University of Nebraska-Lincoln
PI Regulatory Onboarding Checklist

This checklist is intended to be used as a guidance for onboarding new investigators and ensuring compliance with applicable regulations and policies.

The Office of Research and Economic Development's (ORED) offices and policies and procedures should be referenced when using this checklist.

Once you have obtained your UNL email and credentials, make sure to register with the UNL electronic research administration system, NUgrant.

Sponsored Research

Are there awards transferring with you to UNL?

Awards are made to the institution, so it is important to begin work with your previous institution prior to your departure to secure approvals to transfer awards to UNL. If approved, work with your UNL department and Sponsored Programs (OSP) pre-award grants coordinator to prepare for the transfer to UNL.

At your previous institution:

❒ The sponsored programs office, or equivalent, will request instructions from the sponsor on how to transfer their projects to UNL.

❒ You will need to stop charging to the project for a period of time before a transfer can be initiated. The transfer process can take up to several months depending on the sponsor.

❒ Complete appropriate transfer materials/relinquishment forms depending on agency requirements and your home institution policies.

At UNL:

❒ Work with your department to develop budgets and other forms

❒ Route project information, including budget, through NUgrant for approval by your department/college.

Do you have sponsor system registrations that need to be updated?

❒ Update your institution information and/or notify your pre-award coordinator of sponsor system registrations that must be updated (e.g., eRA Commons, Research.gov, GrantSolutions, G5, etc).

Will materials or equipment be transferred with you to UNL?

At your previous institution:

❒ Work with the sponsored programs office, or equivalent, to obtain institutional and sponsor approvals to transfer materials and/or equipment to UNL.

At UNL

❒ If you are transferring material, you may need to establish a Material Transfer Agreement (MTA). Notify UNL Sponsored Programs via unlmta@unl.edu that you plan on bringing

material(s) with you so that this agreement can be initiated as appropriate. (UNL Incoming MTA Request Form).

- Materials that could require an MTA typically include cell lines, tissues, sera, DNA, transgenic animals, plasmids, vectors, etc. or other research materials such as compounds, sensors, and software etc.

❒ Work with your new department to properly record incoming equipment.
- Prior to bringing equipment to campus, ensure you notify Export Control staff if any of your equipment is export controlled.
- Note that equipment purchased with federal funds will typically require sponsor approval prior to transfer to UNL.

Will data (physical or electronic) be transferred with you to UNL?

❒ If you are sharing or transferring data, you may need to establish a Data Use or Data Transfer Agreement (DUA/DTA) between UNL and your previous institution. Verify whether your previous institution requires a DUA/DTA with UNL. If a DTA is required by your previous institution please put them in contact with the OSP Awards Team. The Data Sender is typically responsible for drafting the agreement.

These agreements usually fall into two different categories:
1. Non-human subject data or completely de-identified human research participant data (as determined by UNL's IRB), or
2. Human research participant data which could include Protected Health Information (PHI). This includes data which constitutes a Limited Data Set as defined by HIPAA. UNL IRB will review agreements that involve this type of data and help inform UNL Sponsored Programs of any necessary steps regarding this type of transfer if it involves human subjects research.
    a. *Note that UNL is a hybrid entity under HIPAA, so new researchers may need to clarify whether specific security procedures have been implemented prior to transferring HIPAA regulated information to their new department.*

Institutional Review Board (IRB)

Does your work involve human research participants?

❑ Complete UNL's human subjects research training.

❑ For any human subjects protocols (new or transferring), complete a submission application within the IRB module of NUgrant.

❑ Identify any protocols that may have required ClinicalTrials.gov registration and discuss this with the UNL IRB accordingly regarding appropriate registration responsibility.

❑ Familiarize yourself with UNL's Human Research Protection Program Policies (HRPP), Guidelines, and Templates/Forms, which can all be found on the IRB website linked above.

Note that, unlike most other states, age of majority in Nebraska is 19 y/o, not 18y/o.

Institutional Animal Care Program (IACP/IACUC)

Does your work involve animal subjects?

❑ Complete UNL's institutional animal care- general regulations training (GRT).

- ❑ For any animal protocols (new or transferring), complete a submission application within the IACUC module of NUgrant.
    - *Contact the IACP to seek facility access as appropriate for work with animals.*
- ❑ Familiarize yourself with UNL's IACP Policies, Guidelines, and Templates/Forms, which can be found on the IACP website linked above.

Institutional Biosafety Committee

Does your work involve recombinant and/or synthetic nucleic acid molecules, genetically modified animals or plants, human, animal or plant pathogens, biological toxins, or human materials?

- ❑ Contact the UNL Biosafety Officer at ibc@unl.edu to determine if your research will require a protocol submission to the IBC.
    - Submit a new protocol form within the IBC module of NUgrant.
    - Take online safety training modules required by the IBC.

Research Safety

Does your work involve hazardous materials or laboratory-based research?

- ❑ All UNL employees must take the following online safety training modules:
    - Core – Injury and Illness Prevention Plan
    - Core – Emergency Preparedness
- ❑ Review the EHS Training Needs Assessment and complete the identified applicable training modules.
- ❑ Review the Environmental Health and Safety (EHS) website (linked above) for guidance on UNL requirements regarding Biosafety, Environmental Protection, Ionizing Radiation, Occupational/Lab Safety, and Regulated Waste and contact EHS with any questions.
- ❑ Establish a Virtual Safety Manual and review its content.

Ionizing Radiation

Does your work involve ionizing radiation (open source) or radiation-producing equipment?

- ❑ Contact the Radiation Safety Office at rso@unl.edu for instructions regarding the application and approval process through the Radiation Safety Committee.

Intellectual Property/Start-ups

- ❑ If you have previously filed patents, have been involved in a start-up company, or intend to utilize pre-existing IP in your work, contact NUtech Ventures via the website linked above.

Conflicts of Interest/Commitment (COI/COC)

- ❑ If you are PHS funded, you must complete UNL's conflict of interest in research training prior to receipt of funds.

- ❑ Research personnel are required to complete a COI disclosure annually. The disclosure is required before proposal submission (updates must be submitted within 30 days of a change to your disclosure). This disclosure, called the Interest and Outside Activity Reporting Form (IOARF), can be found within the Interest and Activity Management (IAM) module in NUgrant. Complete your disclosure whether you have anything to report or not.
    - Note that the disclosure (IOARF) satisfies both COI in research and NU Board of Regents requirements for Conflicts of Commitment annual reporting.

- ❑ If you had a management plan for a conflict of interest at your previous institution, please contact the COI Coordinator directly.

- ❑ Familiarize yourself with UNL's COI Policies, Guidelines, and Templates/Forms and the Board of Regents Conflict of Commitment Policies, all which can be found on the COI website linked above.

Export Control Compliance Program (ECCP)

Does your work involve export controls?

- ❑ Confirm whether or not you are engaged in any research or export controlled activities (i.e. ITAR, EAR, or any other projects that have contractual restrictions, specific security requirements, publication restrictions, or foreign national restrictions).

- ❑ Familiarize yourself with UNL's Export Control Policies, Guidelines, and Templates/Forms, which can be found on the website linked above.

- ❑ If you had a technology control plan (TCP) or determination of export controlled activity at your previous institution, please contact the Export Control Coordinator directly.

Scientific Research Oversight Committee (SROC)

Does your work involve human embryonic stem cells (hESC) or human fetal tissue (hFT)?

- ❑ Complete UNL's SROC training.

- ❑ This type of research is permissible in Nebraska but requires approval and has some limitations specific to funding, providers, and cell types. Familiarize yourself with UNL's SROC Policies, Guidelines, and Templates/Forms, which can be found on the website linked above.

Responsible Conduct of Research (RCR) & Research Misconduct

Do you have funding that requires completion of RCR training?

- ❑ Familiarize yourself with UNL's Responsible Conduct of Research & Research Misconduct, Policies, Training, and Guidelines, all which can be found on the website linked above.
- ❑ Familiarize yourself with UNL's Research Integrity Officer (RIO) and Research Misconduct Policy. If you have any questions or concerns regarding research misconduct while you are at UNL, you should direct those questions or concerns to the RIO or the Director of Research Compliance.
    - UNL treats all research misconduct allegations seriously and confidentially. All institutional members are obligated to promptly report observed, suspected, or apparent research misconduct to the Research Integrity Officer (RIO).