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Draft Guidance Issued on Surveillance Activities Not Considered to be Research

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As has been its pattern in the recent past, the HHS Office for Human Research Protections (OHRP) has issued proposed guidance—but it's not on a topic the research community most needs as it grapples with implementing the revised Common Rule.

This rule, which requires new elements of consent forms, expands the use of waivers in minimal risk research and makes other changes, has a general compliance date of Jan. 21. Institutions and the Secretary's Advisory Committee on Human Research Protections (SACHRP) have made it clear they need help understanding how to implement the Common Rule's new key information and "broad consent" options and the more complicated provisions governing the use of biospecimens. SACHRP has already forwarded to HHS its recommendations on key information and others (*RRC 11/18, p. 3*).

In July, OHRP issued three draft (not final) proposed guidance documents that refer to the option of implementing a trio of "burden-reducing" provisions prior to the Jan. 21 date.