**CSUSB IRB Guidelines and Procedures on Research Involving Dietary Supplements**

Developed by the CSUSB Institutional Review Board

Approved by the IRB Committee April 06, 2018

The FDA defines dietary supplements “in part as products taken by mouth that contain dietary ingredients,” such as “vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet.” The FDA indicates that dietary supplements come in several forms, “including tablets, capsules, powders, energy bars, and liquids” and that people use dietary supplements “to compensate for diets, medical conditions, or eating habits that limit the intake of essential vitamins and nutrients” (U.S. Department of Health and Human Service, National Institutes of Health, 2015).

1. **Background**

The FDA (U.S. Department of Health and Human Service, National Institutes of Health, 2015) recommends consulting with a health care professional before taking supplements and notes that dietary supplements are not regulated by the FDA, including ensuring that dietary supplement labeling is accurate. Once dietary supplements are on the market, the FDA is responsible for monitoring reporting of adverse events by the supplement manufacturer and oversight of dietary labels as resources allow.

In addition, according to the FDA (U.S. Department of Health and Human Service, National Institutes of Health, 2015), the safety record of some dietary supplements is clean, but other dietary supplements have been shown to be harmful because of issues including “microbiological, pesticide, and heavy metal contamination, absence of a dietary ingredient claimed to be in the product, and the presence of more or less than the amount of the dietary ingredient claimed on the label.”

If research involving supplements intends to make claims about the dietary supplement’s use in the diagnosis, cure, mitigation, treatment, or prevention of disease, the FDA requires a [New Investigational Drug (IND](https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf)) application (U.S. Department of Health and Human Services, U.S. Food and Drug Administration, 2015). However, if the dietary supplement research examines the effect of the dietary supplement on body function, an IND is not required.

1. **CSUSB IRB Guidelines and Procedures**
2. The CSUSB IRB places the responsibility of deciding whether an IND is required on the researcher before submission to the IRB.
3. In cases in which an IND is not required, if the dietary supplement is sold over the counter in the United States, the FDA has some regulatory authority, and these dietary supplements can be used in human subjects research conducted at CSUSB provided they have a clean safety record and follow the California Health and Safety Code, Division 4, Part 5, Sherman Food Drug, and Cosmetic Law (California Department of Public Health, 2018). For more information regarding California regulations, please visit https://www.cdph.ca.gov. Providing evidence of a clean safety record is the responsibility of the researcher.
4. If the dietary supplement sold over the counter in the United States has been shown by the FDA to be harmful, it cannot be used in human subjects research conducted at CSUSB. The researcher must provide all information about the safety record of the dietary supplement to be used in human subjects research at CSUSB.
5. If the dietary supplement is not sold over the counter in the United States, the CSUSB IRB requires a third party certificate of analysis before such dietary supplements can be used in human subjects research conducted at CSUSB. The National Institutes of Health Office of Dietary Supplements indicates that:

There are a few independent organizations that offer “seals of approval” that may be displayed on certain dietary supplement products. These indicate that the product has passed the organization’s quality tests for things such as potency and contaminants. These “seals of approval” do not mean that the product is safe or effective; they provide assurance that the product was properly manufactured, that it contains the ingredients listed on the label and that it does not contain harmful levels of contaminants” (National Institutes of Health, 2013).

Organizations that the NIH lists include Consumerlab.com, NSF International, and USP. In cases in which a dietary supplement that is not sold over the counter in the United States is to be used in human subjects research at CSUSB, the CSUSB IRB requires a third party certificate of analysis from one of these three organizations.

Tarkan (2016) provides information about the three organizations that conduct third party certificates of analysis of dietary supplements identified by the NIH. Researchers may find the Consumer Reports chart below that details the organizations’ specific practices useful. It is the researcher’s responsibility to ensure that the organization’s services meet the needs of the third certificate analysis relevant to the dietary supplement research being conducted.

**Table 1. Consumer Reports List of Organizations that Conduct Third Party Certificates of Analysis**

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| --- | --- | --- | --- |
|  | Logo for ConsumerLab.com | Logo for NSF International | Logo for U.S. Pharmacopeia (USP) |
| **Does it buy initial test samples in stores or are they provided by the manufacturer?** | Purchased in stores. | Provided by the manufacturer. | Provided by the manufacturer. |
| **How often does it retest or spot-check?** | Once per year using samples purchased in stores. | Once per year using samples provided by manufacturer and occasionally purchased in stores. | One to six times per year using samples purchased in stores. |
| **How much do manufacturers pay to have each product certified?** | $3,000 to $5,000 per product. | $3,000 to $5,000 per product plus an audit fee of about $13,000. | $3,000 to $15,000 per product plus an initial audit fee of $15,000 and a label fee of 1 cent per bottle. |
| **Are there products it won’t test?** | Products containing ingredients known to be unsafe. | Products marketed for weight loss or sexual enhancement. | Products known to contain unsafe ingredients and those marketed for erectile dysfunction, weight loss, or sports. |

(Tarkan, 2016)

1. The researcher must disclose to the CSUSB IRB any potential side effects of the dietary supplement to be used in research at CSUSB as well as how the dietary supplement may interact with drugs and other dietary supplements. Such side effects and interactions must also be disclosed in the informed consent process.
2. All participants of dietary supplement research at CSUSB must complete a PAR Q and/or other medical screenings as needed before they participate.
3. The IRB will not approve human subjects research involving dietary supplements at CSUSB until Risk Management has reviewed, completed, and approved the contracts with the dietary supplement manufacturers or funders as applicable (e.g., in cases in which the dietary supplement is not sold over the counter in the United States). Supplements sold over the counter must meet [FDA Dietary supplement Labeling Guidelines](https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm2006823.htm) (U.S. Department of Health and Human Services, U.S. Food and Drug Administration, 2016). If the supplement under study is a new dietary supplement the investigator must ensure the FDA has been notified through the [New Dietary Ingredients (NDI) Notification Process](https://www.fda.gov/Food/DietarySupplements/NewDietaryIngredientsNotificationProcess/default.htm) (U.S. Department of Health and Human Services, U.S. Food and Drug Administration, 2017). The dietary supplement research must be approved by CSUSB administration. The IRB will not approve human subjects research involving dietary supplements at CSUSB and until all institutional approvals are in place.
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