Minority Opinion to SACHRP letter regarding the Department's Advance Notice of Proposed Rulemaking (ANPRM), "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" Federal Register 76, 143:44512, 2011:

A minority of SACHRP members were in disagreement with the consensus position expressed by SACHRP about the regulations regarding future uses of human-derived research materials.

The ANPRM distinguishes between biospecimens and clinical data regarding future uses. This disconnect may not be held by the public whose trust and support is so critical to the research enterprise.

What type of protections should exist for materials derived from human beings? One should consider protections that can be obtained by seeking permission prospectively and by ensuring greater transparency retrospectively.

It is clear that blanket consent for future uses is not an informed consent. It is a start however, because it allows those who do not want to have their data used to say no. But clearly additional oversight is needed to ensure that future uses preserve patient privacy and are consistent with the consent that they gave. And yet, today, no such oversight is required. OHRP has made it clear that de-identified data and biospecimens do not represent living human subjects and do not need further oversight. This is mistaken. First, the public believes (rightly we might add) that if you have an individual's DNA, the individual could be re-identified, and even if you don't re-identify, you still have that individual's genetic code (and not someone else's). Similarly, if you have an individual's clinical information, even if de-identified, it is about (derived from) that particular individual.

We are not beholden to any particular form of oversight. There are at least 3 options: 1) to consider biobank governance models similar to those being used in Europe which may be instructive; 2) to expand IRB oversight to cover human-derived research materials (including both biospecimens and de-identified clinical data); or 3) to create an alternative biobank oversight structure, consisting of representatives from both the scientific community and the public. The purpose of this oversight is: 1) to determine the scientific validity of the question; 2) to determine that the samples requested are appropriate to answer the question; 3) to ensure that the researchers have proper training and understanding of human subjects protections; 4) to ensure that the research plan protects the privacy and confidentiality of the participants whose data are being used; 5) to obtain assurance that re-identification will not be attempted unless prior consent permitted it; and 6) to ensure that additional risks to vulnerable populations (e.g. identifiable communities) are recognized and minimized. OHRP need not specify how oversight is done, but must mandate the need for oversight (at minimum, registration) for all research involving human materials.

There is also the need for greater transparency. The public is relatively unaware that such research is occurring ubiquitously. Education should focus on why they should want to support research using de-identified human materials both for themselves, for their families, and for society-at-large. Without such education, media attention (both positive and negative) may leave the public feeling that their rights were disregarded and their trust was violated. The public should have the right to know about the uses to which their data (information or biospecimens) were used. The importance of trust in the research enterprise cannot be overstated. This includes transparency regarding all secondary research use of existing biospecimens, whether or not there are identifiers. Within the ANPRM, all such research should be registered with the institution. In this vein, OHRP may need to reconsider who or what is meant by the concept of "human subjects research" and whether it should include materials derived from living human subjects.

This comment should not be understood to reject the use of de-identified research materials (both clinical data and biospecimens) for research, nor is it meant to create undue obstacles, but only to ensure appropriate protections are in place. We want to emphasize that: 1) clinical information and biospecimens should be treated similarly because they are similar; 2) the public has the right to know when their data are used (even when de-identified) and for what purposes; 3) all such research should be subject to some type of oversight to respect the human beings from whom these materials were obtained; and 4) to the extent that de-identified data are being used for research, there should be no attempts at re-identification unless consent was obtained prospectively.