**Please fill in this form and attach to your IRB submission if your study involves the testing or administration of any drugs, biologics, foods, and/or dietary supplements.**

**FDA Definitions:**

[Drug](https://www.law.cornell.edu/uscode/text/21/321) “means:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).”

[Biologic](https://www.law.cornell.edu/definitions/uscode.php?width=840&height=800&iframe=true&def_id=42-USC-1259684400-1720400858&term_occur=999&term_src=) is defined “as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”

[Food](https://www.law.cornell.edu/uscode/text/21/321) is defined “as (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”

[Dietary Supplement](https://www.law.cornell.edu/uscode/text/21/321#f) is defined by the FD&C act and [guidance](https://www.fda.gov/media/79386/download) “as a product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements can be found in many forms such as tablets, capsules, softgels, liquids, or powders.”

**Section Instructions:**

* Do any articles or products involved in this study meet the definition of a **drug** and/or **biologic**? If yes, complete **Section A.**
* Do any articles or products involved in this study meet the definition of a **food**? If yes, complete **Section B.**
* Do any articles or products involved in this study meet the definition of a **dietary supplement**? If yes, complete **Section C**.

**Please fill out all applicable sections.**

**Section A: Drugs and Biologics**

1. Please explain why articles or products involved in this study meet the definition of a drug and/or biologic.
2. a) List each article or product meeting the definition of a drug or biologic and provide the requested information for each.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Common and/or Proprietary Name of Drug or Biologic | Manufacturer | FDA Approval Status\* | Indication | Dose/Dosing Regimen | Unit | Route of Administration | Frequency |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

\*FDA approval status options: FDA Approved, FDA Approved but Proposing New/Unapproved Use (off-label use), Approved IND, IND Exempt, or other FDA determination (documented in writing). For INDs, please provide the # and name of the holder in the table and attach a copy of the IND letter to the submission.

b) If claiming IND Exempt, provide certification that all FDA-required criteria for exemption are met – see [section IV. of FDA’s Guidance](https://www.fda.gov/media/79386/download). Please also see the Decision Tree at the end of this document.

1. Drug and/or Biologic accountability: Describe the procedures for drug accountability. How/where will the drug be obtained? How will the drug/dosage be prepared? Is a prescription required? If so, who will be the prescribing physician? Where will it be stored, and how will access be secured? What is the method for dispensing the drug and how will usage be tracked? How will the drugs be disposed of at the conclusion of the study? If you have written SOPs for these procedures, you may upload them separately to provide these details.
2. Clinical Trial: If the study meets the NIH definition of a [Clinical Trial](https://grants.nih.gov/policy/clinical-trials/definition.htm) (regardless of funding), the study must comply with [ICH E6 Good Clinical Practice](https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf) (GCP). More information is provided in the Regulatory obligations section below. Please explain if the study meets the definition of a clinical trial.
3. Monitoring: Explain how [monitoring](https://www.fda.gov/downloads/Drugs/Guidances/UCM269919.pdf) the conduct of the study and reviewing and evaluating safety information will be performed, and by whom. If you have written SOPs for these procedures, you may upload them separately to provide these details.
4. Additional attachments required: In Mentis, please upload information about the drug for the IRB to consider during protocol review. For example, a package insert, investigator’s brochure, dosing instructions, photos, applicable IND/IND exemption letters, preclinical data reports, literature reviews, or other relevant safety or drug/biologic information. For approved drugs, see [Drugs at FDA](https://www.accessdata.fda.gov/scripts/cder/daf/) for package inserts. If there is information about the drug located on a website, please pdf the information and attach to the submission as links go out-of-date. Please explain here if these documents are not available.

**Section B: Food**

1. Please explain why the articles or products in this study meet the definition of a food.
2. List each article or product meeting the definition of food and provide the requested information for each.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Food | Source/Manufacturer | Study Serving Size | Frequency |
|  |  |  |  |
|  |  |  |  |

Note: When the food is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease it is considered a drug. If the food used in the study meets the definition of a drug, Section A must be filled out instead of this section.

1. Food accountability: How/where will you obtain the food? Where will you store it, and how will you secure its access? What is your method for distributing the food and how will you track usage? If you have written SOPs for these procedures, you may upload them separately to provide these details.
2. Clinical Trial: If the study meets the NIH definition of a [Clinical Trial](https://grants.nih.gov/policy/clinical-trials/definition.htm) (regardless of funding), the study must comply with [ICH E6 Good Clinical Practice](https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf) (GCP). More information is provided in the Regulatory obligations section below. Please explain if the study meets the definition of a clinical trial.
3. Monitoring: Explain how monitoring the conduct of the study and reviewing and evaluating safety information will be performed, and by whom. If you have written SOPs for these procedures, you may upload them separately to provide these details.
4. Additional attachments required: In Mentis, upload information about the food for the IRB to consider during protocol review. For example, a nutrition label, pictures, and any correspondence with the FDA regarding the use of food in the study. If there is information about the food located on a website, please pdf the information and attach to the submission as links go out-of-date. Please explain here if these documents are not available.

**Section C: Dietary Supplement**

1. Please explain why the articles or products used in this study meet the definition of a dietary supplement. Please explain the purpose of the use of the supplement in the study. For example, is the purpose to collect data that will be submitted to the FDA to support an application for an authorized or qualified health claim? Is the purpose solely to evaluate safety of a dietary supplement (or safety of an ingredient in a dietary supplement)? Is the purpose to substantiate a labelling claim for a dietary supplement?
2. List each article or product meeting the definition of a dietary supplement and provide the requested information for each.

|  |  |  |  |
| --- | --- | --- | --- |
| Name of Supplement | Source/Manufacturer | Study Serving Size | Frequency |
|  |  |  |  |
|  |  |  |  |

Note: When the supplement is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease it is considered a drug. If the supplement used in the study meets the definition of a drug, Section A must be filled out instead of this section.

1. Dietary Supplement accountability: How/where will you obtain the supplement? How will the supplement dosage be prepared? Where will you store it, and how will you secure its access? What is your method for distributing the supplement and how will you track usage? How will the supplements be disposed of at the conclusion of the study? If you have written SOPs for these procedures, you may upload them separately to provide these details.
2. Monitoring: Explain how monitoring the conduct of the study and reviewing and evaluating safety information will be performed, and by whom. If you have written SOPs for these procedures, you may upload them separately to provide these details.
3. Clinical Trial: If the study meets the NIH definition of a [Clinical Trial](https://grants.nih.gov/policy/clinical-trials/definition.htm) (regardless of funding), the study must comply with [ICH E6 Good Clinical Practice](https://www.fda.gov/files/drugs/published/E6%28R2%29-Good-Clinical-Practice--Integrated-Addendum-to-ICH-E6%28R1%29.pdf) (GCP). More information is provided in the Regulatory obligations section below. Please explain if the study meets the definition of a clinical trial.
4. Additional attachments required: In Mentis, upload information about the dietary supplement for the IRB to consider during protocol review. For example, a supplement label, pictures, safety information, and any correspondence with the FDA regarding the use of the supplement in the study. If there is information about the supplement located on a website, please pdf the information and attach to the submission as links go out-of-date. Please explain here if these documents or information is not available.

**Regulatory obligations:**

* In studies involving investigational drugs, investigational biologics, or dietary supplements studied as drugs, FDA requirements for informed consent ([21 CFR part 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)) and IRB oversight ([21 CFR part 56)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56) apply. Additionally, FDA requirements for an IND ([21 CFR part 312](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312)) would apply.
* Studies involving FDA regulated drugs, biologics, or dietary supplements must notify subjects in the informed consent document of the possibility that the Food and Drug Administration may inspect the records (add to Confidentiality section of informed consent).
* For research on a dietary supplement NOT studied as a drug but are clinical investigations to support a [health claim](https://www.fda.gov/food/food-labeling-nutrition/authorized-health-claims-meet-significant-scientific-agreement-ssa-standard) or nutrient content claim, 21 CFR parts 50 and 56 apply.
* If the study meets the NIH definition of a [Clinical Trial](https://grants.nih.gov/policy/clinical-trials/definition.htm) (regardless of funding) and/or involves an investigational new drug (IND), the study must comply with ICH E6 Good Clinical Practice (GCP)and complete training.
  + ICH E6(R2), “Guideline for Good Clinical Practice”: <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>
  + GCP Training: <https://resources.uta.edu/research/regulatory-services/human-subjects/good-clinical-practices/gcp-training.php>
  + GCP Resources/Tools: <https://resources.uta.edu/research/regulatory-services/human-subjects/good-clinical-practices/gcp-toolkit.php>
* In Investigator-initiated studies with investigational new drugs/biologics or dietary supplements studied as drugs, the PI is responsible for fulfilling both the Investigator and Sponsor requirements for recordkeeping and reporting as required by [21 CFR 312 Subpart D](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4). In Sponsor-initiated studies, the PI is responsible for fulfilling the Investigator requirements under the same part.