

alternatives in the specific field of study. For example, an immunologist cited as a subject expert may or may not possess expertise concerning alternatives to *in vivo* antibody production.

When a database search is the primary means of meeting this requirement, the narrative should include:

1. the name(s) of the databases searched (due to the variation in subject coverage and sources used, one database is seldom adequate);
2. the date the search was performed;
3. the time period covered by the search; and
4. the search strategy (including scientifically relevant terminology) used.

The Animal Welfare Information Center (AWIC) is an information service of the National Agricultural Library specifically established to provide information about alternatives. AWIC offers expertise in formulation of the search strategy and selection of terminology and databases, access to unique databases, on- and off-site training of institute personnel in conducting effective alternatives searches, and is able to perform no-cost or low-cost electronic database searches. AWIC can be contacted at (301) 504-6212, via E-mail at awic@nal.usda.gov, or via its web site at <http://www.awic.nal.usda.gov>. Other excellent resources for assistance with alternative searches are available and may be equally acceptable.

Regardless of the alternatives sources(s) used, the written narrative should include adequate information for the IACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. If a database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the IACUC may and should ask the PI to explain why an alternative that had been found was not used. The IACUC, in fact, can withhold approval of the study proposal if the Committee is not satisfied with the procedures the PI plans to use in his study.

The rationale for federally-mandated animal testing (for example, testing product safety/efficacy/potency) should include a citation of the appropriate government agency's regulation and guidance documents. Mandating agency guidelines should be consulted since they may provide alternatives (for example, refinements such as humane endpoints or replacements such as the Murine Local Lymph Node Assay) that are not included in the Code of Federal Regulations. If a mandating agency-accepted alternative is not used, the IACUC must review the proposal to determine adequate rationales have been provided, and pain and discomfort limited to that which is unavoidable.

Significant changes are subject to prior review by the IACUC. If those changes include a painful or distressful procedure, a consideration of alternatives or a revision of the prior search may be required

Although additional attempts to identify alternatives or alternative methods are not required by Animal Care at the time of each annual review of an animal protocol, Animal Care would normally expect the principal investigator to reconsider alternatives at least once every 3 years, consistent with the triennial *de novo* review requirements of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (IV,C,5).