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Key Elements of Research Agreement (State of Oregon)

#### **Key Elements of a Research Agreement**

(Adapted from Oregon Department of Justice)

- 1. The Research Agreement is substantially composed of the following legal provisions:
  - a. **Prime Grant Agreement** (if your institution is the pass-through entity). The operative provisions of the Prime Funding Sources must be appropriately incorporated into the Research Agreement. If the University is issuing the Research Agreement, the Research Agreement shall require the recipient to comply with the terms and conditions of the Prime Funding Sources as if the recipient were the University.
  - b. **Work and Statement of Work**. The statement of work shall be sufficiently clear and definite to be enforceable.
  - c. **Term**. The Research Agreement shall have a definite term.
  - d. **Termination.** At a minimum, the Research Agreement shall provide for termination in case of breach. Expenses incurred prior to termination should be reimbursable.
  - e. **Consideration and Allowable Costs**. Consideration shall be payable on a cost reimbursement basis. A maximum not-to-exceed cost and budget schedule shall be set forth in the Research Agreement. Those costs should be allowable and reimbursable by the University only if they comply with the budget schedule, terms and conditions of the Prime Funding Sources, applicable OMB Circulars, and applicable federal regulations.
  - f. **Principal Investigator**. The Research Agreement should establish a principal investigator to conduct the research on behalf of the recipient. The Research Agreement should allow for substitution of the Principal Investigator only by written agreement. *When the University is issuing the Research Agreement* the Research Agreement should permit principal investigator for the University to have control over the research occurring at the University.
  - g. **Reporting Requirements**. The Research Agreement shall comply with federal regulations regarding reporting.
  - h. **Publications**. The Research Agreement shall not place restrictions on publication that interfere with principles of academic freedom. Other than a minimal period of delaying publication (customarily 30-90 days) for purposes of determining patentability, there shall be no restrictions on the dissemination of data, information, findings, and conclusions.

- i. **Ownership**. Ownership provisions in the Research Agreement shall comply with: (1) applicable federal regulations; (2) applicable OMB Circulars; (3) Bayh-Dole Act; and (4) Prime Funding Sources. With respect to particular intellectual property rights:
  - i. Patent. Patent rights shall be allocated in accordance with 37 C.F.R. 401 or granting agency's comparable federal regulations (the applicable law determined from the Prime Grant). University Representative shall consult with the Designated AAG when the Research Agreement provides granting party with any greater interest than a nonexclusive right to make or use (or both) the patented processes and products for academic research purposes.
  - ii. <u>Copyright</u>. Copyrights shall be allocated in accordance with granting agency's applicable federal regulations. The recipient should own the copyright in any work developed under the Research Agreement. The grantor should not receive any greater interest than a royalty-free, nonexclusive, irrevocable right to reproduce, publish or otherwise use the work for academic or research purposes.
  - iii. Research Data. For those Research Agreements that distinguish ownership rights as between intellectual property and research data, Research Agreement shall be consistent with applicable federal regulations regarding Rights in Data.
- j. **Confidentiality**. Confidentiality provisions shall be consistent with the University's obligation to disclose records under your organization's Public Records laws. The University Representative should not approve a Research Agreement that unconditionally requires the University to keep information confidential, unless the University Representative receives authorizing legal advice from their General Counsel.
- k. **Certifications and Assurances**. The Research Agreement shall contain any certifications and assurances required by the Prime Funding Source.
- Records Access and Audits. Research Agreement record keeping and audit requirements shall not be inconsistent with any applicable federal regulations and OMB Circulars.



Sample Agreement Review Checklist (Creighton University)

### **Creighton University Sponsored Programs Administration**

2500 California Plaza, Omaha, NE 68178 • Phone: 402-280-2064 Fax: 402-280-4766 • www.creighton.edu/researchcompliance/Grants

#### Checklist for Faculty/Staff/Administration

# Checklist of Required Elements in an Externally Sponsored Contract/Agreement

NOTE: This Checklist is for informational purposes only and is not an all-inclusive list of legal issues that may arise in a sponsored contract/agreement. The Checklist is not a substitute for review by Legal Counsel. You may use this Checklist to address certain recurring issues within a contract/agreement prior to legal review, which may decrease time to signature.

<b>Contracting Party</b> —List Creighton University or Creighton University through its Department of as the contracting party and provide the legal address of Creighton University as follows: 2500 California Plaza, Omaha, Nebraska 68178.
<b>Governing Law</b> —If the contract includes a section on governing law or choice of law, the governing law listed should be that of the State of Nebraska or the entire section should be eliminated and both parties agree to remain silent on this point.
<b>Information Regarding Payment</b> —Include a statement that all checks should be made payable to Creighton University and include the name and mailing address of the person to whom the checks should be sent (e.g., Principal Investigator, study coordinator, department administrator).
<b>Notices Regarding Administrative Issues</b> —Include a statement that any notices regarding administrative issues (e.g., changes to the agreement, termination of the agreement) must be sent to Sponsored Programs Administration in addition to being sent to the Principal Investigator.
<b>Entity Identification Number</b> —Include Creighton's Entity Identification Number: 47-0376583. (Do not use the Principal Investigator's social security number.)
<ul> <li>Indemnification Clause—An indemnification clause should be included in all contracts. For clinical trial agreements, the indemnification clause should state that the sponsor assumes all financial responsibility for research-related injuries, with the following exceptions:</li> <li>Does not apply when injury is caused by negligence of the faculty member or University</li> </ul>

- Does not apply when the University fails to adhere to the protocol
- Does not apply when the University fails to comply with FDA regulations or other governmental requirements
- If agreement is with a Contract Research Organization (CRO), Creighton must receive a letter of indemnification directly from the sponsor unless the CRO has

legal authority to bind the sponsor. **Confidential Information**—Ensure that any clauses that prohibit the University from releasing or disclosing information include exemptions for information that is: • Known to the University and Principal Investigator prior to receiving the information from the sponsor • Generally known to the public or becomes known to the public through no act or omission of the University or the Principal Investigator • Disclosed to the University or the Principal Investigator by a third party who represents that they have the legal right to disclose it • Independently developed by University without reliance on sponsor confidential information • Required to be disclosed by law or court order • Beware of the definition of Confidential Information and how it affects publication and future use of study data. **Publication/Inventions**— Generally, publication rights should be granted to the University and the investigator; any restrictions should be carefully negotiated. Avoid overbroad definitions of inventions that belong to sponsor. Use standard intellectual property language from Intellectual Resources Management when possible. • If the contract or agreement includes a clause restricting publication for a certain period, negotiate to limit that restriction to no longer than 90 days • Sponsor may want to comment on the content of the publication • Make arrangement for the protection of intellectual property and ensure that confidential information is not improperly disseminating in such publications • It is acceptable to await multi-center publication but have clause that permits publication if multi-center publication is delayed. • If sponsored by the National Institutes of Health (NIH), the University must adhere to the NIH Public Access Policy. Reimbursement/Coverage for Subjects who Suffer Research-Related Injuries— Generally negotiated. If no mention of this in the contract or letter of indemnification from sponsor and it is a study to which this would apply – ask for it to be added. • Look at to whom payment is made (pay versus reimburse) • Watch how broad the coverage is (Physical injury versus all injuries or personal injuries) • Beware of Medicare secondary payor issue Right to Terminate Agreement—In the statement identifying conditions under which the agreement may be terminated, include a statement that the University has the right to terminate the agreement in cases where the safety of subjects is of concern to the Principal Investigator or the University.

<b>Sponsor Notifications to University</b> —Consistent with accreditation standards, negotiate where possible to include the following provisions:
•In a study for which the sponsor conducts research site monitoring visits or conducts monitoring activities remotely, the sponsor must promptly report to the University any findings that could affect the safety of participants or influence the conduct of the study;
•In a study for which the sponsor has the responsibility to conduct data and safety monitoring, the sponsor must send data and safety monitoring reports to the University (the provision must specify the time frame for providing routine and urgent data and safety monitoring reports); and
•The sponsor must notify the University of any findings of a closed research study when those findings directly affect participant safety (the provision must specify the time frame after closure of the study during which the sponsor will communicate such findings).
<b>Signatures</b> —Include the signature of the Principal Investigator and include a space for the signature of the Associate Vice President for Research and Compliance. (Sponsored Programs Administration will obtain this signature.)



Sample Agreement Review Checklist (Florida Atlantic University)

## AGREEMENT REVIEW CHECKLIST

Sponsor	
- F	
Essential Contract Clauses:	
BOT Identified	Tech/Admin Points of Contact Identified
PI Identified	Termination-for cause or without cause (includes payment for non-
Exhibits and Attachments included(SOW & Budget)	cancelable commitments)
Purpose of Agreement Stated	Governing Law is FL
(Research, education or comm. serv)	
Start & End Dates	Amendments (in writing)
Payment Terms net 40	No Indemnification by FAU
Scope of Work has been reviewed	PI has Reviewed and Signed
Note any missing clauses, unacceptable, or unusua	l language:
• •	n patents for inventions created by FAU employees
Patents and Inventions (FAU should own	n patents for inventions created by FAU employees ould be free to publish; no more than 90 days for
Patents and Inventions (FAU should own	
Publications (PI & Graduate Students sh	hould be free to publish; no more than 90 days for
Patents and Inventions (FAU should own Publications (PI & Graduate Students sh sponsor review of patentable material) Copyrights (FAU should own copyright	hould be free to publish; no more than 90 days for



Sample Agreement Review Checklist (Indiana University-Purdue University Fort Wayne)

# CONTRACT REVIEW CHECKLIST

Oth	er Party:		
Con	tract Type:		• •
N/A	Tech Assist Agreement PAI	ffiliation	fisc.
	☐ 1. THE PARTIES TO THE	E CONTRACT ARE CLEARL	Y DEFINED AND CORRECT
	2. ENSURE THERE ARE	NO CONFLICTS OF INTER	EST
	☐ 3. THE DATES AND/OR	TERM OF THE CONTRACT	IS CLEARLY INDICATED
		F OUR RESPONSIBILITIES A RE COMPLETE, CORRECT,	
	5. ORDER OF PRECEDE	NCE IS APPROPRIATE	
	6 CONTRACT DOES NO	OT STIPULATE CONFIDENT	TALITY OF TERMS
	7. AMENDMENTS OR C	HANGES INITIALED/SIGNE	D BY BOTH PARTIES
		NT AND PAYMENT SCHED	ULE ARE CLEARLY DEFINED
	Amount \$ Mailing addre	sses?	
	9. INDEMNIFICATION O	F UNIVERSITY	
	☐ 10. INSURANCE COVERA	AGE / CERTIFICATE OF INS	URANCE
	□ 11. GOVERNING LAW / V	ENUE AND JURISDICTION	State Of Indiana
	☐ 12. USE OF UNIVERSITY	NAME	
	☐ 13. COORDINATION REQ	UIRED WITH OTHER DEPT	'S OF THE UNIVERSITY
	☐ 14. PERSONAL SERVICES	S PAYEE CERTIFICATION	FORM 21
	$\square$ 15. If CO-SPONSORSHIP,		
(	COMMENTS / DESCRIPTION:		
Revie	ewer:	Date:	
For		(School/Dept/Unit)	(Rev. 11/05)



# Sample Agreement Review Checklist (NCURA)

#### **CONTRACT REVIEW REFERENCE TOOL**

<u>Disclaimer</u>: This is not an exhaustive list -- just the most common issues. All contracts should be carefully reviewed to identify any additional language that may be problematic and to ensure that terms comply with your institution's policies.

NEGO	TIATION TOOLS TO CONSIDER:
	Your internal processing timeframes and sponsor-imposed deadlines Various methods to request changes/negotiate and advantages to each Limit redlines, if possible Make assessment on amount of detail/justification to provide with requested changes If language is not applicable – make assessment on remaining silent vs. request to strike Be prepared for "Plan B" with problematic clauses Keep your PI/Dept. informed of status so they allow you to do "your" job Approach negotiations as "Mediator" to facilitate consideration of perspective of each Party's interests University Perspective: use UC Principles as tool in negotiation 1. Open Dissemination of Research Results and Information 2. Commitment to Students 3. Accessibility for Research Purposes 4. Public Benefit 5. Informed Participation 6. Legal Integrity and Consistency 7. Fair Consideration for University Research Results 8. Objective Decision-Making
CONTI	RACT REVIEW CHECKLIST REFERENCE:
Party N	ames:
	Identify Parties of Agreement by their legal name Name, address, type of organization and home state of other party identified
Perforn	nance of Statement of Work:
adminis	On "reasonable efforts" not "best efforts" basis Scope of Work clearly written, matches proposal, if differs obtain confirmation that PI and tration/dept. administrators are agreeable
Deliver	ables:
	Clear due dates for deliverables Not tied to payments Not subject to "satisfaction" or "acceptance" by sponsor If physical samples (not just reports) are deliverables, include "Physical Deliverables" clause PI/Dept. consent to unusually frequent or burdensome reporting PI/Dept. consent to unusual reporting mediums (meetings, telephone, etc.)
Perforn	nance/Budget Period:
	Performance/budget period clearly defined so we know when money can be spent If performance/budget period does not begin on date of contract, the term of the contract is separately defined PI consents to any difference between contract's performance/budget period and proposal performance/budget period

#### **CONTRACT REVIEW REFERENCE TOOL**

Term o	f Agreement:
	The term of the legal contract is clear, particularly the effective date If term is different from performance/budget period, are the two clearly distinguished?
Cost to	Sponsor:
	If contract, clearly identified as "cost reimbursement" or "fixed price" Are any cost standards present (such as UC policy or 2 CFR 200, FAR)? If so, clearly identified and reasonable?
Paymer	nt Terms:
	Advance payments secured? Unusual invoicing requirements cleared with Extramural Accounting and Department? No payments tied to deliverables or research progress/results? Payments terms for invoicing and any requirement for back up is clearly identified?
Princip	al Investigator(s):
	Principal Investigator(s) clearly identified Principal Investigator(s) same as on the proposal
Supplie	es and Equipment:
	Addresses who has title to equipment and supplies? (Mitigate risks, if silent may be OK) If sponsor or government has title, only applies to equipment purchased with contract funds? (supplies are exhausted third party title inappropriate) If sponsor or government has title, obtain PI agreement/consent?
Patents	and Inventions:
	Inventions means:  Any patentable discovery conceived and reduced to practice in the performance of the agreement.  University owns title to all inventions developed by it, joint ownership of all jointly developed?  Ensure definition of "patentable invention" is included and is limited in scope to Agreement  "first conceived and reduced to practice in the performance of the Agreement"  Option to remain silent on what determines ownership, or insert U.S. Patent law applied to do so No "outright grant of license"  Sponsor has only "option to negotiate", Can offer:  Time limited option to negotiate non-commercial license
	<ul> <li>NERF</li> <li>Work with tech. transfer office if a commercial license is requested</li> <li>Option to negotiate qualified with "to the extent legally permissible"?</li> <li>Sponsor agrees to hold University disclosures of inventions "confidential"?</li> <li>Qualifies right to exclusive license to the extent sponsor pays full cost of research?</li> <li>Election Period begin/end clear, no longer than 30 days?</li> <li>Negotiation Period begin/end clear, no longer than 90 days?</li> <li>States University may dispose of invention at its discretion if no election during Election</li> <li>Period or license agreed during Negotiation Period?</li> <li>Sponsor agrees to pay necessary patent costs during Election and Negotiation Period?</li> <li>UC controls filing and prosecution of patent?</li> <li>If internal-use license granted, clearly limited to "non-commercial, internal research purposes only"</li> <li>"No implied license" clause present?</li> </ul>

#### CONTRACT REVIEW REFERENCE TOOL No financial terms for patent license or option appears in clause except that the license will be "royalty bearing"? Any non-standard terms, work with your Tech Transfer/Licensing office Copyright: (University Policy used as reference point) Copyright means: any copyrightable works first created in the performance of the agreement Title to all copyrightable works developed in performance of the agreement belongs to University? If rights to Sponsor, only an option to negotiate a separate license agreement? If internal use license granted, only "non-exclusive license for non-commercial, internal use only"? Royalty Sharing: (University Policy used as reference point) Standard practice not to share with sponsors If requested, University allows for royalty sharing with non-profits **Rights in Data:** Understand your entities standard rights/policy i.e. University must retain ownership of data, analysis and results to allow for unrestricted right to use/publish research results and data • Exceptions may be set forth in Confidentiality and Publication sections; is approval to Policy exception needed? ownership retained by University but sponsor can own "deliverable" Review for any statement of "ownership," (i.e. University must own all research results and data unless an exception to Policy is granted)? Consideration of joint ownership Confidentiality: (University Policy used as reference point) Only applies to pre-existing proprietary information provided by Sponsor (i.e., no University info included)? Requires sponsor to mark confidential info and reduced orally transmitted info to writing marked confidential? Should be clearly identified, reduced to writing, and marked Obligation limited to no more than 5 years? Clause contains the four basic exceptions to confidentiality? University allowed to disclose information "when required by law" (i.e., court order) Sponsor only provides Confidential Information to PI, and on "need to know" basis? University only required to use "reasonable efforts" or (as a second choice) "same standard of care it uses for its own similar Confidential Information"? Publication: (University Policy used as reference point) Cannot accept any restriction on publication Total length of delay (including review) no longer than 90 days? Sponsor only allowed to review for patentable inventions and/or presence of confidential information? We are only required to (a) remove confidential information; (b) delay to allow filing patent protection for any described inventions? Sponsor must notify us in writing during review period if it wants a delay or removal of Controlled Other language in award that may affect Publication: IP, Confidentiality, ownership of data **Governing Law:**

Insert preference to which state law or remain silent

#### **CONTRACT REVIEW REFERENCE TOOL**

	Review "jurisdiction" and risk associated to it
Notice:	
	Allows notice only by overnight courier or US Mail? (no email, fax, etc.) Provides authorized POC for notices to be made
Termin	nation:
	Both Sponsor and University have right to terminate agreement?  Termination for convenience? (no termination for default)  Minimum 60 day period between notice of termination and termination date?  University to receive payment of all direct and indirect costs, non-cancellable obligations up to termination date (not date notice of termination is received)?  University to receive fair close out costs?
Use of 1	Name/Publicity: (University Policy used as reference point for tools)
	Sponsor may not use University name w/o prior approval State Sponsor may not use University name to endorse any product/service University may use Sponsor name in routine reports
Indem	nification/Liability:
	Indemnification language may be noted under or as part of general Liability language Limit University's liability "in proportion to and to extent that" <i>our acts</i> (and those of our employees) caused liability Indemnification clause closely matches standard template language? (If not, seek approval by appropriate authorized official – may require exception to policy) Cannot assume 3 <sup>rd</sup> party liability so limit liability to "University employees, officers and agents"
Miscell	aneous Terms:
	The following terms are present, in similar format to standard research agreement:
Signatu	ure Block:
	PI is not signing, except under separate statement that s/he "read and understood" terms?
Exhibit	ts:
	All exhibits referred to in contract are attached and have been reviewed?  Budget/Payment: Detailed budget is not attached, unless sponsor specifically requested?  (either only payment schedule, or general suballocations)



# Indemnification Clauses

#### **Indemnification Clause Guidance**

Indemnification clauses require one party to pay for losses incurred by the other party. In the research contract setting these losses occur when a third party, not the parties to the agreement, claims that they should be compensated for a loss. If the third party suffers a loss due to the actions of one or both of the contracting parties, the indemnification provision determines which of the contracting parties will pay.

Compare this to Limitation of Liability clauses which determine how much one party is responsible to pay the other party. In Limitation of Liability clauses we can limit damages to a certain dollar amount because both contracting parties are free to agree to terms that only affect those two parties. In indemnification clauses the contracting parties cannot place a limit to what a third party may claim; they can only shift the burden between the two contracting parties. Due to the unknown nature of what this burden may be, indemnification provisions can prove to be very costly and can greatly exceed the value of the contract. This unknown and potentially unlimited risk is why indemnification clauses are routinely the clause that holds up a contract negotiation.

#### **Personal Injury**

Indemnification Example: University and Startup LLC sign a testing agreement to test the strength of a wheelchair. Customer Jane Doe (the Third Party) is injured in wheelchair and sues Startup LLC and University. The testing agreement may have an indemnification provision that requires Startup LLC to pay for any litigation costs and damages University incurs as a result of Jane Doe's lawsuit.

Limitation of Liability Example: University and Startup LLC sign a testing agreement to test the strength of a wheelchair. Customer Jane Doe (the Third Party) is injured in wheelchair. Startup LLC sues University because they lose their customer base because no one wants their wheelchairs. Assuming that University is found to be liable for a certain dollar amount in damages, the limitation of liability clause may limit University's damages due to Startup LLC and as a result University would be able to pay less than the actual damages.

#### **Patent Infringement- How the clauses interact**

Indemnification Example: University and Startup LLC sign a research agreement to develop a new technology. The research project successfully develops a new technology and Startup LLC is a success. Research agreement states that University will indemnify Startup LLC for all patent infringement actions that result from the deliverables. Startup LLC successfully builds a company based on the technology and sells tens of thousands of widgets. Five years later, Big Company determines that they own a patent that is infringed by the widget and sues Startup LLC. Startup LLC may be able to shift all damages to University even if they are far greater than the value of the research agreement.

Limitation of Liability with Indemnification Example: University and Startup LLC sign a research agreement to develop a new technology. The research project successfully develops a new technology and Startup LLC is a success. Research agreement states that University will indemnify Startup LLC for all patent infringement actions that result from the deliverables. Research agreement also states that University has a limitation of liability, that includes any amounts due under the indemnification clause, that caps one party's liability to the other for any liability resulting from the contract at the contract value of the research agreement. Startup LLC successfully builds a company based on the technology and sells tens of thousands of widgets. Five years later, Big Company notices that they own a patent that is infringed by the widget and sues Startup LLC. Startup LLC will try to shift all damages to University under the indemnification clause, but the limitation of liability should limit University's liability to the contract value.



Terminology Crosswalk for International Agreements

Difference in terminology US-EU				
US	EU			
Notice of Award	Grant Agreement			
Final submitted application (incl. Research strategy, budget justification, scope of work, subcontract etc.)	Annex I, Description of Work (DoW), Technical Annex (different words for the same document)			
Uniform Guidance	Annex II			
Subcontractor	Participant/Beneficiary			
Prime	Coordinator			
Vendors/Fee for service	Subcontracting			
OMB A-133 + supplements	Audit guidelines			
Project audit	Certificates on financial statements			
A-133	N/A			
Grants Policy Statement, Grant Proposal Guide	Financial guidelines/amendment guidelines/reporting guidelines			
F&A	Indirect costs			
Effort reporting	Time recording			
Cost sharing	Co-financing			
eRACommons, FastLane, Reserch.gov	Participant Portal			



# Recommended Reference Materials

#### **Recommended Reference Materials**

#### **Books**

Adams, K. A. (2004). A manual of style for contract drafting. American Bar Association.

Bazerman, M. H., & Neale, M. A. (1994). Negotiating rationally. Simon and Schuster.

Fisher, R., Ury, W. L., & Patton, B. (2011). *Getting to yes: Negotiating agreement without giving* 

in. Penguin.

Lampson, S., & Porter, K. (2012). The A-Z Guide to Research Contract Review. Loose Leaf.

#### Websites

FDP Templates for International Subawards: http://sites.nationalacademies.org/PGA/fdp/PGA 063626#P44 3572

Penn State FAR Matrix and Resources: <a href="http://www.research.psu.edu/osp/manage-awards/Sponsor-terms-and-conditions/contract-regulations">http://www.research.psu.edu/osp/manage-awards/Sponsor-terms-and-conditions/contract-regulations</a>

UIDP Contract Accords: https://www.uidp.org/publication/contract-accords/