Human Subject Regulations Decision Charts

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 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) 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, 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?

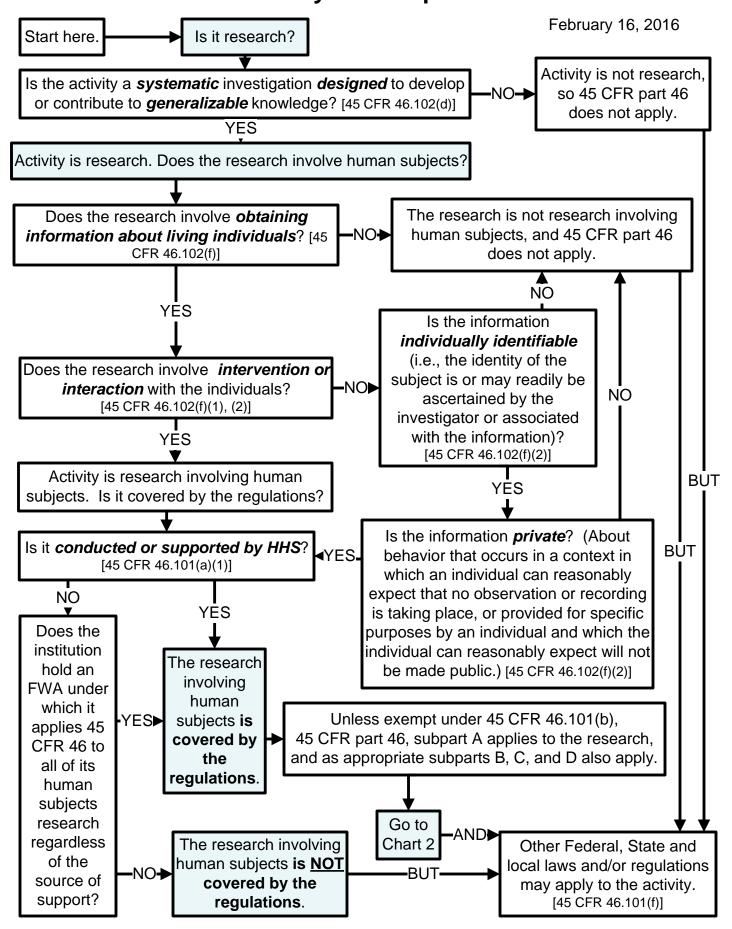


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)? From Chart 1 February 16, 2016 Has HHS *prohibited* exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(i), 45 CFR 46.401(b)] NO ** "Only" means that no nonexempt 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 CFR commonly accepted educational Go to 46.101(b)(1) may YES**→** settings, involving *normal education* Chart 3 apply. practices? If not exempt under (b)(1) 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? If not exempt under (b)(2) or (b)(3) YES Research involving collection or study Exemption 45 CFR of existing data, documents, records, Go to 46.101(b)(4) may YES-▶ or pathological or diagnostic Chart 5 apply. specimens? If not exempt under (b)(4) Research studying, evaluating, or Exemption 45 CFR Go to examining *public benefit or service* YES→ 46.101(b)(5) may Chart 6 programs? apply. If not exempt under (b)(5) Exemption 45 CFR Research involving taste and food Go to

46.101(b)(6) may

apply.

Chart 7

Go to

Chart 8

YES**→**

No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C and D also apply if subjects are from covered vulnerable populations.

quality evaluation or consumer

acceptance studies?

If not exempt under (b)(6)

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

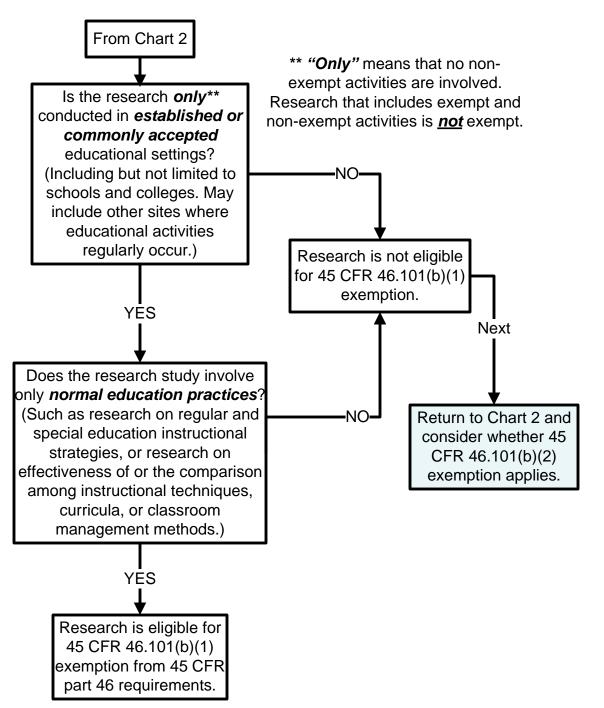


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation)

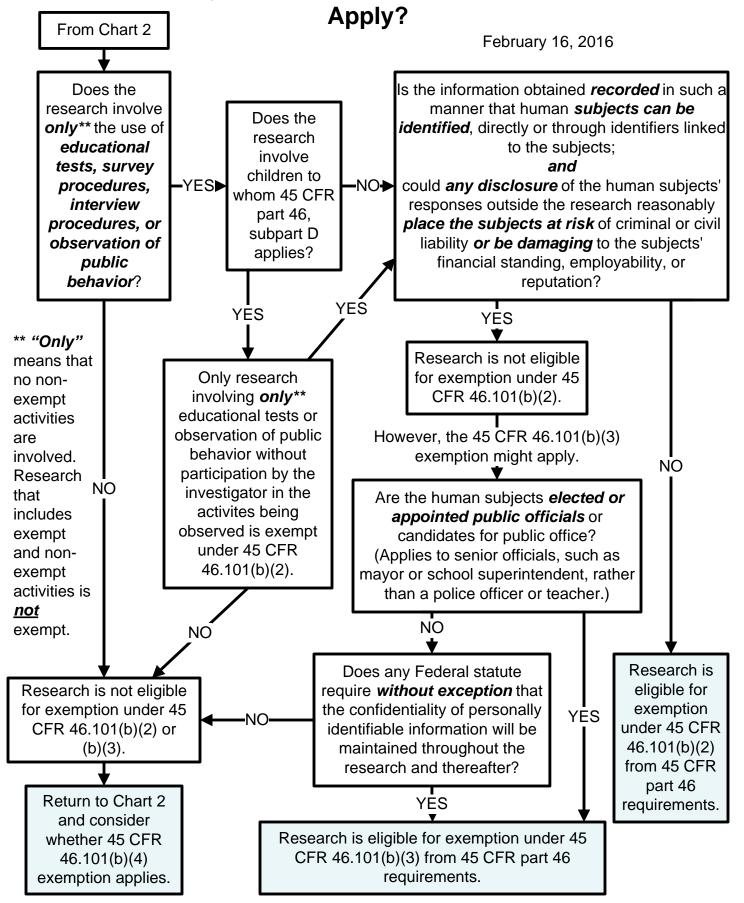
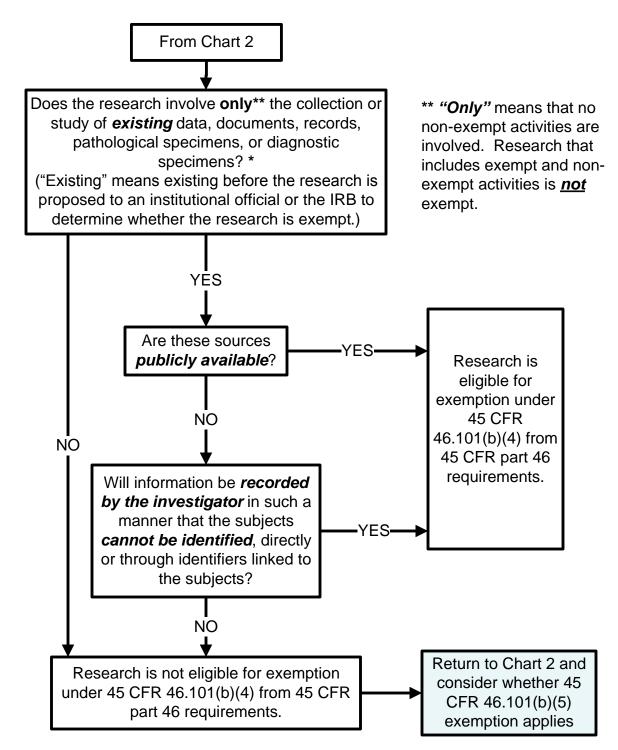


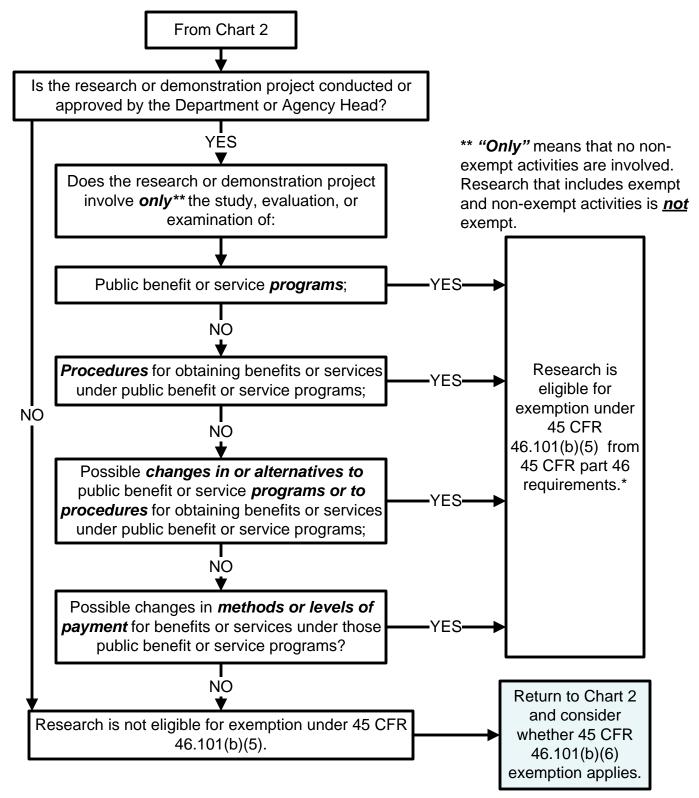
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



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

February 16, 2016

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/regulations-and-policy/guidance/exemptions-for-public-benefit-and-service-programs/index.html 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?

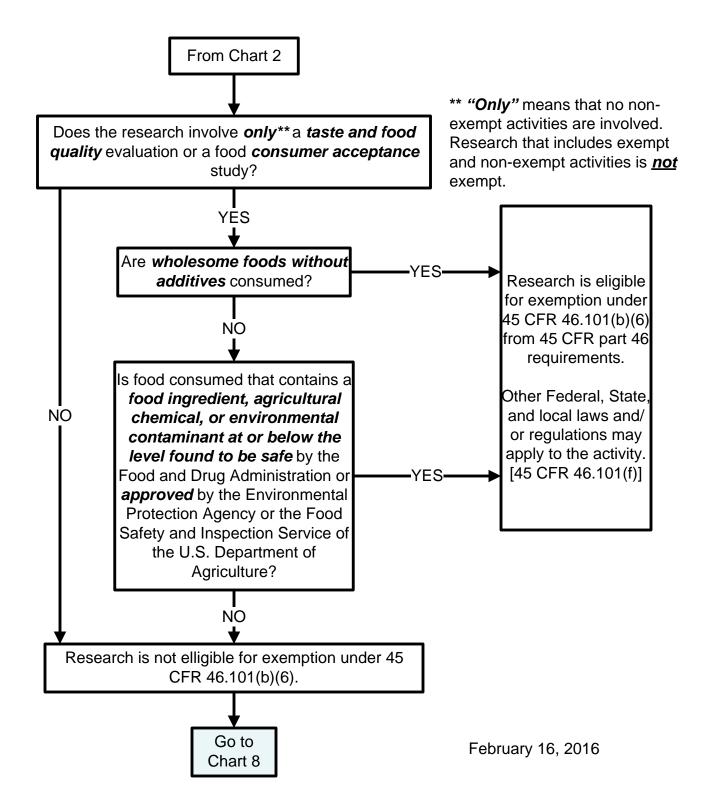


Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

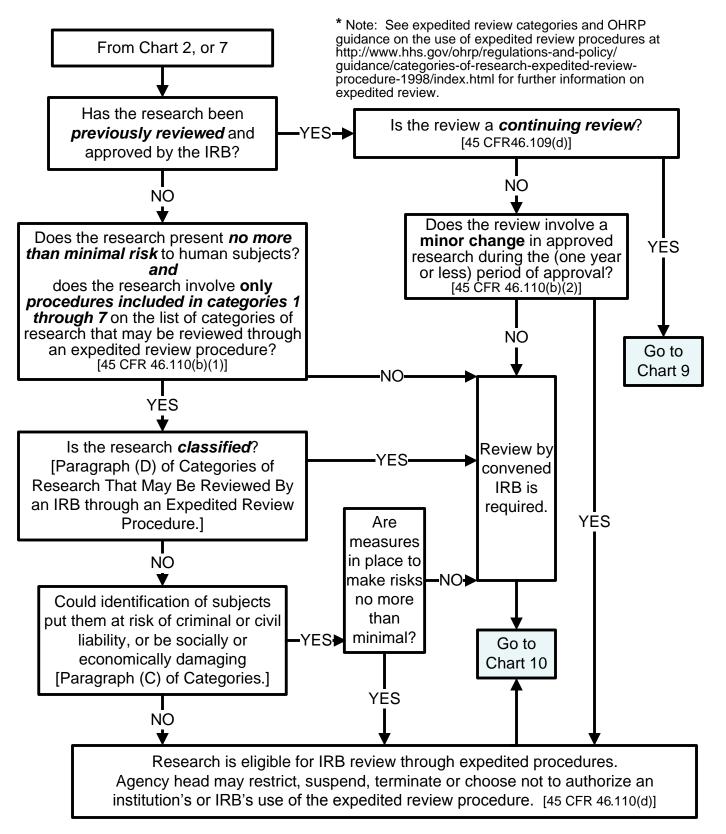


Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

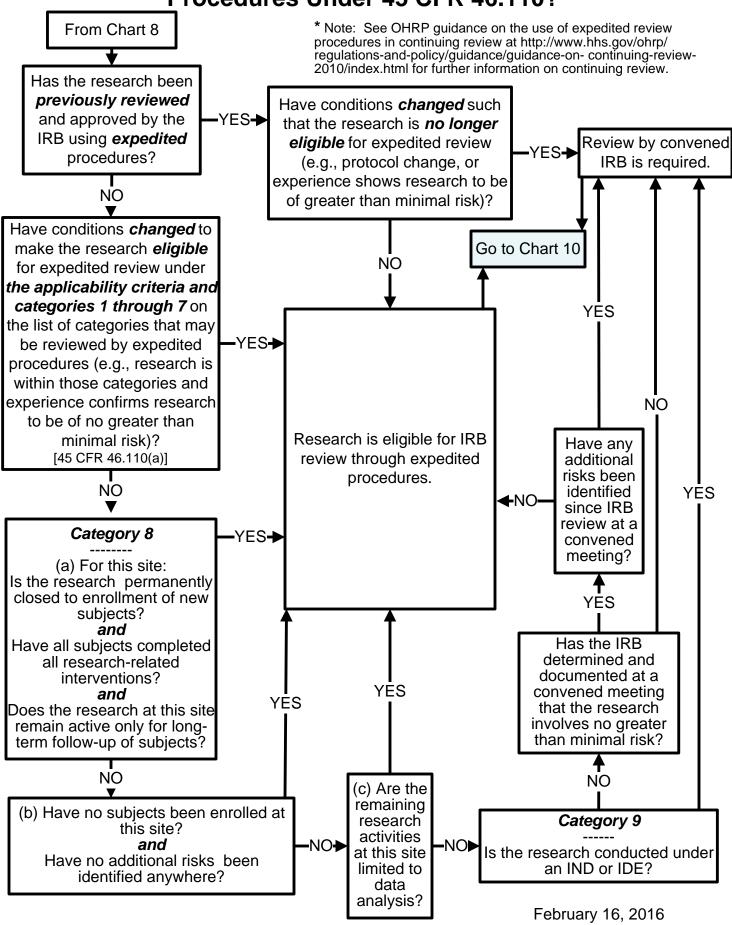
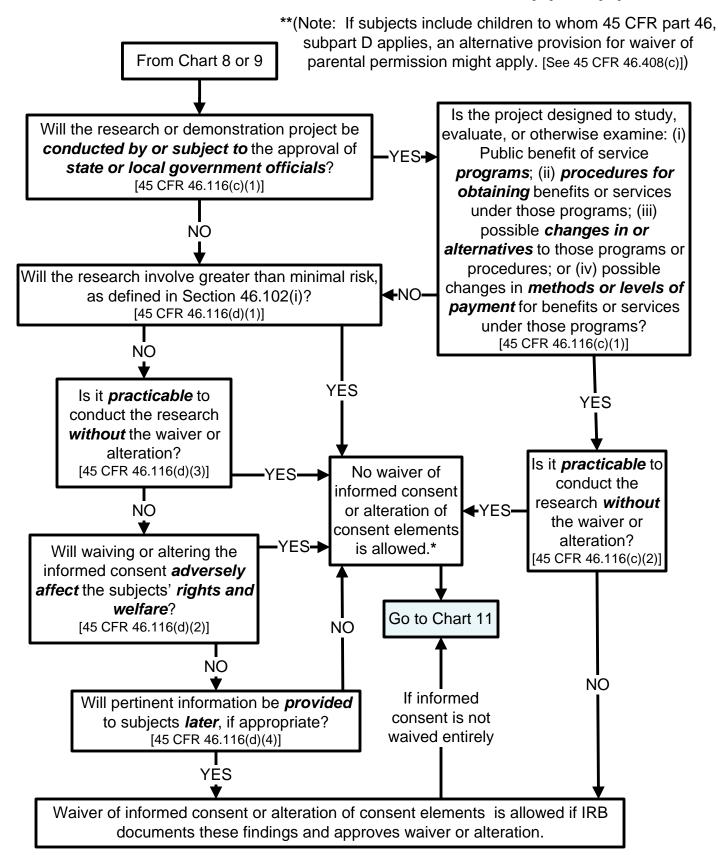


Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



^{*} Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html for further information on emergency research informed consent waiver.

February 16, 2016

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

