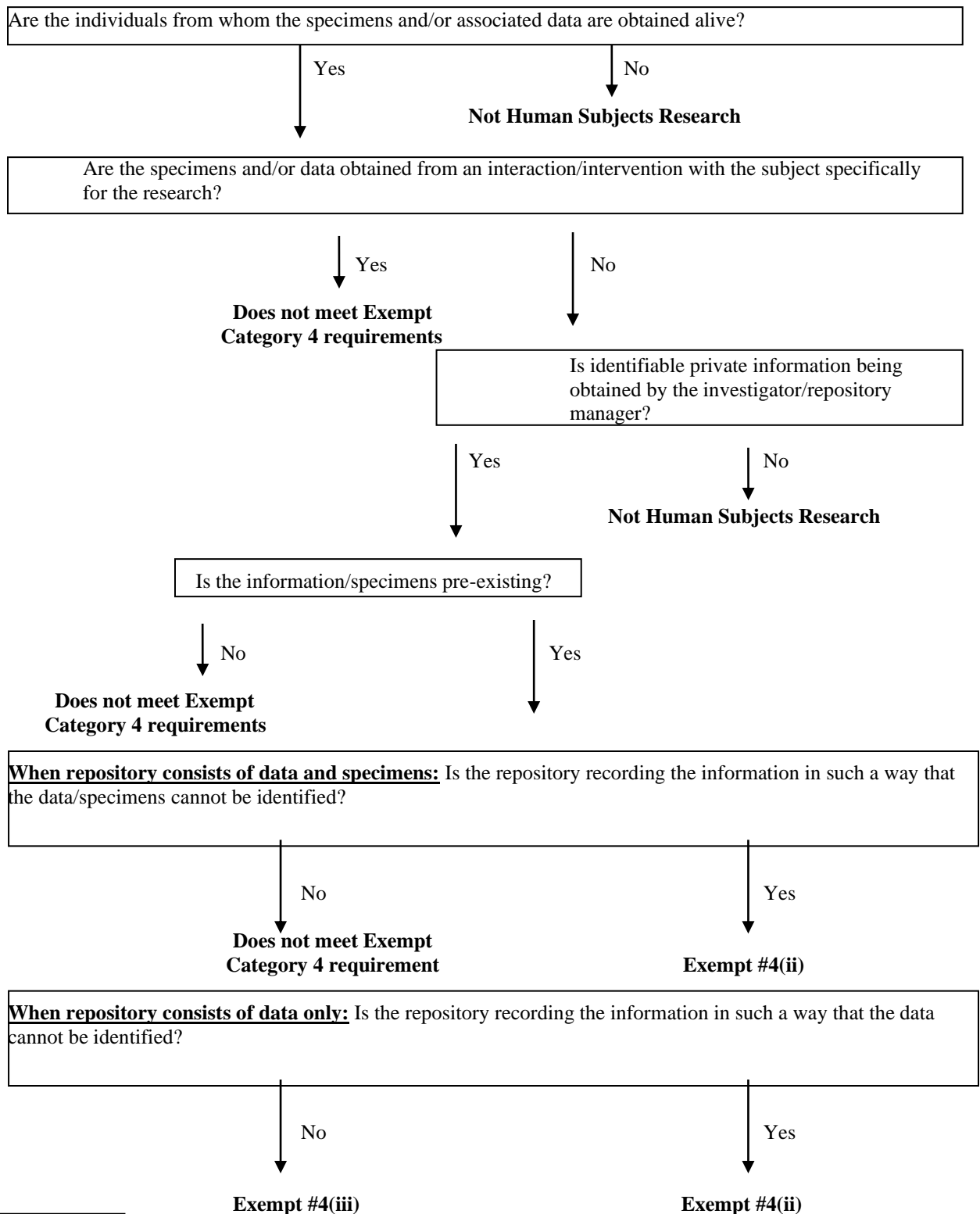


Flowchart 1

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 and when it meets the criteria for Exemption #4 [45 CFR part 46.101(b)].



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 and when it meets the criteria for Exempt #4 [45 CFR part 46.101(b)].

