# VA Portland Health Care System Institutional Review Board

**IRQ Appendix C – Investigational Drugs**

**VAPORHCS PI Name:       Date:**

**Study/Project ID#:**

*This appendix should be completed if a drug(s) is being* ***studied*** *in a clinical investigation. This includes drugs to be studied for an unapproved or approved use, dose, dosage form, administration schedule, or under an IND application, in a controlled, randomized or blinded clinical trial.* ***NOTE:*** *If any fields on this appendix do not allow enough space to provide a thorough answer, state “see attached”, and include the complete answer on a separate page, identifying clearly to which question the answer refers.* ***Unless otherwise noted, all other forms referenced in this document are located at:***[*http://www.va.gov/portlandresearch/piservices/rd\_forms.asp*](http://www.va.gov/portlandresearch/piservices/rd_forms.asp)

1. A. Will an investigational (unapproved) new drug be used? YES  NO

B. Will an approved drug be used for an indication that has

not received Food & Drug Administration (FDA) approval? YES  NO

C. Will an approved drug be used as a comparator drug? YES  NO

*If* ***YES*** *to* ***any*** *of the above, list all drugs to be used and their use(s) in the table below:*

|  |  |
| --- | --- |
| DRUG | USES |
|  |  |
|  |  |
|  |  |
|  |  |

***NOTE:*** *A* ***VA Form 10-9012, the Investigational Drug Information Record****, must be completed for each of the drugs listed in the table, and any other drugs which are specifically studied as a part of this protocol. VA Form 10-9012 is located on the VAPORHCS IRB Forms and Policies webpage located at:*[**https://www.va.gov/portlandresearch/documents/irb/10-9012.doc**](https://www.va.gov/portlandresearch/documents/irb/10-9012.doc) **OR (for studies submitted via VAIRRS);** *by navigating to Forms and Templates, selecting VA Portland IRB, and selecting the IRQ-C Investigational Drugs. Please contact the Research Pharmacy at x55543 or* [*Vhapor-ResearchPharmacy@va.gov*](mailto:Vhapor-ResearchPharmacy@va.gov)*to determine for which drugs the form is needed and for assistance in completing the form(s).*

2. Have you made arrangements with the Research Pharmacy for receiving, storage and dispensing?

YES  NO

If **NO**, please contact the Research Pharmacy at ext. 55543 or [Vhapor-ResearchPharmacy@va.gov](mailto:Vhapor-ResearchPharmacy@med.va.gov).

***NOTE:*** *The VAPORHCS Pharmacy Service Investigational Drugs for Human Use policy is located at*: <http://www.va.gov/portlandresearch/documents/hrpp/investigational-drugs.pdf>

3. Is an Investigational New Drug Application (IND) required? YES  NO

***NOTE:*** *An IND is needed when a drug is administered, dispensed or used, except for the use of a marketed drug in the course of medical practice; e.g. when a new investigational drug is being evaluated, an approved drug is being evaluated for a new indication, or an approved drug is being used in a manner which increases its risk based on a new preparation through the form, route of administration, dose of the drug or use in a new patient population.*

If **YES** to 3, provide the following information:

Name of the person/firm holding the IND:

Address:

IND #:

Date of IND filing:

***NOTE:*** *Include a copy of the IND letter from the FDA and/or any other correspondence with the FDA (e.g. FDA forms 1571 and 1572) regarding the study.*

4. What is the phase of investigation?

Phase 0 – Also known as “human micro-dosing studies,” and are designed

to speed up the development of promising drugs or imaging agents by establishing very early on whether the drug or agent behaves in human subjects as was expected from preclinical studies.

Phase I – Initial study to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness.

Phase II – Controlled clinical study conducted to evaluate the effectiveness of the drug for a particular indication or indications, in patients with the disease or condition under study, and to determine the common short-term side effects and risks.

Phase III – Expanded controlled and uncontrolled trial after preliminary evidence suggesting effectiveness of the drug has been obtained, and is intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.

Phase IV - Post-marketing study to delineate additional information, including the drug's risks, benefits, and optimal use.

6. Does the study informed consent form (ICF) state that research records are subject to inspection by the Food and Drug Administration: YES  NO

***Attach the following (the checkboxes are provided as a tool to assure that all required documents are attached).***

The **Investigator’s Brochure** (including toxicity, previous animal/human studies, lab tests and bibliography) **or package insert** (if investigator’s brochure is unavailable) for each drug listed above.

**VA Form 10-9012, Investigational Drug Information Record,** for each drug listed in the table above. The form(s) must be reviewed by the Research Pharmacy prior to IRB approval and should be forwarded, prior to IRB submission, to the Research Pharmacy at: [VHAPOR-ResearchPharmacy@va.gov](mailto:VHAPOR-ResearchPharmacy@va.gov). The final version(s) (after Research Pharmacy review) should be submitted to the IRB with this application.

IND letter from FDA, FDA correspondence, FDA Forms 1571 and 1572 (if applicable)

Keep a copy of this completed form for your records.