QuickCard: Coeus Special Review Types

Northeastern University
Research Enterprise Services

Coeus can now capture Compliance and Administrative information that is subject to a review by NU-RES and other regulatory compliance and administrative offices. To help provide information on elements that require review, and to be able to report on these elements, NU-RES staff can add information to the Award and/or or Institute Proposal as a Special Review.

- **Human Subjects (IRB):** Human subject research is any research or clinical investigation that involves human subjects. "Human Subject" is defined in the Code of Federal Regulations as "a living individual about whom an investigator conducting research 1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; OR 2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens." Institutional Review Board (IRB) provides assurance and approval for projects involving human subjects, for applicable projects, a copy of the IRB approval should be on file.
- **Animal Usage (IACUC):** All activities involving the use of live vertebrate animals used or intended for use in research, research training, experimentation, biological testing or for related purposes. Institutional Animal Care and Use Committee (IACUC) provides assurance and approval for projects involving vertebrate animals. For applicable projects, a copy of the IACUC approval should be on file.
- **Radiation:** Materials requiring approval from the NU Radiation Safety program. For applicable projects, a copy of the approval should be on file. Materials include:
    - Ionizing radioactive materials (radionuclides in unsealed/sealed sources)
    - Ionizing radiation producing devices (x-rays, scanning electron microscopes)
    - Non-ionizing radiation producing devices (class 3B/4 lasers)
    - High powered magnets (MRI/NMR)
    - Radio frequency producing devices
- **Biosafety Materials:** Materials requiring approval from the NU Biosafety program. For applicable projects, a copy of the approval should be on file. Materials include:
    - Recombinant or synthetic nucleic acids/materials
    - Viral vectors,
    - Human or non-primate cell lines
    - Human sourced materials
    - Biological toxins
    - Infectious agents including bacteria, viruses, fungi, prions, parasites
    - Non-human primate or non-primate source materials
- **Chemical Hazards:** Materials requiring oversight from the NU Laboratory Safety program, there is no official approval process for these, but the NU Laboratory Safety program should be notified if these materials are used to ensure that the appropriate facilities and SOPs are in place for the work. Materials include:

Getting Help
Support: NU-RESHC@northeastern.edu
Grant Officer: https://research.northeastern.edu/nu-res/contact/

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  - Particularly Hazardous Substances (OHS) with high acute toxicity, carcinogens, reproductive toxins, and highly reactive chemicals.
  - Research involving nanoparticles
  - Hazardous gases including flammable gases and toxics
  - Controlled substances
- **Additional/Altered Space:** New or changed space required to carry out the research.
- **Capital Equipment:** Capital equipment will be purchased or fabricated to carry out the research. Capital equipment is defined as an article of nonexpendable, tangible property with a useful life of more than one year, and an acquisition cost of $5,000 or more per unit. Fabricated equipment is defined as scientific or other complex equipment comprised of a number of individual components that are fabricated/built into a single functional unit. Fabricated equipment is capitalized as a single asset for a combined total cost of $5,000 or more and a useful life of more than one year.
- **Proprietary Information:** The research contains information which is proprietary and should not be shared.
- **Course Buy-out:** If the proposal is awarded, the researcher will need a substitute teacher to cover courses he/she might have been leading but will instead be working on the research during the time the course is run.
- **Conflict of Interest (COI):** A divergence between an individual's private interests and his or her professional obligations to the university such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise. This should be selected when the terms and conditions indicate that NU needs to have a COI policy but does not specifically fall under the fCOI parameters. For instance, many funding agencies ask that the organization confirms it has no COI related to the project. The COI policy could also be broader than fCOI in that they want us to review for unpaid/volunteer activities. If you see a reference to reviewing the award for any activities/interests that could bias the work, select this option.
- **Financial Conflict of Interest (FCOI):** A financial conflict of interest (FCOI) as detailed in the PHS regulations and covered in the NU's FCOI Policy, is a financial interest held by an Investigator that could directly and significantly affect the design, conduct, or reporting of the research. This should be selected when the funding agency follows the PHS regulations, is NSF or the NOA specifically indicates that NU must review an individual investigator's financial conflicts of interest. A completed fCOI form should be on file.
- **Responsible Conduct of Research (RCR)**: The practice of scientific investigation with integrity involving the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Many funding agencies and scientific organizations now consider the formal instruction in the responsible conduct of research to be an essential component of research training in science. In keeping with this view, NSF and NIH have specific requirements around RCR

training. This should be selected for awards that support students (undergraduate through doctoral) and/or Post Docs on any NSF funded project or for NIH training awards under the T, F, and K series. Award file should include a copy of the notification we send to the PI regarding their RCR obligations.

- **Clinical Trials.gov**: This should be selected for NIH projects that are classified as clinical trials, for these projects, the PI will need to register the project on clinicaltrails.gov. If this is YES, the human subject (IRB) option should also be selected, and project should have IRB approval on file.
- **Stem Cell Research Oversight (SCRO):** Research activities that include the use of Human Embryonic Stem Cells (hESCs or hES) and may require approval from the Northeastern IRB. In addition, Research Compliance needs to be consulted to ensure work with the particular cells can proceed.
- **Dual Use Research Concern (DURC):** Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security." – NIH OIR. Please see the Oversight of Practices and Procedures for Potential Dual Use Research of Concern document for list of special agents that could pose DURC. Please note, the NU Biosafety Program must be notified if the research involves any agents on the IODURC list.
- **Small Unmanned Aircraft Systems (sUAS)**: The Unmanned Aircraft System (UAS) Review Board is responsible to review, approve, and monitor the use or proposed use of UAS's, also known as unmanned aerial vehicles and drones, on university property for any reason, including for education/research, recreational or commercial purposes. If project involves use of sUAS, approval from the UAS review board should be on file.
- **Restricted Research:** Select this when funding agency restricts who can participate in the performance of the research (ex: no foreign nationals) and/or restricts the dissemination of results (ex: publications require prior approval).
- **e-Verify**…a database system operated by the Department of Homeland Security in partnership with the Social Security Administration. It allows participating employers to electronically verify the employment eligibility of newly-hired employees. Currently NU HR conducts the e-Verify check upon hire. Typically, e-Verify requirements are applicable to Federal Contract/Subcontracts when clause FAR 52.222-54 is included.
- **Export controls**: U.S. laws and regulations that regulate and restrict the release of critical technologies, information, and services to foreign nationals, within and outside of the United States, and foreign countries for reasons of foreign policy and national security. The scope of export-controlled items is very broad and includes, but is not limited to, equipment, software code, chemical and biological materials, and technical data. This should be selected when either:
    - There is a Technology Control Plan (TCP) required by the Contract.

  - When the Contract is not considered fundamental research and export controls may govern the scope of work and/or results
  - When the Contract states that we may be receiving export-controlled information from a funding agency (federal or otherwise).
- **International**: Select this when there is an international engagement under the project. This could include a subaward, international travel to a conference, use of a foreign consultant or collaborator (either paid or unpaid).
- **Cybersecurity Maturity Model Certification (CMMC)**: A unifying standard certification rubric for the implementation of cybersecurity across the Defense Industrial Base (DIB). The CMMC framework includes a comprehensive and scalable certification element to verify the implementation of processes and practices associated with the achievement of a cybersecurity maturity level. CMMC is designed to provide increased assurance to the Department that a DIB company can adequately protect sensitive unclassified information, accounting for information flow down to subcontractors in a multi-tier supply chain. Award documents should indicate if this is applicable to the project.
- **Controlled Unclassified Information (CUI):** A set of data categories that have specified security or dissemination controls of federal non-classified information that the U.S. Government creates or possesses, or that a non-federal entity (i.e. Northeastern) receives, possesses, or creates for, or on behalf of the U.S. Government, that requires certain information security controls to safeguard. CUI may include research data and other project information that a research team receives, possesses, or creates during the performance of a contract funded by the federal government. Award documents should indicate if this is applicable to the project.
- **National Institute of Standards & Technology (NIST):** Cybersecurity requirements for primes and subcontractors that are audit ready, third party verified; for example, NIST 800-171 is one set of specified IT Security controls. Award documents should indicate if this is applicable to the project.
- **Secure Data Enclave (SDE)**: A secure, centralized service for faculty and researchers that work with sensitive research data. The SDE meets the high watermark of security policy to ensure that restricted information is protected per local, federal, and international laws. This applies and should be selected when PII/PHI is being stored, generated, and/or received by NU researchers. For DUAs, Brooks connects with ITS/Research Computing via eCLAWs consult. At award stage, for projects that don't involve DUAs, GOs should review the SOW to see if PII/PHI is being generated, stored, and/or received and ensure ITS/RC have been informed. The idea is to make ITS/RC aware so they can connect with the PI.
- **Personally Identifiable Information (PII):** Any representation of information that permits the identity of an individual to whom the information applies to be reasonably inferred by either direct or indirect means. Further, PII is defined as information: (i) that directly identifies an individual (e.g., name, address, social security number or other identifying number or code, telephone number, email address, etc.) or (ii) by which an agency intends

to identify specific individuals in conjunction with other data elements, i.e., indirect identification. (These data elements may include a combination of gender, race, birth date, geographic indicator, and other descriptors). Additionally, information permitting the physical or online contacting of a specific individual is the same as personally identifiable information. This information can be maintained in either paper, electronic or other media. If the project describes use of identifiable human subject data, the human subject (IRB) option should also be selected, and project should have IRB approval on file.

- **Protected Health Information (PHI):** The HIPAA Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information. At the same time, the Privacy Rule is balanced so that it permits the disclosure of personal health information needed for patient care and other important purposes. This should be selected only when project indicates that NU is receiving identifiable personal health information (PHI) from a Covered Entity (as defined by HIPAA). Even though NU is not a covered entity, diligence in this area is prudent and tracking these instances benefits the University. See this reference chart for more details. If PHI is applicable, the human subject (IRB) option should also be selected, and project should have IRB approval on file.