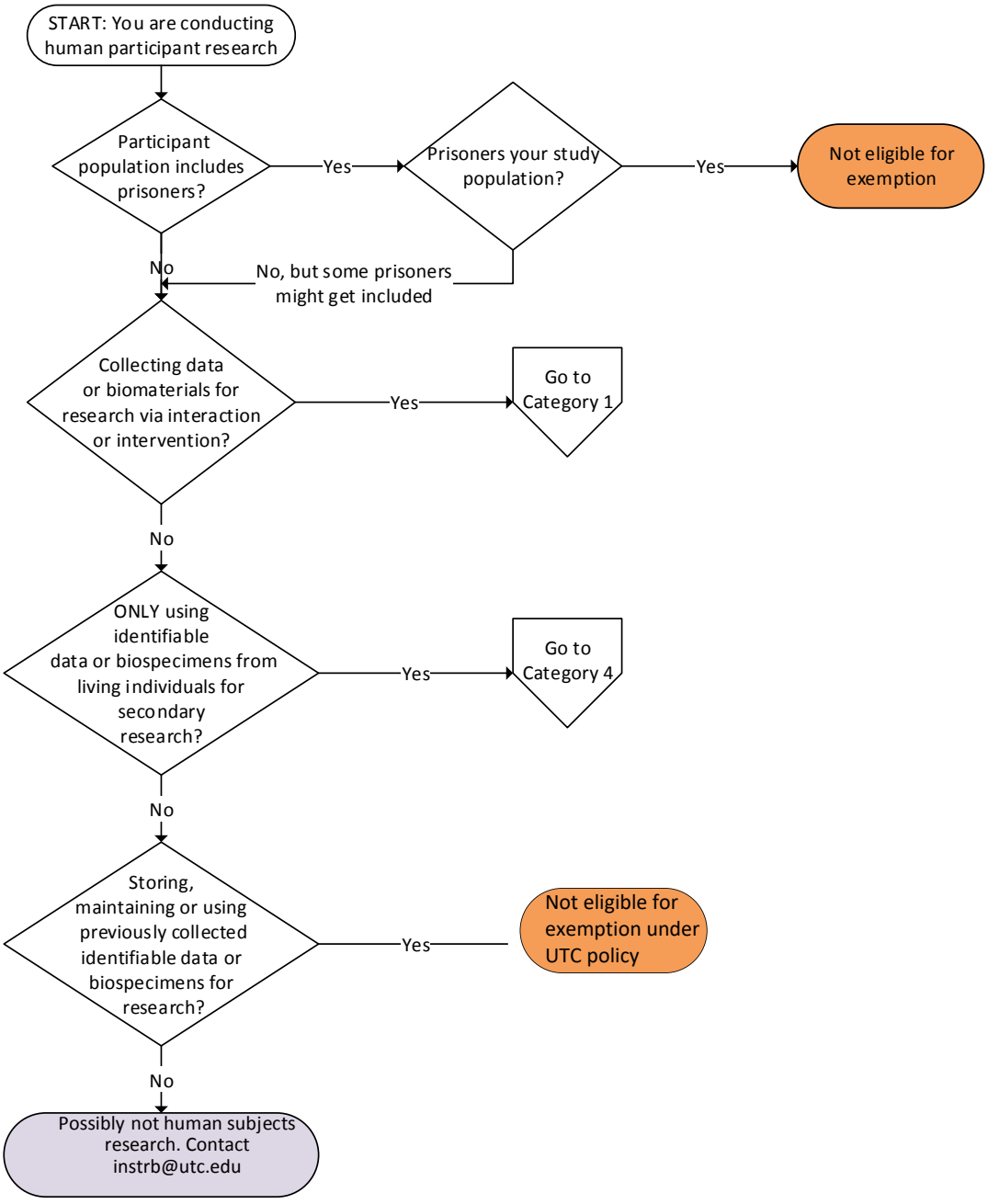
Exemption Decision Charts For General Guidance

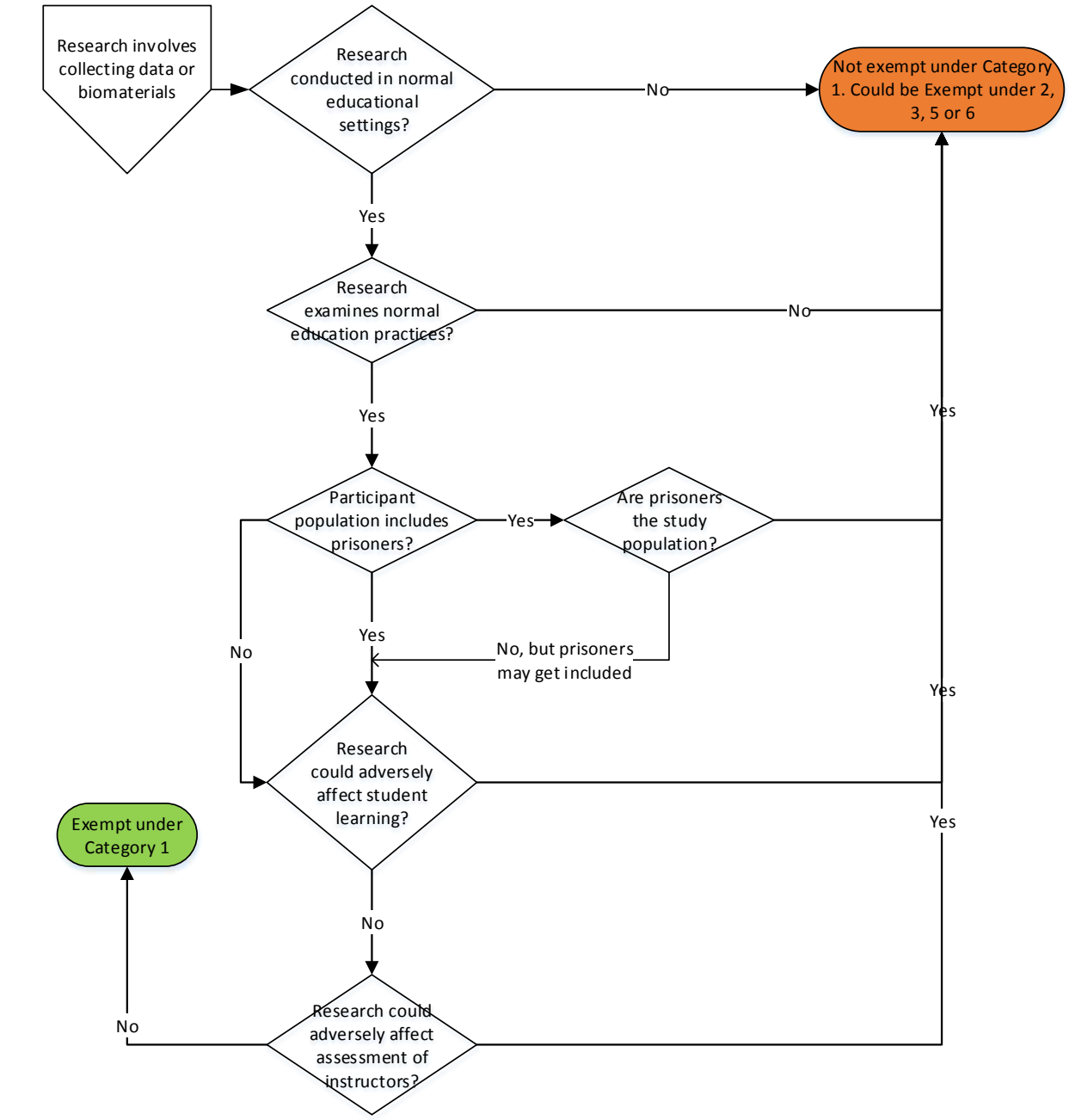
Is Your Human Participant Research Eligible for Exemption?



NOTE:

1. Researchers may not make a self-determination of exemption from IRB review. All research with human subjects must be reviewed by the UTC IRB office and either granted an exemption or approval before study procedures may begin.
2. 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.
3. Definitions and other resources are on the IRB website: www.utc.edu/irb.
4. UTC IRB will review all research that falls under Categories 7 and 8 through Expedited review procedures.
5. See Federal Regulation 46 CFR.104

Educational practices: Does Exemption 1 apply? [45 CFR 46.104(d)(1)]



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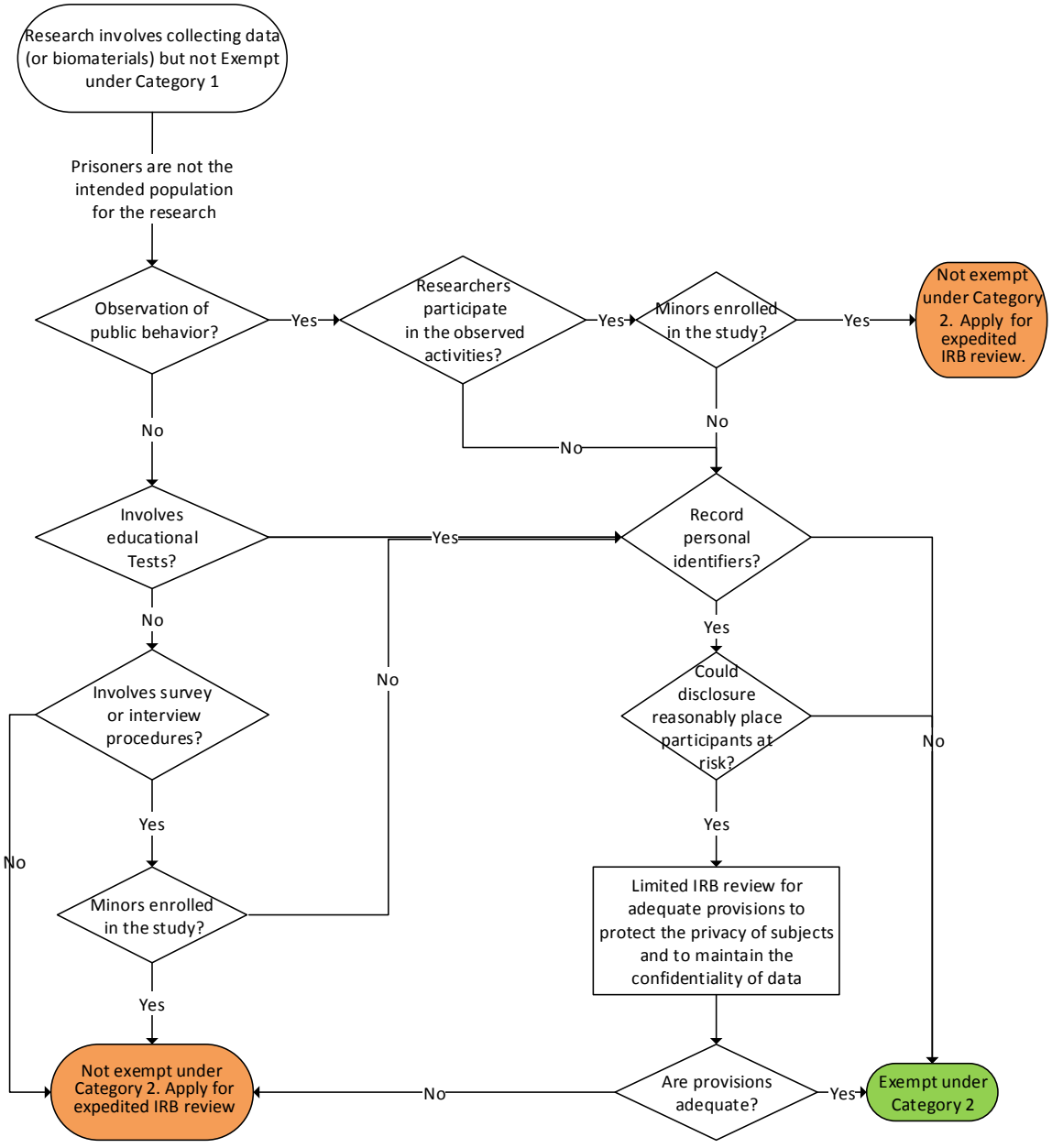
Surveys, tests, observations: Does Exemption 2 apply? [45 CFR 46.104(d)(2)]



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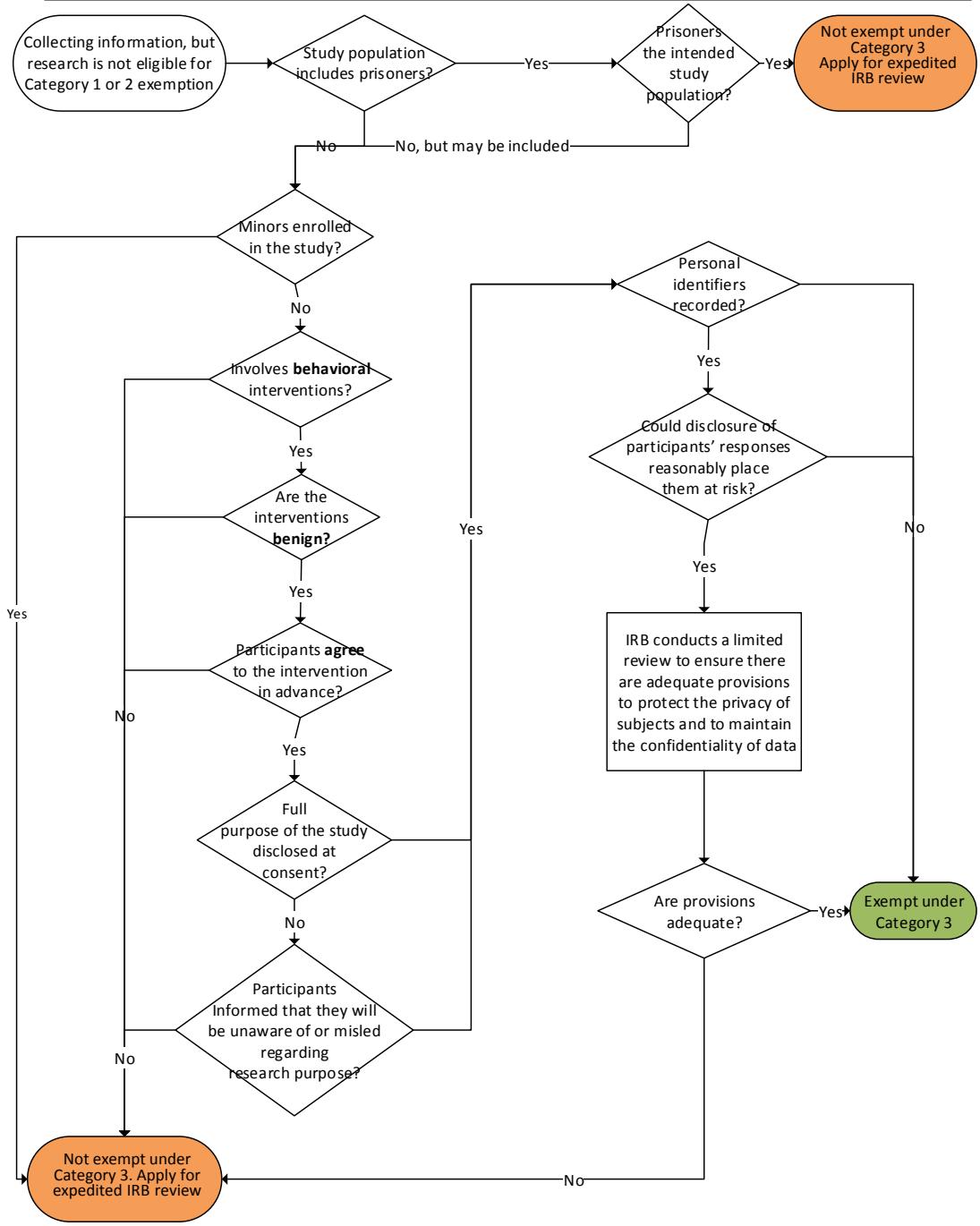
Benign Interventions: Does Exemption 3 apply? [45 CFR 46.104(d)(2)]



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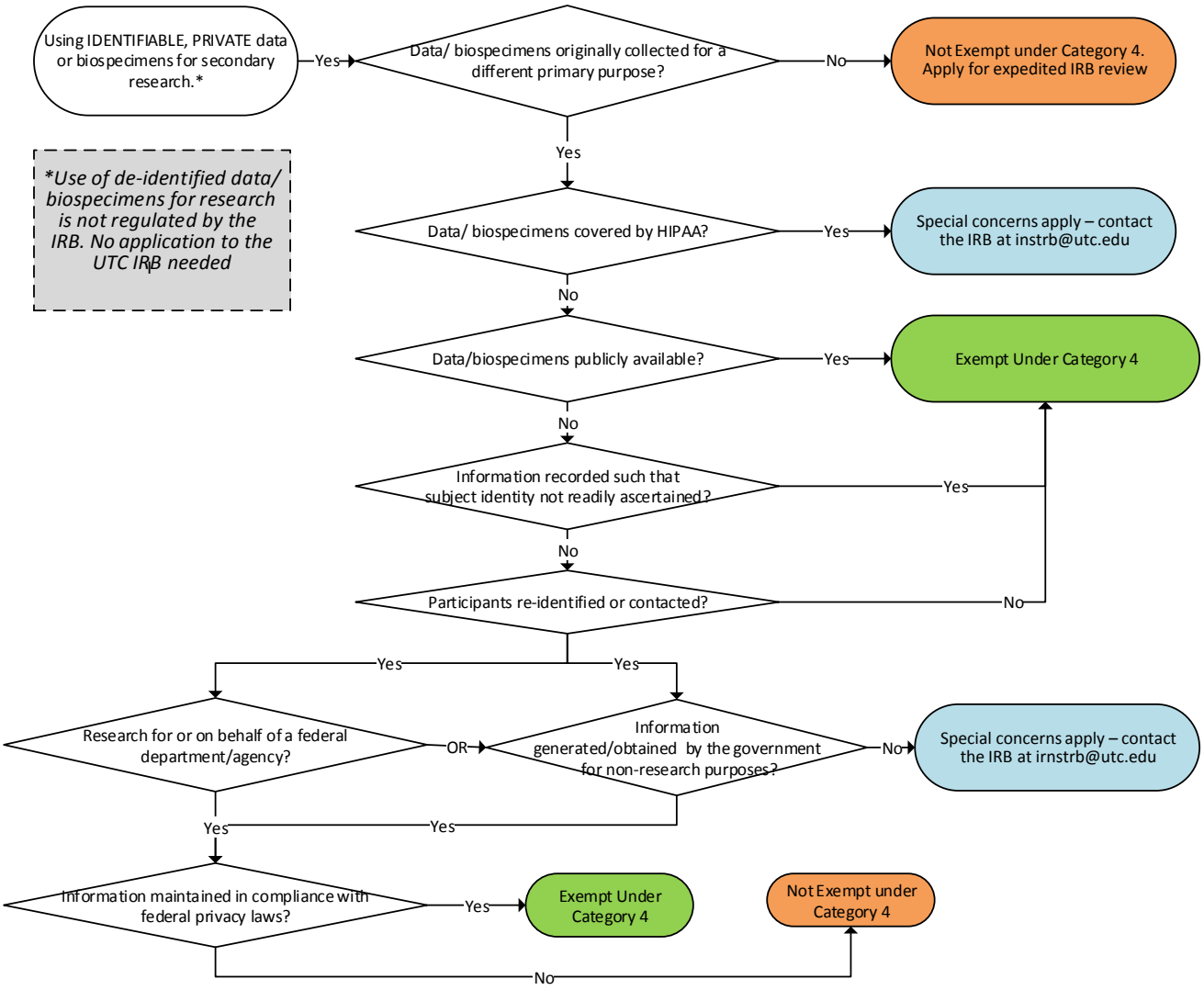
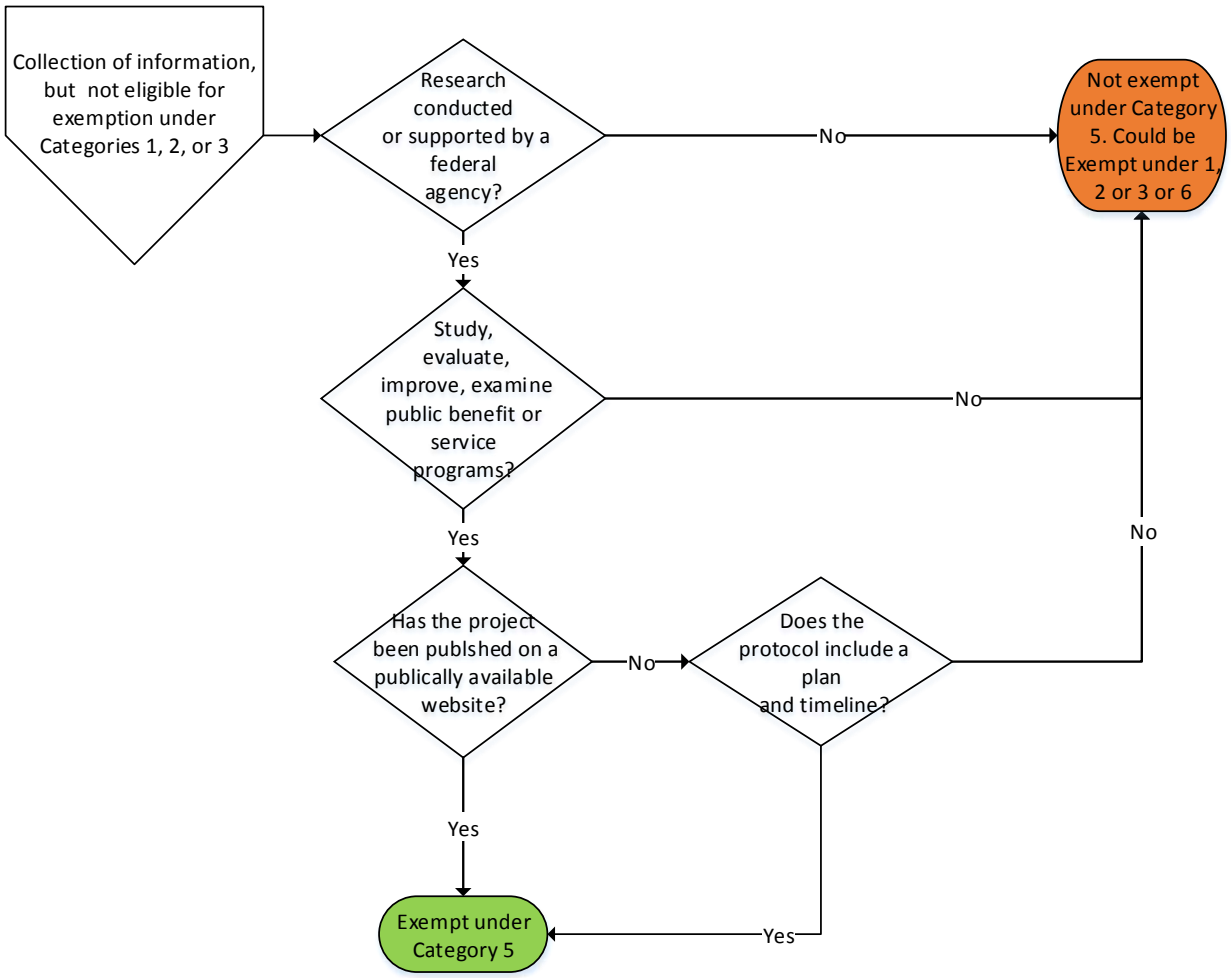
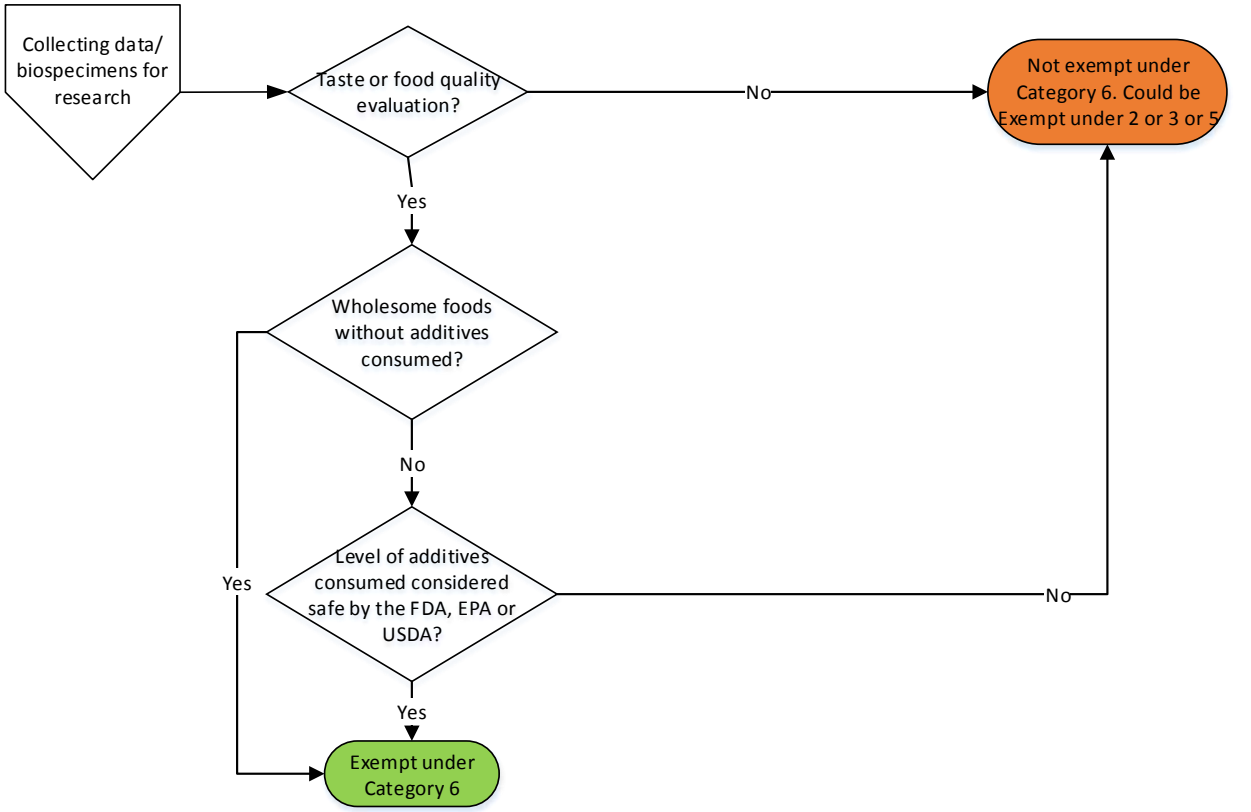
Secondary Research: Does Exemption 4 apply? [45 CFR 46.104(d)(4)]



Public Health or Service Research: Does Exemption 5 apply? [45 CFR 46.104(d)(5)]



Food and Taste Evaluation: Does Exemption 6 apply? [45 CFR 46.104(d)(6)]



Storage, Maintenance or Use of Secondary Data with Identifiers: Do Exemptions 7 or 8 apply? [45 CFR 46.104(d)(7,8)]

NOTE: The University of Tennessee at Chattanooga will not be implementing Broad Consent as defined in exempt Categories 7 and 8. These exemption provisions carry significant requirements for documenting or waiving Broad Consent and for ensuring privacy of subjects and confidentiality of data. The UTC IRB recommends that projects involving secondary use of identifiable private data or biospecimens that cannot be exempted under Category 4 be reviewed by the UTC IRB via the expedited review process. Contact the IRB with questions at instrb@utc.edu.