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May 31, 2002

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To Whom It May Concern:

The American College of Epidemiology (ACE) is a professional organization with 900 members dedicated to continued education and advocacy for epidemiologists in their efforts to promote the public health. Members of the College are engaged in epidemiologic research across the full spectrum of diseases and conditions under the sponsorship of federal and state government and private foundations. The organization, and its members favor sharing information, and have developed a policy in support of data sharing that identifies 'best practices' for professional epidemiologists (policy enclosed). This policy statement was developed with some knowledge of how the NIH policy was evolving concurrently. However, even to those who support data sharing, the proposed NIH requirement raises concerns that must be addressed before the NIH policy is implemented.

Our concerns can be divided into several areas: 1) data requests, 2) IRB and informed consent issues, 3) costs to the investigators, and 4) the timing of data sharing. Each of these points is addressed below.

### **Data Requests**

Data sharing among scientific colleagues is widespread and the principles for epidemiologists are presented in the attached ACE policy statement. However, for requests that may originate from some other, possibly adversarial, source and data are not archived, we urge that the NIH policy be more helpful to address how the requests are fulfilled. The guidelines should provide guidance to population investigators about how to respond to requests coming from special interest groups or non-scientific commercial interests on whom the original research has some impact. The NIH policy should provide guidance to population investigators about how to respond to requests perceived as such. Might the NIH suggest some level of credentialing of requestors? Possibly review

committees could be established, to review these requests, especially when additional funds will be needed for data preparation.

Alternatively, the NIH should establish guidelines to protect researchers from the necessity of providing data for requests from sources without *bona fide* interests in pursuing a scientifically defensible use of the data. We strongly recommend a mechanism for researchers to be able to notify the NIH when their data are requested by sources without appropriate scientific credentials. Could the researcher be penalized if they do not provide the requested data in such cases? How would disagreements about the appropriateness of sharing data with such parties be adjudicated? We urge clarification of who represents a "*bona fide* requestor?"

### **Informed Consent Issues**

It is clear that Institutional Review Boards (IRBs) will have to be educated about the data sharing issues and the new NIH policy, because currently, many of our consents inform the participant that the data will not be shared. The study participants will have to agree to allow the information, laboratory results, etc. to be shared with others for purposes that cannot be specified at the time of the original consent. NIH recommendations on the process of consents for study participants need clarification.

Data sharing and questions of informed consent will involve researchers in negotiations and discussions with their institution's IRBs, and possibly add a burden to informed consent requirements. As research participants become aware that study data may be accessible to investigators, other than the original ones of whom they have personal knowledge, participation rates in population research could be diminished. Despite de-identification of personal information, procedures may be judged incomplete. In the case of ethnic, geographical or even occupational studies, prospective participants may still have concerns about broadcast of data sharing describing a group to which they belong.

The ACE policy states that general informed consent for future studies should be obtained at the time of the original consent, but the requirement for further consent for specific additional studies probably should remain in the jurisdiction of local IRBs. Recruitment into many population-based epidemiologic studies is already difficult. Consent documents that include the possibility of future data sharing will likely decrease participation further. What is the NIH guidance on this issue?

### **Costs to the Investigators**

Preparation of data sets for data sharing could be costly. Although the new policy allows for incorporation of funding for data sharing into budget requests, the exact cost and time required to meet requests could be extremely difficult to estimate for research that does not include one-time data archiving. As indicated in the ACE policy statement, the requestor's need for detailed knowledge of the particularities of a dataset might be a complex process; preparation of the data for a Web page or other transmittable medium could involve technical problems; and researchers may be unable to determine in advance how many requests may be forthcoming for their data (if they choose not to archive). It is

important to clarify how the cost of fulfilling the requirements for data sharing will be borne because research funds may be insufficient, especially if funding has ended before the request occurs.

### **Timing of Data Sharing**

The time requirements for researchers to share data should be clarified, as well. For long-term longitudinal studies the release of data before planned analytical milestones could generate incomplete results or conclusions contrary to the findings that would ultimately emerge from the completed study. How does the NIH policy address studies in progress or data judged incomplete by the original researcher? The proposed NIH policy states that data should be shared in a timely manner, but a specific time line is not set in the guidelines. We believe the date of publication of the primary results of a study mark the point at which the data should be shared, even if that may take several years after the collection of the data for that study is completed. Such intervals are common in epidemiologic research because of their complexity.

### **Other Issues**

Will the new policy only affect new protocols? What happens with competing renewals when the studies are extended and older and newer data are combined?

In summary, we have raised several concerns that must be addressed before this policy is implemented because of the possible confusion or potential adverse impact on epidemiologic and other population sciences. We thank you for the opportunity to comment on the proposed NIH policy and urge you to reconsider these issues before NIH grantees are required to include data sharing in their grant applications.

Sincerely,



Richard Kaslow, M.D., M.P.H.

President

American College of Epidemiology