**VA Boston Healthcare System**

**Pharmacy Impact Form**

# Principal Investigator:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project Name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Project Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Anticipated start date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Expected overall study duration:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. How many research subjects do you plan on enrolling?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Study location (choose all that apply): Brockton Jamaica Plain West Roxbury
3. Study Drug Storage Temperature(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Is an IND (Investigational New Drug) Application required ? **YES NO**

If **YES** to question 4**,** provide the following information and attach a copy of the IND certificate.

* + Name of the person/firm holding the IND: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  + IND number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
  + Date granted:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Identification of Study Design:

# 

|  |  |
| --- | --- |
| Study Design | Phase of Investigation |
| Single-Blind  Double-Blind Placebo Control  Open Trial Cross-Over  Other :\_\_\_\_\_\_\_\_ Expanded Access:IndividualEmergency-UseNon-emergency UseIntermediate-size patient groupWidespread treatment use in larger populations | Phase I Phase II Phase III Phase IV Investigator Initiated Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. Will an investigational drug(s) be used? **YES NO**
2. If **YES** to question 4, will an investigational (unapproved) new drug be used? **YES NO**
3. Will an approved drug be used for an indication that has not received an

FDA post-marketing approval? **YES NO**

1. Will an approved drug for an indication be used as a comparator drug? **YES NO**

If **YES** to question 6, 6a, 6b, or 6c, name the drug(s) and their use(s) in the table below :

|  |  |
| --- | --- |
| **DRUG NAME, STRENGTH, DOSAGE FORM** | **USE** |
|  |  |
|  |  |
|  |  |
|  |  |

1. Will **non-study drug(s)** be used? **YES NO**
2. If **YES** to question 6, will an FDA approved drug be as

part of standard of care? **YES NO**

1. If **YES** to question 6a, will the study sponsor supply the FDA

approved drug(s)? **YES NO**

If **YES** to question 6, 6a, or 6b, list the drug(s) and their use(s) in the table below:

|  |  |  |
| --- | --- | --- |
| **DRUG NAME, STRENGTH, DOSAGE FORM** | **USE** | **SUPPLIER (Sponsor or VABHS Pharmacy)** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Note:** VA Form 10-9012 “Investigational Drug Information Record” and FDA Form 1572 “ Statement of Investigator” should be completed for investigational drug studies. Forms 1571 “Investigational New Drug Application” and FDA Form 1572 should be completed for Expanded Access Intermediate Size Populations and Treatment INDs. FDA Form 3926 ”Individual Patient Expanded Access Investigational New Drug Application (IND)” is developed specifically for single patient Expanded Access.

**Principal Investigator Signature: Date:\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Chief of Pharmacy/Designee Signature: Date:\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Approve Disapprove**

**Estimated Pharmacy Impact:**

|  |  |  |
| --- | --- | --- |
| **Investigational Drug Service Fee Structure** | | |
| **Study Initiation and Closeout Fee** | * Meeting/communicating with study personnel (both in-house and sponsor) * IDS Protocol Binder Setup * Preparation of pharmacy-specific protocol guidelines * Arranging for shipment of study drug, return of study drug, and destruction of study drug (if required) * Creation of drug file in CPRS * Final accountability logs * Document archiving * Final disposition of study materials | $1500 |
| **Maintenance and Storage Fee** | * Maintaining inventory and storage areas * Ordering necessary supplies, and disposal of expired or unused supplies * Meeting with study monitors/auditors * Updating procedures and regulatory documents as protocol is amended | $200 per quarter (every 3 months) |
| **Dispensing Fees – These fees vary and depend on type of dispensing** | | |
| Level 1 | Oral medications (~30 min) | $50 per dose |
| Level 2 | IV Medications (~60 minutes) | $100 per dose |
| Level 3 | More complex dispensing that requires more than 60 minutes to dispense | Fee to be determined on a case-by-case basis |

Please submit form to Research Pharmacist Jane Hughes (Tel: 857-364-4312) at [**Jane.Hughes2@va.gov**](mailto:Jane.Hughes2@va.gov) **.**