

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.

- Contracting Party**—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.
- Governing Law**—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.
- Information Regarding Payment**—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).
- Notices Regarding Administrative Issues**—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.
- Entity Identification Number**—Include Creighton’s Entity Identification Number: 47-0376583. (Do not use the Principal Investigator’s social security number.)
- 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:
 - Does not apply when injury is caused by negligence of the faculty member or University
 - 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.

- Sponsor Notifications to University**—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).

- Signatures**—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.)