**Dietary Supplements and/or Medical Foods Used in Research**

**Study Team:** Please complete this form if using a dietary supplement or medical food in an Emory IRB study. Upload this form in the miscellaneous section of the new submission form. For more information about dietary supplements follow this [link](http://www.irb.emory.edu/documents/dietary_supplement_faq.docx). For FDA guidance about medical foods, please follow this [link](http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/MedicalFoods/ucm054048.htm).

IRB number: Click here to enter text.

PI: Name: Click here to enter text.

Study Title: Click here to enter text.

Person completing this form: Click here to enter text.

**Does this study involve use of a Dietary Supplement?** No  Yes

* If yes, is the dietary supplement used with the intention to evaluate the dietary supplement’s ability to diagnose, cure, mitigate, treat, or prevent a disease including its associated symptoms? No  Yes  (If yes, an Investigational New Drug [IND] submission is required under part 312).

For example, a clinical investigation designed to study the relationship between a dietary supplement’s effect on normal structure or function in humans (e.g., guarana and maximal oxygen uptake) or to characterize the mechanism by which a dietary supplement acts to maintain such structure or function (e.g., fiber and bowel regularity) would not need to be conducted under an IND. However, a clinical investigation designed to evaluate a dietary supplement’s ability to prevent osteoporosis or to treat chronic diarrhea or constipation would need to be conducted under an IND.[[1]](#endnote-1)

**Does this study involve use of a Medical Food?** No  Yes

* If yes, is the medical food used with the intention to evaluate the medical food’s ability to diagnose, cure, mitigate, treat or prevent a disease? No  Yes  (If yes, an IND submission is required under part 312).

An investigation intended to evaluate the effects of a medical food on a disease would require an IND. However, if the medical food is simply being fed to subjects for nutritional purposes during a study examining the effects of another intervention, the use of the medical food in the study would not trigger the need for an IND, although the study might require an IND or investigational device exemption (IDE) for the intervention being studied.The use of a medical food in a study for the specific management of a disease or condition for which distinctive nutritional requirements does not require an IND.

**For IRB review:** If the answer is no to any of these later questions, the dietary supplement or medical food is not being used as a drug and therefore an IND exemption will not apply, and it should not be documented as such in the meeting minutes. The use is allowed if the dietary supplement or medical food is used as such, and does not meet the FDA definition of a drug.

1. From FDA Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) —

   Determining Whether Human Research Studies Can Be Conducted Without an IND. September, 2013. [↑](#endnote-ref-1)