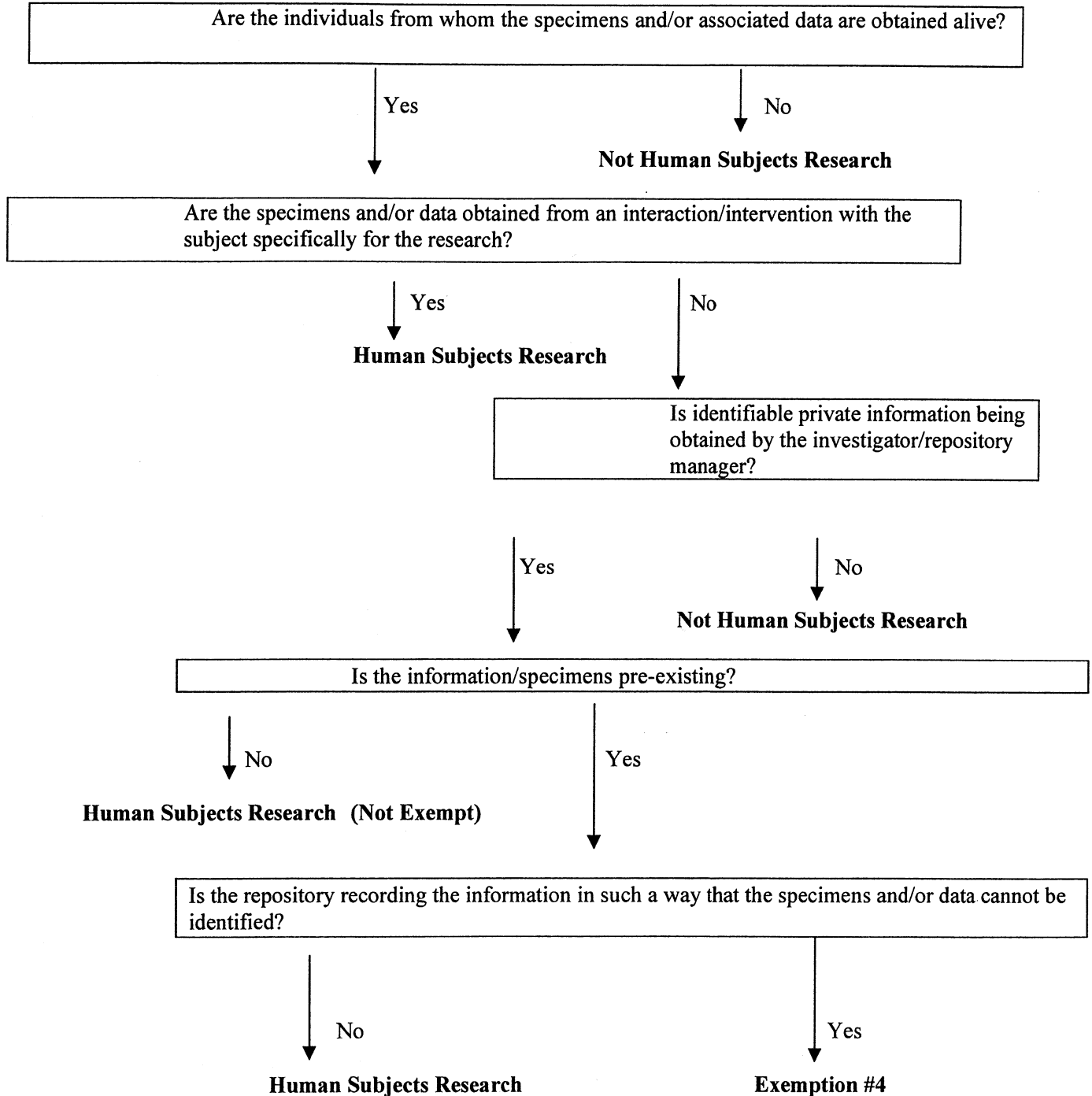


Flowchart 1

COLLECTION AND BANKING OF SPECIMENS AND/OR ASSOCIATED DATA FOR RESEARCH

This flowchart was designed to help illustrate when the collection and banking of specimens and/or associated data for research is considered human subject research under the HHS Human Subject Protection Regulations, 45 CFR part 46 (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>) and when it meets the criteria for Exemption #4 [45 CFR part 46.101(b)]. A second, companion flow chart (Flowchart 2) should be used for the research use of specimens and associated data obtained from a repository.



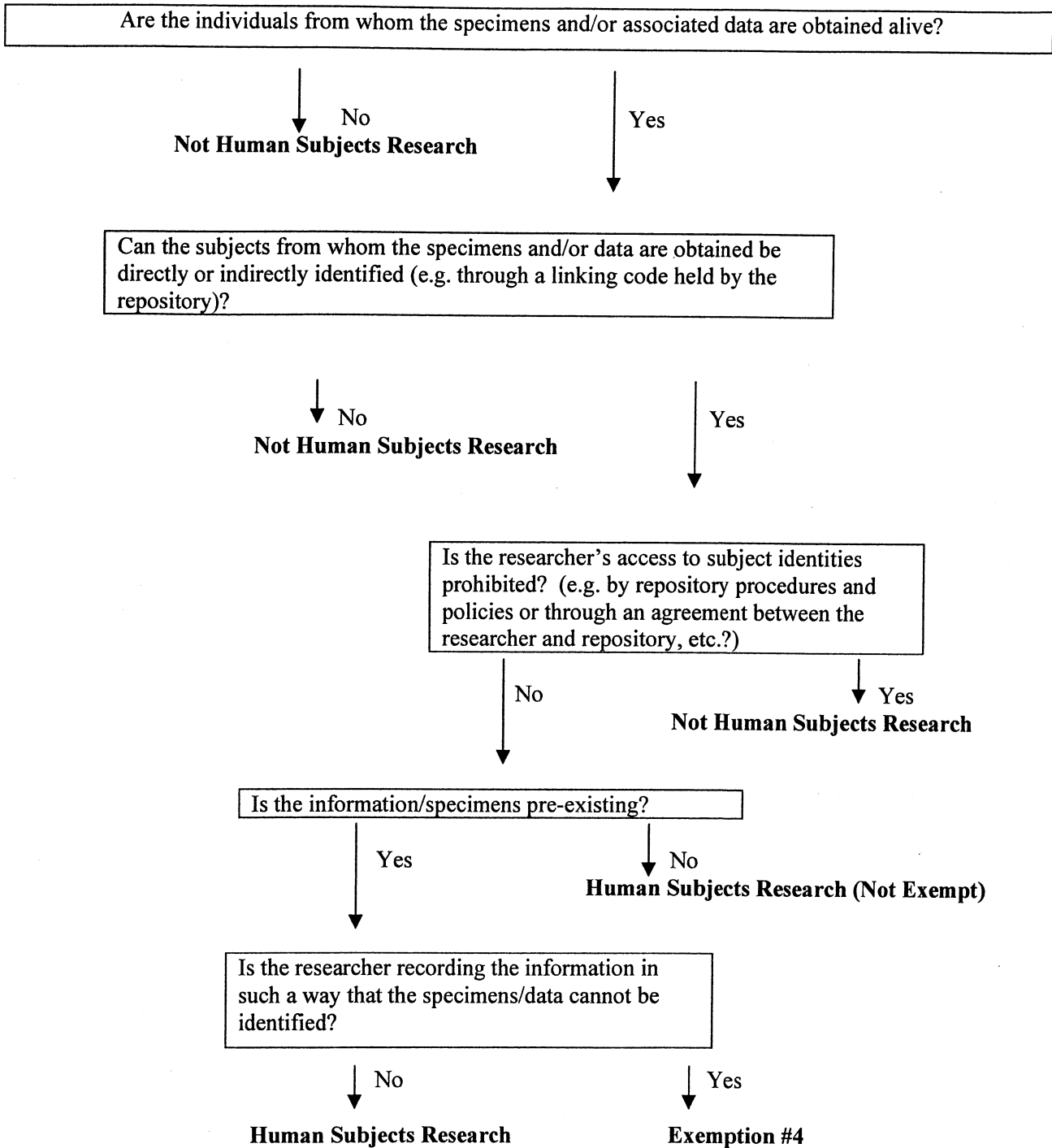
Report of the Public Responsibility in Medicine and Research (PRIM&R)

Human Tissue/Specimen Banking Working Group March 2007

http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/Tissue%20Banking%20White%20Paper%203-7-07%20final%20combined.pdf

Flow Chart 2
RESEARCH USE OF SPECIMENS AND/OR ASSOCIATED DATA

This flowchart was designed to help illustrate when the research use of specimens and/or associated data is considered human subjects research under the HHS Human Subject Protection Regulations, 45 CFR part 46 (<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>) and when it meets the criteria for Exemption #4 [45 CFR part 46.101(b)]. The preceding companion flowchart (Flowchart 1) should be used for evaluating the applicability of the Common Rule to collection and banking of specimens and/or associated data.



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http://www.primr.org/uploadedFiles/PRIMR_Site_Home/Public_Policy/Recently_Files_Comments/Tissue%20Banking%20White%20Paper%2003-7-07%20final%20combined.pdf