National Association *for* Biomedical Research

June 3, 2003

Docket No. 97-033-1
Regulatory Analysis and Development, PPD
APHIS, Station 3C71
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Animal Welfare, Medical Records

Thank you for the opportunity to comment on Docket No. 97-033-1, a proposed rule that would require research facilities, dealers, and exhibitors to maintain medical records as part of their program of adequate veterinary care.

The National Association for Biomedical Research (NABR) agrees that keeping and maintaining appropriate medical records, in most situations, is an important component in documenting adequate veterinary care. We agree that sound veterinary care requires appropriate record keeping. NABR believes that its members currently have in place programs that provide excellent veterinary care which include maintenance of appropriate records in accordance with Animal Care Policy #3.

Although NABR supports the proposition that maintaining appropriate medical records is an important component in documenting adequate veterinary care, NABR believes it is essential for all parties involved to fully understand the rationale, objectives and scope of these new proposed regulations. Our comments will address (1) NABR's concern regarding the lack of detail provided by the agency in explaining its rationale and intended purpose in proposing these new regulations; (2) NABR's concern that APHIS is adopting an engineering standard approach rather than the more flexible and effective performance standard approach to regulating; and (3) NABR's specific comments on the proposed new rules based upon assumptions and guesswork as to what APHIS intends to accomplish, and how the agency may implement and enforce these proposed regulations.

(1) Proposal Too Vague for Meaningful Comment

In NABR's view, the rationale and justification provided in this proposed rule is ambiguous and lacks an adequate factual basis and statement of purpose required for thoughtful and meaningful comment. NABR urges APHIS to commence a second round of notice and comment and reissue this proposal based upon the comments the agency receives in response to the current proposal.

The Administrative Procedures Act (APA) requires that a proposed rulemaking afford "interested persons an opportunity to participate in the rule making. . . ."[1] Courts have interpreted this provision to require that such notice provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully. In NABR's view, the proposed rule does not permit meaningful comment. As drafted, both the background section and the specific regulatory proposals provide inadequate factual basis, detail and rationale to allow meaningful comment.

Without a better understanding of the purpose and clear intent underlying this proposed regulation, NABR believes it cannot provide meaningful comments that will assist the agency in drafting a final rule. As written, the proposed rule raises more questions than it answers with regard to the intended purpose of the proposed requirements as well as the intended means and scope of the agency's implementation and enforcement.

Numerous Issues Not Addressed In Proposed Rule

Many potential issues, the outcome of which would influence NABR's support or opposition to the proposed new requirements, are not addressed at all in the current version of this proposed rule. For example, when and under whose direction is a medical record generated? Is it the intent of the agency that medical records contain protocol-related or created conditions that are approved by the IACUC in its review of proposed activities? Is it the intent of the agency that medical records will be required for research animals even if the animals are treated as a group and develop a disease condition that would make the animals unsuitable for research, thus requiring euthanasia of the group? Is it the intent of the agency that the medical records include animals in which the disease status of a group is monitored by sampling a percentage of the group? If so, would the standard QA reports generated on the status of a colony be an acceptable medical record? These are just a few of the questions that must be addressed before meaningful comments can be provided to the agency.

The remaining comments in this section are intended to provide APHIS with additional information for the development of a new proposal upon which all parties can more

[1] 5 U.S.C. § 553

meaningfully comment. NABR believes that a medical record should be initiated at the direction of the attending veterinarian in accordance with established veterinary medical practices. These records would be used to document medical information associated with clinical disease and subsequent diagnostic or therapeutic procedures, as well as preventative medical procedures routinely performed on individual animals.

NABR does not support the view that conditions created by or related to the experimental design of the project (induced disease) should necessarily be included in an individual animal's health record. Record keeping for this set of conditions is maintained by the researcher as part of the research protocol. APHIS should include language in a new proposed rule exempting the observation, examination and treatment of induced disease covered under an approved protocol from the medical records requirements. In some cases maintaining medical records may be warranted, but in all instances the decision should rest with the attending veterinarian or designee responsible for the animal under the program of adequate veterinary care reviewed by the IACUC.

Several animal species used in laboratories do not receive routine diagnostic tests, nor are they treated with preventative medical procedures. APHIS should clarify in a new proposed rule that there is no need for a medical record for these species.

NABR believes that for species which are managed as a group in which the presence of a disease condition precludes their use in research, the appropriate notation in production records as to the disposition of a group should be sufficient. NABR is unsure whether the agency intends to require more, and would strongly urge the agency to clarify in a new proposed rule that medical records are not required in this situation.

NABR is concerned that, as currently written, this proposal will not permit breeders of laboratory animals to follow their published standards for assuring the quality of the animals they provide to research institutions. In NABR's view, if the health status of animals bred as a group meets recognized published standards, then medical records need not be maintained. Additionally, NABR believes it is unnecessary to require a breeder to forward the group records that are maintained for a particular group to the eventual purchaser of the animals.

Background Information and Rationale Inadequate

The background section of this proposed rule provides minimal and inadequate information as to the factual basis, intended purpose and objectives of the proposed new requirements. Furthermore, the background information is unclear and vague as to the specific need for this regulatory change unless the agency is contemplating expanding the guidelines specified in Policy #3.

The agency states in the background section of this proposal that medical records should be maintained as a means of "communication among all personnel involved in providing care." To what end? In NABR's view, this proposal does not convey the true purpose of medical records, which is to "document" the care being provided. Is the agency suggesting that "communication among all personnel" will improve the quality of the veterinary care provided? If so, what evidence does the agency have to support such a contention? How will this communication improve the quality of care? The agency's rationale is conclusory and does not provide adequate justification or explanation. Again, the lack of an adequate explanation of the agency's intent makes it difficult for NABR to meaningfully comment on whether the proposed new requirements will actually assist the agency in achieving its goals.

The language in the background section also 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 will only provide inspectors a basis for reviewing the engineering standards for record keeping that this regulation will require. If the agency believes that it will be able to make determinations as to the adequacy of veterinary care based upon written medical records, NABR believes the agency is placing far too much reliance on the written medical record. To assess the program of adequate veterinary care, APHIS inspectors will have to assess the entire program based upon generally accepted standards of care and the type of veterinary medical care program described in the NAS *Guide for the Care and Use of Laboratory Animals.*

The fourth paragraph of the background section contains a requirement that medical records include "any known drug sensitivities of the animals." Other than species-specific drug idiosyncrasies, there is no scientific basis for evaluating drug sensitivities in laboratory animals. It is unclear why the agency included this kind of a requirement in the background section of this proposed rule but did not in the proposed amendments to 9 CFR Part 2. NABR's view is that this language is not supported by factual evidence and should be deleted in its entirety during promulgation of any final rule.

(2) Engineering Standards Rather Than Performance Standards

The proposed language would implement rigid engineering standards instead of the performance standards that are necessary to permit the attending veterinarian to use his/her professional judgment in managing a program of veterinary care that is appropriate to an animal care and use program in place at his/her institution. The maintenance of medical records in a research facility does not carry with it the same requirements as those needed in private clinical practice and thus more flexibility is needed in determining the content. The reasons for this are numerous but include the fact that the animals acquired for use in research must be of known health status and the existence of clinical disease would preclude their use in research. There is also not the

same client/patient relationship in a research environment that exists in a private practice situation. Finally, in many instances the options available to the veterinarian in managing clinical conditions are often dictated by the animals' intended use or the requirement of an approved IACUC protocol.

(3) Specific Language in the Proposed Regulations

Section 2.33

a. **Proposed Section 2.33(b)(6)** – NABR requests that everything after the first sentence of this paragraph be deleted as it contains extraneous wording that is better suited for the background section. NABR is also concerned about the use of the word *legible*. While the need for legibility is obvious, using it in this context subjects it to individual, and possibly nonobjective, review during inspections. We therefore suggest that the last sentence be changed by deleting the words, "must be legible and" and inserting "should" after "records".

b. **Proposed Section 2.33(b)(6)(i)** – This section lacks language indicating that routine procedures involved in the production of animal models would be treated the same as routine husbandry procedures. This oversight must be addressed with language such as "Provided, however, that routine husbandry and production procedures, such as vaccinations, preventive medical procedures, production of animal models, or treatments performed on all animals in a group (or herd) may be kept on a single record;"

c. **Proposed Section 2.33(b)(6)(ii) –** NABR is concerned about the inclusion of the phrase "with a tentative diagnosis and prognosis, when appropriate" and urges the agency to delete this phrase from the proposed rule. A tentative diagnosis is generally not included in the medical record of animals intended for use in medical research and requiring a prognosis in a research environment is not realistic. APHIS has not provided any factual basis or rationale to support this requirement. Inclusion of this type of information does little or nothing to improve the care of the animal and imposes an unnecessary burden on the attending veterinarian.

d. **Proposed Section 2.33(b)(6)(iii)** – NABR believes that this section contains the following ambiguous language that should be deleted: "the context of the problems to which the treatment procedures pertain". This provision interferes with and questions the professional judgment of the veterinarian. Medical records should contain the facts and not the thought processes that contribute to the evaluation of those facts when prescribing treatment. NABR is further concerned that this language would appear to require that the veterinarian indicate the "cause" of the condition, which in the case of protocol-related events, could involve revealing proprietary information.

e. **Proposed Section 2.35** – NABR believes that the record keeping requirements are appropriate.

f. **Proposed Section 2.40** – NABR believes that the general concerns for record keeping addressed above apply to this section.

g. **Proposed Section 2.75** – If the health status of animals bred as a group meets recognized published standards, then medical records need not be maintained, and it should not be required that a breeder forward the group records that are maintained to the eventual purchaser of animals from that group.

After careful consideration of the issues addressed above, NABR recommends that APHIS consider confining changes to the current regulations to those programs that do not employ a full time attending veterinarian. This could be done by revising the language in proposed Section 2.33(a)(1) and proposed Section 2.40(a)(1) to read, "Each research facility (dealer or exhibitor) shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangement, the formal arrangements shall include a written program of veterinary care that includes (1) medical records which document medical information associated with clinical disease and subsequent diagnostic or therapeutic procedures; (2) preventative medical procedures routinely performed on individual animals; and (3) regularly scheduled visits to the research facility (to the premises of the dealer or exhibitor):"

NABR appreciates the opportunity to comment on these proposed regulations. NABR supports the proposition that, in most situations, maintaining medical records is an important component in providing adequate veterinary care. However, we find the proposed regulations as currently written ambiguous, ill-defined and reflecting inflexible engineering standards instead of performance standards. NABR strongly recommends that the agency issue a new set of proposed regulations based upon the comments it has received. NABR urges APHIS to more clearly detail its objectives and goals and to provide a factual basis for its proposals. We encourage the agency to solicit additional information from the regulated entities, professional veterinary organizations and other interested parties. By soliciting this information, we believe the agency will gain additional insights and workable approaches for accomplishing its objectives. NABR is prepared to offer assistance through its members to help achieve these important goals.

The National Association for Biomedical Research (NABR) is the only national, nonprofit organization dedicated solely to advocating sound public policy that recognizes the vital role of humane animal use in biomedical research, higher education and product safety testing. NABR's membership is comprised of over 300 public and private universities, medical and veterinary schools, teaching hospitals, voluntary health

agencies, professional societies, pharmaceutical companies and other animal research-related firms.