|  |  |  |
| --- | --- | --- |
|  | Diagram  Description automatically generated | **FORM: Drug Supplement** |

|  |  |
| --- | --- |
| **Date:** |       |
| **FHIRB #:** |       |
| **RG #:** |       | **Protocol #:** |       |
| **Principal Investigator:** |       |
| **Study Title:**  |       |

**Instructions:**

Complete and attach this supplement to your submission in Hutch IRB to provide supporting information.

1. **Drugs or Biologics. Does this study involve evaluation of any drug(s) and/or biologic(s)?**

[ ]  Yes ® Use the table below to list all drugs and/or biologics being evaluated in the study. (You may unlock the form and add more rows to the table as needed.)

Note: Attach in Hutch IRB an investigator’s brochure (IB) or package insert for **each** product being evaluated. The only exception is when the PI is the sponsor-investigator and the product is manufactured at a Fred Hutch/UW Cancer Consortium facility. If this exception applies, indicate below where the relevant risk and dosing language is found (e.g., page number in protocol).

|  |  |  |
| --- | --- | --- |
| Name of Drug/Biologic | Status of Drug/Biologic  | IB or Package Insert attached?  |
|       | [ ]  Drug/biologic without FDA approval[ ]  FDA-approved drug/biologic used *differently from* product labeling[ ]  FDA-approved drug/biologic used *in accordance with* product labeling | [ ]  IB[ ]  Package Insert[ ]  N/A ® Explain:       |
|       | [ ]  Drug/biologic without FDA approval[ ]  FDA-approved drug/biologic used *differently from* product labeling[ ]  FDA-approved drug/biologic used *in accordance with* product labeling | [ ]  IB[ ]  Package Insert [ ]  N/A ® Explain:       |

[ ]  No ® Skip to Question 2.

2. Investigational New Drug (IND) research:

2.a. Is this study being done under an IND number assigned by the FDA?

[ ]  Yes ® Provide the following IND information. (If needed, you may unlock the form and add more rows to the table.)

|  |  |
| --- | --- |
| Name of Drug/Biologic |       |
| Phase of Study (select one) | [ ]  Phase 1 [ ]  Phase 1/2[ ]  Phase 2 [ ]  Phase 3[ ]  Other ® Explain:       |
| Please describe pharmacy responsible for the control (storage, accounting, etc.) of the investigational drug(s) Please describe entity responsible for release of investigational biologic(s) |       |

[ ]  No ® Go to Question 3.

2.b. How is the FDA IND number for this study documented? Select the appropriate check box below and attach documentation in Hutch IRB.

[ ]  Written communication from the FDA documenting the IND number and permission for the study to proceed. Please attach in Hutch IRB.

[ ]  Written communication from the FDA documenting the IND number and a letter from the IND holder confirming that the 30-day review period has passed. Please attach in Hutch IRB.

[ ]  IND number is part of the sponsor’s protocol.

[ ]  IND is pending FDA submission or review, and number is not yet issued.

[ ]  Other, explain:

|  |
| --- |
|       |

3. IND-exempt FDA-regulated research:

3.a. Is this study designed to evaluate any commercially available drugs, biologics, or food supplements that are not under an IND? **Select one:**

[ ]  Yes ® The FDA has confirmed that this study is exempt from IND requirements under 21 CFR 312. Please submit documentation from FDA. Go to Question 4. 

[ ]  Yes ® I would like the IRB to confirm my determination that this research is exempt from the FDA requirement for an IND. Respond to 3.a.i. – 3.a.iv.

[ ]  No ® Go to Question 4.

3.a.i Are you or your sponsor/funding source intending to use results from the study to support FDA approval of a new indication for use of the study drug, or to support any other significant change in the labeling for the study drug?

[ ]  Yes

[ ]  No

3.a.ii. Are you or your sponsor/funding source intending to use study results to support a significant change in the advertising for the study drug?

[ ]  Yes

[ ]  No

3.a.iii. Does the study involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the study drug? **Select one:**

[ ]  Yes

[ ]  No ® The drug, biologic, or food supplement is being used in accordance with FDA-approved product labeling. Attach labeling or package insert in Hutch IRB.

[ ]  No ® The drug, biologic, or food supplement is being used differently from product labeling (e.g., different dosage level or schedule, new combination of drugs, new formulation or route of administration, or for a new indication or population), but there is not a significant increase in risk associated with the proposed use. Please attach a memorandum explaining the difference in usage between the labeling and your proposed use, including your analysis of why there is not a significant increase in risk.

3.a.iv. Will the results from this study be used to promote use of the commercially available drug, biologic, or food supplement for unapproved indications?

[ ]  Yes

[ ]  No

Note: If you responded “yes” to any of the questions (3.a.i. – 3.a.iv.) above, please contact Clinical Research Support Regulatory Affairs at 206.667.1394 or RegulatoryAffairs@fredhutch.org to discuss if an IND is required for this study.

**Note: Failure to address the issue of IND requirements in a timely and thorough manner may delay the approval of your study.**

4. Food and/or Dietary Supplement Research:

4.a. Will this study involve the evaluation of a food and/or dietary supplement?

[ ]  Yes, and the research with this food and/or dietary supplement is intended *only* to have an effect on the structure or function of the body (i.e., not a therapeutic purpose).

[ ]  Yes, and is intended to evaluate the ability of the food and/or dietary supplement to diagnose, cure, mitigate, treat, or prevent a disease ® This research must be conducted under an IND. Please submit written communication from the FDA documenting the IND number, and either FDA permission for the study to proceed or a letter from the IND holder confirming that the 30‑day review period has passed. 

[ ]  No

Note: If you have questions about whether IND regulations apply to specific research on a food and/or dietary supplement, please contact Clinical Research Support Regulatory Affairs at RegulatoryAffairs@fredhutch.org.