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**COGR comments to NIH on the proposed policy for sharing of data**

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COGR comments to NIH on the proposed policy for sharing of data obtained in NIH supported or conducted Genome-Wide Association studies.

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# COGR

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NIH GWAS RFI Comments  
National Institutes of Health  
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Subject: Proposed Policy for Sharing of Data Obtained in NIH  
Supported or Conducted Genome-Wide Association Studies  
(NOT-OD-06-094)

The Council on Governmental Relations (COGR), an association of more than 170 research universities and their affiliated academic medical centers and research institutes, concerns itself with the influence of federal regulations, policies, and practices on the performance of research. We share NIH's goal of seeking to maximize the availability of resources to facilitate research needed to address health needs based on individual genetic information. However, we are concerned about a number of aspects of the proposed Genome-Wide Association Studies (GWAS) policy for Sharing of Data. In the subject RFI, NIH poses several questions for which it seeks public input and advice. Our comments are primarily addressed to the subcomponents of question #3, although they implicitly address some of the other questions raised in the RFI.

#### Applicability:

This policy should apply to active AWARDS; not applications. The proposed policy outlines NIH's expectations for funded investigators and the applicability statement should be consistent with the policy provisions. It is inappropriate to require every applicant to meet these expectations.

#### Data Submission:

The rationale for the required submission of the study protocol, questionnaires, manuals, variables measured and other supporting documentation is unclear. This information does not appear to be necessary for the stated purpose of sharing genotype and phenotype information. Furthermore, general information on individual studies will be available through CRISP. In our view, the posting of these items will invite requests for additional and very likely identifiable, information

required aspect of those plans. If so, this type of requirement or expectation as a criterion for award or a term/condition of the award is problematic and inappropriate. For instance, local Institutional Review Boards (IRBs) may not approve the submission of certain data sets to the repository. Data sets including pedigree information for some rare conditions may be sufficient to disclose the identities of the participants to those investigators working in the field.

There is no discussion of NIH's expectations concerning quality control procedures at the local institution. The recent proposal from NCI for biorepositories established aggressive and burdensome quality control processes for the preparation of biospecimens. It would be important to understand NIH's expectations for GWAS, and to ensure that requirements are reasonable and appropriate.

### **Human Subjects Protections:**

Has NIH/OER discussed with the HHS Office of Human Research Protections (OHRP) the question of seeking consent for use of data for future, unspecified areas of research that were not the original research use? Current OHRP guidance may prohibit collection for future, unspecified research. OHRP directs local IRBs to include "the specific types of research to be conducted." It is troubling and inconsistent with OHRP requirements for NIH to require that data be placed in a central repository when it is not part of the specific research program for which the data (or specimens) were collected. Such a requirement subsumes local IRB autonomy to protect human subjects.

The proposed NIH policy suggests that the release of the identities of participants could occur with the "appropriate institutional approvals." However, OHRP "strongly recommends" that recipient-investigators not be provided access to the identities of donor-subjects. NIH offers no examples or direction describing under what circumstances an institution would consider approving the release of individual information. Without guidance from OHRP, many local IRBs and research institutions may consider the risk too high to approve submission of the data.

### **Human Subjects Protection Management**

The complexity of the management of the submission of the data by institutions might discourage participation. There is no discussion of what constitutes de-identification of data. The most restrictive standard is the de-identification standards for compliance with HIPAA. While we would not recommend these standards for de-identification, covered entities are likely to set these as standards to make the management of data submission simpler. Each local IRB may establish separate standards that reflect questions related to the specific study.

As OHRP suggests in its guidance on repositories, NIH/OER might want to prepare a sample informed consent document or language that describes the conditions under which data are released, NIH procedures for protecting privacy and/or confidentiality, etc. Institutions may want to confirm that an IRB has reviewed the repository operation and the sample documents. These sample documents should be clearly indicated as informational in nature.

Institutions may need to modify these consent documents to reflect the local policies concerning the release of individual identifiers including under what circumstances an institution would approve such a release.

### **IRB Certification:**

The IRB could affirm that information concerning the inclusion of data in the GWAS repository and subsequent sharing was a part of the informed consent process approved by the IRB. However, the IRB is not usually in a position to identify any limits on the use of data required by individual participants. The IRB may sample the consent process but does not normally review each consent form for exclusions. If the institution does not have a good electronic data tracking system for clearly identifying which individual subjects have not consented to the release, a manual tracking would be required. For a study which has a large subject population, this could be fairly substantial.

Is the IRB responsible for review and exclusion or is the investigator? If a subject specifically declines to release the information, it should not be submitted to the repository contrary to the wishes of the subject. If a subject categorically does not want to release the information, then does it become an exclusion from participation in the study criterion? If so, many IRBs will not agree to that condition. Thus, data submission as a requirement will prevent funding of a proposal by NIH.

### **Data Access:**

What is the assurance that the NIH is seeking from the investigators accessing the data? That they will abide by the restriction? How does NIH propose to enforce and/or assure this process? Many patients would be interested in knowing these assurances before signing any consent form.

Beyond review of the stipulations made by the investigators, what is the role of the Data Access Committees? Will the DAC function as peer review panels to assess the scientific merit?

### **Intellectual Property**

We share NIH's goals of assuring wide availability of GWAS data, and do not object to NIH discouraging intellectual property claims on the GWAS datasets to assure unrestricted utilization of the data and information. Datasets are likely to have little or no commercial value and are not likely to be patentable. However, the proposed policy discourages patent claims not only on the genotype-phenotype datasets but also on "all conclusions derived directly from them." Has NIH considered the broad scope of this limitation? Potentially the limitation could reach through to new genomic technologies where patent claims may be necessary to induce the investment required to assure utilization and public benefit. It may actually impede availability of important technologies. We believe this needs clarification. As stated, the proposed policy is overbroad and inconsistent with public policy.

For example, if follow-on research is supported with federal funds and an invention is developed, restrictions on patenting future conclusions derived from the non-patented databases would be in direct conflict with the Bayh-Dole Act. The follow-on research, especially that which is

focused on developing new genomic technologies, would require the filing of patents on the new genomic technologies in order to benefit the public with better access to therapies.

This type of broad restriction is inconsistent with NIH policies that require specific determinations and justifications for exceptions to normal Bayh-Dole rights, especially because of the requirement to execute an NIH Data Use Certification that acknowledges NIH's GWAS IP policy goals. This could be viewed as another example of recent NIH practices that erode Bayh-Dole rights through "back door" approaches.

The proposed policy also cites the NIH Best Practices for the Licensing of Genomic Inventions ([http://www.ott.nih.gov/policy/lic\\_gen.html](http://www.ott.nih.gov/policy/lic_gen.html)) as the "responsible approach" for management of intellectual property derived from NIH-supported genotype-phenotype data. COGR provided extensive comments to NIH on the Best Practices when they were proposed (see January 6, 2006 letter on the COGR website; <http://www.cogr.edu/files/CurrentComments.cfm>). Among the concerns we expressed was that issuance of the Best Practices by NIH inevitably would result in them becoming *de facto* compliance standards for NIH funding recipients, despite the disclaimer both in the Best Practices and in NIH's responses to the public comments received that they are not intended to constitute additional regulations, guidelines or conditions of award for any contract or grant. The proposed GWAS policy confirms the validity of our concerns. It is particularly troubling since NIH specifically stated that the Best Practices would impose no regulations or requirements on any licensing situation for universities.

The proposed GWAS policy, like the Best Practices, encourages patenting of technology only when significant private sector investment is needed to develop products for public benefit. As we pointed out in our previous comments, the merits of patenting an invention may have little to do with the need for significant further development investment. Neither the NIH Best Practices, nor the proposed GWAS policy, recognize that sometimes patenting with exclusive rights to a licensee may be the only way to encourage wide availability, as in the case of a research tool that a university needs to license a small company to mass produce. In contrast, the NIH policy on Sharing Biomedical Research Resources specifically recognizes this possibility. This raises another issue of internal NIH policy consistency.

We hope NIH will seriously consider our concerns both with regard to data submission and access and intellectual property. We appreciate the opportunity to comment.

Sincerely,

Anthony P. DeCrappeo  
President

