WHERE THERE IS NO LAWYER: MEETING ON FAIR RESEARCH CONTRACTING

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Research Contracting in Academia and Big Pharma

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Research Contracting

Standard
- Payment for research
- Intellectual Property
- Confidentiality
- Termination, indemnification
- Research across borders
Research agreement in Academia: Johns Hopkins Model

Major Issues
- Statement of work
- Investigator
- Intellectual property rights
Model Clinical Trial Agreement: Johns Hopkins

Major Issues
- Proprietary information and confidentiality
- Publication
- Intellectual property
- Patient care costs
Findings

• US Standards
• Rules and standards vary greatly around the world
• Biomedical research is expanding globally
• Community engagement is important
Recommendations

- Respect for human subjects
- Ethics training
- Transparency and monitoring
- Compensation for research related injuries
- Harmonization of rules
Contract Research in Big Pharma I

Participants
- Internal organizations
- Academia
- CRO’s
Contract Research in Big Pharma II

CRO issues:
- Types, specialization
- Globalization
- Regulatory processes
- Protection of human subjects