Federal regulations specify that for the IRB to approve non-exempt research, informed consent covering specific elements must be obtained from all research subjects prior to their participation unless (1) the IRB approves a waiver or alteration* of informed consent; or (2) the IRB-Flexibility Policy applies for certain minimal risk research. Use this decision tree to determine if IRB approval of a waiver or alteration of consent is required.

Use of Consent Process Decision Tree 2
If participants will not be asked to sign a consent form, use Consent Process Decision Tree 2 to assess whether IRB approval is required to waive the federal requirement for documentation of consent.

*An alteration of informed consent applies when informed consent does not contain all of the elements required in the regulations (e.g., a simplified consent document is used or the research involves deception or incomplete disclosure).