February 16, 2016

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:

whether an activity that must be reviewed by an IRB

whether the review may be performed by , and

whether or its documentation may be waived.

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

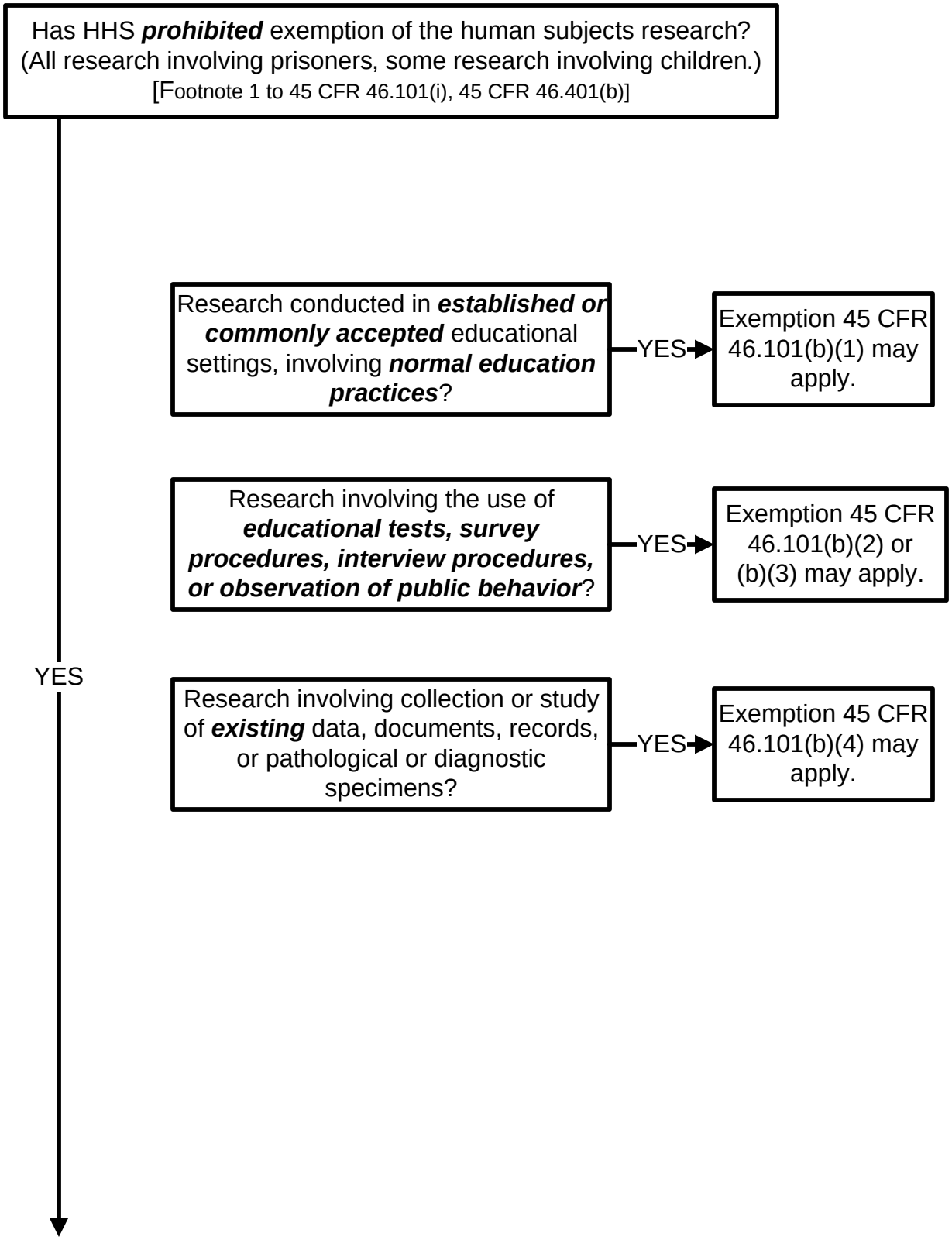


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Is the research ***only***** conducted in ***established or commonly accepted*** educational settings? (Including but not limited to

Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

February 16, 2016

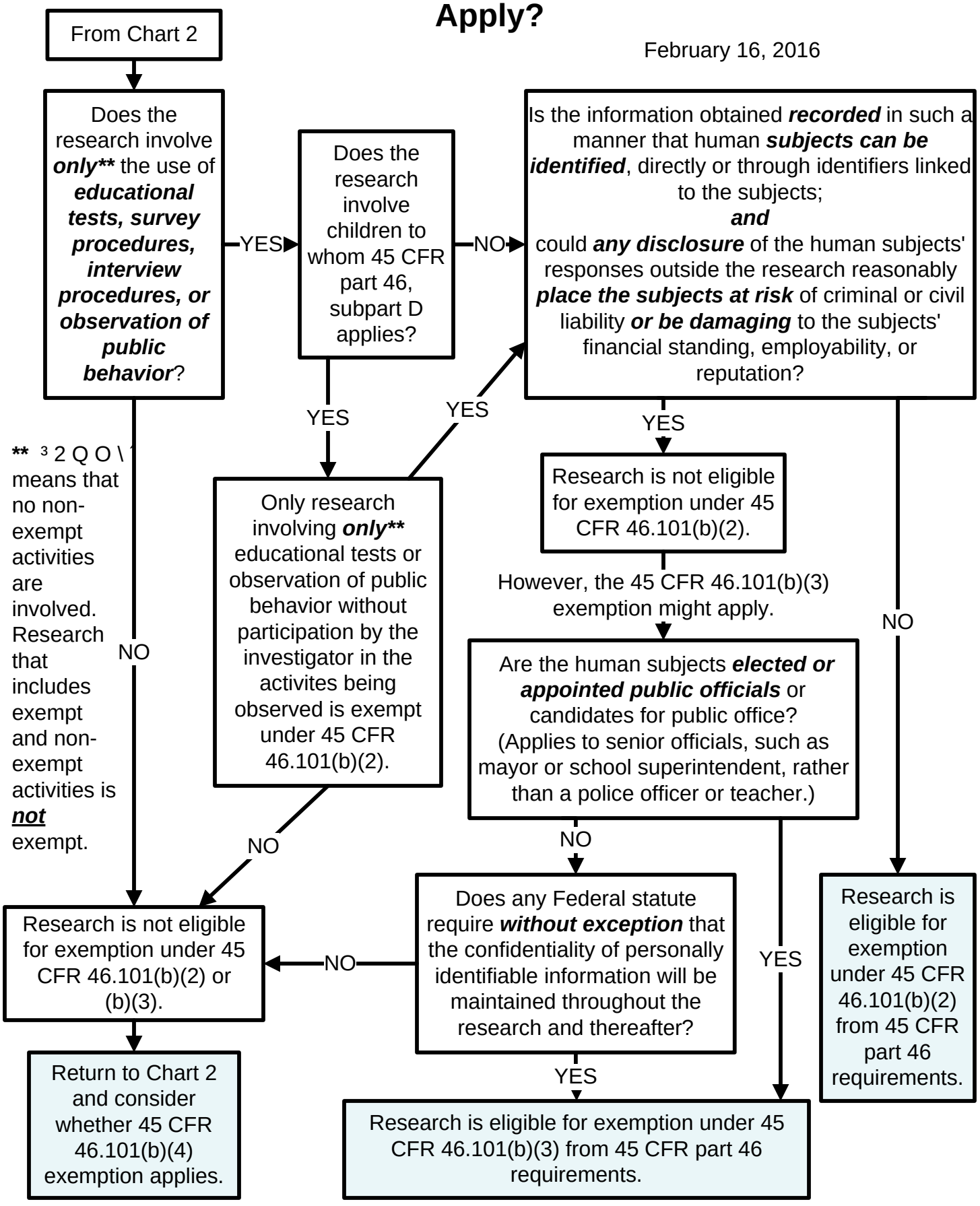
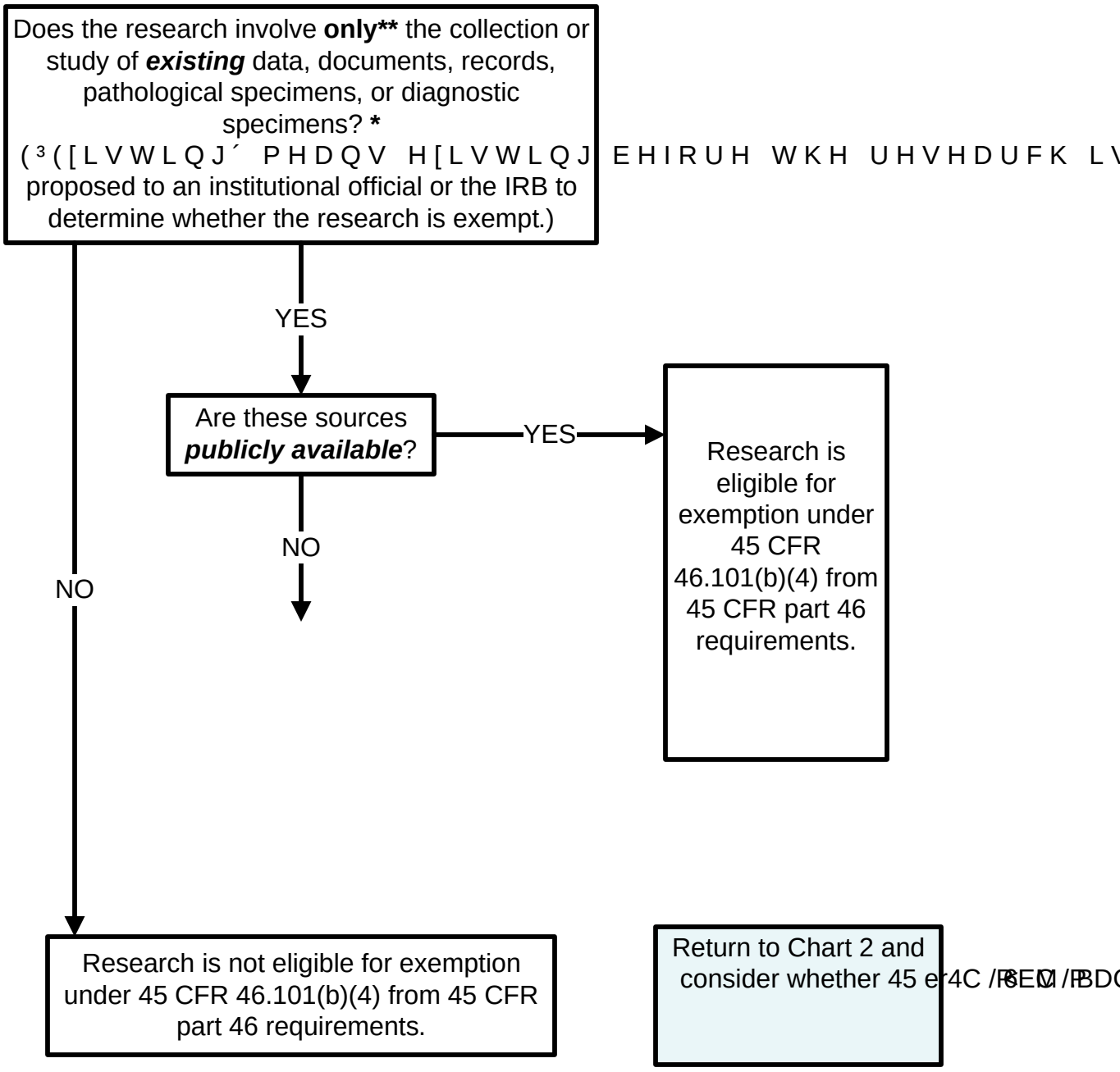


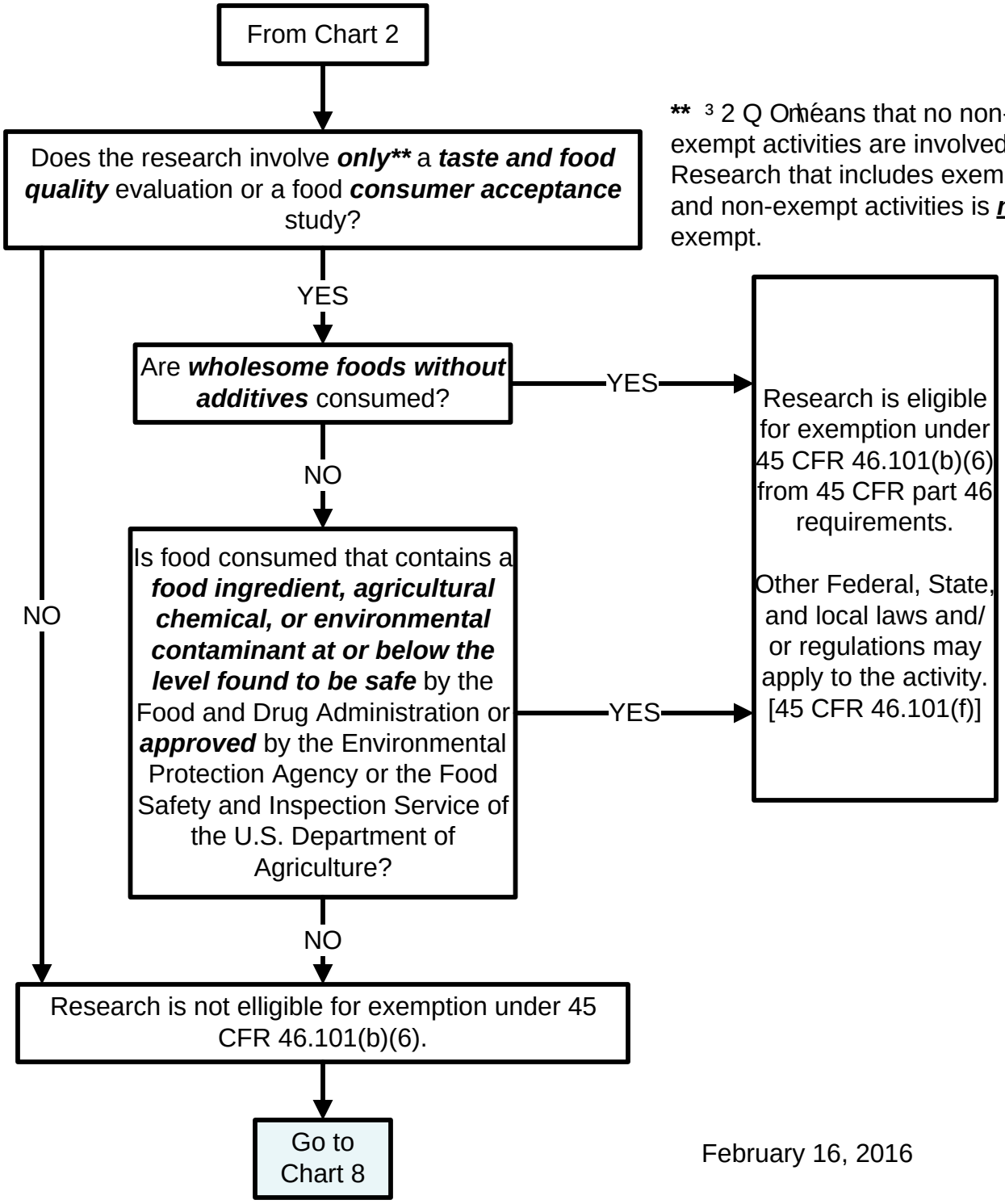
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



February 16, 2016

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

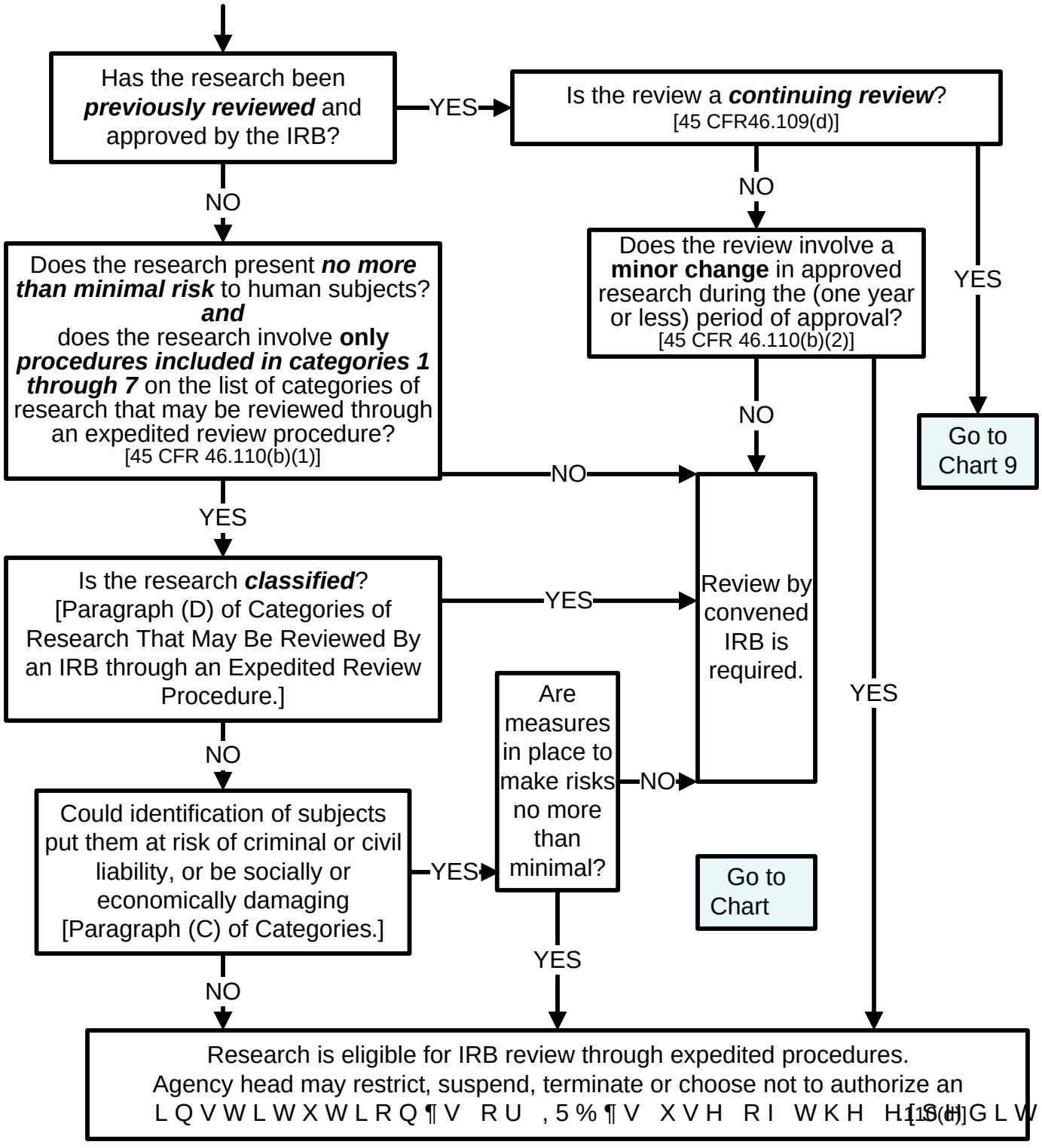
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



** 32 Q Omeans that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is ***not*** exempt.

February 16, 2016

Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*



February 16, 2016

Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

Have conditions ***changed*** to make the research ***eligible*** for expedited review under

Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**

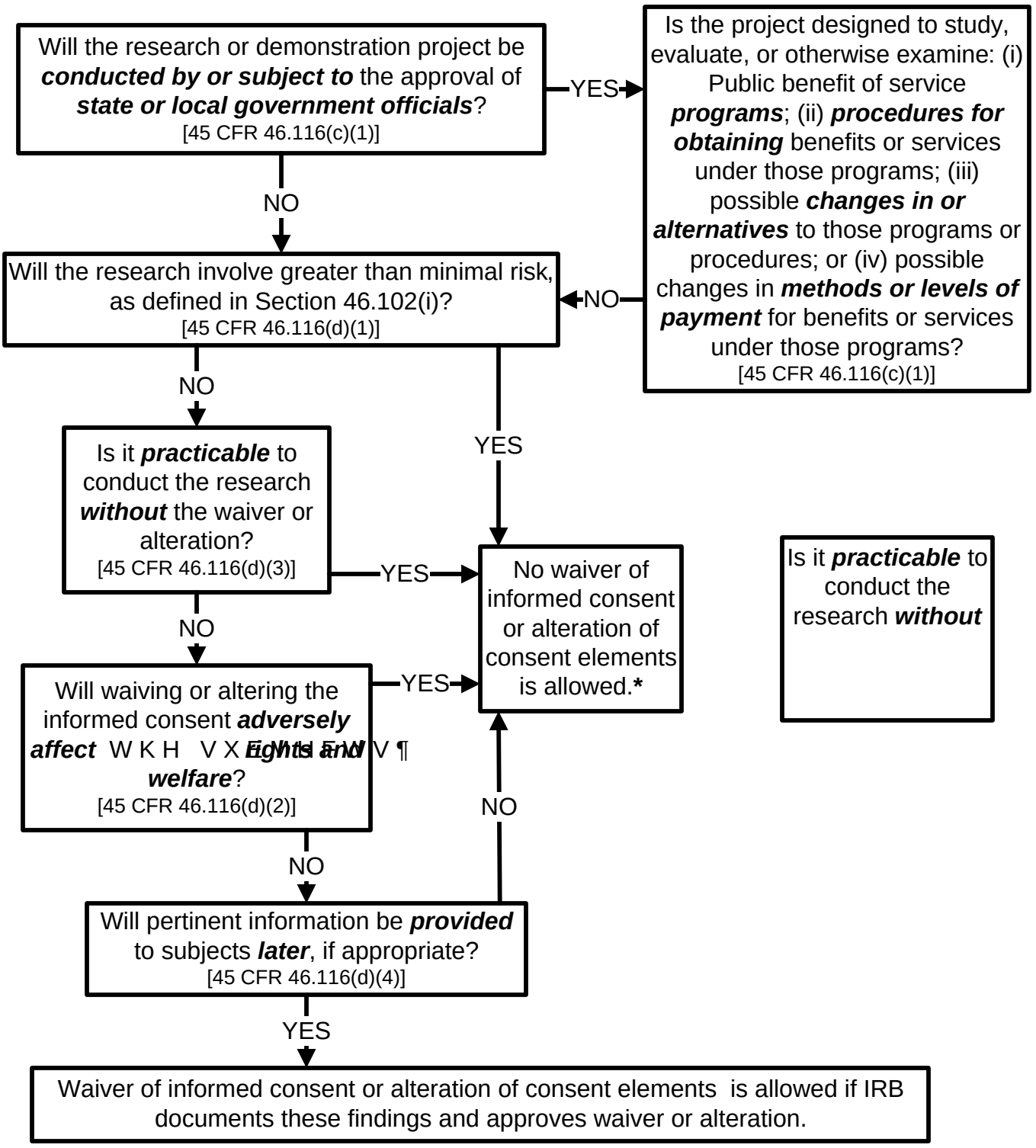


Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

6 X E M H F W ¶ V govern whether informed consent is Z L V K H V Z L