Section 1: About the Drug and Supplements Form

If this human subjects study involves the use of any drugs or chemical or biological agents, the study is subject to the Food and Drug Administration (FDA) regulations. Researchers planning to use these agents in human subjects research must complete this form and include it with their protocol submission.

Learn more:

* <https://oprs.research.illinois.edu/forms-templates/forms/drug-supplements-form>
* <https://oprs.research.illinois.edu/forms-templates/guidance/guidance-ind-exemption-criteria>

Section 2: When to Use This Form

If you answered yes to 12.1.8 (Studying the safety, effectiveness, or outcomes of a drug, dietary supplement, biologic product, or cosmetic) in the New Study Application, you need to complete this form.

If you will be creating or sending data and/or samples to a repository or database to be saved for future research uses for this study, and if you did not yet select yes in Section 12.1.8 of the New Study Application, please update the appropriate New Study Application section and then complete this form.

Section 3: Protocol Information:

Please complete the information below.

1) Principal Investigator:

Please enter the names of the PI’s.

2) Protocol Number:

Please enter the Protocol number. (If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.)

3) Project Title:

Please enter the Project Title.

Section 4: Drugs and Supplements - Questions

1) Please list the name(s) of the product(s) involved

Detail below:

Click or tap here to enter text.

2) For each product listed above, please briefly explain its use and purpose in the study.

Detail below:

Click or tap here to enter text.

3) Is the intent of the product in this study to diagnose, cure, mitigate, treat, or prevent disease?

Select yes or no.

[ ]  Yes [ ]  No

4) Is the intent of the product to affect the structure or function of the human body?

Select yes or no.

[ ]  Yes [ ]  No

5) For any of the products previously listed above (in question 1), please answer the following questions.

5.1) Are you studying the safety of the product in humans?

[ ]  Yes [ ]  No

5.2) Are you studying the effectiveness of the product in humans?

[ ]  Yes [ ]  No

5.3) Are you studying the outcomes on a person's health after using the product?

[ ]  Yes [ ]  No

5.4) Are you comparing the product to another product?

[ ]  Yes [ ]  No

6) Progress Note:

- If any item in the previous questions 3, 4, 5 is "Yes" - then please complete remainder of the questions below on this form.

- If all the previous items were checked "No", you are done. You can skip the remaining form sections.

7) Describe the plan to control, store, and dispense the investigational product. This plan should ensure that the product is only used by qualified investigator(s) for the participants enrolled in this research project.

Detail below:

Click or tap here to enter text.

8) List the location of the product supply.

Detail below:

Click or tap here to enter text.

9) Investigational New Drug (IND) Questions

9.1) Has FDA issued an IND (Investigational New Drug application) for the use of the product(s)?

[ ]  Yes [ ]  No

If you answered “yes” (Investigational New Drug application issued), please answer 9.2, 9.3, and 9.4 below. Otherwise please go to Section 10.

9.2) Please list the IND number(s)

Click or tap here to enter text.

9.3) Who is listed as the IND holder (or person/entity that applied for the IND)?

Click or tap here to enter text.

9.4) Attach documentation of the IND number(s) to the application.

10) Has FDA issued an IND Exemption for the use of the product(s)?

[ ]  Yes [ ]  No

If yes, please attach documentation of the IND Exemption.

11) Are you requesting IRB to issue an IND Exemption?

Check Yes or No.

[ ]  Yes [ ]  No

12) If you answered “yes” in Question 11 (for an IND exemption by IRB), has the product been approved or cleared by FDA for any indication?

Check Yes or No.

Note: If the product is not regulated by FDA (e.g. dietary supplements, answer "No")

[ ]  Yes [ ]  No

13) If you answered “yes” in Question 12 (product is approved by FDA), please select the items below that apply to the product as it is used in this study.

Check the boxes of those items below that are true:

[ ]  A. It is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug.

[ ]  B. It is not intended to support a significant change in the advertising for the product.

[ ]  C. It does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product

[ ]  D. It is conducted in compliance with the requirements for IRB review and informed consent

[ ]  E. The investigation is conducted in compliance with the requirements of 21 CFR 312.7, i.e. the drug may not be represented as safe or effective for any purposes for which it is under investigation, nor may it be commercially distributed or sold.

[ ]  F. Exception from informed consent for emergency research will not be invoked.