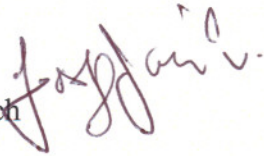




University at Buffalo
The State University of New York

Vice President for Research

To: All UB Researchers

From: Jorge V. José, Ph.D.
Vice President for Research 

Date: March 22, 2007

Re: Research Compliance Guide

This Guide is intended to assist UB faculty and staff to find all information needed to understand and comply with federal, state and university regulations governing the conduct of research. Utilizing a general format developed by the University of Minnesota, the Guide addresses the compliance and regulatory issues that often arise in the course of Proposal Preparation, Award Receipt, Conducting Research and Award Closeout. The Guide identifies the office(s) that can help you conduct your research as efficiently and effectively as possible.

It is in the nature of such guides that new issues and variations on old ones will arise. Hence, we very much need your comments and suggestions on how it can be improved. After a trial period, a hard copy of the Guide will be published for handy reference.

Thank you for using this Guide in the conduct of your research. We believe it will materially assist in navigating the regulatory channels that are essential to ethical and effective research.

Go to Guide: <http://www.research.buffalo.edu/Compliance.pdf>

UNIVERSITY AT BUFFALO
THE STATE UNIVERSITY OF NEW YORK

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DIRECTORY OF CONTACTS QUICK REFERENCE:

List of Key Compliance Telephone Numbers and web sites

Audits, Department of Internal 716- 645-2644
<http://internalaudit.buffalo.edu/>

Environmental Health and Safety (EHS)

<http://www.ehs.buffalo.edu/>

- * Recombinant DNA, Infectious Agents,
Human Blood or Blood Products, Human
or Primate Cell Lines, or Other
Biohazardous Materials 716-829-3301
- * Toxic, Hazardous, or Carcinogenic
Chemicals and Hazardous Waste Disposal 716-829-3301
- * Radiological Materials/Equipment 716-829-3281

General Counsel

- * SUNY 518-443-5400
- * Research Foundation 518-434-8352

Intellectual Property and Technology Commercialization

UB Office of Science, Technology
& Economic Outreach (STOR) 716- 645-5500
<http://www.stor.buffalo.edu/>

Regulatory Affairs

Animal Welfare 716- 829-2752
<http://www.research.buffalo.edu/iacuc/>
Conflict of Interest Deans' Offices
<http://www.research.buffalo.edu/policies/>
Controlled Substances 716-645-3321
<http://www.research.buffalo.edu/policies/>

Research Subjects Protection

<http://www.research.buffalo.edu/rsp/default.cfm>

Institutional Review Boards 716-645-3321
Institutional Animal Care 716-829-2752
& Use Committee

Sponsored Projects Services

<http://www.research.buffalo.edu/sps/default.cfm>

- * Assistant Vice President 716-645-5000 x 1101
- * Compliance & Quality Assurance 716-645-5000 x 1073

DIRECTORY OF CONTACTS:

Office and Committees that Support Research Compliance

<p><u>Animal Care and Use</u></p> <p>Location</p> <p>Institutional Animal Care and Use Committee 150 Parker Hall Buffalo, NY 14214-8004 Phone - (716) 829-2752 Fax - (716) 829-3610 E-Mail - IACUC@research.buffalo.edu</p> <p><u>Comparative Medicine/ Laboratory Animal Facility (CM/LAF)</u></p>	<p>Services</p> <p>The IACUC assures the University is in compliance with all federal, state, and local regulations as well as University policy and Assurance to the Office for Laboratory Animal Welfare (OLAW).</p>	<p>Resources Web site</p>
<p><u>Audits, Department of</u></p> <p>Location</p> <p>University at Buffalo Internal Audit Department 148 Parker Hall Buffalo, NY 14214 Phone: (716) 829-6950 Fax: (716) 829-6042</p>	<p>Services</p> <ul style="list-style-type: none"> • Provides independent, objective assurance and advisory services designed to add value and improve the operations of the University at Buffalo • Helps the University accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes 	<p>Resources Web site</p>
<p>Data Confidentiality,</p>		

<p>Retention and Storage</p> <p>See: Policy on Custody, Maintenance and Retention of research Data</p>		<p>Resources http://www.research.buffalo.edu/policies/datapolicyguide.cfm</p>
<p><u>Comparative Medicine/ Laboratory Animal Facilities (CM/LAF)</u></p> <p>Location 116 Biomedical Education Building (BEB) South Campus Buffalo, NY 14214-3013</p> <p>716-829-2919 (Fax 716-829-3249)</p>	<p>Services</p> <ul style="list-style-type: none"> • Provides for the purchase, care, health and well-being of animals used for research and education at the University at Buffalo • Administers to the animal related needs of University researchers and educators through dissemination of knowledge and resources • Serves the public by ensuring observance of all legal and ethical standards pertaining to the use of animals for research and education at the University at Buffalo 	<p>Resources Web site</p> <p>Resources</p> <ul style="list-style-type: none"> • USDA Animal Welfare Act: • NIH Office of Laboratory Animal Welfare: • AAALAC: http://www.aaalac.org • IACUC: http://www.research.buffalo.edu/iacuc/
<p><u>Environmental Health and Safety, Department of (DEHS)</u></p> <p>Location Environmental Health & Safety 301 Michael Hall, South Campus, 829-3301, FAX 829-2516.</p> <p>Institutional Biosafety Committee (IBC)</p>	<p>Services Provides health and safety-related:</p> <ul style="list-style-type: none"> • Approvals and permits • Consultations and evaluations • Monitoring and sampling • Oversight for various federal and state regulations • Programming 	<p>Resources Web Sites DEHS provides:</p> <ul style="list-style-type: none"> • Safety procedures • Guidelines • Forms • Manuals • Newsletters • Other references that help researchers to comply with regulations and ensure

	<ul style="list-style-type: none"> • Training <p>DEHS' services encompass:</p> <ul style="list-style-type: none"> • Biological materials • Chemicals • Environmental protection • Equipment and protective clothing • Hazardous waste • Public and facility safety • Radioactive materials • Research safety supervision 	<p>safety</p> <p>http://www.research.buffalo.edu/policies/healthsafety.cfm</p> <p>http://www.research.buffalo.edu/policies/biosafety_committee.cfm</p>
<p>General Counsel, Office of (OGC)</p> <p>Location University Counsel and Vice Chancellor for Legal Affairs State University of New York State University Plaza Albany, New York 12246 518-443-5400</p> <p>Research Foundation of State University of New York Office of General Counsel and Secretary 35 State Street Albany, NY 12207 (518) 434-8352</p>	<p>Services</p> <ul style="list-style-type: none"> • Provides legal advice for the University at Buffalo including all campuses and operations • Reviews and approves contracts to which the University at Buffalo is a party 	
<p><u>Intellectual Property and Technology Commercialization</u></p> <p>Location UB Office of Science, Technology and Economic Outreach (STOR) 1576 Sweet Home Road Amherst, NY 14228 (716) 645-5500 x 32 Fax: (716) 645-3341</p>	<p>Services</p> <ul style="list-style-type: none"> • Identifies and protects marketable University technology, including Inventions, computer software and other copyrightable materials, and transfers these 	<p>Resources</p> <p>Website Information for UB Researchers</p> <ul style="list-style-type: none"> • Forms • FAQs • Guidance • Policies & Procedures for

	<p>technologies to the private sector through licensing</p> <ul style="list-style-type: none"> • Prepares outgoing Material Transfer Agreements (MTA) • STOR administers Baird Technology Incubator 	<p>technology transfer</p>
<p><u>Sponsored Projects Services (SPS)</u></p> <p>Location 402 Crofts Hall North Campus Buffalo, NY 14260 716-645-5000 x</p>	<p>Services</p> <ul style="list-style-type: none"> • Assists faculty in identifying funding opportunities • Assists faculty with preparing proposals for submission • Submits proposals to external sponsors • Negotiates and accepts sponsored awards • Administers awards in compliance with sponsor and university policies • Prepares and submits financial reports and invoices 	<p>Resources Website</p> <ul style="list-style-type: none"> • Electronic Proposal Approval System • SPS website
	<p>Select Research Committees</p>	
<p>Vice President for Research (OVR)</p> <p>Location 516 Capen Hall Buffalo, NY 14260 T 716-645-3321 F 716-645-3792 www.research.buffalo.edu</p>	<p>Services</p> <ul style="list-style-type: none"> • Oversees all aspects of research at the University at Buffalo providing guidance to individual researchers and managing the system-wide research enterprise 	<p>Resources</p> <ul style="list-style-type: none"> • Funding and Opportunities • Policies

	Offices which report to the Vice President for Research	
<p><u>Chemical and Radioactive Waste Disposal</u></p> <p><u>Institutional Biosafety Committee (IBC)</u></p> <p>Committee of faculty, staff and community representatives responsible for oversight of all teaching and research activities involving recombinant DNA, artificial gene transfer, infectious agents, and biologically derived toxins.</p> <p><u>Institutional Review Board (IRB – Human Subjects)</u></p> <p>Board composed of faculty, staff, and community members responsible for reviewing projects involving human subjects.</p> <p><u>Institutional Animal Care and Use Committee (IACUC)</u></p> <p>Committee of faculty, staff, students, and community representatives responsible for reviewing all projects involving animals.</p> <p>Research Advisory Council (RAC)</p> <p>Committee of senior faculty who advise the Vice</p>		

President for Research on all matters relating to research at the University.		
	Research-Related Committees within the University at Buffalo	
Associate Deans for Research http://www.research.buffalo.edu/ad_r.cfm	Faculty Senate Committee on Research and Creative Activity http://www.research.buffalo.edu/research_membership.cfm	

RESEARCH COMPLIANCE Q&A

✓ Compliance Item	Resource
<input type="checkbox"/> Have you identified particular laws or regulations that may govern your proposed research?	<ul style="list-style-type: none"> ■ Common Rule ■ OMB Circulars
<input type="checkbox"/> Have you identified particular requirements that the sponsor of your proposed research may have?	Sponsored Projects Services
<input type="checkbox"/> Have you identified particular University, collegiate or departmental policies and procedures that may govern your proposed research?	Sponsored Projects Services <ul style="list-style-type: none"> • VPR Policies & Procedures
<input type="checkbox"/> Do you know who to contact with legal or policy questions?	Sponsored Projects Services
<input type="checkbox"/> Have you reviewed the University's Principal Investigator Eligibility on Sponsored Projects policy, including the roles and responsibilities of the principal investigator?	Sponsored Projects Services <ul style="list-style-type: none"> * Asst VP * PI eligibility

GENERAL

✓ Compliance Item	Resource
RESEARCH FUNDING	
<input type="checkbox"/> Have you properly classified the funding for your research as either a gift, grant, contract, or external sale?	Sponsored Projects Services
GRANT/CONTRACT	
<input type="checkbox"/> If your funding comes from a sponsored project, have you notified Sponsored Projects Services (SPS)?	Sponsored Projects Services
<input type="checkbox"/> If your research is a sponsored project, have you properly classified the type of sponsored project; research, outreach, public service or training?	Sponsored Projects Services
INTELLECTUAL PROPERTY	
<input type="checkbox"/> If your project involves Intellectual Property developed by you at another institution have you disclosed that IP to the other institution and made appropriate arrangements for its use?	Office of Science, Technology Transfer & Economic Outreach (STOR)

Have you clarified ownership of intellectual property (IP) developed before, during, after and ancillary to the project? Office of Science, Technology Transfer & Economic Outreach (STOR)

Will you provide your research materials (biological, datasets, cell lines, seeds, plants, germplasm release, etc.) to an external source? If so, and you believe the materials have commercial significance, contact STOR. UB Office of Science, Technology Transfer & Economic Outreach (STOR)

GIFTS

If the funding for your research is a gift, have you notified the University Foundation of the proposed gift? School Development Officer

Have you confirmed with the donor that the project is truly a gift? Meaning, for example, the results of your work have no commercial value to the donor and the donor retains no rights to the IP? School Development Officer
Sponsored Projects Services

OUTSIDE CONSULTING

Have you ensured that you are not using University staff or resources? Department chair or dean

Are you confident that you have not implied University endorsement of the consulting project? Department chair or dean

Have you identified and disclosed potential conflicts of interest associated with the consulting arrangement? Dean
* UB Policy

If any proposed consulting work involves the use of Intellectual Property developed at UB, have you contacted STOR? UB Office of Science, Technology Transfer & Economic Outreach (STOR)

CLINICAL TRIALS

Are you aware of the additional compliance obligations associated with clinical trials? Research Subjects Protection

FIXED PRICE AGREEMENTS

Are you aware of the financial risks and special closeout requirements for fixed price agreements? Sponsored Projects Services

PROPOSAL PREPARATION

GUIDELINES AND APPROVALS

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Have you reviewed and followed the sponsor's proposal instructions? | Sponsored Projects Services |
| <input type="checkbox"/> Did you make the necessary changes to the proposal and Sponsored Projects Approval Form as requested by your department or college before sending it to Sponsored Projects Services (SPS)? | Department chair/dean |
| <input type="checkbox"/> Did you obtain the appropriate approvals on the Approval Form that include: co-investigators, department heads, and deans? | Sponsored Projects Services |
| <input type="checkbox"/> If your research proposal requires approval from University regulatory committees (IRB, IBC, etc.), do you have written standard operating procedures for your research protocols? | See Committees listed in Full Directory of Contact

Office of the Vice President for Research |
| <input type="checkbox"/> If you are applying for a Department of Defense grant, have you received approval from the Department of Environmental Health & Safety (DEHS)? | Sponsored Projects Services |
| <input type="checkbox"/> Have you secured appropriate approvals for extra-departmental resources? | |

PROJECT RESOURCES

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------|--|
| <input type="checkbox"/> Do you have sufficient administrative staff to manage financial and programmatic obligations of your proposed project(s)? | |
| <input type="checkbox"/> Have you identified adequate space and facilities for the project? | |

BUDGET AND FINANCES

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Does the budget narrative include proper written justification for all proposed costs? | Sponsor guidelines

Sponsored Projects Services |
| <input type="checkbox"/> Have you listed all other sources of support for your research as required on the grant application? | Sponsored projects Services |
| <input type="checkbox"/> Will you generate program income as a result of your project? For example, conference fees, lab services, or reagents. If so you need to determine if your program income is reportable or nonreportable. | Sponsored Projects Services |
| <input type="checkbox"/> Did you use the negotiated Facilities & Administrative (F&A or indirect cost) rates, including proper University and sponsor rate determinations? | Sponsored Projects Services
■ UB Rate Table |
| <input type="checkbox"/> Did you obtain a waiver if the F&A rate is other than the University negotiated rate? | Sponsored Projects Service
■ UB Policy
■ UB F&A waiver form |

<input type="checkbox"/> Have you appropriately allocated direct and indirect costs in your proposed budget?	Sponsored Project Services * Direct & Indirect rates
<input type="checkbox"/> Does the budget narrative include proper written justification to direct charge normally indirect type costs? For example, clerical and administrative salaries, local phone, or office supplies.	Sponsored Projects Services
<input type="checkbox"/> If your sponsor has salary cap limitations (e.g. NIH) have you adhered to them?	Sponsored Projects Services
<input type="checkbox"/> Have you confirmed the sponsor is able to meet its financial obligations? If you have concerns have you notified SPS?	Sponsored Projects Services
<input type="checkbox"/> Do you anticipate patents or potentially marketable intellectual property as a result of your project?	Sponsored Project Services

SPENDING PRIOR TO PROJECT START DATE

<input type="checkbox"/> Do you need to begin spending funds prior to the project start date?	Sponsored Projects Services
<input type="checkbox"/> Does the sponsor allow pre-award or advance costs?	Sponsored Projects Services
<input type="checkbox"/> If so, have you completed the required University Pre-award/Advance Account Request form and received approval prior to spending?	Sponsored Projects Services UB Forms library

SUBAWARDS AND SUBRECIPIENTS

<input type="checkbox"/> Have you determined whether work is a contract for professional services or subaward?	Sponsored Projects Services
<input type="checkbox"/> If you plan to use a subrecipient, have you applied the correct F&A rate?	Sponsored Projects Services * Subawards
<input type="checkbox"/> If you plan to use subrecipients, have you obtained commitment letters, budgets, and work scopes?	Sponsored Projects Services

EFFORT AND COST SHARING

<input type="checkbox"/> Does the committed effort in the Approval Form match the committed effort shown in your proposal?	Department chair Sponsored Projects Services
<input type="checkbox"/> Have you reviewed proposed cost sharing and determined whether it is appropriate and necessary?	Department chair UB Policy
<input type="checkbox"/> Does your proposal effort only meet the sponsor's required cost share, match or in-kind contributions?	Department chair Sponsored Projects

CONFLICT MANAGEMENT

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
| <input type="checkbox"/> Do you understand the University's conflict of interest disclosure and approval process? | Department chair
UB Policy on
Investigator Disclosure |
| <input type="checkbox"/> Annual Reporting: Does your Annual Financial Disclosure form include all relevant business or financial interest, including interest of immediate family members that could affect research? For example, executive board positions or fiscal relationships with the sponsor. | Dean
UB Policy on
Investigator Disclosure |
| <input type="checkbox"/> Do you have an Annual Financial Disclosure form on file for the most recent reporting period? | Dean |
| <input type="checkbox"/> Anticipated Potential Conflicts: Have you received the University's required prior approvals for any anticipated conflicts of interest associated with the project and amended your Disclosure Form accordingly? | Associate dean for research or department chair |
| <input type="checkbox"/> Substantial Changes in Business or Financial Interests Occur: Have your business or financial circumstances changed since filing your Disclosure Form and if so, have you amended your Disclosure Form? | Associate dean for research or department chair |
| <input type="checkbox"/> Do you need a conflict management plan? | Associate dean for research or department chair |
| <input type="checkbox"/> Disclosure by Team Members: Have all team members with responsibility for the design, conduct or reporting on the research project filed an AID regardless of employment classification or status? | Dean |
| <input type="checkbox"/> Have you notified all key personnel listed on the proposal of their obligation to file an Annual Financial Disclosure Form ? | Dean |

RESEARCH MATERIALS

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| <input type="checkbox"/> Is an external source providing you with research materials? For example, biological, datasets, or reagents. If so, did you complete a material transfer agreement (MTARF) prior to receipt of the materials? | Sponsored Projects Services
• UB MTAs |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|

CONFIDENTIAL INFORMATION AND DATA

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| <input type="checkbox"/> Have you requested your sponsors or any party providing data to specifically designate and mark data that are to be treated as "confidential"? | Sponsored Projects Services |
| <input type="checkbox"/> Do you have appropriate safeguards in place to maintain the confidentiality of proprietary information provided to you or members of the research team? | Sponsored Projects Services |
| <input type="checkbox"/> Has your sponsor proposed restrictions on your ability to publish research results? | Sponsored Projects Services |

Has your sponsor proposed restrictions that may conflict with principles of academic freedom or the University's research policies? For example, export controls, involvement of foreign nationals, or publication restrictions. Sponsored Projects Services

Is any of your proposed research subject to federal export control regulations? Sponsored Projects Services

Are you aware of the restrictions imposed on international students and staff you may want to work on the project, based on their country of origin, if export controlled research or technology is involved? Sponsored Projects Services

Are you aware of your obligations regarding information subject to export controls? Sponsored Projects Services

LABORATORIES

Do you have a written lab safety plan? Environmental Health & Safety

HAZARDOUS MATERIALS - GENERAL

If applicable, do you have lab safety, hazardous waste, radiation safety, blood borne pathogen training records for yourself and staff which have been updated within the last year? Department chair
Environmental Health & Safety

HAZARDOUS MATERIALS - BIOHAZARDS

Do you know which materials constitute "biological toxins, rDNA, or infectious agents"? Environmental Health & Safety
• [IBC forms](#)

Have you obtained Institutional Biosafety Committee (IBC) approval to use rDNA, artificial gene transfer, infectious agents or biologically derived toxins before submitting your proposal? Environmental Health & Safety
• [IBC forms](#)

Have you registered your plans to use rDNA molecules with the IBC, and, if necessary, the NIH Recombinant DNA Advisory Committee? Environmental Health & Safety

If you plan to use a regulated "Select Agent" or "toxin", are you aware of the extensive administrative procedures and lead time required prior to starting work? Have you received IBC approval? Environmental Health & Safety

HAZARDOUS MATERIALS - CHEMICALS

Do you know which chemicals constitute "hazardous chemicals"? Environmental Health & Safety

If your research involves manufacturing, synthesizing, or importing chemicals, have you evaluated your compliance status regarding toxic substances you create as a byproduct of your research? Environmental Health & Safety

If your research involves studying the treatment of hazardous waste or polychlorinated biphenyls (PCBs), have you submitted a "treatability study" to the Environmental Health & Safety

Environmental Protection Agency (EPA)?

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| <input type="checkbox"/> Do you know what constitutes regulated "hazardous radiation"? If you are unsure, contact DEHS. | Environmental Health & Safety |
| <input type="checkbox"/> Do you have a permit for any radioactive materials or ionizing radiation producing equipment your project may use? | Environmental Health & Safety |

HAZARDOUS MATERIALS - CONTROLLED SUBSTANCES

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <input type="checkbox"/> Are you aware of DEA regulations and do you have a license for any controlled substances your project may use? | Office of the Vice President for Research |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|

HUMAN SUBJECTS

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| <input type="checkbox"/> Does your proposal involve human subjects? | Research Subjects Protection |
| <input type="checkbox"/> Do you know of the laws and guidelines governing research that affects human subjects? | Research Subjects Protection |
| <input type="checkbox"/> Do you know what research the IRB must review and their review process? | Research Subjects Protection |
| <input type="checkbox"/> Does your research involve the transfer of rDNA form to human subjects? If so, have you obtained both IBC and IRB approval? | Research Subjects Protection
UB Institutional Biosafety Committee |
| <input type="checkbox"/> Do you plan to use ionizing radiation, chemicals, infectious agents, rDNA, biological toxins, or anesthetic gases on animal subjects? If so contact the IBC. | UB Institutional Biosafety Committee |
| <input type="checkbox"/> Does your patient consent form allow you to use samples and biomaterials collected from your subjects in future research and the freedom to use intellectual property derived from them? | Research Subjects Protection |

ANIMALS

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| <input type="checkbox"/> Do you understand your obligations under the laws and guidelines governing the use of animals in research or teaching? | Research Subjects Protection |
| <input type="checkbox"/> Do you know which types of research the Institutional Animal Care & Use Committee (IACUC) must approve? | Research Subjects Protection |
| <input type="checkbox"/> Do you know the IACUC review process for your animal activities and have you applied for IACUC approval for your protocol? | Research Subjects Protection |
| <input type="checkbox"/> Do you plan to use ionizing radiation, chemicals, infectious agents, rDNA, biological toxins, or anesthetic gases on animal subjects? If so contact DEHS. | Research Subjects Protection |

AWARD

✓ Compliance Item

Resource

GUIDELINES AND APPROVALS

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <input type="checkbox"/> Have you reviewed the Award Terms & Conditions? | Sponsored Projects Services |
| <input type="checkbox"/> Do you understand your compliance roles and responsibilities set out in the award? | Sponsored Projects Services |
| <input type="checkbox"/> Have you obtained sponsor-required approvals from the coPI, department Chair and SPS award analyst for administrative or programmatic changes? | Department chair
Sponsored Projects Services |
| <input type="checkbox"/> Has the authorized University representative signed the award acceptance? | Sponsored Projects Services |

TERMS AND CONDITIONS

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <input type="checkbox"/> Does your award restrict your ability to publish or present your research results or require prior notice to the sponsor? | Sponsored Projects Services |
| <input type="checkbox"/> Have you reviewed the terms and conditions of the award with your SPS agreement administrator to ensure adherence to University policies and procedures? | Sponsored Projects Services |
| <input type="checkbox"/> Have you reviewed the award terms and conditions with your departmental administrators to ensure adherence to departmental policies and procedures? | Department chair |
| <input type="checkbox"/> Do you know your responsibilities as principal investigator (PI) related to providing oversight, cost-sharing, technical reporting, effort reporting, publishing rights and specifications, and reporting of intellectual property? | Department chair
Sponsored Projects Services |
| <input type="checkbox"/> Does your award require you to purchase from small, minority, or women-owned businesses? | Sponsored Projects Services
Purchasing |

BUDGET AND FINANCES

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| <input type="checkbox"/> Is the amount awarded sufficient to complete the scope of the proposed project, or do you need budgetary or programmatic changes? | Sponsored Projects Services |
| <input type="checkbox"/> Have you received an amendment if your budget needs have changed? | Sponsored Projects Services |

EFFORT AND COST SHARING

Has the effort for yourself or project personnel changed since you submitted your proposal to the sponsor? Department chair
Sponsored Projects
Services

Do you know your cost sharing or matching obligations and commitments? Sponsored Projects
Services

SUBAWARDS AND SUBRECIPIENTS

Have you made subrecipients aware of their responsibilities based on your prime award, work scope, cost sharing, technical reporting, financial audit requirements (A133), and invoicing methods? Sponsored Projects
Services

HAZARDOUS MATERIALS - BIOHAZARDS

Have you received final Institutional Biosafety Committee approval? Environmental Health
& Safety

HUMAN SUBJECTS

Have you and your staff completed the research education requirements for human subjects research? Research Subjects
Protection

Have you received final Institutional Review Board (IRB) approval? Research Subjects
Protection

ANIMALS

Are you certified by the Institutional Animal Care & Use Committee (IACUC) to use animals in your research? Research Subjects
Protection

Have you and your staff enrolled in the training and certification courses required by IACUC? For example, care and use of animals and occupational health? Research Subjects
Protection

Have you received final IACUC approval? Research Subjects
Protection

AGRICULTURAL MATERIALS

Will you work with exotic pests or plants and, if so, have you obtained proper state and federal permits? Comparative
Medicine/
Laboratory Animal
Facilities (CM/LAF)
* [US Department of
Agriculture](#)
Environmental Health
& Safety

CONDUCTING RESEARCH

✓ Compliance Item

Resource

PERSONNEL - HIRING AND TRAINING

<input type="checkbox"/> Have you followed University hiring policies and procedures?	Research Foundation (RF) Human Resource Services (HR)
<input type="checkbox"/> Will you use a standard offer letter? If not, have you consulted RF HR?	Research Foundation (RF) Human Resource Services (HR)
<input type="checkbox"/> Have you detailed clear project roles and responsibilities and, where appropriate, written job descriptions?	Department chair Research Foundation (RF) Human Resource Services (HR)
<input type="checkbox"/> Have you classified student employees, employees, or independent contractors correctly?	Department chair Research Foundation (RF) Human Resource Services (HR)
<input type="checkbox"/> Have you instructed staff on rules governing confidential or proprietary data?	Sponsored Projects Services
<input type="checkbox"/> Does your team need additional education? For example, on issues like human subjects, animals, safety, occupational health and safety.	Office of the Vice President for Research
<input type="checkbox"/> Are your project volunteers trained and orientated and have they completed all proper documentation?	Research Foundation (RF) Human Resource Services (HR)
<input type="checkbox"/> If you are working with technology or data subject to export control regulations, have you ensured any international project team member is not unfairly restricted based upon country of origin?	Sponsored Projects Services
<input type="checkbox"/> Does your proposal involve programmatic work conducted by others external to the University? For example, subcontractors or consultants.	Sponsored Projects Services

PERSONNEL - DELEGATING DUTIES

<input type="checkbox"/> Is it appropriate to delegate the duties you seek to delegate?	Sponsored Projects Services
<input type="checkbox"/> Does the person to whom you delegate have the competence, time, and resources to carry out the duties?	Principal investigator
<input type="checkbox"/> Does the person you have delegated to understand their responsibilities?	Principal investigator
<input type="checkbox"/> Is an oversight process in place to ensure delegated duties are carried out correctly?	Principal investigator

PERSONNEL - TEAM DYNAMICS

<input type="checkbox"/> Has your project team discussed and reached consensus regarding	Associate Dean for Research
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authorship, inventor credit, data collection and management relating to your project?

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| <input type="checkbox"/> Have you defined each team member's roles and responsibilities on the project? | Principal Investigator |
| <input type="checkbox"/> Have you identified potential disputes and tried to respectfully resolve them? | Principal Investigator |

BUDGET & FINANCES

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| <input type="checkbox"/> Have you correctly allocated project expenditures to the appropriate research projects, especially those projects closely related in scope and objectives? | Sponsored Projects Services |
| <input type="checkbox"/> Are you charging direct costs appropriately and with adequate justification? | Sponsored Projects Services |
| <input type="checkbox"/> Do you review project expenses to assure they are timely, allowable, allocable, necessary, and reasonable per sponsor guidelines? | Sponsored Projects Services |
| <input type="checkbox"/> Are you supplying adequate justifications and documentation for grant expenses? | Sponsored Projects Services |
| <input type="checkbox"/> Do your accounting staff alert you about inadvertent unallowable costs? If so, did they identify and remove them? | Sponsored Projects Services |
| <input type="checkbox"/> Are you and your administrators monitoring the financial status of your project, in particular, key high risk financial areas such as deficit spending, program income, cost sharing, and cost transfers? | Sponsored Projects Services |
| <input type="checkbox"/> Are you required to report program income information to the sponsor? | Sponsored Projects Services |
| <input type="checkbox"/> Have you properly documented program income and submitted it to SPS for deposit? | Sponsored Projects Services |
| <input type="checkbox"/> Do you receive updates from your accounting staff about accounts receivable balances that identify sponsors not paying on time? | Sponsored Projects Services |
| <input type="checkbox"/> If your sponsor is not paying on time, have you adjusted your spending accordingly to minimize your departmental liability? | Sponsored Projects Services |
| <input type="checkbox"/> Do you review sponsor final and end of budget period reports or invoices prepared by SPS ? | Sponsored Projects Services |
| <input type="checkbox"/> Does your account have an overdraft? If so, did you contact SPS to ask your sponsor for additional funding? | Sponsored Projects Services |
| <input type="checkbox"/> Did you contact SPS to ask your sponsor about proper handling of excess funds? | Sponsored Projects Services |
| <input type="checkbox"/> Will your excess funds be treated as "carry forward" from one budget period to another? If so, what are your responsibilities regarding "carry forward" funds? | Sponsored Projects Services |

EFFORT AND COST SHARING

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| <input type="checkbox"/> Have you and other researchers on the project met the anticipated effort specified in your award? | Sponsored Projects Services |
| <input type="checkbox"/> Have you and other team members submitted effort reports by effort reporting deadlines? | Sponsored Projects Services |
| <input type="checkbox"/> Did you correctly calculate effort? Effort includes all time spent conducting University business and may never be greater than 100%. | Sponsored Projects Services |
| <input type="checkbox"/> Are all your University projects, including nonsponsored projects, included in the effort reports you complete? | Sponsored Project Services |
| <input type="checkbox"/> Do you have direct, first-hand knowledge of others' time before you approve their effort reports? | Sponsored Projects Services |
| <input type="checkbox"/> Did you amend your effort reports if your proposed effort allocation changed by five percent or more? | Sponsored Projects Services |
| <input type="checkbox"/> Do your Award Terms and Conditions specify that you are required to report your cost share information to the sponsor? | Sponsored Projects Services |
| <input type="checkbox"/> Have you properly documented your cost share requirements as the cost sharing takes place? | Sponsored Projects Services |
| <input type="checkbox"/> Did you submit proper documentation to SPS when cost sharing is reportable back to the sponsor? | Sponsored Projects Services |
| <input type="checkbox"/> Did you certify all effort that is listed as cost share, even if you are not required to report it to the sponsor? | Sponsored Projects Services |
| <input type="checkbox"/> Are you meeting and documenting your cost sharing requirements? | Sponsored Projects Services |
| <input type="checkbox"/> If you know you will not meet your cost sharing requirements, have you contacted your SPS agreement administrator to notify the sponsor? | Sponsored Projects Services |

CHANGES TO WORKSCOPE

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| <input type="checkbox"/> Have you obtained appropriate prior approvals for administrative or programmatic changes during the project period? For example, budget, no-cost extension, key personnel, or carry forward of funds. | Sponsored Projects Services |
| <input type="checkbox"/> Have you obtained sponsor-required approvals for administrative or programmatic changes from the SPS agreement administrator ? | Sponsored Projects Services |
| <input type="checkbox"/> Have you contacted the IBC, IACUC, IRB, Radiation Protection Committee, or other review committees as appropriate, for changes to your protocol? | UB BC
Research Subjects Protection
Office of the Vice President for
Research |
| <input type="checkbox"/> Are you conducting your research under approved protocols? | Contact appropriate approving committee (such as IRB, IBC, etc.) Directory of Contacts |

SUBAWARDS AND SUBRECIPIENTS

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| <input type="checkbox"/> Did you review subrecipient work for satisfactory progress and approve the invoices prior to submission for payment? | Sponsored Projects Services |
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TECHNOLOGY TRANSFER

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| <input type="checkbox"/> Have you identified potential intellectual property (IP) created during your research that you must disclose under terms of the grant? | Office of Science, Technology Transfer & Economic Outreach (STOR) |
| <input type="checkbox"/> Have you alerted the UB Office of Science, Technology Transfer and Economic Outreach (STOR) of any IP, and completed an IP disclosure form? | Office of Science, Technology Transfer & Economic Outreach (STOR)
*IP Disclosure Form |
| <input type="checkbox"/> Do you have mechanisms in place for participants in the project that generated the IP to identify and report their involvement according to the grant? | Office of Science, Technology Transfer & Economic Outreach (STOR) |
| <input type="checkbox"/> Have you carefully documented the following IP details: when was research conducted leading to the IP, what funding sources contributed to the IP, who worked on the IP, and records demonstrating the IP? | Office of Science, Technology Transfer & Economic Outreach (STOR) |

CONFLICT MANAGEMENT

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| <input type="checkbox"/> Have you identified all research team members who must disclose potential conflicts of interest? For example, anyone responsible for the conduct, design, or reporting of the research. | Associate Dean for Research |
| <input type="checkbox"/> Has the research project or your personal situation changed any of the answers you made on your most recently filed Annual Investigator Disclosure? If so, have you updated and filed a new Form? | Associate Dean for research |
| <input type="checkbox"/> Are you disclosing potential conflicts by filing a Financial Disclosure Form at least once a year? | Associate Dean for Research |

CONFIDENTIALITY

- | | |
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| <input type="checkbox"/> Have you taken measures to protect the confidentiality of your research subjects? | Research Subjects Protection |
| <input type="checkbox"/> Have you taken measures to protect the privacy of personal information contained in your data sets? | Research Subjects Protection |
| <input type="checkbox"/> Have you ensured that the personal records of your project staff are kept confidential? | Research Subjects Protection |

DATA AND DOCUMENTATION

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| <input type="checkbox"/> Have you ensured that any designated confidential information provided to you by a sponsor or third party is kept confidential? | Sponsored Projects Services /Office of Science, Technology Transfer & Economic Outreach (STOR)/Research Subjects Protection |
| <input type="checkbox"/> Does your computer, server, and other equipment have up-to-date security and antivirus software and are your electronic research data | Computing & Information Technology (CIT) |

stored in a secure manner?

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| <input type="checkbox"/> Are your physical research data stored in a secure place? | Computing & Information Technology (CIT) |
| <input type="checkbox"/> Do you have a contingency plan in place for recovery or duplication of any important materials, documents or electronic records in the event of unanticipated loss, disaster or business interruption? | Computing & Information Technology (CIT) |
| <input type="checkbox"/> Prior to any presentation or publication, have you reviewed and met all obligations required by your sponsor? For example, prior notice or copies, review period, or verification regarding sponsor's confidential information. | Sponsored Projects Services |
| <input type="checkbox"/> Do you have procedures in place to track progress of the research, who is responsible for what development, and when it happened? Is it recorded in official laboratory notebooks and records? (In the case of Intellectual Property, contact STOR.) | Dean/Department Chair
Office of Science, Technology Transfer & Economic Development (STOR) |
| <input type="checkbox"/> Are you maintaining the required documentation for the project: cost sharing, progress reports, effort, and scientific data? | Sponsored Projects Services |

SAFETY

- | | |
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| <input type="checkbox"/> Have you identified everyone needing to enroll in an occupational health program? | Environmental Health & Safety |
| <input type="checkbox"/> Do you know who your research safety officer (RSO) is, and have you consulted with him or her for any particular safety concerns? | Environmental Health & Safety |

PROGRESS REPORTING

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| <input type="checkbox"/> Are you meeting your due dates for scientific progress reports and other deliverables? | Sponsored Projects Services |
| <input type="checkbox"/> Do you know your sponsor's deliverable requirements and their relationship to the payments made to your project? | Sponsored Projects Services |

PUBLISHING AND PRESENTING

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|
| <input type="checkbox"/> Have you reviewed the terms of the award to confirm ownership and rights to any intellectual property developed under the award and reporting requirements? | Sponsored Projects Services |
| <input type="checkbox"/> If your presentation or publication may describe a potentially patentable invention, have you contacted the UB Office of Science, Technology Transfer and Economic Outreach (STOR) ? | Office of Science, Technology Transfer & Economic Development (STOR) |
| <input type="checkbox"/> Does your presentation or publication include someone else's copyrightable work? If so, have you obtained a copyright permission or concluded your use of the material is permissible as "public domain" or "fair use"? | Dean/Department Chair/University Library |
| <input type="checkbox"/> Have you reached agreement with your collaborators and research team about authorship? | Associate Dean for Research |

- Have you registered your work with the U.S. copyright office? This is recommended. University Library

LABORATORIES

- Do you have appropriate personal protective equipment available and working in the lab? Environmental Health & Safety
- Have you educated all people working in the lab about your lab safety plans? Environmental Health & Safety
- If you have a laboratory, have you filed A Report of Materials used in Education and Research (ARMER) form for every reporting period? Environmental Health & Safety
- Do you have procedures in place to prevent staff from inadvertently mixing materials subject to material transfer agreements? Sponsored Projects Services
• [MTAs](#)

HAZARDOUS MATERIALS - GENERAL

- If applicable, do you have lab safety, radiation safety, hazardous waste, blood borne pathogen training records for yourself and staff updated within the last year? Environmental Health & Safety

HAZARDOUS MATERIALS - BIOHAZARDS

- Are you fulfilling your IBC continuing review reporting requirement? Environmental Health & Safety
- If you need to make changes in your IBC protocol (added genes, reagents changed procedures etc.), have you contacted the IBC? Environmental Health & Safety

HAZARDOUS MATERIALS - CHEMICALS

- Do you send your chemical waste to the Chemical Waste Program? Environmental Health & Safety
- Do you have specific approval to dispose of waste in the sewer or trash? Environmental Health & Safety
- Are you complying with waste container management guidelines? Environmental Health & Safety

RADIOACTIVE MATERIAL/IONIZING RADIATION PRODUCING

- Do you have a permit to possess and use radioactive material from the All-University Radiation Protection Advisory Committee (AURPAC)? Environmental Health & Safety
- Have you registered your ionizing radiation producing equipment with the University Radiation Protection Division? Environmental Health & Safety

HAZARDOUS MATERIALS - CONTROLLED SUBSTANCES

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <input type="checkbox"/> Do you have the required storage and record keeping procedures in place for your controlled substances (including anesthetics, analgesic for animals)? | Vice President for Research
Comparative Medicine/Laboratory
Animal Facilities |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|

HUMAN SUBJECTS

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| <input type="checkbox"/> Are you following the appropriate procedures concerning human subjects? For example, compensation and consent forms. | Research Subjects Protection |
| <input type="checkbox"/> Are you fulfilling your IRB continuing review reporting requirement? | Research Subjects Protection |
| <input type="checkbox"/> If you need to make changes in your human subject protocol, have you contacted the IRB? | Research Subjects Protection |
| <input type="checkbox"/> Do you know the requirements for reporting unanticipated problems? | Research Subjects Protection |
| <input type="checkbox"/> If you have added personnel to your human subject research have they completed their research education requirements? | Research Subjects Protection |
| <input type="checkbox"/> Consent Forms: Are staff who are obtaining consent forms from subjects authorized and trained to obtain consent? | Research Subjects Protection |
| <input type="checkbox"/> Did you adequately document the consent process? | Research Subjects Protection |
| <input type="checkbox"/> Pharmaceuticals: If you are a sponsor-investigator using an investigational new drug (IND) or an investigational device exemption (IDE), do you have a monitoring plan in place for routine review of research records? | Research Subjects Protection |
| <input type="checkbox"/> If you are a sponsor-investigator do you have case report forms to document adequate and accurate case histories recording all data pertinent to the investigations for each research subject? | Research Subjects Protection |
| <input type="checkbox"/> Have you registered your research with Fairview Investigational Drug Service if you are using an IND? | Research Subjects Protection |
| <input type="checkbox"/> Are you using the required labeling for the investigational product? | Research Subjects Protection |

ANIMALS

- | | |
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| <input type="checkbox"/> Are you fulfilling your IACUC continuing review reporting requirement? | Research Subjects Protection |
| <input type="checkbox"/> If you need to make changes in your animal protocol, have you contacted the IACUC? | Research Subjects Protection |
| <input type="checkbox"/> If you have added personnel to your animal subject activity, have they attended the orientation seminar and enrolled in the occupational health program? | Research Subjects Protection
Comparative Medicine/Laboratory
Animal Facilities |

AWARD CLOSEOUT

✓ Compliance Item

Resource

PROTOCOLS AND REGULATORY REQUIREMENTS

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| <input type="checkbox"/> If research continues once funding ends, are you aware you must continue to comply with regulatory requirements pertaining to your research? | Sponsored Projects Services |
| <input type="checkbox"/> Have you disclosed any inventions derived from this grant to STOR so STOR can comply with reporting obligations to the funding agency? | Sponsored Projects Services or Office of Science, Technology Transfer & Economic Outreach (STOR) |

DATA AND DOCUMENTATION

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|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <input type="checkbox"/> Do you know the University records retention schedule and policy and have you maintained, stored, and destroyed records according to this policy? | Office of the VP for Research
* Data Policy |
| <input type="checkbox"/> Do you know the University guidelines for the destruction of research information? Do you know your sponsor's requirements for record retention? | Office of the VP for Research
* Data Policy |

BUDGET AND FINANCES

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| <input type="checkbox"/> Have you worked with your department to address any deficit spending or cash balance situations? | Dean
Sponsored Projects Services |
| <input type="checkbox"/> Does your documentation support and show that for a particular project, each funding source was charged appropriately? | Sponsored Projects Services |
| <input type="checkbox"/> If this was a fixed price award, have all deliverables been met and unspent money handled according to University policies and procedures? | Sponsored Projects Services |
| <input type="checkbox"/> Does your account have an overdraft? If so, have you directed your grant accountant how to handle the deficit? | Sponsored Projects Services |
| <input type="checkbox"/> Has spending stopped on projects that have ended? | Sponsored Projects Services |

FINAL REPORTING

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| <input type="checkbox"/> Have you submitted all required information within the sponsor's deadlines? | Sponsored Projects Services
* Closeout |
| <input type="checkbox"/> Does your sponsor require you to submit final reports? | Sponsored Projects Services |

BIOHAZARDS

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| <input type="checkbox"/> Animal and Human Tissue: Have you separated the human or animal tissue from the liquid preservative? | Environmental Health and Safety |
| <input type="checkbox"/> Have you rendered large animal tissue or placed it in a biohazard waste bag for incineration? | Comparative Medicine/Laboratory Animal Facilities |
| <input type="checkbox"/> Have you prepared the liquid preservative for disposal as a hazardous waste? | Environmental Health and Safety |
| <input type="checkbox"/> Microorganisms and Cultures: If an autoclave is available, have you decontaminated the waste and disposed of it in the regular trash? | Environmental Health and Safety |
| <input type="checkbox"/> If the material cannot be decontaminated, have you placed it in a biohazard bag for disposal? | Environmental Health and Safety |

CHEMICALS

- | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| <input type="checkbox"/> Are all chemical containers appropriately labeled and securely closed? | Environmental Health & Safety |
| <input type="checkbox"/> Have you determined which chemicals are useable? If so, do you know who is responsible for the chemicals? | Environmental Health & Safety |
| <input type="checkbox"/> Have you identified which chemicals can be disposed of in the sewer or trash and which ones must be collected for disposal? | Environmental Health & Safety |
| <input type="checkbox"/> Have all remaining chemicals, especially hazardous chemical wastes, been prepared for pick-up by DEHS? | Environmental Health & Safety |

RADIATION

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| <input type="checkbox"/> Do you know the Radiation Protection Division's (RPD) procedures for packaging, labeling and pickup of radioactive waste? | Environmental Health and Safety |
| <input type="checkbox"/> Have you contacted RPD about transferring radioactive materials to a new use area? | Environmental Health & Safety |
| <input type="checkbox"/> Have you performed a contamination survey of all former storage and use areas within the lab or under the permit? | Environmental Health & Safety |
| <input type="checkbox"/> Have you scheduled the Radiation Safety closeout survey by RPD? | Environmental Health & Safety |

CONTROLLED SUBSTANCES

- | | |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------|
| <input type="checkbox"/> Have you completed the appropriate forms for transfer or disposal of all controlled substances? | Vice President for Research |
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ANIMALS

- If research activity continues once funding ends have you ensured your animals be maintained on a currently approved protocol? Research Subjects Protection

RESEARCH RELATED MATERIALS

- If you provide your research materials (biological, datasets, cell lines, seeds, plants, germplasm release, etc.) to an external source, have you prepared a Material Transfer Agreement? If you believe the material has commercial significance, contact STOR. Office of Science, Technology Transfer & Economic Outreach (STOR)
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- Did you return any unused materials to the sponsor or vendor? Otherwise, did you destroy any unused materials or documents? Sponsored Projects Services