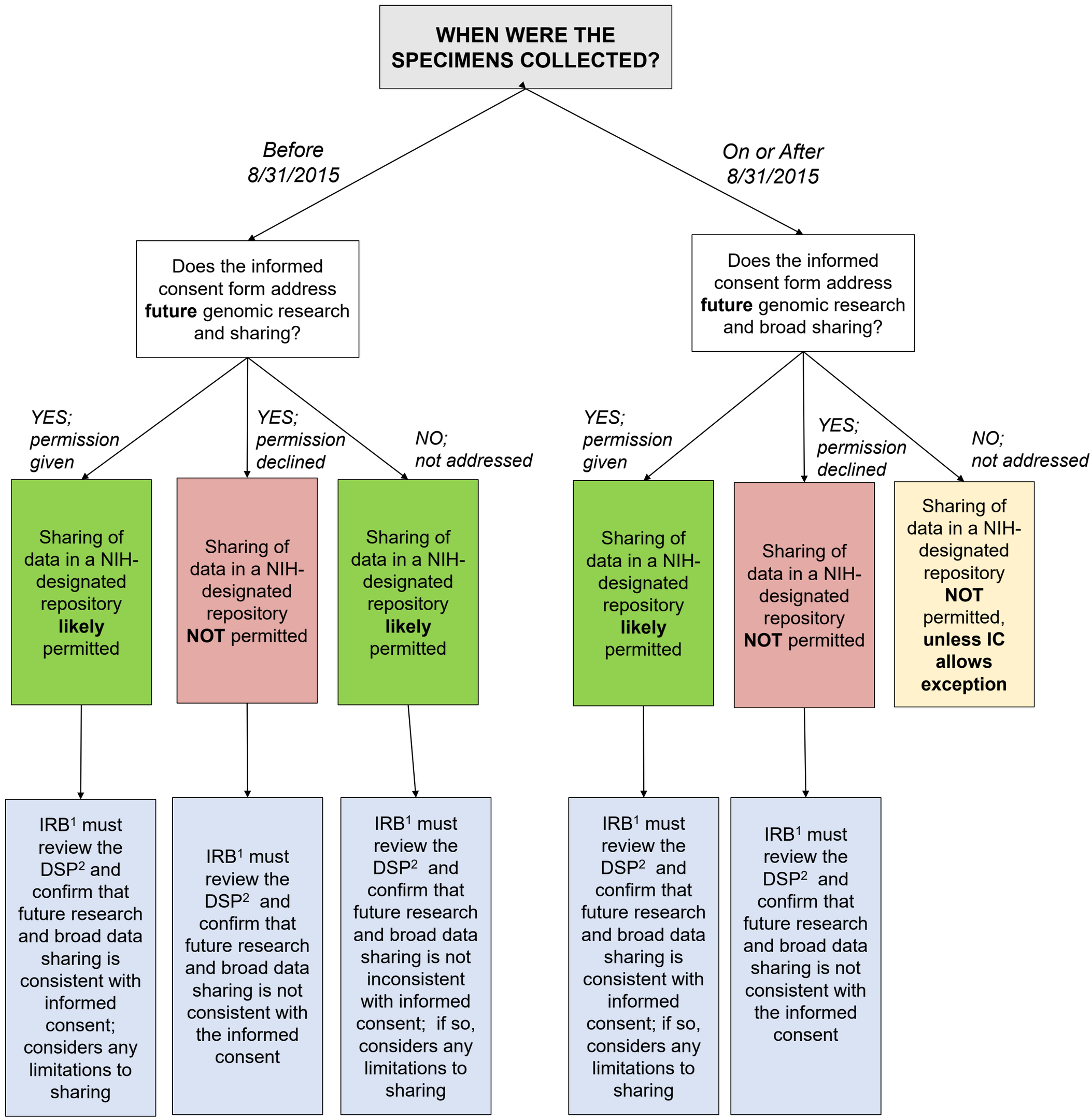
NIH Genomic Data Sharing Policy:
Flowchart for Informed Consent Expectations and the Role of the IRB

A. Specimens Collected under an IRB-Approved Protocol with Consent



[1]The IRB that reviewed the original protocol, under which the specimens that were used to generate genomic data were originally collected, should provide this assessment. If the specimens used for the genomic research were collected under an NIH IRB-approved protocol, the NIH IRB will provide this assessment. If the specimens used for the genomic research were collected under an external IRB-approved protocol, the external IRB should provide this assessment.

[2] Data Sharing Plan

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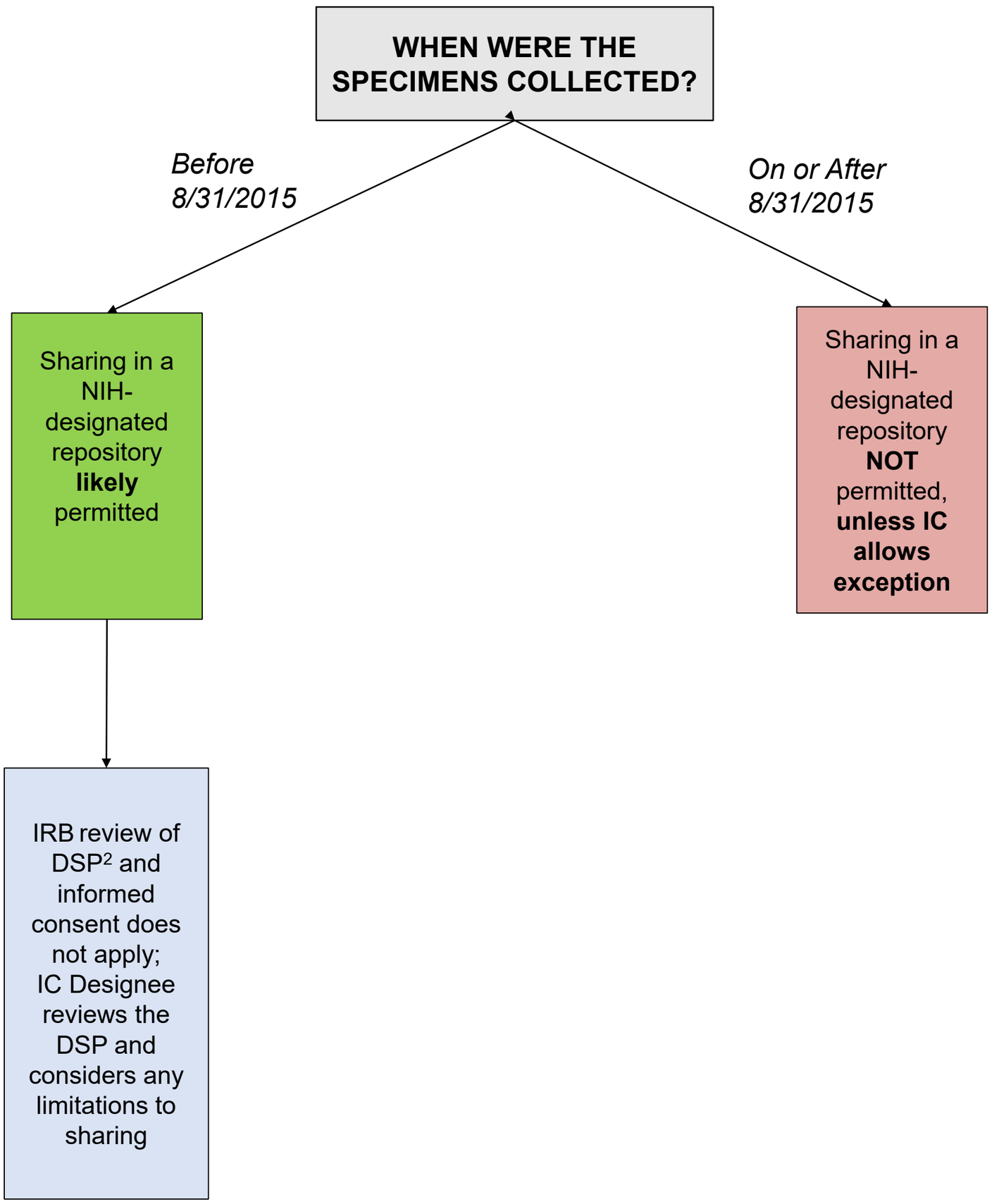
B. Specimens <u>NOT</u> Collected under an IRB-Approved Protocol with Consent



[1]The IRB that reviewed the original protocol, under which the specimens that were used to generate genomic data were originally collected, should provide this assessment. If the specimens used for the genomic research were collected under an NIH IRB-approved protocol, the NIH IRB will provide this assessment. If the specimens used for the genomic research were collected under an external IRB-approved protocol, the external IRB should provide this assessment.

[2] Data Sharing Plan