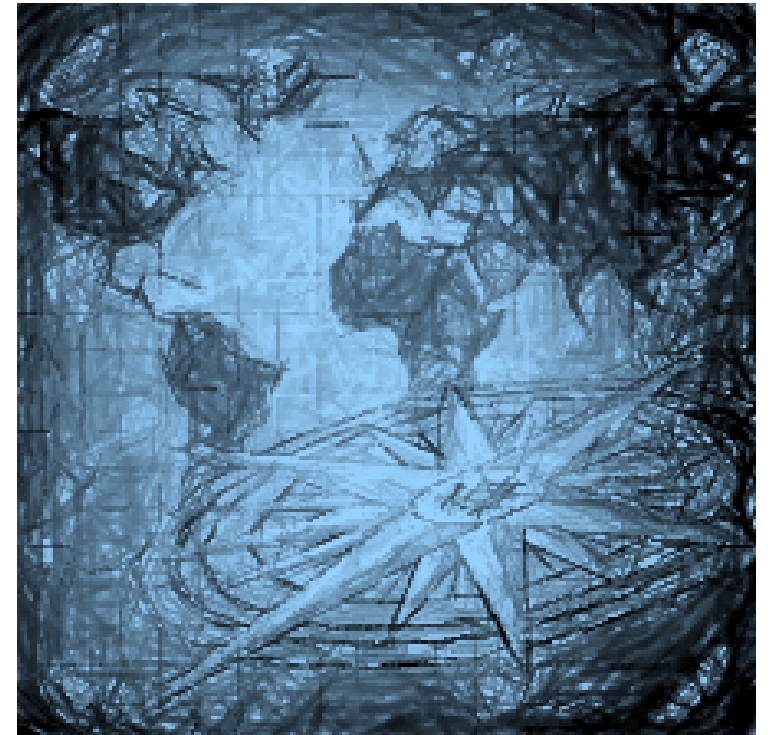
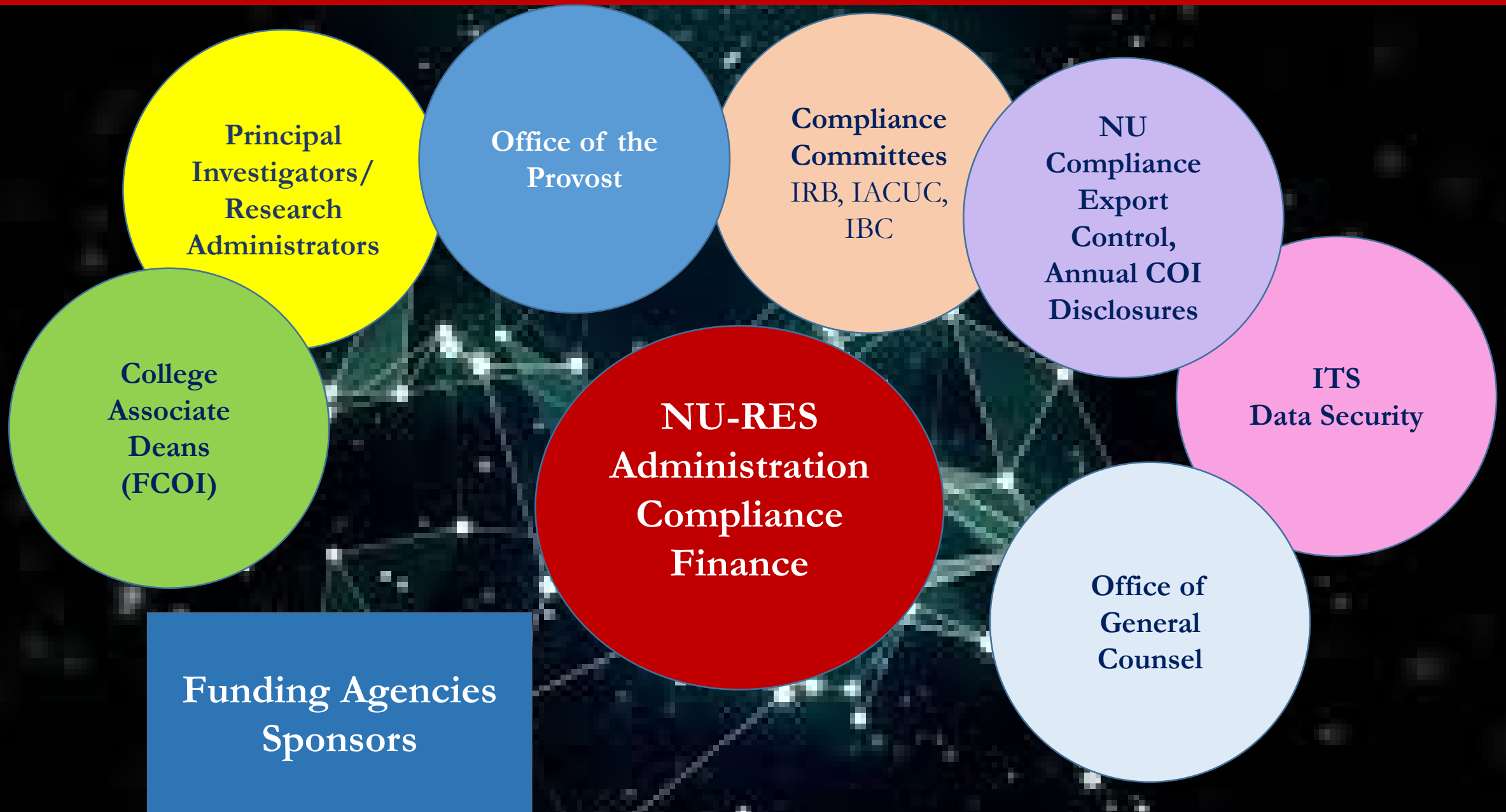


LEARN MORE: **Regulatory** **Refresh & Updates**

NU-RES
April 2021



Northeastern University



Institutional Certifications and Assurances

- Northeastern University, as a grantee, provides at the time of proposal submission and throughout the life-cycle of an award certifications and assurances that it is in full compliance with all relevant laws, rules and regulations.
- How each grantee implements its research management responsibilities varies but all grantees should include documented practices that address specific regulatory requirements.
- Some regulations required that the grantee monitor the research activity; monitoring involves verification and tracking of compliance with a specific term or condition of the award.

Learning Objectives

- Understand your and NU-RES' roles in assisting investigators and Northeastern in complying with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (more commonly known as UG or Uniform Guidance) and non-financial regulatory requirements (e.g., OLAW, 45 CFR 46, Biosafety, Export Controls, etc.)
- Identify the various institutional offices responsible for non-financial research regulatory oversight;
- Understand the consequences of failure to properly monitor (verify & track) award compliance.

2021

NIH: Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021

Other Support includes *all* resources made available to a researcher in support of and/or related to all of their research endeavors, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant. This includes but is not limited to:

Resources and/or financial support from all foreign and domestic entities, that are available to the researcher. This includes but is not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.). Institutional resources, such as core facilities or shared equipment that are made broadly available, should not be included in Other Support, but rather listed under Facilities and Other Resources.

Consulting agreements, when the PD/PI or other senior/key personnel will be conducting research as part of the consulting activities. Non-research consulting activities are not Other Support.

In-kind contributions, e.g. office/laboratory space, equipment, supplies, or employees or students supported by an outside source. If the time commitment or dollar value of the in-kind contribution is not readily ascertainable, the recipient must provide reasonable estimates.

Reminder - NSF

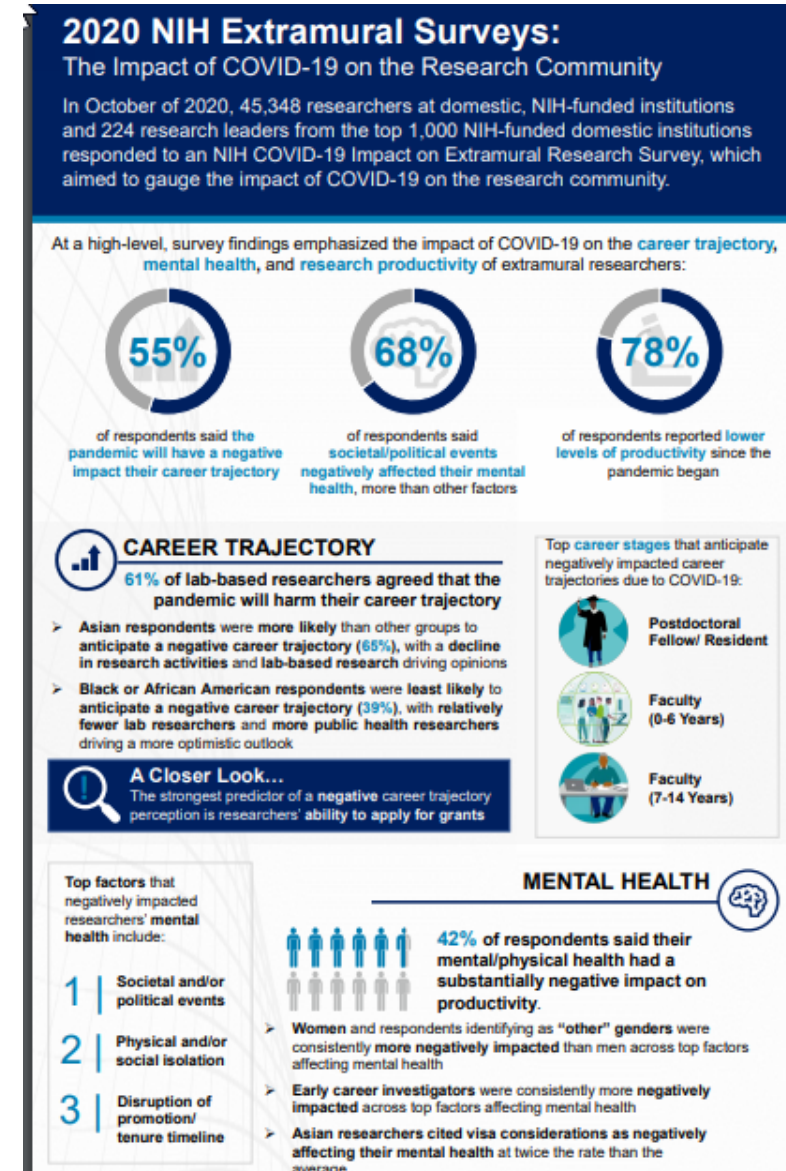
(b) Appointments

A list, in reverse chronological order by start date of all the individual's academic, professional, or institutional appointments, beginning with the current appointment.

Appointments include any titled academic, professional, or institutional position **whether or not remuneration is received**, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary)

2021

- NIH Survey Impact On Research:
- COVID-19 Flexibilities: OMB M-21-20 and agency implementation guidance.



2021

Data Privacy & Security

- Protected Health Information (PHI),
- Confidential and/or Proprietary
- Controlled Unclassified Information
- ITS' Secure Data Enclave
- Controlled Unclassified Information
- Cybersecurity Maturity Model Certification
- GCC@northeastern.edu

2021

Measurable Effort on Research Awards & Total Professional Effort

Although voluntary uncommitted cost sharing will no longer be included in the organized research base, it should be noted that current A-21 provisions for payroll distribution (section J.8.b) require that the apportionment of salaries and wages must be supported by a payroll distribution system that "will encompass both the sponsored and all other activities on an integrated basis." The process must also identify significant changes in the corresponding work activity. As such, when an institution reduces a faculty member's level of activities dedicated to other institutional responsibilities in order to shift his/her activities to organized research activities, the institution must reflect this reduction in the payroll distribution system (as an increase to the research effort component) and in the F&A proposals.

In addition, most Federally-funded research programs should have some level of committed faculty (or senior researchers) effort, paid or unpaid by the Federal Government. This effort can be provided at any time within the fiscal year (summer months, academic year, or both). Such committed faculty effort shall not be excluded from the organized research base by declaring it to be voluntary uncommitted cost sharing. If a research program research sponsored agreement shows no faculty (or senior researchers) effort, paid or unpaid by the Federal Government, an estimated amount must be computed by the university and included in the organized research base.

KEY CONCEPTS

Financial:

- Fraud
- Waste
- Abuse
- Monitoring = Verification & Tracking
- Documentation
- Consequences: Administrative, Civil, Criminal

Non-Financial:

- Protection Against Harm

INSTITUTIONAL OVERSIGHT

| Office | Areas of Research Compliance |
|--|--|
| NU-RES: Research Administration | Authorized Organizational Official |
| NU-RES: Research Compliance | Chief Research Compliance Officer; NSF and Sponsored Programs Award Compliance Program; Research Misconduct; Responsible Conduct of Research, Export Controls; Human Subject Research, Animal Use. |
| NU-RES: Research Finance | Grant and contract expenditures; cost share, institutional base salary; measurable effort; Time & Effort (salary) certification. |
| Office of General Counsel (OGC) | Research, Data Compliance; Conflicts of Commitment & Interests |
| Information Technology Services | Data Security |
| Office of the Provost | Lab Safety; BioSafety; Faculty Affiliations |
| College Deans | Designated Official: Financial Conflicts of Interest |

General:

GUIDANCE

Northeastern University:

- [Animal Welfare](#)
- [BioSafety](#)
- [Human Subject Research](#)
- [Uniform Administrative Requirements, Cost Principles, and Audit Requirements](#)
(aka Uniform Guidance)
- [Federal Acquisition Regulations \(FAR\)](#)

- Policies
- NU-RES Guidance

Funding Agencies:

- NIH Grants Policy Statement <https://grants.nih.gov/policy/nihgps/index.htm>
- NSF PAPPG https://www.nsf.gov/publications/pub_summ.jsp?ods_key=papp

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|-----------------------------------|--|-------------------|--------------------------|--|---|---------------|
| Financial | Non-allowable Expenditures | PI/College | NU-RES Finance | Financial Reports, T&E Certifications | Uniform Guidance 2 CFR 200 et.seq. and/or FAR | Certification |
| COVID-19 Financial Impacts | Allowability of award expenditures during an Emergency when personnel are idle or the expense was incurred but the event did not occur (e.g., travel,). | PI/College | NU-RES Finance | Documentation of expenditure and explanation of specific COVID-19 impact | OMB/Agency specific guidance | Certification |

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|----------------------|--|----------------------|--|---|-------------|-----------|
| Non-Financial | | | | | | |
| Animals | Humane Use and Care for Animals Used in Testing, Research & Training | PI/Project Personnel | NU-RES Compliance: Department of Laboratory Animal Medicine (DLAM) and Institutional Animal Care and Use Committee (IACUC) | Congruence between an approved IACUC proposal & the research activity | OLAW | Assurance |

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|----------------------|---|----------------------|---|---|--------------------------|----------------|
| Non-Financial | | | | | | |
| BioSafety | Lab Safety <ul style="list-style-type: none"> • Personnel • Environment | PI/Project Personnel | Environmental Health & Safety (EHS) and the Institutional Biosafety Committee (IBC) | EH&S and/or the IBC reviews research activities to identify hazards (chemicals, materials, waste); regulatory registration requirements, select agents, and dual-use research concerns. | Local, state and federal | Certifications |

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|--------------------------------------|--|--------------------------|---|--|------------------------------|---------------|
| Non-Financial | | | | | | |
| Conflicts of Interest | | | | | | |
| COI: Organizational Conflicts | Northeastern will improperly benefit from an award | Provost's Office | Center for Research Innovation (CRI) and NU-RES Compliance | Documentation of the University's interests in or relationships with other entities that may interfere with impartial performance or give the University unfair advantage. | Agency specific requirements | Certification |
| COC: Conflicts of Commitment | Investigators' commitments will create conflicts of appearance of improper | PI and Project Personnel | Provost's Office; University Compliance; NU-RES | Documentation of affiliations; disclosure via eCD and, as applicable, proposal documentation | Agency specific requirements | Certification |

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|--|---|-------------------|---------------------------------------|---|-----------------|---------------|
| Non-Financial | | | | | | |
| Conflicts of Interest | | | | | | |
| COI: Objectivity in Research (Bias) | Research findings and results may be biased by an investigator's financial interest in the research outcomes. | PI/College | NU-RES Compliance | PHS Financial Conflict of Interest Management Plans | PHS | Certification |
| COI: Financial Conflicts | Investigators or Project Personnel will improperly financially | PI/College | University Compliance and Procurement | Northeastern's CMAP | Agency-Specific | Certification |

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|---|---|--------------------------|----------------------------------|--|--------------------|---------------|
| Data Security | | | | | | |
| Personal Health Information (PHI) or Personally Identifiable Information | Privacy | PI and Project Personnel | NU-RES Compliance: IRB | IRB Protocol | 45 CFR 46; GDRP | Certification |
| Confidential or Controlled Unclassified Information (CUI) | Investigators or Project Personnel will improperly store or disclose confidential information | PI | NU-RES Compliance; ITS | Terms & Conditions of Award and/or Agreement | Agency-Specific | Certification |

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|-----------------------------------|---|---|-------------------------|--|-----------------|---------------|
| Non-Financial | | | | | | |
| Export Controls | Protect controlled technologies | PI/Project Personnel | NU-RES Compliance – | NU-RES Compliance reviews all research activity that is not governed by the Fundament Research Exclusion (FRE) and issues a Technology Control Plan (TCP) | EAR, ITAR, OFAC | Certification |
| Restricted Party Screening | Preventing engagement with individuals who may be disbarred or otherwise prevented from receiving federal funds | College/NU-RES and/or University Compliance | NU-RES Compliance | For Research & Sponsored Activities NU-RES documents in the other party's profile. | Federal | Certification |

MAJOR AREAS OF CONCERN

| Area | Issue | Responsible Party | Institutional Oversight | Verification Tracking | Regulations | NU |
|--|--|----------------------|---|---|---------------------------------|---------------|
| Non-Financial | | | | | | |
| Human Subjects | Protecting study subjects in research projects, privacy re: personally identifiable data | PI/Project Personnel | NU-RES Compliance – Office of Human Subject Research Protections | IRB’s certification that it has reviewed the research activity. <ul style="list-style-type: none"> Human Subjects Determination Form Exempt Studies Self-Determination Form IRB Protocol or Reliance Agreement | 45 CFR 46 (aka the Common Rule) | Assurance |
| Stem Cells <ul style="list-style-type: none"> hESC Non-Human Stem Cells | | | NU-RES Compliance Stem Cell Review Oversight (IRB and/or IBC) | Review of research activity against applicable protocols. | State and Federal | Certification |

BEST PRACTICES

Review Compliance Requirements/Checklists

General

Eligibility

Duplicate Funding

Matching Funds

Misrepresentations

Financial

Allowability

Allocability

Non-Financial

Failure to obtain required approvals and/or training;

Failure to disclose or report.

For more information please see
<https://research.northeastern.edu/nu-res/>



Or contact NU-RES@northeastern.edu