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DATE: April 29, 2002  
TO: Record  
FROM: Director, Office of Laboratory Animal Welfare  
SUBJECT: Compliance Oversight Procedures

The Office for Laboratory Animal Welfare (OLAW) is responsible for oversight of compliance by awardee institutions with the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals. This memorandum updates and summarizes the procedures utilized by OLAW in conducting compliance oversight activities. These procedures have been developed over a period of years, and their effectiveness has been demonstrated in a number of investigations. Deviations from these procedures should occur only in extraordinary circumstances and must be approved by the Director, OLAW.

### Background

As a condition of receipt of PHS support for research involving laboratory animals, awardee institutions must provide a written Animal Welfare Assurance of Compliance (Assurance) to OLAW describing the means they will employ to comply with the PHS Policy. OLAW negotiates and approves these Assurances on behalf of the Director, National Institutes of Health. Each Assurance is a detailed document tailored to the individual institution's needs, research practices, and procedures. It must be consistent with the PHS Policy. An Assurance approved by OLAW commits the institution and its personnel to full compliance with the PHS Policy.

In carrying out its oversight responsibility, OLAW evaluates all allegations or indications of noncompliance with the PHS Policy, derived from any source. All compliance oversight evaluations are predicated on the PHS Policy and the institution's Assurance of Compliance. Therefore, OLAW holds accountable and depends upon institutional officials, Institutional Animal Care and Use Committees, research investigators, and other agents of the institution to assure conformance with the institution's Assurance and thus with the PHS Policy and other Federal statutes and regulations relating to animals. Only through the partnership established by the Assurance can the shared responsibility for the welfare of laboratory animals be effectively discharged in accordance with Section 495 of the Public Health Service Act.

## Compliance Oversight Evaluations

When OLAW initiates a compliance oversight evaluation, appropriate institutional officials are so advised and informed as to the likely administrative course of events. Activities expected of the institution are carefully explained initially and as appropriate during the course of the evaluation. Except in rare circumstances when sound ethics dictates the need to act immediately, OLAW takes no action against any institution without first affording the institution an opportunity to take remedial action or to offer information which might refute or mitigate adverse determinations. In all cases, appropriate institutional officials are afforded an opportunity to identify errors of fact before OLAW issues reports of findings.

Under HHS regulations at 45 CFR 5, documents related to compliance oversight evaluations may be subject to the provisions of the Freedom of Information Act (FOIA). In most cases, such documents are exempt from the disclosure provisions of the FOIA while the evaluation is in progress, and OLAW treats them with confidentiality. However, OLAW routinely advises appropriate HHS and USDA officials concerning the status of its evaluations and may be required to inform members of Congress. Most documents related to compliance oversight evaluations become publicly available under the FOIA when OLAW issues its findings.

Under HHS regulations at 45 CFR 5b, records which can be retrieved by an individual's name or other personal identifier are subject to the provisions of the Federal Privacy Act. Information regarding OLAW's compliance oversight activities is maintained only in a system of records identifying the institution under evaluation. Records can be retrieved by institutional name or assurance number. OLAW maintains no system of records related to compliance oversight activities through which records can be retrieved by individuals' names or other personal identifiers. Inasmuch as the PHS Policy does not contain explicit whistle blower protections, whistle blower protection or anonymity will be honored only to the extent allowed under the FOIA.

## Possible Outcomes

Corrective actions based on compliance oversight evaluations are intended to remedy identified noncompliance with the PHS Policy and to prevent reoccurrence. Because each case is different, OLAW tailors its corrective actions to foster the best interests of laboratory animals, the institution, the research community, and the PHS funding component. Most compliance oversight evaluations and resultant corrective actions are resolved at the OLAW level. In some instances, OLAW also refers concerns to other PHS components or to the USDA's Animal and Plant Health Inspection Service or to other Federal entities for their consideration.

OLAW's compliance oversight evaluations may result in one or more of the following outcomes:

1. OLAW may determine that an institution is operating in accordance with the provisions of its Assurance and the PHS Policy.

2. OLAW may determine that an institution is operating in accordance with the provisions of its Assurance and the PHS Policy, but recommend certain actions to enhance compliance.

3. OLAW may restrict its approval of an institution's Assurance of Compliance. In such cases, affected research projects may not be supported by PHS unless the terms of the restriction are satisfied. Examples of such restrictions include, but are not limited to:

(a) suspending the Assurances applicability relative to some or all research projects until specified corrections have been implemented;

(b) requiring prior OLAW review of some or all research projects to be conducted under the Assurance;

(c) requiring that some or all investigators conducting research under the Assurance receive appropriate animal welfare education;

(d) requiring special reporting to OLAW.

4. OLAW may withdraw its approval of an institution's Assurance. Affected research projects cannot be supported by any PHS component until an appropriate Assurance is approved by OLAW.

#### Sequence of Events

The typical sequence of events in an OLAW compliance oversight evaluation is as follows:

1. OLAW discovers or receives an allegation or indication of possible noncompliance with the PHS Policy. OLAW may receive such allegations or indications from a variety of sources, including the institution itself. Under the PHS Policy, institutions are required to report any serious or continuing noncompliance to OLAW.

2. OLAW determines whether it has jurisdiction in the matter on the basis of PHS support and/or an applicable Assurance of Compliance. Once jurisdiction has been established, OLAW may, at any time, require interim corrective actions under an Assurance of Compliance, or temporarily suspend the Assurance, when it considers such actions necessary for the welfare of laboratory animals.

3. OLAW either acknowledges the institution's report of noncompliance or notifies the institution's Assurance signatory official of the possible noncompliance, and, as necessary, requests that the institution investigate the matter and report to OLAW by a specified date. Depending upon the circumstances involved, OLAW may communicate directly with other affected institutional officials or personnel. Where the possible noncompliance involves a specific research investigator, OLAW may notify the investigator involved.

4. OLAW evaluates the institution's report and any other pertinent information to which it has access. If OLAW determines that the matter has not been resolved satisfactorily at this stage, OLAW may request additional information from the institution or conduct an on-site evaluation of an animal care and use program under the applicable Assurance of Compliance. On-site evaluations under an Assurance may also be conducted in the absence of specific allegations or indications of noncompliance.

5. Most compliance oversight evaluations can be resolved through correspondence with the institution and do not require an on-site review or a formal report of findings. In such circumstances, complainants are ordinarily informed of the outcome of OLAW's evaluation upon its completion.

6. Where a report of findings is to be issued, OLAW forwards it to: (i) the signatory official with an invitation for institutional identification of errors of fact, and (ii) the complainant(s), as appropriate, with an invitation for individual identification of errors of fact.

7. OLAW attaches any institutional or individual identification of errors of fact, and its report is then issued to the institution and complainant. If factual errors were identified, these errors are addressed in the Preface to the report.

8. Except as noted above, OLAW ordinarily makes no official announcement that a final report of compliance oversight findings has been issued. Once issued, however, the final report becomes subject to the terms of the FOIA, as do various related documents.



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