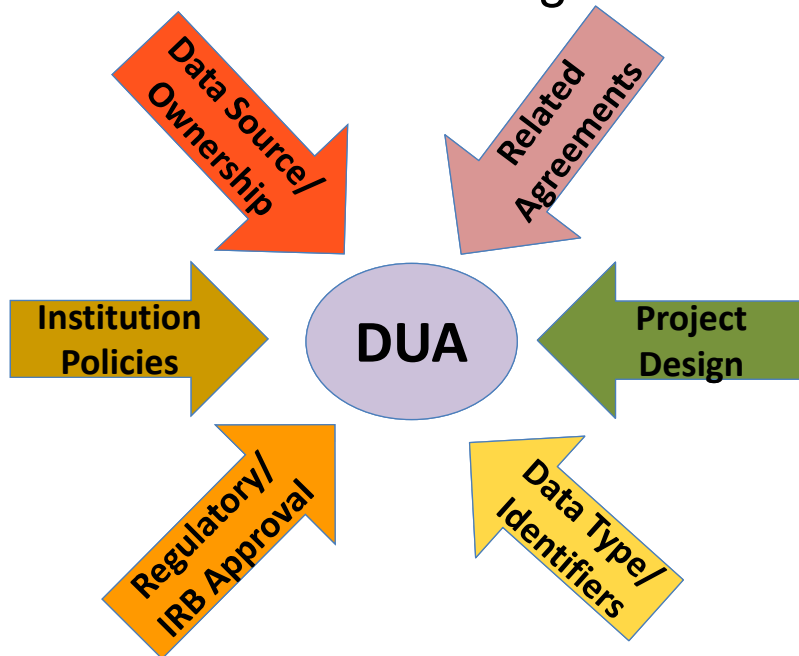
- Infinite potential use
- Highly portable
- Data sharing plans often complex
- Human identifiers often integral to dataset



- Often consumed or degraded
- Special considerations for transfer
- Typically one-way sharing
- Identifiers not typically necessary for transfer



Considerations when Drafting a DUA



Identification and Vetting Data Requests



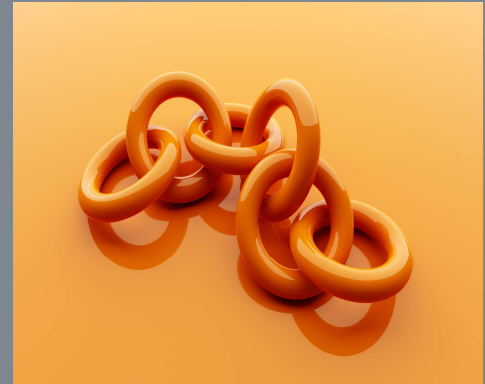
- Who - Who is the custodian of the data? Do they support transfer?
- What - What Data and Data elements are being provided?
- Where - Where were the Data collected/created and where is it going?
- When - When were the data generated and when will it be transferred?
- Why - Why are we providing the data? For what purposes?
- How - How were the data obtained? How will it be transferred?



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Clean Chain of Title

- Informed Consents (IRB and Ethics Review)
- Data obtained from Third Party(ies)?
- Data collected under a Funded Research Project?
- Obtained under Clickwrap/Clickthrough Agreement?
- Publicly Available (double check the source)?



Pertinent Provisions in DUAs

- Permitted Use of the Data
- Data Security Standards/ Applicable Laws
- Sharing Data with Third Parties?
- Re-Identification, Merging or Linking the Data
- Representation of Compliance with Ethics Standards
- Data Disposition at Termination/Expiration
- Breach Notification & Mitigation Response
- Disclaimer of Accuracy of Data
- Liability for Use and Storage of Data and Insurance Requirements



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Unpopular Provisions for DUAs



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Unusual:

- Transfer of Ownership
- Intellectual Property
- References to Specific Technology Standards

Do Not Use:

- Not a Replacement for Collaboration Agreement
- Concerns with Reciprocal Data Transfer



Factors Impacting Data Value

DATA



SORTED



ARRANGED



PRESENTED VISUALLY



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- Size of Data Set
- Rarity
- Freshness
- Increased Usability
- Clean Title/Use
- Compliance with Troublesome Legal Paradigm
- Accuracy



Resources

1. **FDP Data Stewardship Website:**
<http://thefdp.org/default/committees/research-compliance/data-stewardship/#:~:text=Data%20Stewardship%20Reviews%20existing%20and%20new%20administrative%20requirements,agencies%2C%20reduction%20of%20redundancies%20and%20identifying%20good%20practices.>
2. **CDC HIPAA Guidance:**
<https://www.cdc.gov/phlp/publications/topic/hipaa.html>
3. **NIH HIPAA Guidance:**
<https://www.hhs.gov/hipaa/for-professionals/special-topics/research/index.html>
4. **Common Rule Guidance:**
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>
5. **FERPA Guidance:**
<https://studentprivacy.ed.gov/privacy-and-data-sharing#:~:text=While%20the%20general%20rule%20under,or%20evaluate%20programs%2C%20enforce%20or>



Q&A

Thank you. Please submit any Questions via the Chat Window.

