AMERICAN PSYCHOLOGICAL ASSOCIATION

Science Directorate

June 10, 2003

Regulatory Analysis and Development, PPD
APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737

Re: Docket No. 97-003-1
Animal Welfare; Medical Records

The Committee on Animal Research and Ethics (CARE) of the American Psychological Association (APA) submits these comments on the proposed rule on medical records (Docket No. 97-003-1). As a standing committee of the APA, representing a membership of over 150,000 researchers, educators, clinicians, consultants, and students, committed to the humane treatment of laboratory animals for over 75 years, CARE has been involved in developing and regularly updating guidelines for the humane care and treatment of nonhuman animals in research. Because research with laboratory animals is an integral component of the science of behavior, APA has strongly supported the efforts to improve laboratory animal welfare while ensuring that proposed policies or regulations do not compromise scientific research.

CARE has two major concerns regarding the proposed rule: (1) The degree of specificity regarding record keeping supplants the attending veterinarian's professional judgement, which may be to the detriment of the individual research

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animal. In addition, (2) the requirement needlessly increases regulatory burden while doing nothing to enhance the care already provided to research animals. CARE thus urges withdrawal of the proposed rule and urges USDA to replace it with a broad statement regarding the importance of maintaining medical records in order to facilitate communication between all those charged with animal care within the research setting.

GENERAL COMMENTS

The background section is unclear regarding the specific need for the proposed regulatory change when existing Policy # 3 already meets the proposed intent of these regulations. Although CARE concurs with the stated rationale for the maintenance of medical records -- namely that medical records serve as a means of ensuring "communication among all personnel involved in providing care" -- CARE is concerned by language in the proposed rule that further states that "medical records provide a basis for APHIS inspectors to assess a veterinary care program and ensure that animals receive adequate veterinary care." Medical records can only provide inspectors a basis for reviewing the engineering standards for record keeping required by this regulation. To assess the program of adequate veterinary care, APHIS inspectors have to assess the entire program based upon generally accepted standards of care and the type of veterinary care program described in the *Guide for the Care and Use of Laboratory Animals* (ILAR, 1996).

The background section also contains a requirement that medical records include "any known drug sensitivities of the animals." Other than responses to a drug that are idiosyncratic to a particular species, there is no scientific basis for evaluating drug sensitivities in laboratory animals. This language is not included in the proposed amendments and CARE believes that it should be deleted from the preamble.

Furthermore, although CARE agrees that medical records are an essential part of any program of adequate veterinary care, CARE believes that the level of prescriptive detail that is being mandated by the proposed rule is inappropriate, particularly within the research setting. The requirements identified by the proposed rule appear to be based on a clinical veterinary medicine model, and is being inappropriately applied to the research setting. The level of detail in the proposed should be left to the discretion and professional judgement of the institutional laboratory animal veterinarian, who is better situated to make such decisions on a case-by-case basis depending on the species, medical problem, and research context.

SPECIFIC COMMENTS

- Section 2.33(b)(6)(ii) of the proposed rule states that records should include "the date, description of the problem, pertinent history, observations, examination findings, test results, and plan for treatment and care with a tentative diagnosis and a prognosis, when appropriate." The first part of this information is appropriate for inclusion in animal health records, but a differential diagnosis or prognosis may be neither relevant nor necessary in a research setting. Specifying the inclusion of a diagnosis and prognosis "when appropriate" will lead either to unnecessary diagnostic testing or will require veterinarians to provide extensive justifications for why no diagnosis or prognosis was supplied. This language should be deleted.

- The proposed rule states in Section 2.33(b)(6)(iii) that medical records should include "The type and chronology of treatment procedures performed, the context of the problem to which the treatment procedures pertain, and the identification of the medication used, the date given, dosage, route of administration, frequency and duration of treatment." Providing "the context of the problem to which the treatment procedures

pertain" will be time-consuming and likely will not improve the care provided to animals. The only justification for generating such records is to enable APHIS Veterinary Medical Officers (VMOs) to review veterinary decisions after the fact. This language should be deleted.

- Both Section 2.33(b)(6)(i) of the proposed rule and existing Policy #3 state that husbandry and preventive medical procedures routinely performed on a group of animals may be recorded on herd-health type records. In such cases, individual medical records are needed only in the event that an animal has a special health problem. Once that problem is resolved, no further entries on the individual health record are required. These procedures should be acknowledged as standard practice.

- When a group of animals has a disease condition that precludes its use in research and the animals must be euthanized, this fact should be noted in production records. However, no medical records should be required.

- The proposed rule should state explicitly that medical records are not required for conditions that are created by, or related to, the IACUC-approved experimental procedure. In addition, within the research setting, species for which routine diagnostic or preventive procedures are not performed should be explicitly exempted.

Contrary to the APHIS claim that the cost associated with implementation of the proposed rule would be minimal, CARE asserts that there would be a substantial increase in cost due to the regulatory burden on research institutions. Moreover, CARE asserts that implementation of the proposed rule will have no impact on the care already afforded lab animals by current regulations and good lab practices. Furthermore, the proposed rule requires medical records to include information that may be superfluous or excessive, and could lead to unnecessary

diagnostic procedures that offer little, if any, benefit to the individual laboratory animal. Thus, CARE recommends that research institutions be exempted from the requirements of the proposed rule.

CARE thanks the USDA-APHIS for affording the research community an opportunity to comment on the proposed rule, thereby ensuring its appropriateness within the research context.

Sincerely,

APA Committee on Animal Research and Ethics

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