Pediatric Dermatology Research Alliance

January 29, 2015

TO: NIH Office of Science Policy

RE: Comments on the Draft NIH Policy - Use of a Single Institutional Review Board for Multi-Site Research

We are writing today on behalf of the 68 institutions and 197 clinicians and researchers who have joined together under the umbrella of the Pediatric Dermatology Research Alliance (PeDRA) to bring new solutions to the field of pediatric dermatology care. PeDRA provides the platform from which investigators can join together in multi-center collaborative research studies. Unified and working together in this manner has greater impact and brings results for patients, multiplying the power of each individual researcher. Since PeDRA's inception in 2012, enthusiastic engagement in this organizational concept has continued to escalate.

Given this mandate, the prospect of using a single Institutional Review Board (IRB) for multi-center studies is particularly exciting. In the current environment, having to coordinate 20 or more IRBs for a study is common and the burden increases greatly for longitudinal investigations. A central IRB improves efficiency, streamlines the work, minimizes overlap of effort, and encourages collaborative research.

We heartily agree with Dr. Sally Rocky that the "proposed policy is a step forward to reducing burdens associated with NIH-funded clinical research and enhancing the efficiency of the process while still ensuring protections of all the volunteers who generously participate in human subjects research for the betterment of us all." Having the NIH support a policy of use of single IRBs for multi-site studies not only facilitates NIH-funded research, but sets an example for multi-site studies funded from other sources as well.

Unmet needs in pediatric dermatology

Many pediatric skin diseases are so uncommon that meaningful study is difficult without collaborative effort. Conducting clinical trials in young children, even in common diseases, is also challenging. Recruitment of eligible subjects can be difficult, especially given the busy clinical practice, limited time, poor funding and lack of infrastructure for most pediatric dermatologists to perform high-quality research. These challenges mean that many – perhaps most – of our therapies for pediatric skin disease are based on anecdotal evidence, expert opinion, and precedent. There is a lack of accepted clinical guidelines for many dermatology conditions, including life-threatening skin disorders.

Standardized treatment protocols that exist in pediatric oncology and pediatric rheumatology are sorely lacking in our field and, to date, scant NIH funds have been allotted to pediatric dermatology research. Better evidenced-based management for children with skin disorders requires well-designed, multi-center collaborative clinical trials that would be facilitated by working with a single IRB.

Creating a research alliance to meet needs

In 2012, pediatric dermatology leaders came together to plan a collaborative clinical and translational pediatric dermatology research network and PeDRA was born. Since that time, PeDRA has developed a leadership structure to drive the work, a seminal website, http://pedraresearch.org, and a free-standing annual conference, which NIH R13 funding supported in 2013 and 2014. These meetings were designed to bring together clinicians, basic scientists, and patient advocates to enhance opportunities for translational research. Study groups have formed focused on specific research areas, drawing senior and junior investigators from diverse geographic regions into collaborative projects.

Through these early successes, PeDRA is well on its way to achieving the mission so well articulated by its founders: to promote and facilitate high quality collaborative clinical, translational, educational, and basic science research in pediatric dermatology. PeDRA's vision is to create sustainable collaborative research networks to better understand, prevent, treat and cure dermatologic diseases in children.

Barriers to successful research collaboration

Studies requiring research blood and tissue specimens are critical to investigation of genetic pathogenesis, biomarker development, and disease natural history. For rare disorders, procuring biological samples at one site is limited by population frequency, with some disorders present in fewer than one in 500,000 individuals. When samples must be obtained from more than one institution, it is frequently necessary to generate a local version of the study protocol at the clinical site, even if for just one patient, and materials transfer requirements are also often necessary. This places an administrative burden both on the investigator and on collaborating physicians, slowing the speed, and increasing the cost of research. The same cross-institutional barriers exist in the conduct of clinical and translational research, including clinical trials and studies of disease natural history.

In addition, private practice physicians are eager to participate in translational research but, unless associated with a university or hospital, do not have access to an IRB. Such individuals may be subject to liability/risk without IRB oversight, creating a barrier to participation by the large group of private practice dermatologists who could contribute meaningfully to research.

Ensuring a future for multi-center studies

Our PeDRA founding members and each of us have extensive experience in both translational basic science research and clinical trials. We strongly agree that eliminating redundant local IRB review will lead to enhanced protection for research participants and will expedite research, while reducing administrative burden and cost.

We support the proposed policy stating that central IRB utilization will be "expected" rather than optional, as this will lead to necessary changes in institutional culture, permitting broad adoption of central IRBs in intramural, extramural, and privately-funded studies.

The provision of direct costs in awards for fee-based IRBs recognizes the administrative costs that can be associated with large studies. By stating that "use of the designated single IRB will be a term and condition of award," this policy ensures its rapid implementation.

Recommendations and conclusion

Adoption of a policy for use of a single centralized IRB for multi-center studies would greatly facilitate research towards meeting the goals of our Pediatric Dermatology Research Alliance. We currently have several studies ready to benefit from this policy. Although we understand the draft policy to pertain to NIH-funded studies, enforcement of this policy by NIH will serve as an important precedent that others will obligatorily follow. We are committed to working with the NIH to enact this policy and offer the resources of PeDRA for further deliberation and discussion.

Sincerely,

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