More than just “not identifiable”…

Recent federal regulations and guidance have impacted the scope of IRB review. Previously, a general rule of thumb was that if something is considered *not identifiable* then IRB review is not required. Based on some recent congressional legislative actions and policies announced by the National Institutes of Health, there are some very specific instances where this is no longer the case.

Receiving a direct sponsored award as the lead and working with a collaborator
According to federal guidance, if you receive a sponsored award directly from HHS for a research study that involves human subjects, even where all activities involving human subjects are carried out by another institution, you are still required to have IRB review. For example, you are the lead recipient receiving a sponsored award for a study that involves collecting survey information from respondents from various locations in the United States. As the lead, you will be issuing a sub-award to five different sites to collect the data as well as contracting to a site that will act as a data coordinating center. Even though you will not be conducting human subjects research directly, as the lead recipient of the sponsored award, you are responsible for receiving IRB review.
http://www.hhs.gov/ohrp/policy/engage08.html

Genomic Data Sharing (GDS) certification
The GDS policy pertains to all NIH-funded research generating large-scale ***human*** or ***non-human*** **genomic data** and the use of these data for subsequent research. The policy requires that genotypic and phenotypic data resulting from genomic research be deposited in a NIH-designated repository. Investigators are expected to de-identify the data per HIPAA regulations and assign a random, unique code to the data to protect participants’ privacy and confidentiality. While these de-identified data would no longer meet the definition of “human subject”, it is a requirement that all data submitted to the NIH-designated repository receive certification by an IRB. The IRB is to ensure that “data submission and subsequent data sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained” as well as consider the potential risks of having data included in a national repository to the individual and those related to them.
http://gds.nih.gov/PDF/NIH_GDS_Policy.pdf

Newborn blood spots
The Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240), an extension of the Newborn Screening Saves Lives Act of 2008, includes two significant changes to the human subjects regulations as they apply to research with newborn dried blood spots. First, the law requires that all research funded pursuant to the Public Health Service Act using newborn dried spots be considered human subjects research **regardless of whether the specimens are identifiable**. Second, the law eliminates the ability of the IRB to waive informed consent under 45 CFR 46.116(c) and 116(d) for research involving newborn dried blood spots. Note that this law applies only to HHS-funded research. This law went into effect Monday, March 16, 2015.
http://www.hhs.gov/ohrp/newsroom/announcements/2015.html

For questions or assistance determining whether your activities require IRB review, please contact your IRB office:

Longwood Medical Area (HMS, HSDM, HSPH) IRB
617-432-2153

University Area IRB
617-496-2847