Consumer Food Preference, Taste, and Quality in Human Subjects Research

This guidance is intended to provide information to researchers who plan to implement taste tests.

Updated 12/3/2024

Eligible for Exemption

Consumer acceptance studies are eligible for exemption when:

- Wholesome foods without additives are consumed, or
- If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).
- If a food is consumed that contains an agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA).

Taste and food quality evaluation studies are eligible for exemption if they:

- Do not involve the consumption of any type or volume of food that would present any risk to the participants
- Do not involve the consumption of alcohol, vitamins, and nutritional supplements because these items are not considered “foods.”
- Fall into what would be considered reasonable eating behaviors.
- Involve children in taste test studies parental/guardian permission.

Eligible for Expedited Review

Expedited review is appropriate when the proposed research poses no more than minimal risk to participants and study procedures involve only one (or several) of the categories of research outlined by 45 CFR 46 and supplemental guidance. Review the NC State University unit standard on expedited review procedures (Word document).

Some taste tests require expedited review because they are testing consumer preferences for items that cannot be considered “wholesome” or a “food” but through intentional study design, the study is determined to be minimal risk.

Convened Full Board Review

A taste test or consumer preference study would require convened full board review and approval when the item being studied does NOT have FDA approval, is NOT yet considered generally recognized as safe (GRAS), or it is being tested for safety and effectiveness and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases.

Information to Provide the IRB

In the IRB Application

- State if the food/drink is ingested or not (e.g., expectorated)

- State if the food/drink is:
  - Approved by the FDA as a whole
  - Made entirely with FDA approved ingredients
  - Not FDA approved – in these cases, provide additional information to include:
    - What the ingredients are
    - What the acceptable amount of each ingredient is
    - What the risks or dangers of ingesting the sample(s) are and provide literature if necessary or the IRB requests it

- Use of palette cleanser(s) between samples
  - What are they
  - If food is prepackaged
  - If food is generally recognized as safe (GRAS)
  - If food was produced in a facility with good manufacturing practices (GMP)

- Discussion compensation
  - If the compensation is food, describe what the food is (e.g., pre-packaged food treat made in a commercial kitchen with good manufacturing practices)

- Inclusion/exclusion criteria must include age limits, food sensitives and allergies, and, where appropriate, the ingredients and label information. When deciding on the inclusion/exclusion criteria, consider the following:
  - Intolerances and allergens to ingredients, colorings, foods, etc.
  - Age and chewing capabilities of the participants
  - How the sample could interact with any kind of medicine, supplement, or condition a person may have
  - Pre-existing digestive issues such as indigestion, IBS, nausea, etc.
  - People who are pregnant
  - People who have conditions (loss of taste and smell from Covid-19) or behavioral practices that may influence their ability to assess taste and smell (regular cigarette smoking)

- Common risks that must be identified in the protocol include:
  - triggering allergies and intolerances.
  - possible choking or gagging.
  - negatively affecting dental work such as pulling out fillings or cracking crowns.
  - gastrointestinal issues such as nausea, diarrhea, heartburn, indigestion, bloating, gas.
  - increased thirst or leave a feeling of “film” in the mouth.

- Risk mitigation strategies used in the research design to address the noted risks include procedures such as:
  - screening out ineligible participants.

- portioning samples.
- expectorating samples instead of completely ingesting them.
- targeting people who already ingest foods/drinks like the one under investigation.
- articulating eligibility/ineligibility criteria in the recruitment and consent.
- providing ingredients list to participants prior to sampling.

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

In the Informed Consent Materials
Aside from using the NC State University IRB informed consent form templates (Word document), the consent form must clearly discuss requirements for participant eligibility and risks associated with the item being studied.

Common risks to consumer preference testing for food or drink related items that must be discussed in the consent form where appropriate, include:

- Triggering allergies and intolerances
- Possible choking or gagging
- Negatively affecting dental work such as pulling out fillings or cracking crowns
- Gastro-intestinal issues such as nausea, diarrhea, heartburn, indigestion, bloating, gas
- May cause increased thirst or leave a feeling of "film" in the mouth

**Note, select the "common risks" associated with the item being studied. For example, if the item tested is yogurt, it will likely not crack a crown or pull a filling, so that risk would not need to be articulated in the IRB application as it does not typically apply to soft food taste tests.*

Specific Taste Test Guidance
The next section of this guidance addresses specific considerations for taste tests that involve CBD, dietary supplements, nicotine, caffeine, and alcohol

Taste Tests Involving Alcohol
Taste tests involving alcoholic products are permitted and they must be implemented in accordance with NC State University's alcohol regulation (opens in a new window). Taste tests involving alcohol are not eligible for exemption because alcohol is not considered a food.

Taste tests involving alcohol may occur with either "qualified consumers" or with "trained panelists."

Qualified consumers are consumers over 21 years of age and requirements and self-reported criteria (age, usage, purchase frequency). Qualified consumers do not

necessarily reside in our building and reasonably expect to leave within an hour. Note that consumer tests are performed in the morning when alcohol is not normally consumed.

Trained panelists are individuals who meet the legal age and weight requirements for alcohol consumption but have also received objective training to identify sensory attributes of alcoholic beverages. Trained panelists typically reside in the workplace where the project is being conducted and do not leave the location of within an eight-hour workday. Trained panels are normally performed in the morning or immediately after lunch so that alcohol is not consumed on an empty stomach.

For a taste test that involves alcohol to be eligible for expedited review, the following procedures must be in place:

With General Qualified Consumers

- Qualified consumers must be 21 years of age or older and provide a photo ID.
- Provided samples are not of a volume that can lead to intoxication.
- The number days, the number of sessions, and number of samples, must be communicated in the IRB protocol and informed consent.
- The type of alcohol, volume of liquid, and percentage of alcohol must be communicated in the IRB protocol and informed consent.
- The taste test must be implemented in a controlled environment.
- Qualified consumers should be provided measured, coded samples which should be removed once sampling is completed.
- Qualified consumers should be told to expectorate the sample after sufficient tasting.
- Additional safety procedures of qualified consumers
    - Qualified consumers will read the standard government alcohol consumption risk statement and certify that they have read the statement before arrival at test location.
    - Qualified consumers must self-report weight and must weigh at least 100 pounds. State this requirement in the IRB application and use the below fill-in-the-blank to explain why the body weight minimum is a requirement.
        - The 100-pound body weight minimum is a requirement for inclusion in the study because a person who is at least 100lbs and has consumed <insert ounces of alcohol provided in the study for tasting> of alcohol, will have a blood alcohol level of <insert likely range of blood alcohol level for someone who is 100lbs> which is below the legal blood alcohol content (BAC) limit of 0.08 mL.
    - Before and after the taste test, qualified consumers must undergo baseline measurements including a breathalyzer to assess blood alcohol level before the taste test, heart rate and cognitive function (recite alphabet), and a breathalyzer test *implemented* by a medical professional.

        - These baseline tests are not used as data for research because they are taken to verify participant eligibility, for research due diligence, and best safety practices.
    - Whenever possible, the research team should aim to recruit on-campus only (i.e., walk-in) consumers.
    - Qualified consumers should be advised to walk to the test, come with a safe ride, or provide their car keys on arrival to the taste test location.

- In the IRB protocol, clearly articulate alcohol specific information:
    - The test will require qualified consumers to taste <insert number> samples for each session. There will be <insert number> total sessions in one day and <insert number> total sessions for the entire study.
    - Qualified consumers will only be served <insert number> ml of each sample, with a total of <insert number> ml per day.
    - Qualified consumers will be told to taste, not consume the sample.
    - Qualified consumers will be provided a spit cups to expectorate to reduce the likelihood of overconsumption of alcohol.
    - Detail any additional alcohol-specific safety procedures for qualified consumers that the study plans to implement that are not already described.

IRB Record Keeping for Qualified Consumers Tests

- Previous conferral with subject matter experts indicated that taste tests with alcohol, wherein less than one drink per hour is consumed and the legal limit is not reached (or even close) pose minimal risk to healthy participants.
- The amount of alcohol consumed is less than one drink, samples are expectorated, and vulnerable populations are screened out.
- Because the participants are general qualified consumers, additional protections are implemented such as:
    - pre/post baseline testing for alcohol level and breathalyzer (only used for inclusion/exclusion);
    - participants are encouraged to walk or have a safe ride; and
    - participants will read the standard government alcohol consumption risk statement prior to the taste test
- These studies are eligible for expedited review under categories 4 and 7.

With Trained Panelists

- Trained panelists must be 21 years of age or older.
- Provided samples should not be of volume that can lead to intoxication.
- The number days, the number of sessions, and number of samples, must be communicated in the IRB protocol and informed consent.
- The type of alcohol, volume of liquid, and percentage of alcohol must be communicated in the IRB protocol and informed consent.
- The taste test must be implemented in a controlled environment.
- Panelists should be provided measured, coded samples which should be removed once sampling is completed.

- Trained panelists should be told to expectorate the sample after sufficient tasting.
- Trained panelists must self-report weight and must weigh at least 100 pounds. State this requirement in the IRB application and use the below fill-in-the-blank to explain why the body weight minimum is a requirement.
    - The 100-pound body weight minimum is a requirement for inclusion in the study because a person who is at least 100lbs and has consumed <insert ounces of alcohol provided in the study for tasting> of alcohol, will have a blood alcohol level of <insert likely range of blood alcohol level for someone who is 100lbs> which is below the legal blood alcohol content (BAC) limit of 0.08 mL.

- In the IRB protocol, clearly articulate alcohol specific information:
    - The test will require panelists to taste <insert number> samples for each session. There will be <insert number> total sessions in one day and <insert number> total sessions for the entire study.
    - Panelists will only be served <insert number> mL of each sample, with a total of <insert number> mL per day.
    - Panelists will be told to taste, not consume the sample.
    - Panelists will be provided a spit cups to expectorate to reduce the likelihood of overconsumption of alcohol.

IRB Record Keeping for Trained Panelist Tests

- Previous conferral with subject matter experts indicated that taste tests with alcohol, wherein less than one drink per hour is consumed and the legal limit is not reached (or even close) pose minimal risk to healthy participants.
- The amount of alcohol consumed is less than one drink, samples are expectorated, and vulnerable populations are screened out.
- These studies are eligible for expedited review under Category 4 and 7.

Taste Tests Involving Caffeine

The FDA addresses issues with pure and highly concentrated caffeine. Up to 400 milligrams (mg) of caffeine a day appears to be safe for most healthy adults. Keep in mind that the actual caffeine content in beverages varies widely, especially among energy drinks.

Caffeine is found in many foods and beverages, including coffee, teas, chocolate, and many sports and energy drinks and in variable amounts.

- Coffee typically contains 95-200 mg of caffeine per cup.
- Black tea typically contains 25-110 mg of caffeine per cup.
- Green tea typically contains 30-50 mg of caffeine per cup.

Caffeine products sold in very concentrated or pure forms can be a health concern because people can easily take doses that are much too high by mistake. Avoid using these products in taste tests where possible.

Although caffeine use may be safe for adults, it is not a good idea for children to consume caffeine. It is recommended that people who are pregnant, who are trying to become pregnant, and those who are breast-feeding should talk with their doctors about caffeine intake.

When completing taste tests with people who already ingest caffeine, food and drink items that contain caffeine are unlikely to expose to people to increased risks or direct benefits as the amount of caffeine ingested is minimal. However, the possible risks and benefits of ingesting caffeine should be noted:

Benefits of an appropriate amount of caffeine:

- May help with mental alertness
- In combination with some pain relievers, likely to help headaches and migraines
- Possibly benefits athletic performance
- Possible benefits memory

Risks of too much caffeine include:

- Headache
- Insomnia
- Nervousness
- Irritability
- Frequent urination/inability to control urination
- Fast heartbeat
- Muscle tremors
- Interactions with medications or supplements

Taste tests involving caffeine that are likely eligible for exemption when they include the following procedures:

- The participants who are included in the research pool are:
    - healthy adults who already ingest caffeine on a regular basis.
    - people who have no, dietary restrictions, food allergies, intolerances.
    - people who are not taking any medication that would interact with caffeine.
- The people who are excluded from the research pool include:
    - those who are pregnant
    - those who are trying to become pregnant.
    - those who are breast-feeding.
- The recruitment and informed consent form/process must specify that the taste test includes caffeine, and the amount of caffeine is described in lay terms.
- All test items with caffeine are commercially available, FDA-approved, or GRAS.
- The IRB application must include the following information:
    - if participants swallow or expectorate the item with caffeine.
    - the dosing of caffeine (maximums and minimums) that could be ingested during the course of the taste test.
    - if the caffeinated item(s) is/are hot or cold (and, if hot, how the temperature is balanced to mitigate risk to burns).

Taste tests involving caffeine that are likely require convened full board approval include the following procedures:

- The participants who are included in the research pool are:
    - Minors
    - People sensitive to caffeine
    - Individuals with food allergies, intolerances, or sensitivities
    - People who are pregnant, trying to become pregnant, or who are breast/chest-feeding
- Any of the tested items are not commercially available, FDA-approved, or are not GRAS.
- The caffeine dosage of the taste test item(s) exceeds the safe daily limit of caffeine consumption established by the FDA (opens in a new window).
- The caffeine product is being tested as a drug, which is beyond the scope of a taste test.
- The recruitment and/or the informed consent materials do not disclose that the taste test includes caffeine or the amount that is involved in lay terms to the participant.

Caffeine Quick Reads

- Caffeine: How Much is Too Much, Mayo Clinic, 2022 (opens in a new window)
- The safety of ingested Caffeine: a Comprehensive Review, 2017 (opens in a new window)
- FDA: Pure and Highly Concentrated Caffeine, Consumer Warning, 2018 (opens in a new window)
- Is Caffeine Friend or Foe, 2022 (opens in a new window)

Taste Tests Involving Cannabidiol (CBD)

With the passage of the 2018 Farm Bill, hemp and hemp products became fully legal across the United States. The legislation also cleared up a gray area as to whether CBD from hemp was also legal or considered a controlled substance.

As long as the CBD comes from hemp, the CBD is legal, there is no age restriction, and it is not considered a controlled substance (opens in a new window).

The state of North Carolina has a Hemp Commission which regulates the growing and processing of hemp but CBD products are not within their jurisdiction. The FDA regulates CBD if the sellers/manufactures of CBD claim “in their marketing and promotional materials that they’re intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases” because the FDA regulates CBD when it makes health claims like a drug (opens in a new window). Taste tests involving CBD are not eligible for exemption because CBD is not considered a food.

Taste Tests Involving Cannabis
Researchers must possess a Schedule I research registration (opens in a new window) from the Drug Enforcement Administration to conduct research with cannabis products containing more than 0.3% delta-9 THC on a dry weight basis as described in the USDA regulation 7 CFR Part 990 (PDF file). Convened full board review will be required for this type of study.

Before applying to the NC State University IRB to complete this type of research, read the following guidance entitled "Research and Cannabis: Ethical Research in a Changing Regulatory Landscape" (opens in a new window) and please contact IRB-Coordinator-Pre@ncsu.edu for a consultation.

Taste Tests Involving Dietary Supplements
The FDA (opens in a new window) categorizes dietary supplements (opens in a new window) as under the "umbrella" of foods. The FDA regulates dietary supplements as a "drug" when the dietary supplement is being tested to see if it treats, prevents, cures, or alleviates the symptoms of a disease or claims to have an impact on a health-related condition (WCG IRB - opens in a new window).

For a dietary supplement to be used in a taste test, the study design and intention must be specific and clearly articulate that the researchers are testing consumer preferences around taste. For example, the protocol should state in the IRB application that "The <insert name> dietary supplement is being tested for the following consumer preferences: <insert information>"

Additionally, the IRB protocol must clearly articulate what the researchers are not testing. For example, the protocol should state: "This study is not designed to assess a health claim nor is it designed to assess the safety or effectiveness of the supplement regarding the treatment or prevention of disease. This study is not designed to address "structure/function" of the body, general well-being, or make claims any claims regarding nutrient deficiency."

Taste Tests Involving Nicotine
The FDA address how non-tobacco nicotine products (opens in a new window) are regulated. "Congress passed a federal law which went into effect on April 14, 2022, clarifying FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic nicotine." As a result, taste tests involving nicotine should be implemented using FDA's standards. All studies should include information about nicotine dosage (opens in a new window) used in the protocol including timing and frequency.

Procedures to include in the IRB application when appropriate to study design
- Add statement: All <insert number> nicotine products evaluated are FDA-approved and commercially available or are produced in commercial facilities with FDA-approved ingredients.

- Add statement: The nicotine load and the window of time wherein samples would be consumed is within the recommended dosage limits established by the FDA
- Add statement: Pregnancy tests will be available and required of all individuals unless they report that they cannot possibly be pregnant. Once the participant has taken the pregnancy test, the used pregnancy test will be disposed of without IDs in a manner that is consistent with biohazard waste. If the subject chooses not to consent to the test at any time, their data will not be recorded.
- Whether participants must refrain from the use of nicotine when participating in this research and what guidance will be given by the research team to participants on this matter.

Eligibility Criteria

- All participants are adults, ages 18 years old and older.
- Participants blood pressure reading less than 140/90 as measured by medical professional prior to taste test with the medical professional's subsequent assessment of eligibility.
- Participants resting heart rate is less than 100 as measured by medical professional prior to taste test with the medical professional's subsequent assessment of eligibility.
- Participants routinely use of nicotine-delivery products <insert number> times per week.
- Participants must affirm knowledge and accept that the tested nicotine product(s) may interact with medications.

Ineligibility Criteria

- Participants cannot have any dietary restrictions, food allergies, intolerances, or any illness that would affect ability to taste and/or smell.
- Participants cannot have heart disease, diabetes, high blood pressure, asthma, lung disease, be pregnant, trying to conceive, or nursing.
- Participants cannot be taking medication for depression.
- Participants cannot be taking medication for asthma.
- Participants cannot be taking non-nicotine stop smoking drugs.
- Participants cannot be taking insulin.

Research Risks

- Nicotine is a chemical known to the State of California to cause birth defects or other reproductive harm.
- Nicotine is addictive and habit-forming, and it is very toxic by inhalation, in contact with the skin, or if swallowed.
- Physical effects of nicotine may include increased heart rate and accelerated blood pressure.
- Should there be any emotional risk of obtaining a positive result which would be unexpected for the participant would be handled by the onsite medical professional. The medical professional will discuss with the participant to contact their health care provider and will provide information about their local health department.

Appendix A: Definitions and Common Terms

Agricultural Chemical

A substance that is a fertilizer or a non-household pesticide and that is a hazardous substance. Any chemical prescribed as an insecticide, fungicide or herbicide, or as an agricultural chemical or fertilizer or any preparation containing a chemical so prescribed.

Color Additive

A color additive (opens in a new window) is any dye, pigment, or other substance which when added or applied to a food, drug, cosmetic, or to the human body, is capable (alone or through reactions with other substances) of imparting color. A substance capable of imparting color is a color additive unless the substance is used in a product solely for a purpose other than coloring and the substance is clearly unimportant to the marketability of the product. In addition, a chemical that reacts with another substance and causes formation of a color may be a color additive. Under the Federal Food, Drug, and Cosmetic Act (opens in a new window), all color additives and new uses for listed color additives must be approved by the FDA before they may be used in foods, drugs, cosmetics, or certain medical devices, or on the human body. Color additives are classified as straight colors, lakes, and mixtures.

Commercially Available

Any item customarily used by the general public and has been sold, leased, or licensed to the general public; or has been offered for sale, lease, or license to the general public; or is an off-the-shelf item. Sold in in the commercial marketplace.

Consumer Preference Acceptance Study

Consumer preference studies apply rigorous sensory evaluation methodology to obtain product acceptance/liking data from targeted consumers. Consumers indicate their overall opinion of a sample using a simple liking scale in a controlled central testing location.

Dietary Supplements

The FDA (opens in a new window) defines a dietary supplement is a product intended for ingestion that, among other requirements, contains a "dietary ingredient" intended to supplement the diet.

- The term "dietary ingredient" includes vitamins and minerals; herbs and other botanicals; amino acids; "dietary substances" that are part of the food supply, such as enzymes and live microbials (commonly referred to as "probiotics"); and concentrates, metabolites, constituents, extracts, or combinations of any dietary ingredient from the preceding categories.
- There are two types of ingredients that may be used in dietary supplements: “dietary ingredients,” discussed above, and “other ingredients.” These “other

ingredients” include substances such as fillers, binders, excipients, preservatives, sweeteners, and flavorings.
- To be a dietary supplement, a product must also be labeled as a dietary supplement; that is, the product label must include the term "dietary supplement" or equivalent (e.g., "iron supplement" or "herbal supplement").

Environmental Contaminate

Any physical, chemical, biological, or radiological substance or matter that has an adverse effect on air, water, soil, or living organisms. The release of a hazardous substance, or the potential release of a discarded hazardous substance, in a quantity which is or may become injurious to the environment or to the public health, safety, or welfare.

Food Additives

In its broadest sense, a food additive is any substance added to food. Legally, the term refers to "any substance the intended use of which results or may reasonably be expected to result (directly or indirectly) in it becoming a component or otherwise affecting the characteristics of any food." This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food.

Direct Food Additive

If a substance is added to a food for a specific purpose in that food, it is referred to as a direct additive. Many direct additives are identified on the ingredient label of foods.

Indirect Food Additives

are those that become part of the food in trace amounts due to its packaging, storage or other handling. Food packaging manufacturers must prove to the HHS Food and Drug Administration (FDA) that all materials coming in contact with food are safe, before they are permitted for use in such a manner.

Food & Food Ingredients

Substances, whether in liquid, concentrated, solid, frozen, dried, or dehydrated form, that are sold for ingestion or chewing by humans and are consumed for their taste or nutritional value. Food and food ingredients do not include alcoholic beverages and tobacco.

Food Grade

Food grade means that the material is fit for human consumption or permitted to come into contact with food.

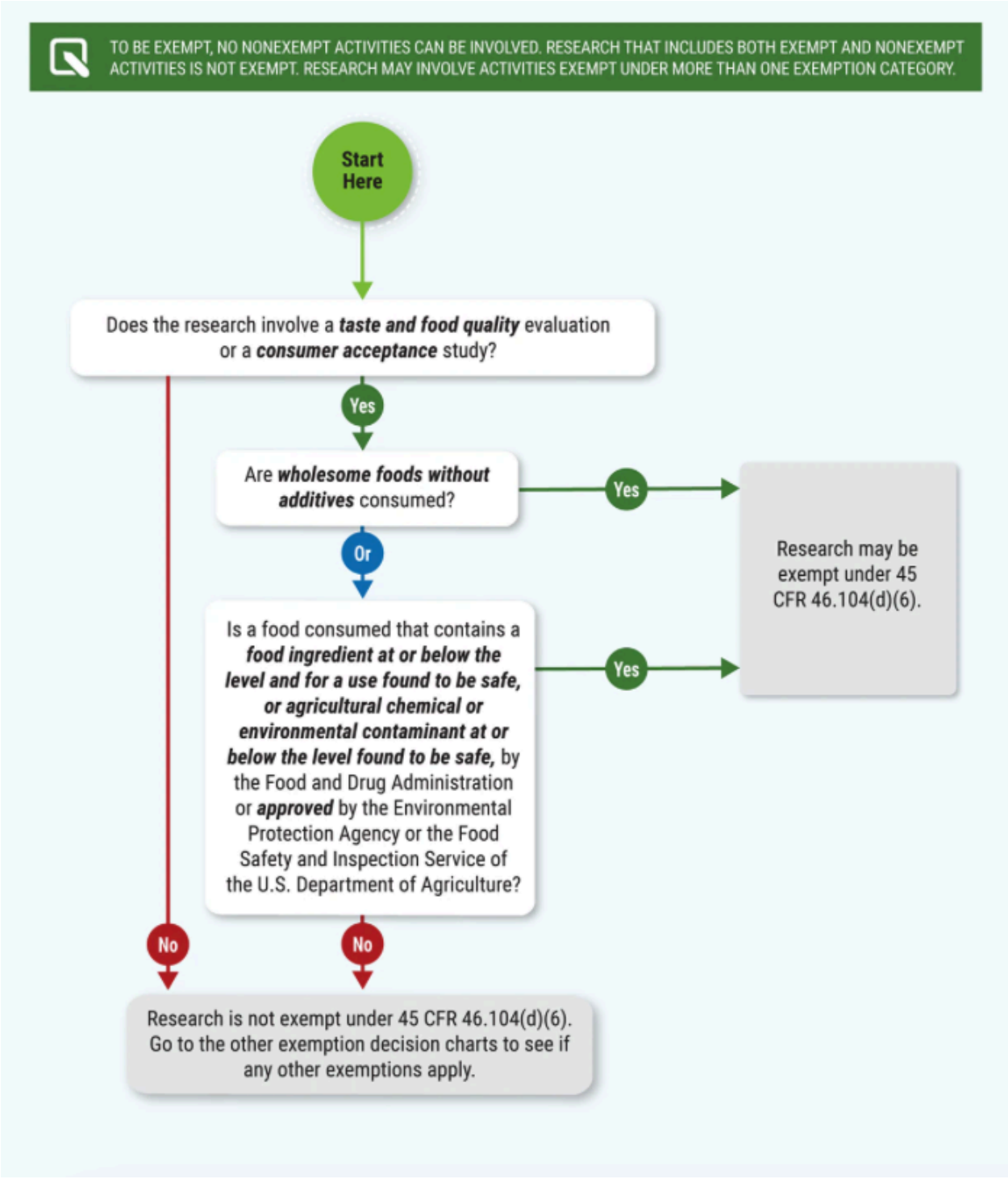
Food Safe

Food-safe means that the material is fit for its current purpose and will not be a food safety risk as long as it is used according to the manufacturer’s directions.

GRAS
GRAS (opens in a new window) is an acronym for the phrase generally recognized as safe. Any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

Wholesome Foods
A raw, cooked, processed or prepared edible substance or beverage that is intended for human consumption and that meets all quality and labeling standards imposed by federal, state and local laws and regulations,

Appendix B: OHRP's Exemption Eligibility Chart



Appendix C: Types of Food Ingredients

https://www.fda.gov/food/food-additives-and-gras-ingredients-information-consumers/types-food-ingredients

Type of Ingredient	What They Do	Examples of Uses	Ingredient Names That May be Found on Product Labels
Preservatives	Prevent food spoilage from bacteria, molds, fungi, or yeast (antimicrobials); slow or prevent changes in color, flavor, or texture and delay rancidity (antioxidants); maintain freshness	Fruit sauces and jellies, beverages, baked goods, cured meats, oils and margarines, cereals, dressings, snack foods, fruits and vegetables	Ascorbic acid, citric acid, sodium benzoate, calcium propionate, sodium erythorbate, sodium nitrite, calcium sorbate, potassium sorbate, BHA, BHT, EDTA, tocopherols (Vitamin E)
Sweeteners	Add sweetness with or without the extra calories	Beverages, baked goods, confections, table-top sugar, substitutes, many processed foods	Sucrose (sugar), glucose, fructose, sorbitol, mannitol, corn syrup, high fructose corn syrup, saccharin, aspartame, sucralose, acesulfame potassium (acesulfame-K), neotame
Color Additives	Offset color loss due to exposure to light, air, temperature extremes, moisture and storage conditions; correct natural variations in color; enhance colors that occur naturally; provide color to colorless and "fun" foods	Many processed foods, (candies, snack foods margarine, soft drinks, jams/jellies, gelatins, pudding and pie fillings)	FD&C Blue Nos. 1 and 2, FD&C Green No. 3, FD&C Red Nos. 3 and 40, FD&C Yellow Nos. 5 and 6, Orange B, Citrus Red No. 2, annatto extract, beta-carotene, grape skin extract, cochineal extract or carmine, paprika oleoresin, caramel color, fruit and vegetable juices, saffron (Note: Exempt color additives are not required to be declared by name on labels but may be declared simply as “artificial color” or “color added”
Flavors and Spices	Add specific flavors (natural and artificial)	Pudding and pie fillings, gelatin dessert mixes, cake mixes, salad dressings, candies, soft drinks, ice cream, BBQ sauce	Natural flavoring, artificial flavor, and spices
Flavor Enhancers	Enhance flavors already present in foods (without	Many processed foods	Monosodium glutamate, hydrolyzed soy protein, autolyzed yeast extract, disodium guanylate or inosinate

	providing their own separate flavor)		
Fat Replacers	Provide expected texture and a creamy "mouth-feel" in reduced-fat foods	Baked goods, dressings, frozen desserts, confections, cake and dessert mixes, dairy products	Cellulose gel, carrageenan, polydextrose, modified food starch, microparticulated egg white protein, guar gum, xanthan gum, whey protein concentrate
Nutrients	Replace vitamins and minerals lost in processing (enrichment), add nutrients that may be lacking in the diet (fortification)	Flour, breads, cereals, rice, macaroni, margarine, salt, milk, orange juice energy bars, instant breakfast drinks	Thiamine hydrochloride, riboflavin (Vitamin B2), niacin, niacinamide, folate or folic acid, beta carotene, potassium iodide, iron or ferrous sulfate, alpha tocopherols, ascorbic acid, Vitamin D, amino acids (L-tryptophan, L-lysine, L-leucine, L-methionine)
Emulsifiers	Allow smooth mixing of ingredients, prevent separation. Keep emulsified products stable, reduce stickiness, control crystallization, keep ingredients dispersed, and to help products dissolve more easily	Salad dressings, peanut butter, chocolate, margarine, frozen desserts	Soy lecithin, mono- and diglycerides, egg yolks, polysorbates, sorbitan monostearate
Stabilizers and Thickeners, Binders, Texturizers	Produce uniform texture, improve "mouth-feel"	Frozen desserts, dairy products, cakes, pudding and gelatin mixes, dressings, jams and jellies, sauces	Gelatin, pectin, guar gum, carrageenan, xanthan gum, whey
pH Control Agents and acidulants	Control acidity and alkalinity, prevent spoilage	Beverages, frozen desserts, chocolate, low acid canned foods, baking powder	Lactic acid, citric acid, ammonium hydroxide, sodium carbonate
Leavening Agents	Promote rising of baked goods	Breads and other baked goods	Baking soda, monocalcium phosphate, calcium carbonate

Anti-caking agents	Keep powdered foods free-flowing, prevent moisture absorption	Salt, baking powder, confectioner's sugar	Calcium silicate, iron ammonium citrate, silicon dioxide
Humectants	Retain moisture	Shredded coconut, marshmallows, soft candies, confections	Glycerin, sorbitol
Yeast Nutrients	Promote growth of yeast	Breads and other baked goods	Calcium sulfate, ammonium phosphate
Dough Strengtheners and Conditioners	Produce more stable dough	Breads and other baked goods	Ammonium sulfate, azodicarbonamide, L-cysteine
Firming Agents	Maintain crispness and firmness	Processed fruits and vegetables	Calcium chloride, calcium lactate
Enzyme Preparations	Modify proteins, polysaccharides and fats	Cheese, dairy products, meat	Enzymes, lactase, papain, rennet, chymosin
Gases	Serve as propellant, aerate, or create carbonation	Oil cooking spray, whipped cream, carbonated beverages	Carbon dioxide, nitrous oxide