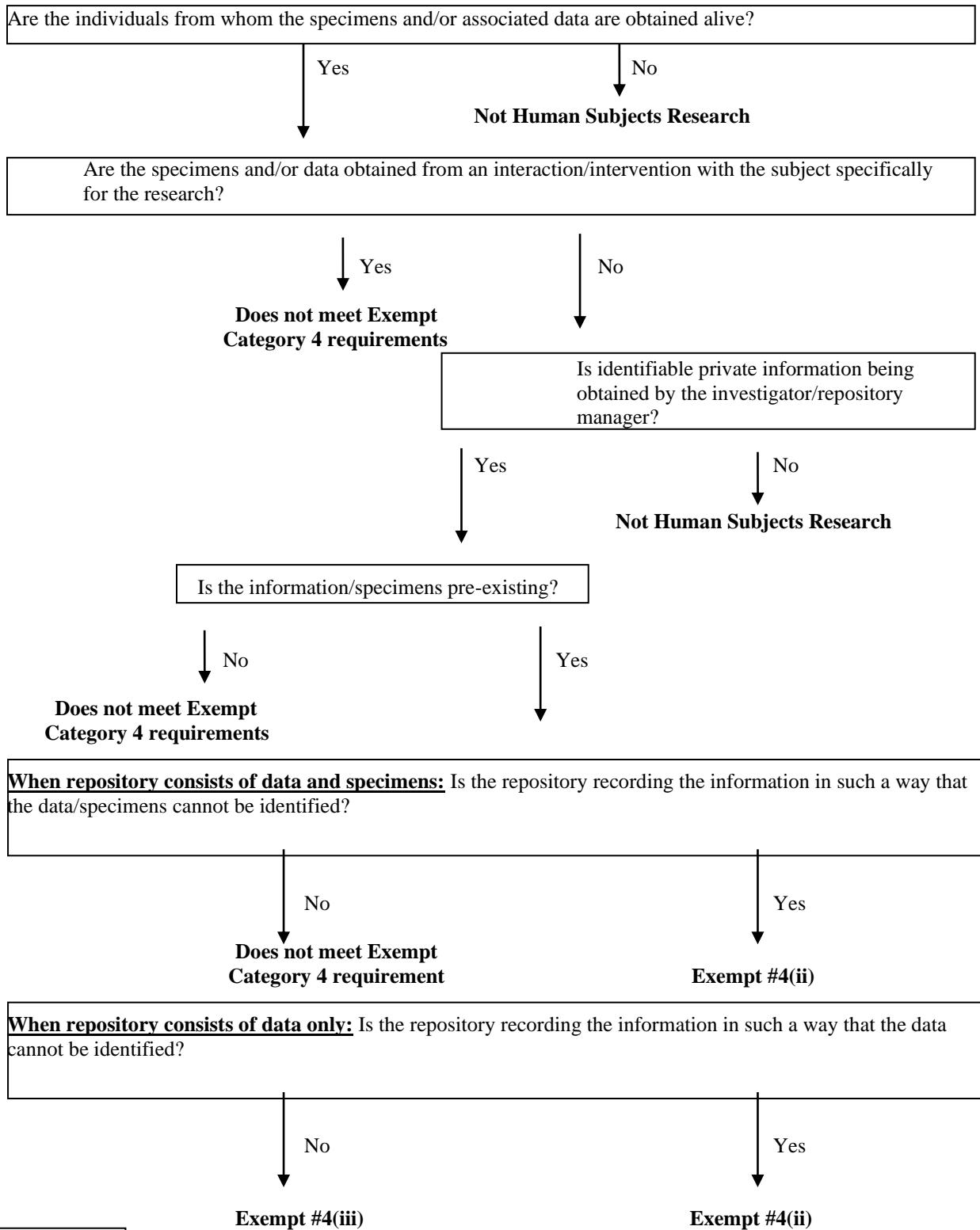


**Flowchart 1**
**COLLECTION AND BANKING OF SPECIMENS AND/OR ASSOCIATED DATA FOR RESEARCH**

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)].

