

WHERE THERE IS NO LAWYER: MEETING ON FAIR RESEARCH CONTRACTING

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Research Contracting in Academia and Big Pharma

**Adel Mahmoud, M.D., Ph.D.
Princeton University**

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

Research Across Borders

Presidential Commission for the study of Bioethical Issues I

Findings

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

Research Across Borders

Presidential Commission for the study of Bioethical Issues II

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