# VA Portland Health Care System Institutional Review Board

**IRQ Appendix D – Dietary Supplements, Herbal Remedies, or Other Complementary/Alternative Agents**

**VAPORHCS PI Name:       Date:**

**Study/Project ID#:**

This appendix should be completed if the study will utilize dietary supplements, herbal remedies, or other complementary or alternative agents.

1. What is the generic name of the study agent?

2. What is the commercial name of the study agent?

3. For which indication is the study agent being used in this investigation?

 3.a. Is the investigational use of this agent different from the common use of this agent?

 [ ]  Yes [ ]  No

 3.b. If YES to 3.a, what is the common use of this agent?

4. What is the dose of the agent used in this investigation?

 4.a. Is the dose of the agent in this investigation different than the common dose?

 [ ]  Yes [ ]  No

 4.b. If YES to 4.a, what is the common dose of the agent?

5. What is the route of administration that will be used in this study? (Check all that apply)

 [ ]  Oral [ ]  Subcutaneous

 [ ]  Intravenous [ ]  Topical

 [ ]  Intramuscular [ ]  Ocular

 [ ]  Other (Please list):

5.a. Is the route of administration in the investigation different from the common route?

 [ ]  Yes [ ]  No

5.b. If YES to 5.a, what is the common route of administration? (Check all that apply)

 [ ]  Oral [ ]  Subcutaneous

 [ ]  Intravenous [ ]  Topical

 [ ]  Intramuscular [ ]  Ocular

 [ ]  Other (Please list):

6. What is the dosing regimen (frequency) for the study agent in this investigation?

6.a. Is the dosing regimen in this investigation different than the common dosing regimen? [ ]  Yes [ ]  No

 6.b. If YES to 6.a, what is the common dosing regimen of the agent?

7. In what patient/subject population(s) will the study agent be used?

 7.a. Is the population(s) in this investigation different than the common population?

 [ ]  Yes [ ]  No

 7.b. If YES to 7.a, what is the common population in which the agent is used?

8. What is the source/manufacturer of the agent?

 9. Does the product meet United State Pharmacopeia (USP) standards?

 (*The USP standards can be found in the USP/NF Official Compendia of Standards manual, which*

 *can be accessed by contacting the Research Pharmacy at x55543*.)

[ ]  Yes

[ ]  No; one of the following must be attached (check one):

[ ]  Proof of Good Manufacturing Practices (GMP) by the manufacturer and a certificate of analysis for the final product, **OR**

[ ]  The results of purity, pyrogenicity and potency testing. (*For phase II safety studies, High Performance Liquid Chromatography [HPLC] testing may be used in place of potency testing.*)

10. Has an IND been submitted for this study? [ ]  Yes [ ]  No

(*An IND should be requested if the supplement/remedy is being investigated to diagnose, treat, or prevent disease or other abnormal conditions, or if the supplement/remedy is not available as a finished product from the manufacturer. Please consult with the Research Pharmacy to determine if an IND is required and for assistance with submitting an IND.*)

11. For each agent being used in this study, attach a [VA Form 10-9012](http://www.va.gov/portlandresearch/documents/irb/10-9012.doc) (Investigational Drug Information Record)

[ ]  VA Form 10-9012(s) is attached for the following agent(s):

12. For plant substances, attach information on the botanical description, extraction

 procedures, and verification of identity.

[ ]  Information attached for the following plant substance(s):

[ ]  N/A; study will not use plant substances

13. The following should be addressed in the protocol:

1. Any potentially toxic or dangerous components that may be included within the study

agent(s).

[ ]  These are described on page       of the protocol, and

1. How purity of the sample will be evaluated, either through independent toxicity testing to

be conducted, or by obtaining a certificate of good manufacturing process from the

manufacturer.

 [ ]  These are described on page       of the protocol.

In order to assure the contents of the product, it may be necessary in some cases to obtain a profile of chemical constituents of the material by high performance liquid chromatography (HPLC) or other suitable chromatographic technique.

It is **strongly recommended** that a meeting with the Research Pharmacy take place prior to submission to the IRB. The Research Pharmacy may be able to provide guidance on possible safety concerns and/or potential sources of the supplement(s) in order to reduce risk to potential subjects.

**Keep a copy of this completed form for your records.**