Washington University in St. Louis

Human Research Protection Office
FWA00002284

Barnes Jewish Hospital
St. Louis Children's Hospital
Washington University

May 9, 2012

Dear Department Chairs:

I am hoping you can disseminate this important information to investigators in your Department. With the increasing feasibility of conducting genomic research, it is essential that investigators understand certain issues that are unique to conducting this research.

Genomic research funded through the NIH is required to be shared, typically by submission to dbGaP. Similarly, most major journals also specify the data must be made available in some manner. Submission of these sequences to most databases, including dbGaP, requires certification by the institution that the samples were collected with appropriate research consent. Data from samples that were collected without specific research consent are absolutely not able to be submitted to these databases. This applies even if the IRB waived consent for the initial collection of the tissue. This remains true even if the subjects are now deceased. The NIH has been absolutely crystal clear and specific on this point.

Many investigators wish to use previously collected specimens that are stored in tissue banks, such as the Washington University Tissue Procurement Core (TPC), for genomic studies. While these represent a potentially very valuable resource for conducting genomic research, there are important caveats. Most notably, a significant percentage of samples in the TPC were collected without research consent, the so-called consent waived samples. The conditions under which the sample was collected specify that it can only be released completely anonymized, therefore there is no possibility of re-identifying the subjects and obtaining consent after the fact. These samples should NOT be used for genomic research, as these data will be ineligible for submission to any databases that require institutional certification of consent.

I realize this may seem to some as overly restrictive and perhaps contrary to current regulations. In fact, under the current regulatory framework, much of this research does not even meet the definition of human subject's research and therefore does not require IRB review and approval. However, the conditions for submission to dbGaP are separate rules established by the NIH completely outside of and separate to the human subjects regulations. These are rapidly being accepted throughout the scientific community as the appropriate standard for the conduct of this research.

If you have questions, please feel free to contact me or the staff at the IRB.

Sincerely,

Jonathan M. Green, MD
Professor of Medicine, Pathology and Immunology
Associate Dean of Human Studies
Executive Chair of the IRB