

Research Compliance	Effective Date: 09/08/2020
Institutional Review Board Policies and Procedures	Revised:

IRB-29: Review of Research Involving Dietary Supplements

PURPOSE

Since the FDA does not determine whether dietary supplements are safe and effective prior to marketing, this policy is intended to provide standards for dietary supplements used in research and for the IRB review of research when such research involves the use of dietary supplements in human subjects.

BACKGROUND

Dietary supplements are regulated under the Dietary Supplement Health and Education Act (DSHEA) of 1994. Manufacturers are required to produce dietary supplements in a quality manner and ensure that they do not contain contaminants or impurities, and are accurately labeled according to current Good Manufacturing Practice (cGMP) and labeling regulations. If a serious problem associated with a dietary supplement occurs, manufacturers must report it to FDA as an adverse event. However, the FDA is not authorized to review dietary supplement products for safety and effectiveness before they are marketed. 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. The IRB has determined that to protect the health, safety, and welfare of research participants, it needs to set standards for dietary supplements used in research at Baylor University in order to reasonably ensure the safety of participants who will be using the supplement.

POLICY

If the dietary supplement is sold over the counter (OTC) in the U.S., the FDA has some regulatory authority, and these dietary supplements can be used in human subjects research provided they have a good safety record. A “good safety record” means that the supplement is generally safe for use in the target population and the FDA has not issued any warning letters to the manufacturer in the last 5 years. “Over the counter” means that the dietary supplement is sold in stores or online if the online seller is physically located in the U.S. If the dietary supplement is not sold over the counter in the U.S., the IRB requires a third-party certificate of analysis before such dietary supplements can be used in human subjects. The third-party certificate of analysis must be from one of three (3) of the following independent organizations: Consumerlab.com; NSF International; U.S. Pharmacopeia (USP).

The researcher must disclose to the IRB any potential side effects of the dietary supplement to be used in research 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. All participants of dietary supplement research must complete a medical screening as needed before they participate.

If the supplement under study is a new dietary supplement the researcher must ensure the FDA has been notified through the New Dietary Ingredients (NDI) Notification Process. If research involving supplements intends to make claims about the dietary supplement's use in the diagnosis, cure, mitigation, treatment, or prevention of disease, an Investigational New Drug Application is required. It is the responsibility of the researcher to decide whether an IND is required prior to submission to the IRB.

The IRB review of research involving the use of dietary supplements in human research may be reviewed by the full board or by expedited review. If reviewed by expedited review, it is reviewed under category 1(a) and one of the expedited reviewers must be a medical professional with knowledge of dietary supplements.

PROCEDURES

1. At the time of initial submission, IRB staff will ensure that the researcher has submitted the F-04 Supplement for Drugs, Biologics, Supplements, & Botanicals.
2. IRB Staff will review the F-04 for completeness.
3. IRB staff will search the FDA Warning Letter Database to determine if the source/manufacture has received any warning letters in the past 5 years. If the source/manufacture has received a warning letter in the past 5 years, the researcher will be asked to change the source/manufacture. If the researcher is unable to change, a third-party certificate of analysis will be required.
4. If the researcher indicates that the supplement is not sold OTC in the U.S., IRB staff will verify that a third-party certificate of analysis has been submitted. If it is not submitted, IRB staff will alert the researcher to the requirement for a third-party certificate of analysis and will indicate that the submission will not be reviewed by the IRB until it is submitted.
5. In their review, IRB members are encouraged to research and review third-party information about the dietary supplement and its safety profile, especially as it relates to the target population of the research. IRB is allowed to impose stricter inclusion/exclusion criteria on the research for participants.

REFERENCES

FDA Dietary Supplements website (<https://www.fda.gov/food/dietary-supplements>)

NIH, Office of Dietary Supplements (<https://ods.od.nih.gov/>)

REVISIONS FROM PREVIOUS VERSION

None