

March 21, 2012

Dr. Steven Hirschfeld MD, PhD
Director, National Children's Study
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Building 31, Room 2A03
31 Center Drive
Bethesda, MD 20814

Dear Dr. Hirschfeld:

On behalf of the twenty members of the Community Advisory Board from the University of Mississippi Medical Center (UMMC) National Children's Study Center, Hinds County MS Study Location, we are writing to express our confusion, deep exasperation, and substantial concern with the recent changes communicated in direction for the National Children's Study (NCS). As a group composed of key community leaders and representatives of the full gamut of children's health issues and concerns, we feel misled. Together, we touch all aspects of the lives of children in our county. This Study brings hope and potential for healthier children. We signed on as volunteers, lending our good names, positions, and reputations to promulgate the Study in our community because we believed that, for the first time, Mississippi children would have the opportunity to tell their story of disparity and of resilience thus contributing to understanding what keeps children healthy. We signed on because the Study was being implemented in our state by our state's only academic medical center with its rich history of teaching, research and patient care to our citizens. We trusted that they, in partnership with our State Department of Health and Blair E. Batson Children's Hospital, would carry out the Study with integrity and attention to the needs of our community. We have volunteered countless hours to assure that the women and families of our area receive the message that Study participation offers hope for their future and the future of children across the country and that their trust will not be betrayed. Asking us to accept this new mandate without input or adequate explanation breaches our trust and impairs our hope in a better future for our children's health.

We are now questioning all that we have been told. Communications from the initiation of our contract, including information on national web sites, news media, and other NIH publications, have included that 105 counties across the nation, including two counties in Mississippi – Hinds and Coahoma—would provide a national probability sample to be included in the Main Study for the NCS. We are deeply concerned to now hear that will no longer be the case. If we as leaders in our community feel this way, imagine the response of participants, providers, and wider community members when they hear that the potential for inclusion in the Main Study is in question. The only certainty currently being communicated is that the women and children who have committed to the Vanguard Study will continue to be followed (assuming, they choose to stay involved) for 21 years – but by some, perhaps external and unknown entity. There is a strong history in the South from prior studies where participants

were provided with less than full information. Anything that even potentially evokes that memory raises serious concern for long-term participation in any research study. Our association with such a potential interpretation risks all that we represent in our communities.

We have worked hard as a CAB to assure our community that taking part in this and other research offers significant potential. We want to express our heartfelt distress regarding any decision to abandon the national probability sample and, in all likelihood, Mississippi as a part of that sample. Converting to a 'convenience' sample from HMO's or other large health care agencies will only provide information on children who are covered entities. We had hope that this study would finally reach the children and families with limited voice--the children we see daily but who do not always show up on health care rolls. These are the hidden children in our county, but are those from whom we have the most to learn in terms of how they maintain the level of health they do achieve in the face of adverse environmental conditions. "Covered entities" and data collection using electronic health records can never capture that reality.

We were delighted when our CAB Chairperson, Maggie Wade, was selected to serve on the national community advisory group and appreciated that appointment as an opportunity to offer our expertise and support via that channel. Rather, we have witnessed what seems to be rushed plans which have excluded the affected entities – communities, scientists from our academic institutions, and advisory bodies, from the decision making process. Despite the NCS and NICHD Director's calls for an "evidence-based" study, the rapidity with which the decisions have been made has not allowed for a thorough analysis of the data gleaned by the Vanguard Study centers. Certainly Hinds County Study Location, under the leadership of the UMMC, has met its recruitment targets, has submitted high quality data, and is poised to work with our providers to implement a modified provider-based sampling design within our community. We are gravely concerned with the loss of the significant expertise that has been developed in existing academic centers and communities, particularly the expertise of the original seven Vanguard Study centers who have been doing this work for seven years; it will be very costly to recreate that infrastructure and nearly impossible to regenerate the lost trust in affected communities. We encourage you to design the Main Study with substantial input from all involved parties, including experts in probability sampling, so that we can assure our communities of a study that provides sound evidence of feasibility and scientific value.

We are in touch with the pulse of our community. Our county is committed to the NCS. However, if the NCS in Hinds County is moved to another entity, we are concerned with the loss of currently enrolled participants, thus removing even further the potential impact of Mississippi children, even in the Vanguard Study. As voices for our community and brokers for this Study in our community, our integrity is our major contribution; it may be impossible for us to continue to put our personal reputations on the line for some unknown entity that does not reside within our community. From our perspective, the strength of the NCS in our community—and across the country—lies in the associations with local institutions and communities. Any change in implementation of this study must consider ways to continue to involve local academic institutions and the communities they serve.

Despite these issues, we continue to have hope and faith that there is still opportunity for adjusting the course for the continuation of the Vanguard Study and initiating a Main Study that will provide sound scientific evidence to guide children's health care for decades to come. The local communities and associated academic institutions designated for this Study, especially the 40 that have been actively engaged, have made a commitment to the Study. To abandon them from the Main Study is a travesty that needs to be avoided. This is particularly true for Mississippi whose population holds the unenviable position of having the highest prevalence of poor pregnancy and birth indicators and of significant environmental and disease disparities. The Mississippi Delta is the closest thing our nation has to a third world country; abandoning the Coahoma County and Hinds County location seriously undermines the validity of the NCS.

We hope that you and your staff are willing to carefully examine existing evidence, including input from local communities, before making irrevocable decisions regarding the logistics of continuing the Vanguard Study and design for the Main Study. What has been communicated thus far, for example in the Administration's budget and interviews reported in several science journals, suggests that final decisions have already been made. We hope that all of this is simply taken out of context, is premature, and awaits careful examination of the evidence and conversation with key constituencies. Should no such intentions be forthcoming, we strongly suggest that the title National Children's Study be abandoned and a new, more honest title reflecting the limited sampling design be adopted.

Thank you for your attention and consideration of this crucial matter. We continue to hope that the NCS will develop its potential as a national treasure of knowledge and knowledge development that offers unprecedented opportunity for impacting our understanding of children's health, development and disease outcomes; building community engagement in this and future research so as to assure wider representation of the most health-affected individuals; and involvement of academic centers to assure training for current and future health researchers and clinicians. Our nation and its children deserve nothing less.

Sincerely,

Maggie Wade Dixon
Chair, Community Advisory Board
Attached Signature list for all CAB Members

CC: Alan Guttmacher, MD
Director, Eunice Kennedy Shriver National Institute for Child Health and Human Development

Frances Collins MD, PhD
Director, National Institutes of Health

Jimmy Keeton, MD
Vice Chancellor for Health Affairs, University of Mississippi Medical Center

The Honorable Thad Cochran
Senator, Mississippi