Covered by 45 CFR part 46? Start here. September 24, 2004 Is the activity a systematic investigation designed to develop or Activity is not research, so 45 CFR part 46 does not apply. contribute to generalizable knowledge? [45 CFR 46.102(d)] YES Activity is research. Does the The research is not research involving research involve obtaining human subjects, and 45 CFR part 46 Information about living does not apply. individuals? [45 CFR 46,102(f)] ΝŌ YÉS Is the information Does the research involve individually identifiable intervention or interaction with the (i.e., the identity of the NO. subject is or may readily be individuals? NO [45 CFR 46.102(I)(1), (2)] ascertained by the investigator or associated YÉS with the information)? [45 CFR 46.102(f)(2)] Activity is research YĔS BÚT involving human subjects. Is it conducted or Is the information private? (About YES supported by HHS? behavior that occurs in a context in **BÚT** [45 CFR 46.101(a)(1)] which an individual can reasonably expect that no observation or recording YÉS is taking place, or provided for specific NO purposes by an individual and which the ndividual can reasonably expect will not Unless exempt be made public.) [45 CFR 46.102(f)(2)] under 45 CFR Is the 46.101(b), research 45 CFR part 46. covered by subpart A áι Go to Chart 2 equirements apply applicable to the research. OHRP As appropriate, approved subpart B, C, and AND assurance D requirements created also apply. under 45 Other Federal, State and local laws and/or CFR NO regulations may apply to the activity. [45 CFR 46.101(f)] 46.103?

Chart 1: Is an Activity Research Involving Human Subjects

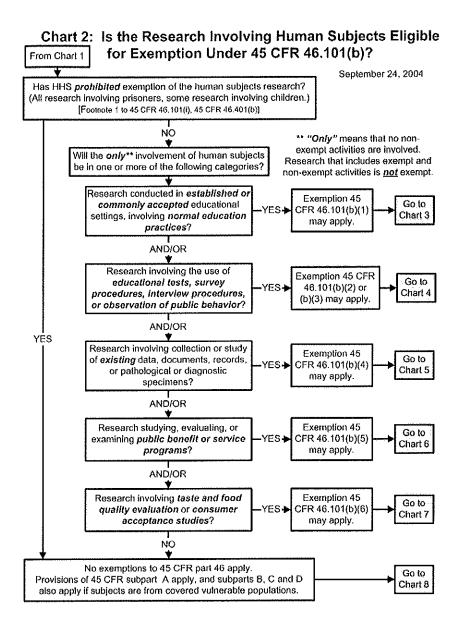


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

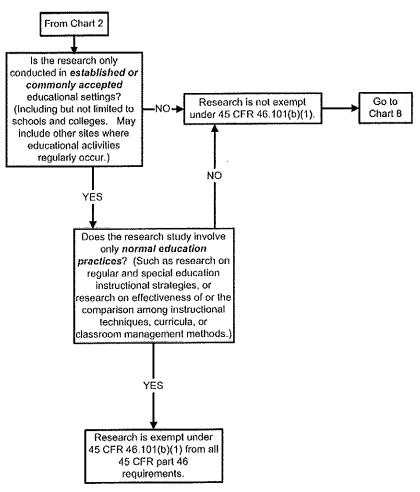


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation)

Apply?

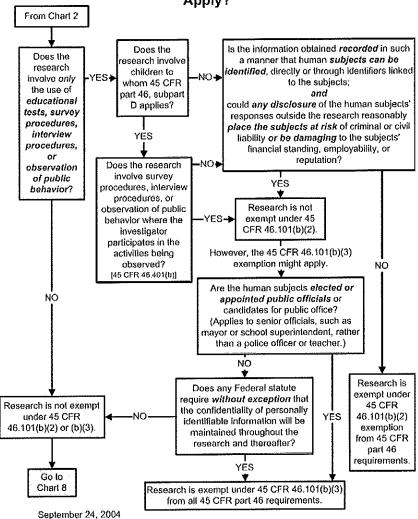
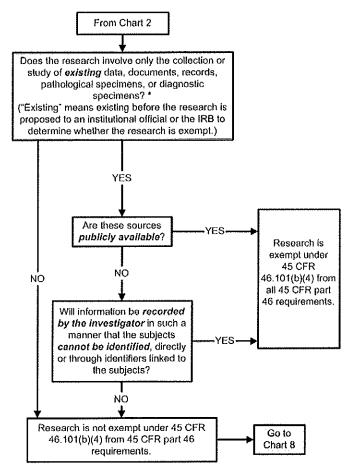
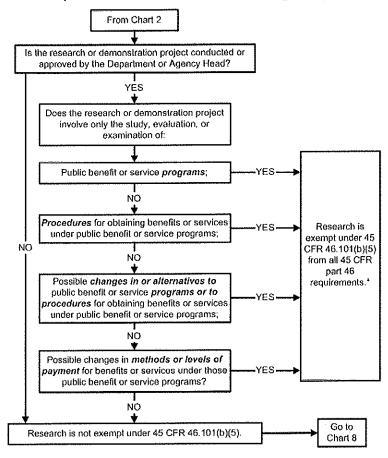


Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



^{*} Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/policy/index.html#tissues and #stem, and on coded data or specimens at #coded for further information on those topics.

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



^{*} Note: See OHRP guidance on exemptions at http://www.hhs.gov/ohrp/policy/index.html//exempt for further description of requirements for this exemption.

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

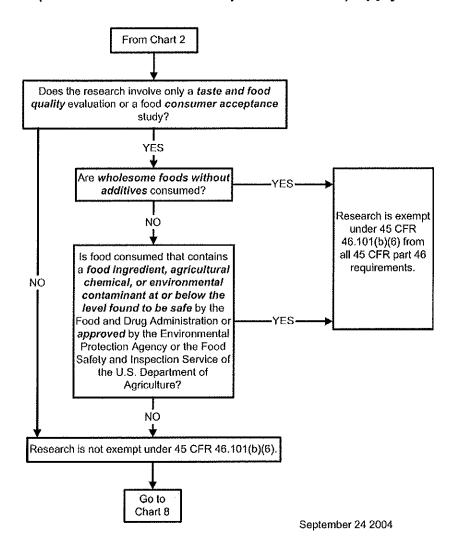
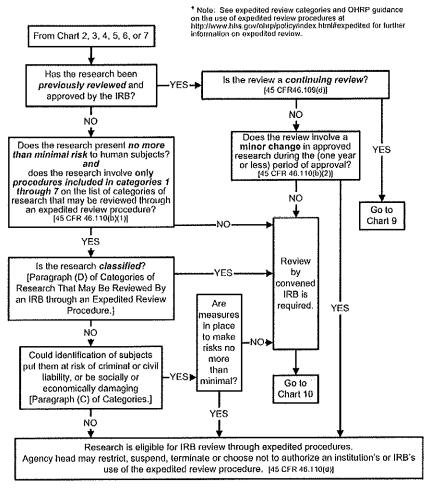
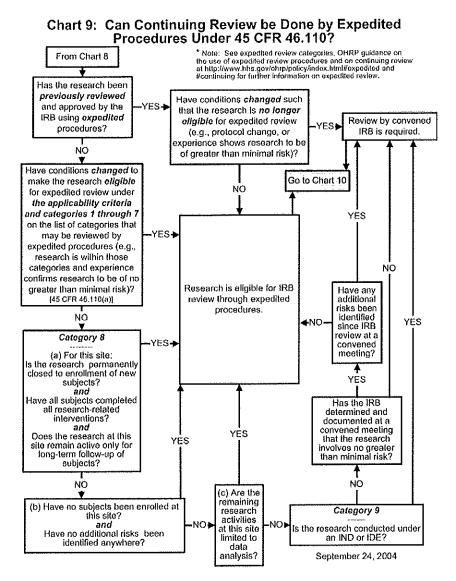


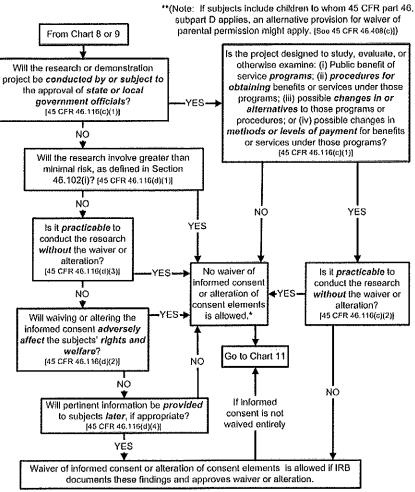
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*





10/28/2013

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



^{*} Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ehrp/poticy/index.html#emergency for further information on emergency research informed consent waiver.

September 24, 2004

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

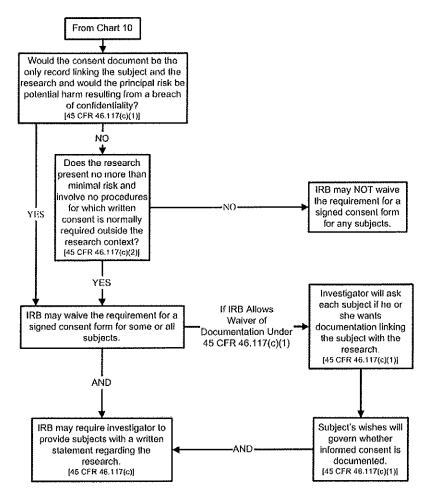


Chart 12: Determining if and Adverse Event is Reportable

The flow chart below provides an algorithm for determining whether an adverse event represents an unanticipated problem that needs to be reported under HHS regulations at 45 CFR part 46.

