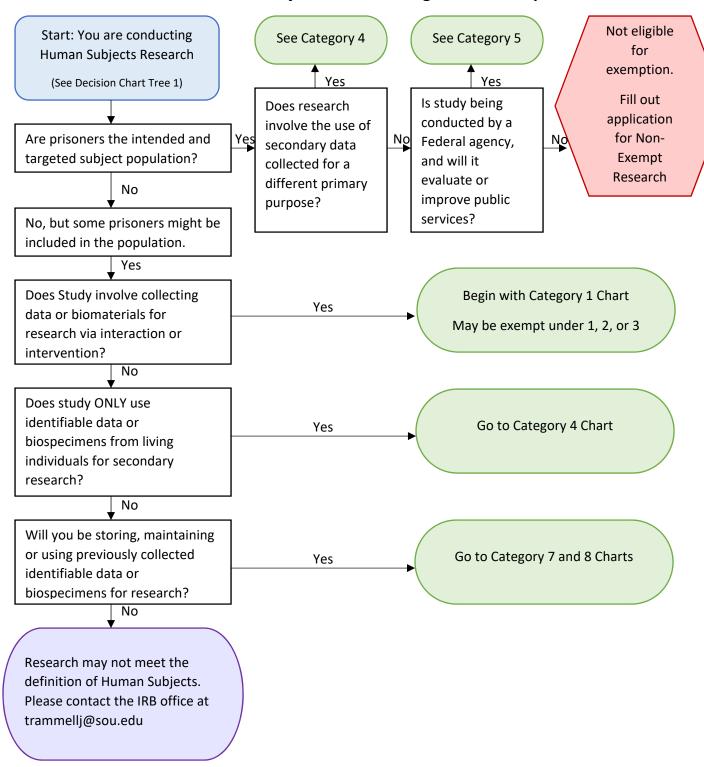
Is Your Human Subjects Research Eligible for Exemption?



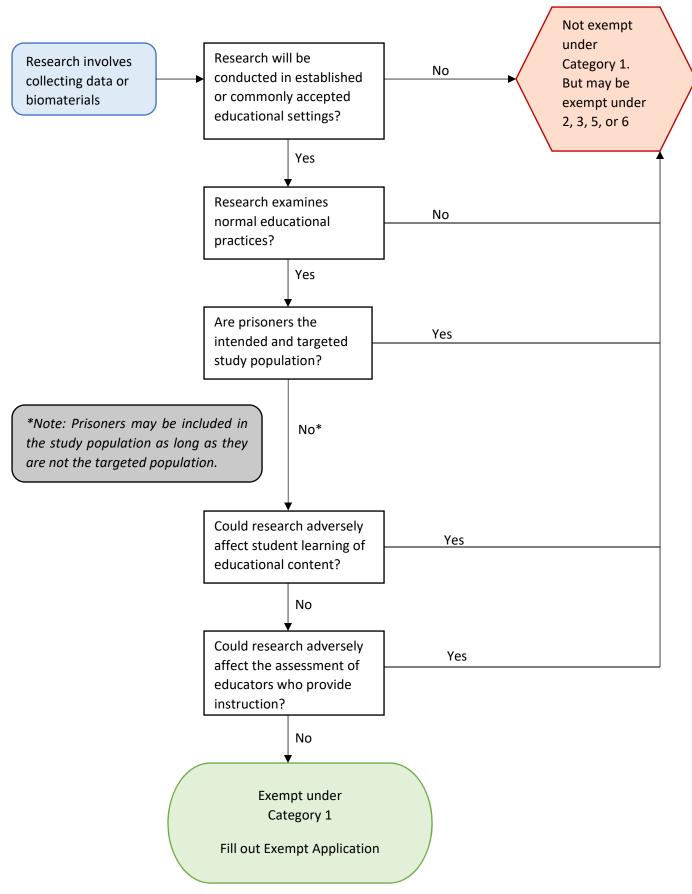
NOTE:

- 1. A IRB Request for Review application must be submitted to the IRB office regardless of exempt self-
- 2. Researchers may not make self-determination of exemption from IRB review. All research involving human subjects must be reviewed by SOU's IRB office, and granted either an Exemption or Approval before study procedures may begin.
- 3. In order for the research to be eligible for exemption, the only involvement of human participants in the research must fall into one or more of the exemption categories.
- 4. Definitions and other resources are on the IRB website www.sou.edu/irb

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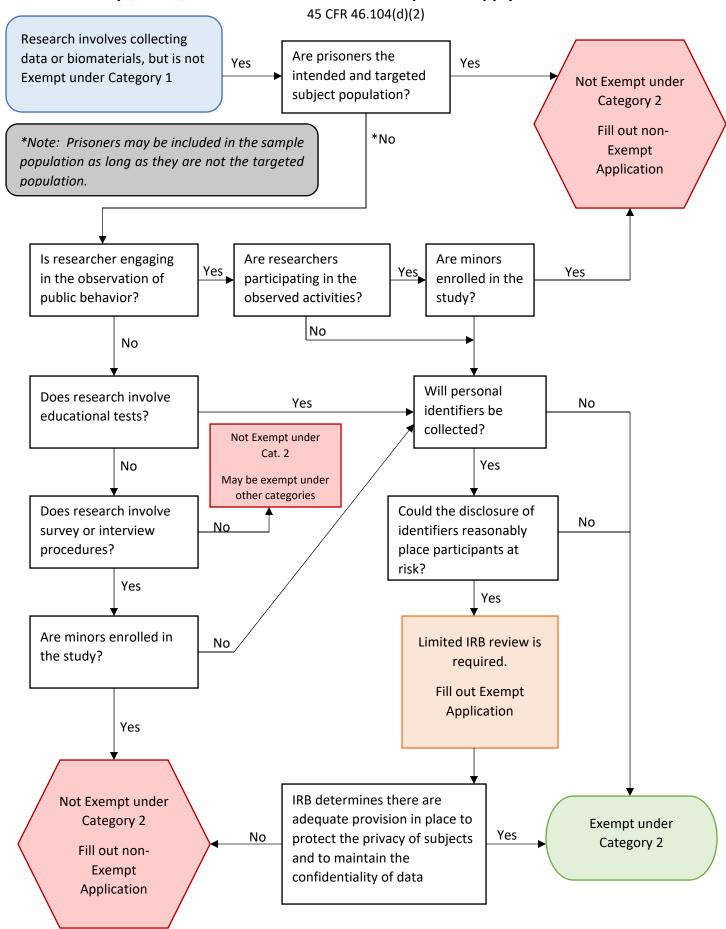
Educational Practices: Does Exemption Category 1 Apply to Your Research?

45 CFR 46.104(d)(1)



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Surveys, Tests, or Observations: Does Exemption 2 Apply to Your Research?



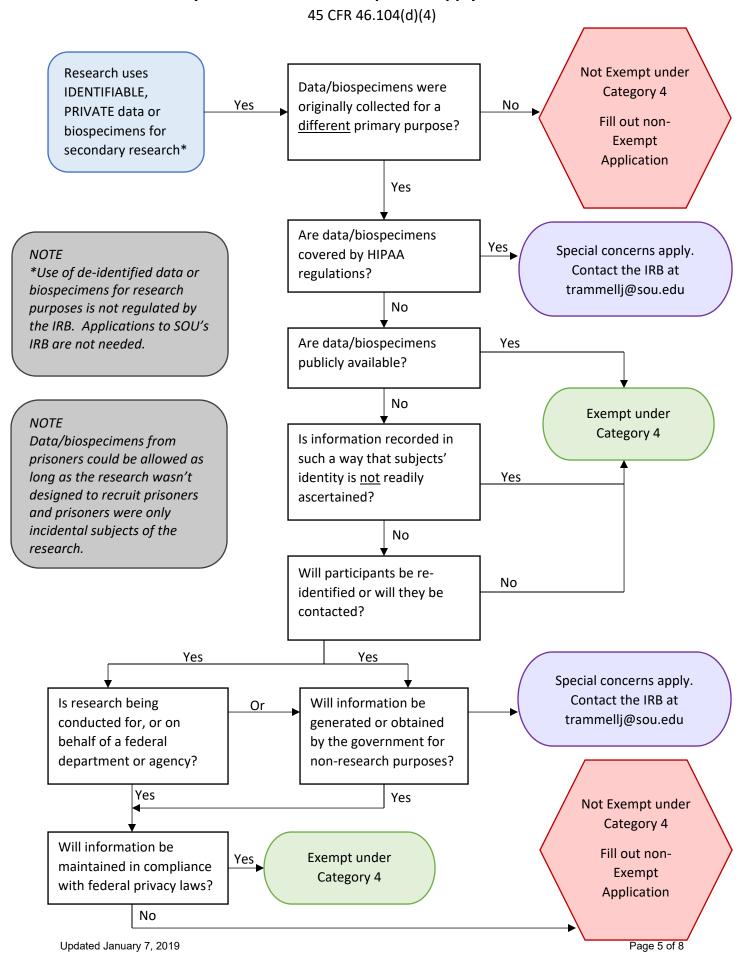
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Benign Interventions: Does Exemption 3 Apply to Your Research? 45 CFR 46.104(d)(3) Research involves collecting information, Are prisoners the but is not eligible for intended and exemption under Yes Yes targeted study Categories 1 or 2. population? Not Exempt under Category 3 *Note: Prisoners may be included in the *No sample population as long as they are not Fill out nonthe targeted population. Exempt **Application** Are minors Yes enrolled in the study? No Exempt under Category 3 Will personal Does research No No involve behavioral identifiers be recorded? interventions? Yes Yes No, Could disclosure of Are the Limited IRB review is No interventions identifiers reasonably required. Yes benign? place participants at Fill out Exempt risk? Application Yes Did participants agree to the No intervention in advance? IRB determines there are adequate provision in place to Yes No protect the privacy of subjects and to maintain the Is full purpose of Yes confidentiality of data the study disclosed in consent? Yes No Not Exempt under Are participants informed Category 3. Check Exempt under that they will be unaware of other categories or Yes No Category 3 or misled regarding research fill out non-Exempt purpose? Application

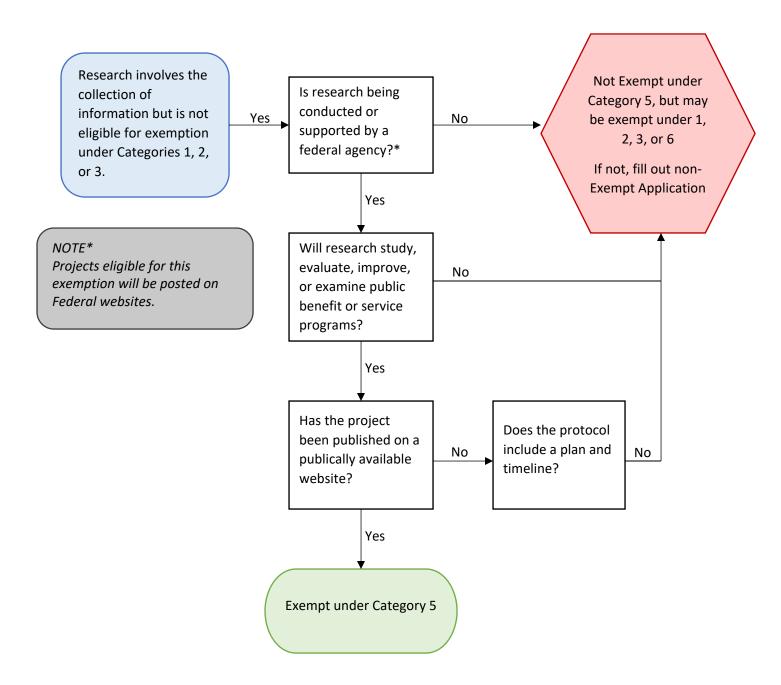
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Secondary Research: Does Exemption 4 Apply to Your Research?

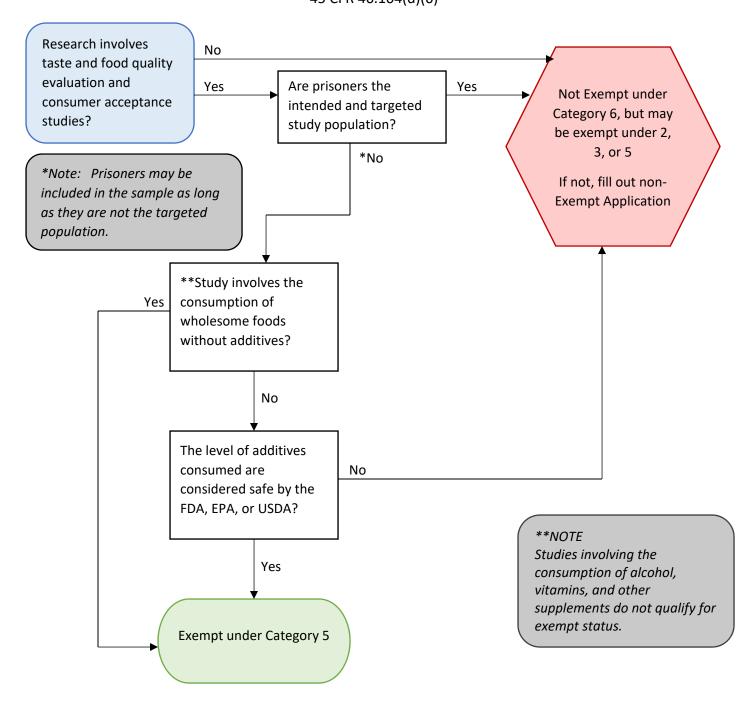


Public Health or Service Research: Does Exemption 5 Apply to Your Research? 45 CFR 46.104(d)(5)



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Food and Taste Evaluation: Does Exemption 6 Apply to Your Research? 45 CFR 46.104(d)(6)

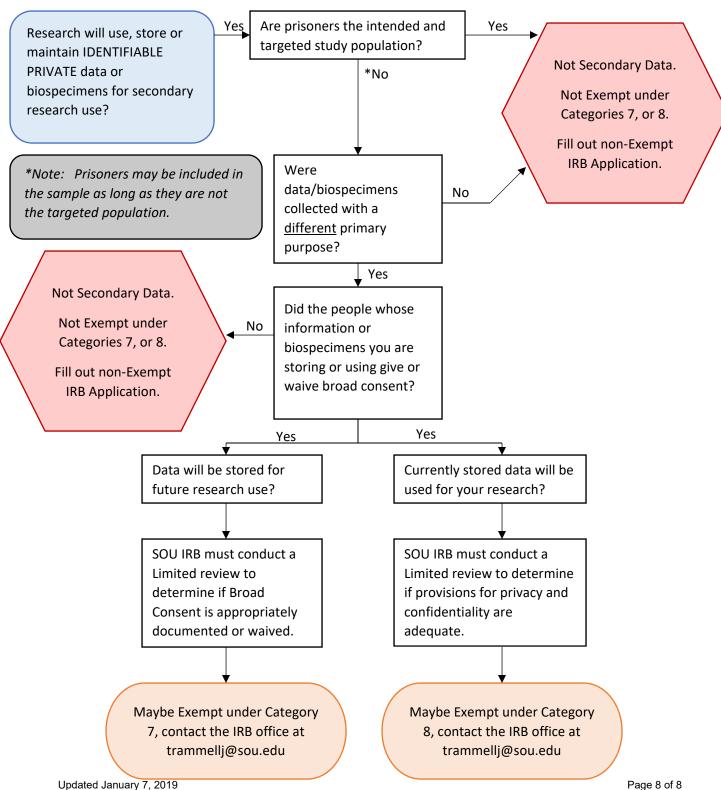


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Storage, Maintenance, or Use of Secondary Data with Identifiers: Do Exemptions 7 or 8 Apply to Your Research?

45 CFR 46.104(d)(7,8)

Note: These exemption provisions carry significant requirements for documenting or waiving Broad Consent and for ensuring privacy of subjects and confidentiality of data. The SOU IRB recommends that projects involving secondary use of identifiable private data or biospecimens that cannot be exempted under Category 4, are reviewed by the SOU IRB via the non-exempt review process and granted IRB approval. Contact the IRB with questions at trammellj@sou.edu



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