



Duke University & Duke University Medical Center Animal Care & Use Program Policy



PROTECTION OF PROTOCOL INFORMATION

PERFORMANCE STANDARD: Animal program information that is confidential, proprietary, or of a business nature will be distributed to those have a 'need to know,' as outlined in this policy

BACKGROUND:

1. The animal care and use program manages significant quantities of confidential, proprietary, or business information concerning researchers, their laboratories, their staff, and their practices.
2. Researchers expect that their protocol and procedure information is secure and protected, and provided on a required or 'need to know' basis.
3. Federal law, granting policy, accreditation standard, or Duke management/oversight procedures require access to perform necessary processing, approval, and oversight.
4. This policy applies only to the OAWA and the IACUC and animal program information. It does not apply to documents maintained outside of the IACUC / OAWA server, or non-protocol related information.

POLICY:

1. All materials obtained from or sent to Duke researchers or their staff; from or to the IACUC; from to the OAWA, and maintained in the program server as a master protocol or communication file of the Duke animal program are considered confidential and/or proprietary and/or protected business information.
2. The researcher may share any or all of their protocol information with any individual they determine requires the document (e.g. laboratory staff, animal care team, granting agency, departmental staff).
3. No member of the Duke animal care and use program may share animal protocol related information (e.g. files, reports, documents) with any other individual, except as described below.
4. The OAWA is the information manager for this information. The Director, OAWA will approve information release beyond the 'Core Group of Approved Access Participants' (item 5 below).
5. Core Group of Approved Participants:
 - a. Appointed Duke IACUC leaders (Chair & Vice Chair), DLAR veterinarians, and the OAWA staff have access to all stored animal protocol information on a 'need to know' basis.
 - b. IACUC members may obtain any document they require for the performance of their IACUC related duties by requesting the document via email from the IACUC, Chairman; Director, OAWA; or the Assistant Director, OAWA. Copies will be provided electronically soon as practical.
 - c. Any individual listed as an 'approved protocol participant' in the ROLES section of the approved animal protocol, may receive a copy of the protocol file via email from the OAWA staff.

6. Other Information Requests:

- a. Protocol or file information may be shared with the following individuals:
 - i. A federal agency performing its obligations under federal statute. (e.g., USDA inspection, NIH requirement, or VAMC requirement).
 - ii. An AAALAC accreditation review of the institution.
 - iii. The Department Chairman for the department where the researcher holds a faculty appointment.
 - iv. A Duke grants and contracts officer (e.g. ORA, ORS).
 - v. A senior institutional official (e.g. Assistant Vice Deans or above).
 - vi. A Duke Compliance official (e.g. SOM or DU Compliance Office).

NOTE: The researcher will be alerted to the sharing of their protocol information except where there is a formal review of records concerning potential non-compliant activity.

- b. A 'REQUEST FOR INFORMATION' log will be maintained by the OAWA for all requests falling under this item (item 6).
- c. Requestors in this category must answer to the following questions:
 - i. Who (or what Office) is requesting the information?
 - ii. General purpose for the information?
 - iii. How will the information be protected?
 - iv. How long is the information required to be maintained at requestor's location?
 - v. Who will have access to the information (beyond the requestor)?
 - vi. Confirmation that the information will be returned (or destroyed) when no longer required

7. Protocol or file information may also be shared with other individuals, if authorized by the PI. For example, the PI authorizes another department's business manager access to their protocol or information files.
8. Information access may also be granted by the Institutional Official (Dean, SOM) on a case-by-case basis.
9. The institution's PIs will be advised of this information sharing policy and process in the 'Approval Letter' provided with their IACUC approval.