

Laboratory Start-Up and Closeout Procedure

1.0 Purpose and Scope

1.1 The purpose of this procedure is to help new faculty with establishing a safe and compliant laboratory and to provide guidance to existing faculty to ensure proper decommissioning or relocation of existing laboratories.

2.0 Responsibilities

2.1 Department Chair / Dean

- 2.1.1 Ensures that faculty in the department/college receive communication of this procedure.
- 2.1.2 Notifies RMS when new research faculty are hired if they will be assigned a laboratory.
- 2.1.3 Provides the New Faculty Checklist to incoming research faculty.
- 2.1.4 Notifies RMS at least 30 days before faculty will be vacating lab.
- 2.1.5 Assumes the responsibilities or identify a Laboratory Director/Principal Investigator when the space is a shared area such as a cold room or cell culture room.
- 2.1.6 Accepts the cost of the relocation or disposal of hazardous materials and/or waste left if the Principle Investigator vacates the laboratory without complying with this procedure.

2.2 Laboratory Directors or Principal Investigators

- 2.2.1 Complete the New Faculty Checklist (see Appendix A) and forward the hazardous materials inventory to RMS.
- 2.2.2 Complete Laboratory Close-Out Checklist (see Appendix B) and forward to RMS two (2) weeks prior to vacating their laboratory.
- 2.2.3 Work with RMS to ensure the proper relocation or disposition of hazardous materials and/or waste in the lab.

2.3 Risk Management and Safety (RMS):

- 2.3.1 Conduct initial lab safety inspections for radioisotope use and Biosafety Level 2 (BSL2).
- 2.3.2 Conduct pre-closeout assessments to develop an exit strategy.
- 2.3.3 Conduct decommissioning (Close Out) inspections.
- 2.3.4 Arrange for any disposition of surplus materials/waste.
- 2.3.5 Provide guidance on shipping requirements of DOT Dangerous Goods.

3.0 New Laboratory Start-Up Procedures

3.1 Department shall notify RMS when new faculty have been hired and will require laboratory space.

- 3.2 Departments shall provide the New Faculty Checklist (Appendix A) to incoming faculty.
- 3.3 Principal Investigator shall provide RMS an inventory of all hazardous materials (chemicals, radioactive materials, biological materials, and select agents) that will come to campus.
- 3.4 Principal Investigator shall provide their department a list of equipment and, where applicable, decontamination certificate for equipment that will come to campus.
- 3.5 Lab Space Acceptance
 - 3.5.1 Principal Investigator shall walk through the lab to accept or reject any remaining chemicals and/or equipment.
 - If there are unwanted “legacy” chemicals and equipment the PI shall request the department remove prior to moving into the lab.
 - All accepted “legacy” chemicals and equipment become the sole responsibility of the new PI.
- 3.6 The PI shall submit Required Protocols as appropriate
 - 3.6.1 Institutional Biosafety Committee (IBC) – Work with Biohazards (blood, other bloodborne pathogens, cell/tissue cultures, parasites, bacteria, fungi, viruses, etc.)
 - 3.6.2 Recombinant DNA (rDNA) – rDNA Registration Document
 - 3.6.3 Institutional Animal Care, Use and Control Committee (IACUC) – animal work
 - 3.6.4 Institutional Review Board (IRB) – Human subject work
- 3.7 The PI shall schedule laboratory certification inspections as necessary with RMS.
- 4.0 Laboratory Closeout Procedures (Refer to Appendix B)
 - 4.1 Department shall notify RMS 30 days (or as soon as possible) of any faculty leaving the University that will require lab decommissioning.
 - 4.2 Faculty shall complete the Laboratory Closeout Survey (Appendix B) and submit to RMS at least 2 weeks prior to vacating the lab.
 - 4.3 Upon receipt, RMS shall schedule a walk through to review the closeout survey and assess disposal costs, shipping needs, etc.
 - 4.4 PI is responsible for general housekeeping including but not limited to:
 - 4.4.1 Hoods cleaned out and wiped down.

- 4.4.2 Bench tops and other work surfaces wiped down.
 - 4.4.3 Storage cabinets cleaned out and wiped down.
 - 4.4.4 Broken glass placed in broken glass container.
- 4.5 Biohazards and Biological Wastes
- 4.5.1 Identify biohazardous materials that will be relocated on campus or to new institution.
 - 4.5.2 Make arrangements to ship biohazards per DOT/IATA regulations.
 - 4.5.3 Place all sharps in a sharps container and dispose through RMS.
 - 4.5.4 Collect and autoclave all biohazardous waste. Double bag waste after autoclaving.
- 4.6 Chemicals and Chemical Waste
- 4.6.1 All containers shall be properly sealed (parafilm is acceptable, foil is not acceptable).
 - 4.6.2 All chemical containers shall be properly labeled (chemical name, concentration if appropriate and hazard class).
 - 4.6.3 Prepare inventory of all chemicals that will be left for next PI and give a copy to the Department Chair.
 - 4.6.4 All waste containers shall be properly labeled with a completed chemical discard tag.
 - 4.6.5 All unknowns shall be identified (at a minimum fingerprinted: pH, inorganic, organic, possible heavy metals).
- 4.7 Radioactive Hazards
- 4.7.1 Identify radioactive materials, sources and radiation producing machines that will be relocated at on campus or to new institution.
 - 4.7.2 Make arrangements to ship radioactive materials per DOT / IATA regulations with assistance from RMS.
 - 4.7.3 Perform swipe test on all areas where radioactive materials were stored or used.
- 4.8 Controlled Substances
- 4.8.1 All controlled substances shall be kept under lock and key, in a substantially constructed cabinet or safe until disposed or relocated.
 - 4.8.2 Arrange to keep all Controlled Substance records at least three (3) years.
 - 4.8.3 Make arrangements for either the destruction of unused controlled substances or to ship your controlled substances per DOT / IATA by emailing compliance@nd.edu.
- 4.9 Physical Hazards
- 4.9.1 Refrigerators/Freezers shall be cleaned and defrosted.

- If refrigerator and contents are remaining, arrangements shall be made to transfer ownership of refrigerator and contents to another PI.
 - If refrigerator/freezer and contents shall be moved to another institution, arrangements must be made with a licensed mover.
- 4.9.2 Any equipment that will be moved to another institution (centrifuges, liquid scintillation counters, Biosafety Cabinets, etc.) shall be decontaminated prior to shipping.
- 4.9.3 Lab equipment that will be discarded shall be decontaminated prior to departure.
- 4.9.4 Lab equipment that will be left for the next occupant shall be decontaminated prior to departure.
- 4.10 Final Laboratory Closeout - Appendix C
- 4.10.1 Departing PI shall complete and submit Final Laboratory Closeout document to the Department head for signature.
- 4.10.2 Department head shall forward a copy of signed Final Laboratory Closeout to Risk Management and Safety.

Appendix A: New Faculty Checklist (*This checklist does not need to be submitted.*)

The intent of this checklist is to help incoming faculty new to the University of Notre Dame navigate regulatory compliance and University procedures as they establish their laboratories. Research requiring approvals from a University committee or Risk Management and Safety are identified and appropriate contact information is provided. Understanding the requirements and starting the approval process prior to arrival helps to facilitate the prompt start-up of research programs at the University of Notre Dame.

Consideration	Yes	No	Action/Contact
Grant Transfers			Contact: Office of Research , 574-631-7432
Material Transfer Agreement (MTA)			Contact: Office of Research , 574-631-7432
Transfer equipment from another institution.			Develop an inventory of the laboratory equipment - including but not limited to: <ul style="list-style-type: none"> ● Refrigerators/Freezers ● Incubators ● Biosafety cabinets ● Centrifuges ● Lasers ● Machine shop equipment (band saws, drill press, lathe, etc.) ● Hoists/Lifts/Rigging Equipment ● Signed documentation from former institution regarding ownership If there is potential for biohazard, chemical or radiological contamination, there shall be a decontamination certification - including but not limited to: <ul style="list-style-type: none"> ● Biosafety cabinet ● Centrifuges ● Cell sorters ● Incubators ● Vacuum pumps The equipment inventory shall be sent to their Department Coordinator at least four (4) weeks prior to shipment. Contact: Procurement Services , 574-631-4289.
Transfer chemicals, biohazards (viruses, bacteria, fungi, parasites, cell lines, blood and tissues) and select agents.			Forward inventory (of all the materials to be moved to the University of Notre Dame) to Risk Management and Safety at least three (3) weeks prior to shipment. Shipping of chemicals, biohazards, and select agents may require a DOT

		<p>trained/licensed transporter package and ship.</p> <p>Contact: EHS at originating institution or the Biosafety Officer, Risk Management and Safety, (574)631-5037</p>
Transfer radioactive materials or radiation producing equipment.		<p>Radioactive materials or Radiation Producing Equipment must meet the University of Notre Dame's Radiation License requirements.</p> <p>Conduct an inventory of all materials to be moved to campus and forward to the Radiation Safety Officer at least three (3) weeks prior to shipment:</p> <ul style="list-style-type: none"> • Liquid Scintillation Counter • X-Ray units • Isotopes • Sealed and Non-Sealed Sources • Lasers <p>Contact: Radiation Safety Officer, Risk Management and Safety, (574)631-5037</p>
Research work involving rDNA, biohazards including but not limited to viruses, bacteria, human cell lines, mammalian embryonic stem cells and/or Select Agents.		<p>This research work requires an approved University of Notre Dame Institutional Biosafety Committee (IBC) protocol. Form can be found at https://nd.keyusa.net/.</p> <p>Contact: Biosafety Officer, Risk Management and Safety, 574-631-5037</p>
Research work involving human subjects.		<p>This research requires an Institutional Review Board (IRB) approval. Form can be found at https://nd.keyusa.net/.</p> <p>Contact: Office of Research, (574)631-7432</p>
Research work involving animals.		<p>Work involving animals requires an approved Institutional Animal Care and Use Committee (IACUC) protocol. Form can be found at https://nd.keyusa.net/.</p> <p>Contact: Office of Research, (574)631-7432</p>
Research work involving radioactive material or radiation producing machines.		<p>This research requires approval from the University's Radiation Control Committee. Form can be found at the RMS Radiation Safety webpage.</p>

		Contact: Radiation Safety Officer, Risk Management and Safety, (574)631-5037
Research work involving explosives, Investigative New Drug, importing vectors or plants.		Any other government agency licenses, permits, including but not limited to Food and Drug Administration (FDA), Alcohol, Tobacco and Fire Arms, (ATF), US Dept. of Agriculture (USDA), Indiana Dept. of Natural Resources (DNR) Contact: Chemical Hygiene Officer , Risk Management and Safety, 574-631-5037
Research involving other special concerns (not covered above).		Contact: Department Coordinator or the Biosafety Officer , Risk Management and Safety, 574-631-5037



Appendix B - Laboratory Pre-Closeout Survey

Top half to be completed by researcher at least 2 weeks prior to departure. Once completed, call RM&S (1-5037) to conduct a close out inspection.

Researcher Name: _____ Email: _____ Phone: _____

Contact Name/Information if Researcher not available: _____

Dept.: _____ Building and Lab#(s): _____

Departure/Move-out Date: _____

Types of Hazardous Materials Used and/or Still Present:

- Chemicals Biohazardous Materials
- Gas Cylinders/Lecture Bottles Radioactive Materials
- Controlled Substances

Are all containers clearly labeled?..... Yes No

Are all containers sealed?..... Yes No

Were any of the above transferred to other ND personnel? Yes No If yes, who?

_____ Will any need to be shipped to another institution/facility? Yes No

Are there any waste containers?..... Yes No

Are all waste containers clearly labeled?..... Yes No

Are all waste containers sealed?..... Yes No

TO BE COMPLETED BY RISK MANAGEMENT AND SAFETY

Chemicals: _____ Estimated Cost: _____

Biohazards: _____ Estimated Cost: _____

Gas Cylinders: _____ Estimated Cost: _____

Radioactive Materials: _____ Estimated Cost: _____

Waste: _____ Estimated Cost: _____

Shipping Needed: _____

Additional Comments: _____

Researcher or Designee Signature: _____ Date: _____

RMS Signature: _____ Date: _____

RMS Signature: _____ Date: _____

Dept. Chair or Designee Signature _____ Date: _____

Appendix C - Final Laboratory Closeout Checklist

TASK	Date Completed or N/A
Biohazardous Materials	
Sharps (razor blades, syringes, scalpel blades) collected and placed in sharps containers for disposal with RMS.	
Collect and autoclave all biohazardous waste. Double bag for trash disposal.	
Moving biohazards off campus, arrangements made for shipment.	
Clean and disinfect work surfaces, refrigerators, incubators, centrifuges, etc.	
Chemicals	
Inventory of chemicals completed and provided to Department Chair.	
Moving chemicals off campus, arrangements made for shipment	
Transfer ownership of chemicals to another PI who has agreed to take them.	
Identify unknowns: Fingerprinted (pH, inorganic/organic/heavy metals).	
Label all wastes with a chemical discard tag.	
Dispose (or arrangements made for disposal) of all unwanted chemicals through RMS.	
Place broken glass in sharps container.	
Clean all surfaces with detergent.	
Controlled Substances	
If transferring substances to another DEA registrant, submit appropriate forms to the DEA prior to transfer.	
If disposing substances, submit appropriate forms to the DEA prior to and after disposal.	
Conduct appropriate transfer or disposal of controlled substances.	
Gas Cylinders	
Remove regulators/gas connections and replace safety caps.	
Return to supplier.	
Contact RMS to arrange for disposal of non-returnable cylinders.	
Radioactive Materials, Sources, Radiation Producing Machines	
Inventory of radioactive materials, sources and/or radiation producing machines that will be moved to another institution	
Arrangements have been made to ship materials/equipment.	
If transferring materials to another RI at Notre Dame, notifications have been made to Risk Management and Safety.	
Prepare wastes for disposal.	
Arrangements have been made for RMS to conduct final decommissioning inspection.	

Equipment	
Clean and decontaminate equipment that will be moved or left in place.	
Contact RMS for assistance with disposal of equipment.	
Shared Space	
Check all shared space for chemicals, biohazardous materials and radioactive materials and sources.	
Clean all work surfaces.	
Department Sign-Off	
Submit Completed Checklist to Department Head for signature	
TASK	Date Completed or N/A

Researcher Signature: _____ Date: _____

Department Head Signature: _____ Date: _____

Laboratories Closed Out (Building and Room #'s) _____

Send a copy of the Signed Final Laboratory Closeout to Risk Management and Safety