NU–IACUC POLICY

Northeastern University Institutional Animal Care and Use Committee

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| **Northeastern University Post-Approval Quality Assurance Program** |

*Re-Approved: 02/08/2022*

**Performance Standard:**

The goal of the post-approval quality assurance (QA) program is to work with, and support, research staff members and to confirm accurate and consistent protocol adherence in a collegial and unobtrusive manner.

**Background:**

Post approval oversight of Institutional Animal Care and Use Committee (IACUC) protocols is performed to assure regulatory agencies and Northeastern University that animal experiments comply with approved IACUC protocols. The DLAM Director will designate DLAM staff member(s) as QA Assessors to carry out the post-approval quality assurance program to assess compliance with approved protocols practices.

**Roles:**

* Investigators and research personnel: Will work with the visiting DLAM QA Assessor to facilitate observation of procedures and to document compliance with approved protocols. The PI can request to be present during the assessments.
* DLAM QA Assessor: Will work with the investigator and research personnel to observe activity, prepare accurate reports, and provide training and recommendations for maintaining compliance, if necessary. Will coordinate visits, correspondence, and documentation, maintain record, and correspond with the IACUC.
* Institutional Animal Care and Use Committee (IACUC): Shall provide operational oversight of the DLAM QA Assessor and the post-approval quality assurance program, ensure that the IACUC receives reports or updates on items of concern, and provide training and support as required for compliance.

**Required Protective Measures:**

The DLAM QA Assessor, as well as other visitors, shall wear the personal protective equipment (PPE) prescribed for the specific activity/procedure of the laboratory. Due to the sensitive nature of some experiments, the DLAM QA Assessor will use extra caution not to disrupt the procedures and experiment.

**Policy Expectations:**

1. Selection of Protocols for Review:
2. Active protocols will be checked randomly, or at the direction of the IACUC and/or veterinary personnel. This will be based on active protocols.
3. In general, the DLAM QA Assessor or designee will schedule monitoring sessions with the Principal Investigator or other research personnel in advance.
4. “For cause” monitoring may be conducted at any time, with or without advance notice to the Principal Investigator or research personnel, as per standard and current IACUC practices.
5. All new sessions will be independent of previous assessments and the DLAM QA Assessor will give an unbiased assessment.

II. Process of the QA Program:

1. The DLAM QA Assessor shall make an appointment for visits (follow-up visits may also be scheduled).
2. The DLAM QA Assessor shall use the IACUC-approved “Post-Approval Quality Assurance Checklist” for the review (document attached to this policy).
3. During each assessment session, the DLAM QA Assessor will compare procedures conducted in the laboratory with those listed in the approved protocol. Discrepancies between procedures performed in the lab and those listed in the protocol will be brought to the attention of the Principal Investigator. Items to be reviewed during the session are listed on the attached “Post-Approval Quality Assurance Checklist” and include the following:
* Protocol and Personnel
* Study Procedures
* Anesthesia
* Surgery
* Post-Surgical Care
* Euthanasia
* Record Keeping
* Laboratory Work Space

Animal misuse, mistreatment or neglect (welfare Issues), and discrepancies which result in animal welfare concerns (deliberate animal misuse, mistreatment or neglect, or those that involve willful disregard for appropriate animal care) will be immediately reported to the IACUC in accordance with IACUC Policy and federal regulations. The IACUC staff and the IACUC Chair will gather information to present to the IACUC for review and, if necessary, further investigation.

1. Process of Sharing Information Concerning the Review:

The DLAM QA Assessor shall discuss quality assurance results with the Principal Investigator and/or other research personnel before leaving the laboratory. Issues that pose an immediate threat to animal welfare shall be reported to the IACUC for immediate resolution.

The DLAM QA Assessor shall send a written draft report of the quality assurance assessment results to the Principal Investigator, and other research personnel. Investigators will have an opportunity to respond to the draft report before the final report is prepared.

The DLAM QA Assessor shall send a final written report of the quality assurance assessment results to the Principal Investigator.,.

Report to the IACUC the laboratories visited.

1. Process Follow-Up:
2. The DLAM QA Assessor will follow up on any issues that require protocol modification, orientation of new personnel, or training. The DLAM QA Assessor will support the laboratory corrective action by providing required training and/or assistance with addendum submission. The investigator will have a reasonable amount of time to correct the issues. If the issues are serious, then immediate correction would be required.
3. On occasion, additional quality assurance sessions may be part of the follow-up to assist with proper corrective actions.
4. Recordkeeping:
5. A copy of the final quality assurance assessment results report shall be kept on file in the DLAM/IACUC Office. A file will be created for each investigator.
6. Details of non-compliance issues will be entered into a Compliance Database for use as institutional trending or follow-up and determination of general training and informational needs.
7. Program Evaluation/Update:

The program will be evaluated by the IACUC at every three years and then as needed.