January 28, 2015

Office of Clinical Research and Bioethics Policy
Office of Science Policy, NIH
Email: SingleIRBPolicy@mail.nih.gov

Dear Comment Review Board:

The Council on Governmental Relations (COGR) is an association of 190 research universities, and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies, and practices on the performance of research conducted at its member institutions.

We appreciate the opportunity to provide our comments on the Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-15-026) and understand, although not stated in the draft guidance, that this applies only to multi-site research with a single protocol. While we recognize the need to reduce regulatory burden and support efforts to make IRB processes more efficient, we are concerned that the proposed policy as currently written will create new burdens for institutions conducting NIH-supported human research and would be very hard for our member institutions to accommodate in such a short timeframe.

For several years, many of our University members have embraced the use of single IRBs (e.g., Western IRB [WIRB], NCI CIRB, the Hutchinson Center’s Cancer Immunotherapy Trials Network [CITN] single IRB, NeuroNEXT, and StrokeNet), but it took many years and great effort for our members to obtain the support of their institutional leadership and to implement the new processes required. The draft guidance as currently written does not recognize the amount of time and effort it will take to get all NIH-funded institutions to adopt this approach, nor the effort it takes to develop and negotiate agreements with multiple clinical sites, each with its own policies and procedures, regulations, and institutional systems.

Our member institutions that have experience with single IRB review models have learned that it can be a good investment and can save time when there are multiple studies planned for the same participating sites, but it can be time consuming and expensive when used for only a single study. This is particularly true for institutions that utilize information management systems that need to be customized to allow for local review by ancillary committees such as investigational drug services, radiation safety review, and institutional biosafety committee review of gene therapies. Generally, reliance on an external IRB does not save administrative costs to our institutions, but rather shifts resources from supporting internal IRBs to managing the external relationships and reporting requirements.
Some of our member schools with no experience ceding IRB review have echoed the above concerns about electronic systems and the ancillary review process. In support of having a local IRB, many member schools cite institutional culture as an important consideration. A central IRB may not have, or be aware of, certain values and norms that can help guide decisions. Further, a local IRB contact often proves critical, particularly when sites span the nation and are several time zones away from the IRB of record. For smaller institutions, the extra administrative burden of external reporting and responding to audits might prohibit participation in multi-site trials.

While we appreciate that the proposed policy indicates that the costs of using a fee-based IRB can be included as a direct cost of a grant, the majority of academic institutions already include the cost of operating IRBs in the Administration component (capped at 26% since 1991) of their Facilities and Administrative cost rate. Therefore, for academic institutions, the added cost of operating as the single IRB of Record will be yet another unfunded mandate with zero cost savings due to the added burden of communicating between IRBs and monitoring compliance of unknown entities. The net result will be more costs with little or no time-savings for investigators when new reliance agreements need to be established.

While we endorse the concept of a single IRB review of multi-site studies and the goal to accelerate timeliness and reduce duplicative processes, we urge you to move us towards this goal by encouraging the use of a single IRB for certain types of multi-site clinical trials (e.g., those that can follow the NCI model or other established models) rather than to mandate this for all NIH-funded multi-site studies.

With the vast amount of research that has been done over the years suggesting models for IRB improvements, some currently in practice or being piloted, we believe that other efforts can be made to streamline IRB review with minimal cost impact to our members. We believe that with more emphasis on education regarding IRB reliance agreements, a concerted effort towards change management, i.e., changing from a from culture fed by fear of non-compliance or legal liability, combined with efforts of the NIH to pilot the NCI model with other NIH institutes will be a more productive course of action. In addition, we caution against any policy implementation prior to clarification of the status of the ANPRM regarding human research; as it will be costly for our members to implement and operationalize regulatory change in a piecemeal approach.

Thank you for the opportunity to comment.

Sincerely,

Anthony P. DeCrappeo
President