Items to Include for Food Quality Tests

✓ In the protocol, state if the food/drink ingested is:
  o Approved by the FDA as a whole or made entirely with FDA approved ingredients
  o If a product or ingredient will be used that is not FDA approved, go into detail about the ingredients and talk about what the acceptable levels of the ingredients are and what happens if a person of a certain weight ingests them (and how much). If necessary, provide literature about risks or dangers of ingesting the sample.
  o Address the palette cleansers (pre-packaged ___ )
  o Address the compensation if it is food (pre-packaged food treat)
  o If food is NOT to be ingested, but will be spit out, note so in the proposal.

✓ In the consent form, discuss requirements for participant eligibility
  o Think about allergens to colorings and foods
  o Think about the age and chewing capabilities of the participants
  o Think about how the sample could interact with any kind of medicine, supplement, or condition that the person may have.

✓ Your consent form must include (suggest using the template found on IRB site)
  o Description of people who should not participate (outlining allergies and capabilities)
  o Detail the risks of participation (sometimes this includes potential choking, allergies, pulling out fillings)
  o Compensation for participation

✓ Include with your protocol
  o E-mail recruitment scripts (must include eligibility requirements)
  o Flyers to be used (must include eligibility requirements)
    ▪ Example: “You must be 18 years old and you must not be allergic to peanuts, soy, or yellow 5”
  o Scripts of announcements (must include eligibility requirements)
  o Surveys/Screeners/Interview Questions/Focus Group Questions

If using a template from a past study, make sure you have changed all information from that past study template. All information must match current proposed study.

Your food quality study is likely exempt if it is made with FDA approved everything. Your study is exempt if
  o if wholesome foods without additives are consumed or
  o if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Your food quality study is not exempt if it is made with ingredients or levels of ingredients that are NOT FDA approved.

If you are testing an over the counter product that is not clearly a food ingredient, please provide brief information about the product and discuss FDA approval.