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Letter to NIH on Genomic Arrays Policy

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COUNCIL ON GOVERNMENTAL RELATIONS

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May 27, 2010

Ms. Sally Rockey
Acting Deputy Director for Extramural Research
National Institutes of Health
Building 1 – Shannon Building 144
1 Center Drive
Bethesda, MD 20814

Dear Ms. Rockey,

The Council on Governmental Relations (COGR) is an association of 182 research universities and their affiliated academic medical centers and research institutes, which together account for over 90 percent of the Federally-funded basic research conducted by colleges and universities. COGR concerns itself with the influence of federal regulations, policies and practices on the performance of research and other sponsored activities carried out at its member institutions.

We are writing in response to the recently released NIH Policy Notice regarding the treatment of Genomic Array expenditures made on NIH funded programs (*Budgeting for Genomic Arrays for NIH Grants, Cooperative Agreements and Contracts – Notice Number: NOT-OD-10-097, May 13, 2010*). COGR and its member institutions enjoy a productive relationship with the NIH, and the high quality of our relationship is demonstrated by the mutual willingness to communicate on those issues that raise significant concerns. The new policy is troublesome on several fronts and COGR and its members believe that additional dialogue would be beneficial.

Below is a list of talking points and issues, and upon your earliest convenience, we would like to meet with you to further elaborate on these topics of concern.

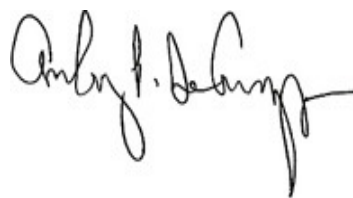
1. Disproportionate Administrative Burden. Per OMB Circular A-21, F&A rate determination is premised on the “averaging concept” where it is recognized that the actual cost burden across both grants and cost items will vary. The averaging concept is the prescribed Circular A-21 solution – otherwise, an unmanageable number of F&A rates would have to be established. The Genomic Array policy opens the door to unilateral reduction of F&A in any situation where there is a real or perceived disproportionate administrative burden. Under this logic, other grants or cost items should be assessed higher F&A rates when administrative burden is disproportionately higher – most likely, this logic would not be acceptable to NIH.
2. F&A Rate Proposal Adjustments. Institutions that negotiated F&A rates based on rate proposals that included significant Genomic Array costs in their organized research MTDC base could be penalized under this policy. Each institution should have the option to document the impact on their organized research MTDC base and the F&A rate calculated in their most recent F&A rate proposal. Based on the results, an institution should be entitled to a unilateral increase in their negotiated F&A rate.

3. High-Throughput Commodity and Service. The NIH policy establishes a new category of cost that could, in an arbitrary manner, be generically applied to other cost items. Any new policy should be narrowly defined to the cost items in question and should not introduce new terminology that could then be referenced in other situations.
4. Specialized Service Facility (SSF) Treatment. If Genomic Array services are provided by an internal SSF, the policy is not clear as to the application of F&A. The F&A rate normally is applied as an increment to an SSF cost. While it is clear that the incremental F&A cannot be applied after the threshold has been reached on Genomic Array costs generated through an external source, it is not clear if the same approach is applicable to Genomic Array costs generated through an SSF.
5. Manual Accounting Burden. University accounting systems are not designed to automatically calculate when thresholds have been exceeded. Consequently, implementation of the new policy will necessitate special accounting methodologies and manual intervention.
6. Making Effective Public Policy. While we appreciate the sense of urgency felt by NIH to address this issue, the process whereby a significant policy change is made without the opportunity for public comment is troublesome. The approach taken in this case lacked transparency and has created concern throughout the research community.
7. Reconciling Inconsistent NIH Policies on Cost Reimbursement. The new policy on Genomic Array cost reimbursement is especially disturbing when considered in the context of the NIH policy on F&A reimbursement associated with the Career Development (K Award) program. K awards incur research F&A costs exactly like the awards issued through the Research Project Grant (R01) program. However, the K Award program continues to restrict the F&A rate at 8%. For NIH to cite disproportionate administrative burden in selected situations, while not recognizing those situations where research universities are financially harmed, damages the NIH – University partnership.

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Again, we value the long-term and productive relationship COGR has shared with NIH. However, this issue is problematic on several levels and we would appreciate the opportunity to meet with NIH representatives at your earliest convenience.

Sincerely,



Anthony P. DeCrappeo
President, COGR