Human Subject Regulations Decision Charts

September 24, 2004

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 is research that must be reviewed by an IRB
- whether the review may be performed by expedited procedures, and
- whether informed consent or its documentation may be waived.

Considerations

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 be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic. OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

Chart 2: Is the Human Subjects Research Eligible for Exemption?

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

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, Records and Specimens) Apply?

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?

Chart 8: May the IRB Review Be Done by Expedited Procedures?

Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

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

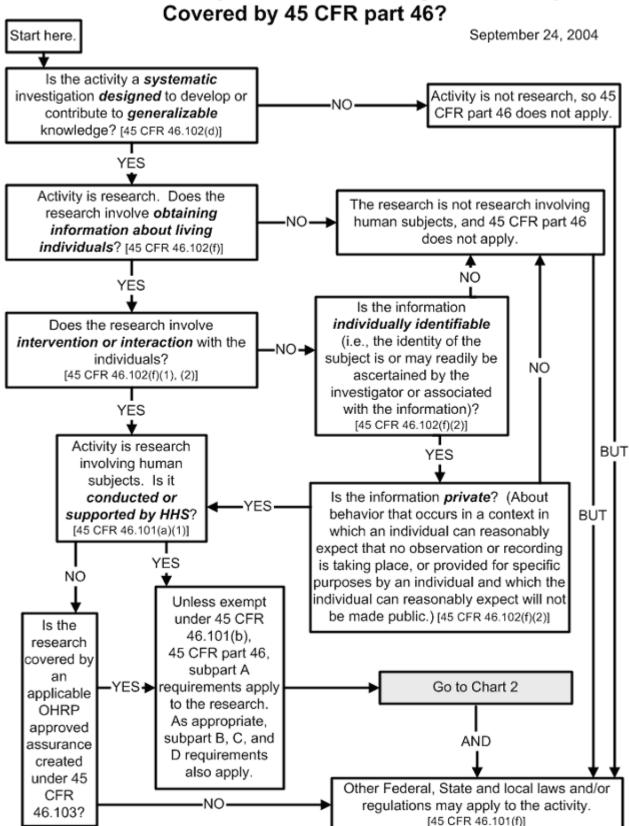


Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Chart 2: Is the Research Involving Human Subjects Eligible From Chart 1 for Exemption Under 45 CFR 46.101(b)?

September 24, 2004 Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)] т NO ** "Only" means that no non-* exempt activities are involved. Will the only** involvement of human subjects Research that includes exempt and be in one or more of the following categories? non-exempt activities is not exempt. Research conducted in established or Exemption 45 commonly accepted educational Go to YES 🌢 CFR 46.101(b)(1) settings, involving normal education Chart 3 may apply. practices? т AND/OR × Research involving the use of Exemption 45 CFR educational tests, survey Go to 46.101(b)(2) or YES procedures, interview procedures, Chart 4 (b)(3) may apply. or observation of public behavior? AND/OR × YES Research involving collection or study Exemption 45 of existing data, documents, records, Go to YES-CFR 46.101(b)(4) or pathological or diagnostic Chart 5 may apply. specimens? AND/OR ۲ Research studying, evaluating, or Exemption 45 Go to CFR 46.101(b)(5) examining public benefit or service YES-Chart 6 programs? may apply. Т AND/OR ¥ Research involving taste and food Exemption 45 Go to quality evaluation or consumer YES♪ CFR 46.101(b)(6) Chart 7 acceptance studies? may apply. NO No exemptions to 45 CFR part 46 apply. Go to Provisions of 45 CFR subpart A apply, and subparts B, C and D Chart 8 also apply if subjects are from covered vulnerable populations.

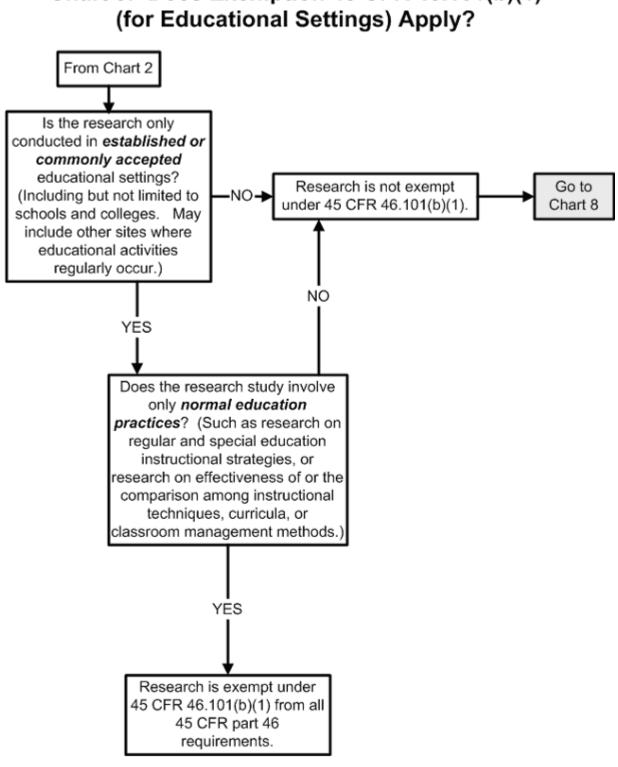


Chart 3: Does Exemption 45 CFR 46.101(b)(1)

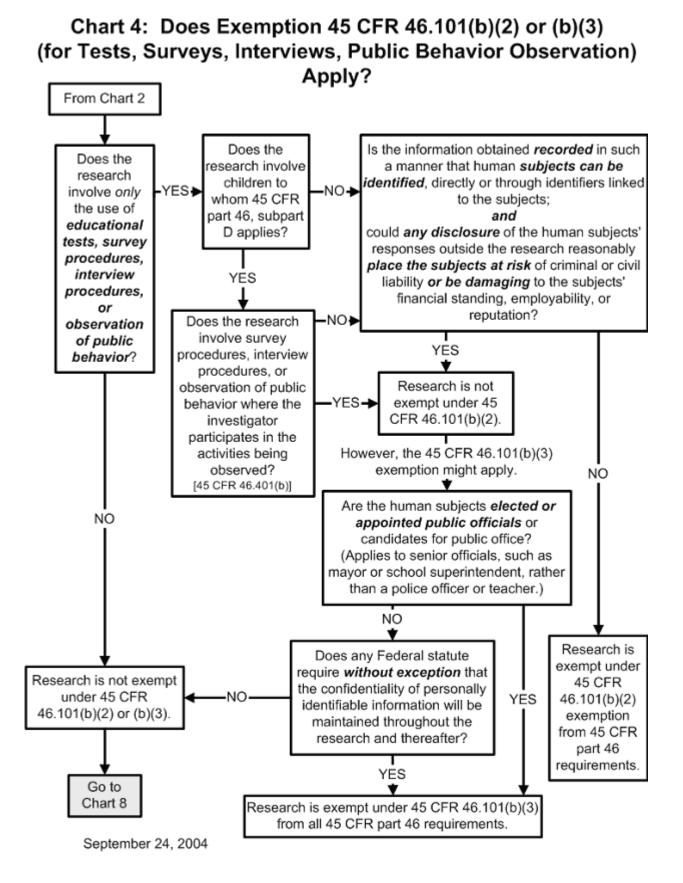
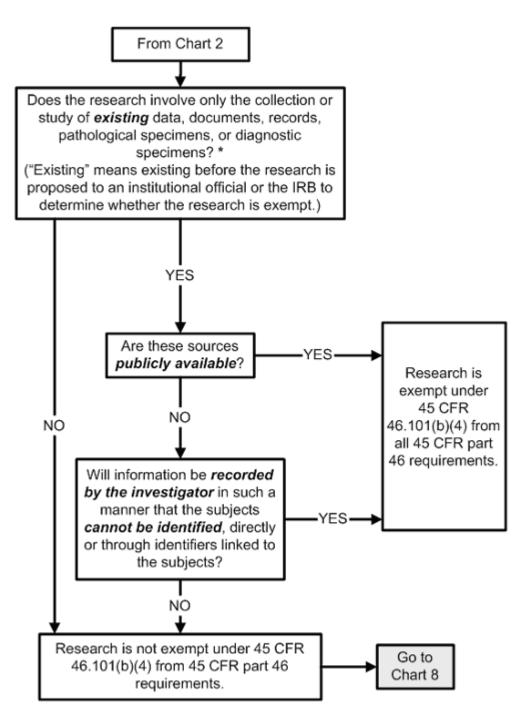
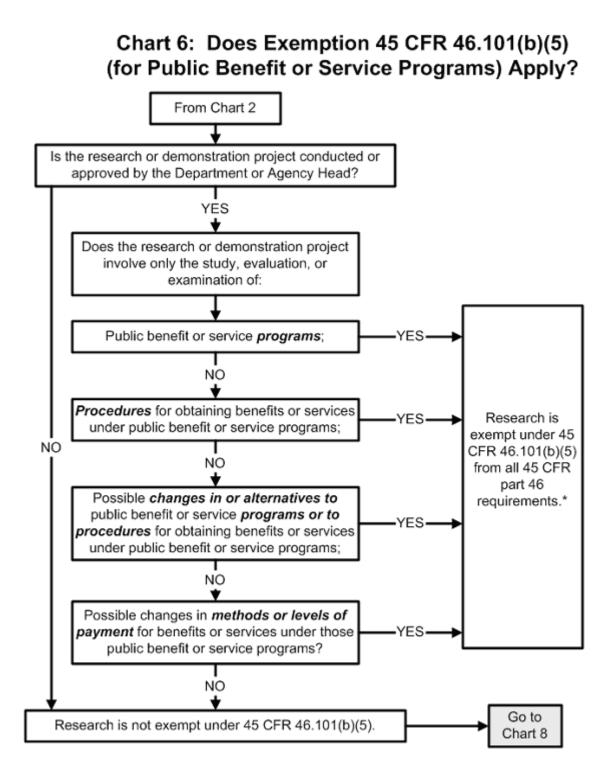


Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* 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.



* 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?

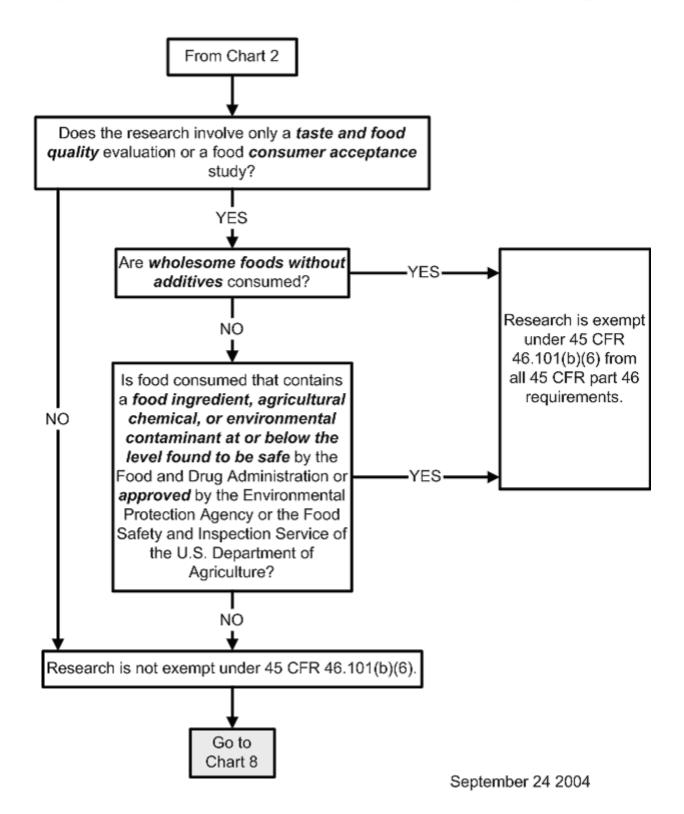
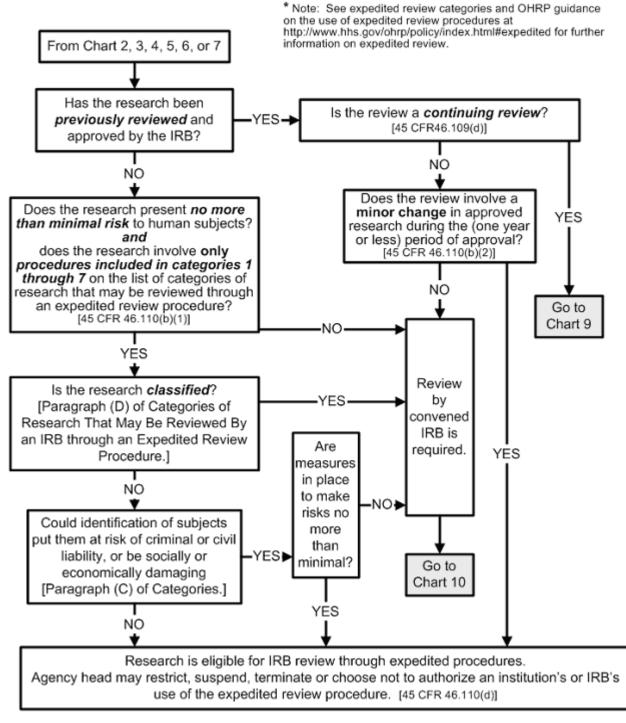


Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*



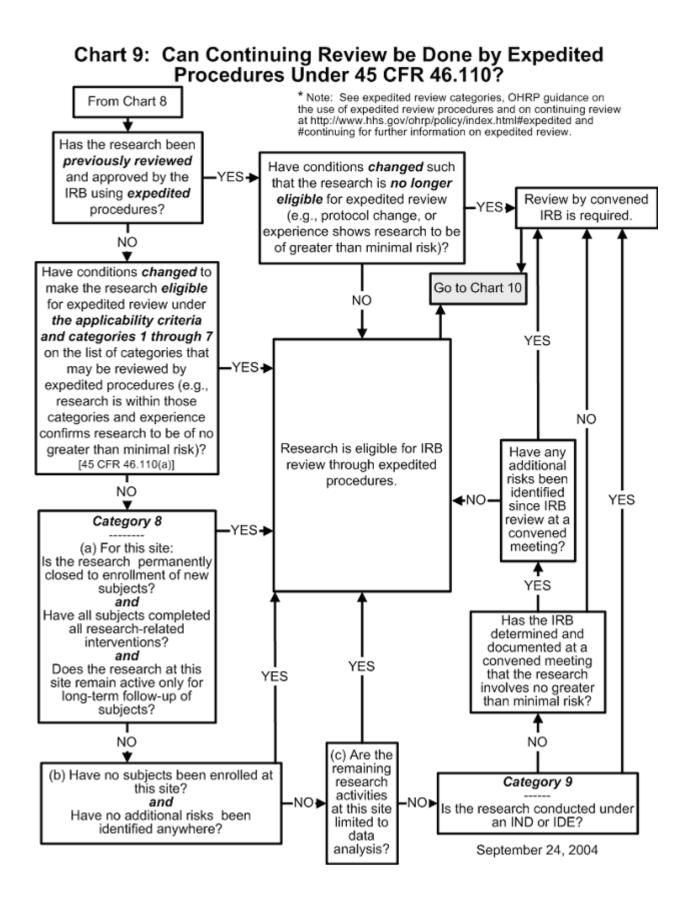
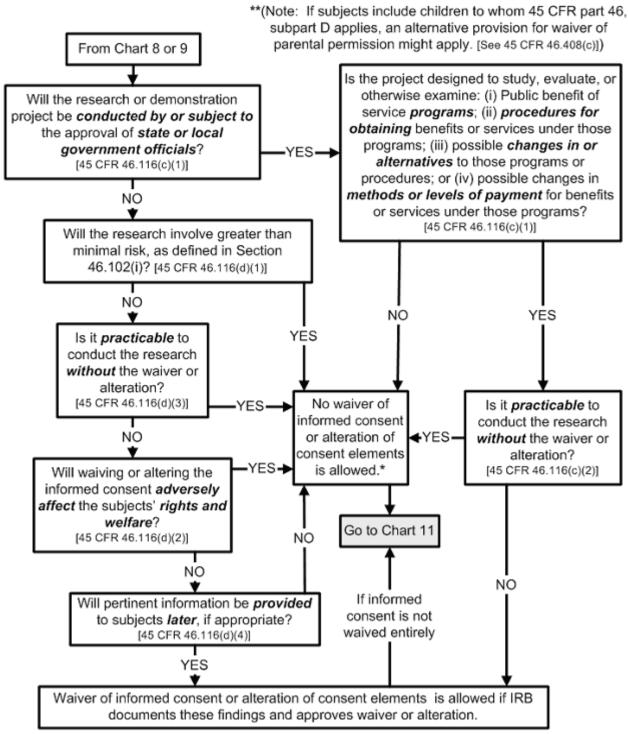


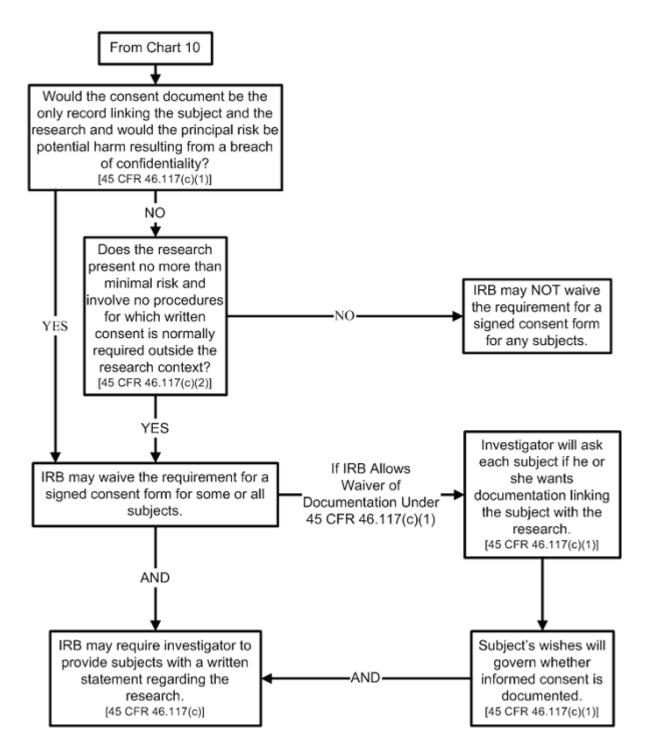
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



* Note: See OHRP guidance on informed consent requirements in emergency research at

http://www.hhs.gov/ohrp/policy/index.html#emergency for further information on emergency research informed consent waiver.

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



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