

**Society of Research Administrators International  
Managing The Legal Regulatory Research Landscape**

# **M20: CONTRACT LAW 101**

Presented by

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# CONTRACT LAW: WHAT'S THAT?

- Many different areas of law
  - Family law and intergenerational law (wills, estates and trusts)
  - Public regulation and safety
  - Property
  - Employment
  - Duties to others (“Torts”)
  - Contracts and commercial activities
- Another taxonomy is civil v. criminal
- So what’s a contract?

# ***COMMERCIAL LAW INCLUDES CONTRACT LAW AND LAW RELATED TO PROMISES BETWEEN PERSONS OR ORGANIZATIONS***

- *Governs promises made and made to be kept*
  - Contracts governing any type of commercial transaction
  - Misrepresentations, fraud and Breach of Warranty
  - Consumer protection, antitrust law and other laws that limit any party's commercial freedom

# BACKGROUND

- U.S. law is multi-tiered:
  - Federal
  - State
  - County
  - City
- The federal government is constitutionally limited

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## BACKGROUND (2)

- Anything not granted to the feds belongs to the states
- Within its scope, federal law overrides (preempts) inconsistent state law
- In the event of dispute, the Supreme Court decides what powers are federal

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## BACKGROUND (3)

- Commercial law generally belongs to the states
- Interstate commerce belongs to the Feds
- Federal contracts belong to the Feds
- But sub-agreements may belong to both

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## BACKGROUND (4)

- America follows the “common law” model
- Statutes go so far in specifying the law, but the courts have to apply the law to the facts, often crafting new law
- “Common law” is judge-made law
- A judge sets a *precedent* - decision will be followed by other judges in the future
- Precedents are coercive; subsequent judges “have to” follow them, or explain why not

# WHAT IS A CONTRACT?

- A mutually binding legal relationship
- Obligating the “seller” (Contractor) to furnish supplies or services and
- Obligating the “buyer” to pay for them
- A promise or promises constituting agreement between the parties that gives each a legal duty to the other and also the right to seek remedy for breach (Council for Advancement and Support of Education [CASE])

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# WHAT IS A CONTRACT? (2)

Required elements:

- Offer
- Acceptance
- Consideration (and mutuality)
- Competent parties
- Lawful purpose

# LEGAL WEASEL WORDS AND CONCEPTS

- “Constructive” and implied terms
- “Time is of the essence” and other “magic words”
- Warranties
- “Christian Rule” and other ways to make contract clauses appear where they weren’t before
- “Battle of the forms”
- Material vs. non-material
- Some rules apply only to special classes of people or institutions (like *eleemosynary* institutions)

# BASIC UNDERPINNING

## Freedom of contract

- Allows the parties to make the agreements they choose to make
- Issues that may affect this are:
  - Access to information
  - Ability to bargain
  - Ability to understand the bargain
  - Public policy limitations
- An essential aspect of economic freedom is the freedom to make a bad deal

# OTHER IMPORTANT TERMS

- Offer
- Counter-offer
- Acceptance
- Consideration
- Battle of the forms
- Warranty
- Modification
- Oral contracts v. the “Statute of Frauds”
- Conduct (parties, the “trade, waiver, acquiescence, etc.)
- Remedies

# NOW BEFORE WE START: WHAT IS A GRANT?

- A grant may be donative in nature, bestowed voluntarily and without expectation of tangible results (CASE)
- A grant shares the attributes of both a gift and a contract

# COMMON CLAUSES

- Preamble and/or recitals
- Schedule
- Special provisions
- General provisions
- Statement of Work (SOW)
- Key personnel
- Period of performance
- Consideration/ financial arrangement
- Reports/deliverables
- Publishing copyrights
- Equipment
- Patents and licensing
- Records and audits
- Termination
- Assignments
- Execution

# CHOOSING THE TYPE OF AGREEMENT

- Research contract
  - Specific research objective to be accomplished by one party for other party's use
- Consulting agreement
  - Guidance or advice needed from one party for other party to proceed with in-house project
- Contract/subcontract
  - Supplies or services needed to support research effort

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# CHOOSING THE TYPE OF AGREEMENT (2)

- Partnership
  - Joint effort to conduct on-going research
- Limited partnership
  - Joint effort to conduct on-going research where passive investors involved
- Joint venture
  - Joint effort to undertake specific research project
- License agreement
  - Transfer of rights held by one party to be used by other party



# AREAS OF LAW AFFECTING RESEARCH CONTRACTS

- Basic contract law
- Agency
- Business organizations (corporate and partnership)
- Negligence-product liability and insurance law

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# AREAS OF LAW AFFECTING RESEARCH CONTRACTS (2)

- Intellectual property law
- Public contract law and administrative procedures
- Bankruptcy
- Anti-trust
- Civil procedure

# AGAIN – FOR ALL CONTRACTS

## Required Elements:

- Offer
- Acceptance
- Consideration
- Competent parties
- Lawful purpose

# **OTHER TYPES OF AGREEMENTS**

## **Contracts (or Not?)**

- Clinical trials
- MOU
- NDA/CDA
- Material transfer agreements
- Master agreements

# RESEARCH AGREEMENT TERMS: Scope Of Work

- Best efforts or completion?
- Phases included (single phase, multiple or options)
- Key personnel/required staff/support
- Who provides the outside services/supplies, etc.?
- Reporting, data and document management and treatment responsibilities

# RESEARCH AGREEMENT: Term

- Completion or period of time
- Extensions
- Delays
- Force majeure

# RESEARCH AGREEMENT: Payment

- Method(s) of payment (e.g., per hour at fixed rate, cost reimbursement, fixed sum for a specific deliverable)
- Time of payment(s)
- Amounts
- Exclusivity of payer (i.e., are multiple sponsors allowed?)

# RESEARCH AGREEMENT: Other Cost Issues

- Costs of unexpected or changed events
- Costs growth risk
- Other payments (e.g., other compensation from company if any injury occurs, license fees, “program income”)
- Follow-on costs (patent management, for instance)
- Prohibited costs and payments



# **RESEARCH AGREEMENT: Principal Investigator and Other Key Personnel**

- Can Sponsor approve the Principal Investigator (PI)?
- PI's commitment to conduct the Study
- If the PI becomes unable to complete the Study, must Sponsor consent to a new PI?
- Can Sponsor follow PI?
- Multiple PIs?
- Other key personnel

# RESEARCH AGREEMENT: Records

- Lab records/deliverable records/audit of records
- Records retention
  - Time for retention
    - Completion or termination of the Study
    - Marketing application approval
    - Discontinuation of the IND
- Maintenance of Study records for the period

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# RESEARCH AGREEMENT: Records (2)

- Transfer of Study records
- Ownership of documents
  - Health Insurance Portability and Accountability Act of 1996 (HIPAA) and state laws on patient records
  - Bayh-Dole
  - Prime/sub ownership issues

# RESEARCH AGREEMENT: Confidentiality

- Information which is disclosed by Sponsor to the Institution
- Information which is disclosed by Institution to Sponsor
- Third-party information
- Patient/subject information
- Obligations of Investigator, staff and students

# **RESEARCH AGREEMENT: Promotional Activities**

- Use of name of Sponsor/Institution
- Use of PI's name
- Trademarks
- Publicity
- Advertisement for patients
- Press releases
- Inquiries from media and financial analysts



# **RESEARCH AGREEMENT: Publications and Scientific Communications**

- Right to publish the results of the Study
- Other rights to discuss Study (e.g., conferences – where and when)
- Notification to Sponsor
  - Prior to submission

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## **RESEARCH AGREEMENT: Publications and Scientific Communications (2)**

- Notice if publication contains patent information
- Right to delay
- Nonscientific journals, newspapers, radio or television

# RESEARCH AGREEMENT: Intellectual Property Rights

- Inventions
  - Ownership
  - Licensing
  - Joint inventions
- Data
  - Copyright
  - Databases

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# **RESEARCH AGREEMENT: Intellectual Property Rights (2)**

- Administration of Intellectual Property
- Biological materials

# **RESEARCH AGREEMENT: Indemnification/Insurance and Liability to Third Persons**

- Who indemnifies and who is indemnified?
- From what?
- Expenses of claims and suits related to what injuries?
- Caused by – IN WHOLE OR IN PART?
- Indemnification without prior payment by Institution

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# RESEARCH AGREEMENT: Indemnification (2)

- What about damages from faulty Study design or from use of the results
- And what about:
  - Effects on “fourth parties and the community or environment for the results of the Study
  - Product liability

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# RESEARCH AGREEMENT: Indemnification (3)

- Exclusions from obligation to indemnify
  - Failure of the Institution to comply with any applicable governmental requirements or to adhere to the terms of the protocol?
  - Negligence of the Institution, officers, agent or employee, subcontractors?
- Some states will not allow indemnification of negligence or failure to comply with law

# RESEARCH AGREEMENT: Conditions to Indemnification

- Notice of any claim or lawsuit
  - Right to defend the lawsuit
    - Subject to Institution's right to retain the counsel of its choice?
- Right to settle the claim
- Right to require the indemnified party to cooperate fully in the investigation and with defense of any such claim or lawsuit

# **RESEARCH AGREEMENT: Additional Indemnification Issues**

- Costs of extra unanticipated tests, treatments, and repairs/cleanup, etc., required as a result of adverse events
- Costs covered by insurance or by governmental programs providing such coverage

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# **RESEARCH AGREEMENT: Additional Indemnification Issues (2)**

- Governmental programs and indemnification (e.g., worker's compensation, environmental injuries, public health costs)
- Insurance

# **RESEARCH AGREEMENT: Compliance with Laws**

- Debarment Certification (FDA certification)
- Conflict of interest
- Integrity in science
- Misconduct
- UBIT
- State laws
- Foreign countries



# RESEARCH AGREEMENT: Additional Topics

- Independent contractor status
  - What is the difference between an independent contractor relationship and a “Master-Servant” or Principal and Agent?
- Notices
  - To whom, where and for what?
- Modifications and amendments
  - Who has the right to require, when and what if required by Government or science?

# **RESEARCH AGREEMENT: Inspections and Access**

- May Sponsor inspect Institution's procedures, facilities and Study records?
  - May information obtained from such inspections be shared?
  - With whom and for what purposes?
- Access to patients, records, data, faculty, treatment facility, etc.

# **RESEARCH AGREEMENT: Study Materials/Devices**

- For what purpose(s) may material be furnished for Study be used? What about devices? Who gets the leftovers?
- When and how is material or device provided?
- Maintenance, storage and accounting for material, risk of loss
- Derivative compounds, by-products and waste disposal

# **RESEARCH AGREEMENT: Disputes**

- Method(s) of dispute resolution
- Costs and attorney's fees
- Jurisdiction and venue
- Right to jury
- Subcontractor disputes

# RESEARCH AGREEMENT: Termination

- Reasons for termination
- Payment on termination
- Responsibility for patients/subjects/graduate students on termination
- Responsibility for personnel upon termination; continuing obligations
- Close-out

# COMPLIANCE ISSUES IN CONTRACTS

- Ethics
  - Improper business practices and personal conflicts of interest
  - Contractor gratuities to Government personnel
  - Reports of suspected antitrust violations
  - Contingent fees
  - Kickbacks
  - Responsible prospective contractors (sub-agreements and personnel)

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# COMPLIANCE ISSUES IN CONTRACTS (2)

- Ethics
  - Debarment, suspension and ineligibility
  - Organizational and consultant conflicts of interest
  - Contracts with Government employees or organizations owned or controlled by them
  - Payment of funds to influence Federal transactions
  - Whistleblower protections
  - Contractor code of business ethics and conduct
  - Personal conflicts of interest

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# COMPLIANCE ISSUES IN CONTRACTS (3)

- Records and Information
  - Safeguarding classified/confidential/personal information
  - Contract reporting
  - Contractor records retention
  - Protection of privacy and Freedom of Information
  - Individual privacy/HIPAA/FERPA/etc.
  - Freedom of Information Act

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# COMPLIANCE ISSUES IN CONTRACTS (4)

- Extra-contractual
  - Taxes and exemptions
  - Representations and certifications
  - Executive compensation
  - American Recovery and Reinvestment Act—reporting requirements
  - Policies to ban text messaging while driving

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# COMPLIANCE ISSUES IN CONTRACTS (5)

- Extra-contractual
  - Bonds and insurance
  - State and local taxes
  - Animals
  - Human subjects
  - Select agents
  - CLIA
  - Responsible Conduct of Research

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# COMPLIANCE ISSUES IN CONTRACTS (6)

- Sources
  - Competition at the sub-agreement level
  - Lease or purchase
  - Required sources of supplies and services
  - Responsible prospective contractors (sub-agreements and personnel)
  - Debarment, suspension and ineligibility
  - Organizational and consultant conflicts of interest
  - Contractor team arrangements
  - Priorities and allocations

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# COMPLIANCE ISSUES IN CONTRACTS (7)

- Contract pricing
  - Truth in negotiation
  - Cost principles
  - Allowable costs
  - Accounting and accounting standards
  - Records and reporting costs
  - Reimbursement, penalties and self-policing
  - Funding and appropriations

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# COMPLIANCE ISSUES IN CONTRACTS (8)

- Preference programs
  - Small business programs
  - Historically Underutilized Business Zone (HUBZone) program
  - Service-Disabled Veteran-Owned Small Business Procurement program
  - Women-Owned Small Business (WOSB) program

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# COMPLIANCE ISSUES IN CONTRACTS (9)

- Labor laws
  - Convict labor
  - Contract Work Hours and Safety Standards Act
  - Labor standards for contracts involving construction
  - Walsh-Healey Public Contracts Act
  - Equal Employment Opportunity
  - Nondiscrimination because of age
  - Service Contract Act of 1965, as amended

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# COMPLIANCE ISSUES IN CONTRACTS (10)

- Labor laws
  - Professional employee compensation/effort reporting
  - Veterans
  - Workers with disabilities
  - Prohibition of acquisition of products produced by forced or indentured child labor
  - Employee rights under the National Labor Relations Act
  - Combating Trafficking in persons
  - Employment eligibility verification
  - Drug-free workplace

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# COMPLIANCE ISSUES IN CONTRACTS (11)

- Environment, energy and environment
  - Energy efficiency, renewable energy technologies
  - Occupational safety, and drug-free workplace
  - Hazardous material identification and material safety data/chemical database
  - Recovered materials and bio-based products
  - Radioactive material
  - Environmentally preferable products and services
  - Ozone-depleting substances
  - Compliance with right-to-know laws and pollution prevention requirements

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# COMPLIANCE ISSUES IN CONTRACTS (12)

- Foreign acquisition
  - Export control
  - Visas and immigration
  - Buy American Act
  - Contracts performed outside the United States (FCPA, Export Control, etc.)
  - Trade agreements
  - Prohibited sources – OFAC
  - Customs and duties

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# COMPLIANCE ISSUES IN CONTRACTS (13)

- Patents, data and copyrights
- Authorization and consent
- Bayh-Dole
- Reporting and commercialization
- “Sensitive but unclassified” data

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# COMPLIANCE ISSUES IN CONTRACTS (14)

- Administration of the contract
  - Assignment of claims/novations
  - Protests
  - Disputes and appeals
  - Audit
  - Indirect costs
  - Modifications
  - Subcontracting policies and procedures
  - Government property
  - Contractor liability for loss of or damage to property of the government