Study qualifies as exempt category 2(iii)

YES

Study qualifies as exempt category 3(i)(C)

NO

Study qualifies as exempt category 8(iii)

NO

YES

Requires Approval under Limited IRB Review .111(a)(7)

.111(a)(7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(i) The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

Study qualifies as exempt category 7

NO

Limited IRB Review
After 21 Jan 2019

Limited IRB Review Does Not Apply

STOP

.111(a)(8) (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of Sec. .116(a)(1)-(4), (a)(6), and (d); (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with Sec. .117; and (iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

2(iii) Educational Tests, survey procedures or observations of public behavior that use identifiable data that might place the subjects at risk for criminal or civil liability and does not involve children.

3(i)(C) Benign behavioral interventions that use identifiable data that might place the subjects at risk for criminal or civil liability.

8(iii) Use of identifiable data or specimens that were collected under broad consent

7 Storage or Maintenance of identifiable data and/or specimens for secondary research under broad consent