|  |
| --- |
| **Principal Investigator:**  **Lexington VA Study# (*office use only*):**  **Project #** [From Sponsor]**:**  **Project Title**[175 characters w/ spaces maximum]**:** |

1. **Study Personnel Information**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Investigator** | **Name/Degree** | **Service** | **Phone** | **Is a scope of practice needed?\*** | **Verification of completed training requirements** | **Appointment Type**  [If VA, provide 8ths (i.e. 8/8 = FT, 4/8 = PT)] |
| **Principal** |  |  |  | **Yes**  **No** | **Completed** |  |
| **Alternate** |  |  |  | **Yes** **No** | **Completed** |  |
| **Co-PI**  **[VA Only]** |  |  |  | **Yes**  **No** | **Completed** |  |
| **Co-I #1** |  |  |  | **Yes**  **No** | **Completed** |  |
| **Co-I #2** |  |  |  | **Yes**  **No** | **Completed** |  |
| **Coordinator** |  |  |  | **Yes**  **No** | **Completed** |  |
| **Technician(s)** |  |  |  | **Yes** **No** | **Completed** |  |
| **Others** |  |  |  | **Yes**  **No** | **Completed** |  |

**\* *All study staff must have*** [***Scope of Practice Human***](http://www.lexington.va.gov/healthprofessionals/research/docs/Scope_of_Practice.docx) ***or*** [***Scope of Practice Lab/Animal***](http://www.lexington.va.gov/healthprofessionals/research/docs/Scope_of_Practice-Animal_Lab.docx) ***Lexington VAMC [Mark No if it is confirmed that a scope of practice is already on file in the R&D office and covers all procedures done in this protocol]***

1. **Funding Source and Funding Administration Codes**[Codes are on a separate sheet]

|  |  |  |  |
| --- | --- | --- | --- |
| **Source Code**[4 digits]**:** | **Name:** | **Admin. Code**[2 digits]**:** | **Completed**  **CRADA**  **In Progress**  **NA** |

1. **Project Uses** [Mark each item and submit pertinent forms]**:**

|  |  |  |
| --- | --- | --- |
| **Human Subjects\***  **Yes**  **No** | **Investigational Drugs**  **Yes**  **No** | **Investigational Devices**  **Yes**  **No** |
| **Biohazards**  **Yes**  **No** | **Recombinant DNA**  **Yes**  **No** | **Animal Subjects#**  **Yes**  **No** |
| **Hazardous materials**  **Yes**  **No**  **(e.g., chemicals, toxins)** |  | **Radioisotopes**  **Yes**  **No** |

**\* Please complete** [**Application to Conduct Human Research**](http://www.lexington.va.gov/healthprofessionals/research/docs/Application_for_Human_Research_Form.doc) **form and other necessary forms**

**# Please complete** [**Animal Research (ACORP)**](http://www.lexington.va.gov/healthprofessionals/research/animalstudy.asp) **forms**

**NOTE: All studies need to complete** [**Research Protocol Safety Survey**](http://www.lexington.va.gov/healthprofessionals/research/safety.asp) **form**

**Will any study personnel handle biohazardous samples (i.e. packaging, shipping, spinning etc.)?** **Yes**  **No**

**International Research: Does this study involve international research as defined in VHA 1200.05** ?  **Yes**  **No**

1. **Protocol and Abstract (Please attach a copy of Project Abstract)**

**The Abstract should be organized under the following headings a) Relevance to VA Mission, Veterans’ health and/or healthcare issues b) Objective of the project, c) research plan, d) methodology, e) findings, results or conclusions reached to date.**

1. **Keywords** [3 [MeSH terms](http://www.ncbi.nlm.nih.gov/mesh) needed]**:**

1.)

2.)

3.)

1. **VA Institutional Resources & Support** [If yes, signature of corresponding VA Service Chief is required on #8 of this form]**:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Medicine**   **Yes** **No** | **Psychiatry**  **Yes** **No** | **Surgery**   **Yes**  **No** | **Nursing**   **Yes**  **No** |
| **Pharmacy**   **Yes** **No** | **Laboratory**   **Yes**  **No** | **Radiology**   **Yes**  **No** | **Nuclear Medicine**  **Yes** **No** |
| **Outpatient Services**  **Yes** **No** | **IRM**   **Yes** **No** |  |  |

1. **Other Institutions(s) Involved** [If yes, include names]**:**  **Yes**  **No**

Name(s):

1. **SIGNATURES:** The principal investigator and all research personnel listed below must sign this document to certify that they understand the Lexington VA Medical Center Research & Development policies/regulations and accept responsibilities pertinent to the conduct of the project, i.e., scientific quality, protection of human and/or animals in research, and compliance with applicable federal and state laws.

|  |  |  |
| --- | --- | --- |
| **Investigator** | **Printed Name:** | **Signature:** |
| **Principal** |  |  |
| **Alternate** |  |  |
| **Co-PI [VA Only]** |  |  |
| **Co-Investigator** |  |  |
| **Co-Investigator** |  |  |

1. **VA INSTITUTIONAL RESOURCES & SUPPORT:** I have discussed this project with the Principal Investigator and reviewed the proposed resources required of my Section/Service to conduct this project.  I approve the support, requirements, and the investigator's (PI, Co-PI, Sub-investigators within my Section/Service) time commitments\*, as they relate to my Section/Service.  I certify that the investigator(s) (PI, Co-PI, Sub-investigators within my Section/Service) have the appropriate credentialing and privileges to conduct this research [If disapproved, the reason(s) for disapproval must be submitted in writing].

**\*For Clinical Investigators Only**

Requesting Protected Research time for Research Related Activities

Yes If yes fill out [Medical Center Memorandum 11-21](http://vaww.lexington.va.gov/viewpublicfile.aspx?did=hL/ihnXu/Tk=) (link only available on VA intranet)

No

|  |  |  |
| --- | --- | --- |
| **Service:** | **Printed Name:** | **Signature:** |
|  |  |  |
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1. **CHIEF OF STAFF :** I am aware of the existence of this research activity and agree with the statements made above.



