

R&D Committee Annual Review Form

Research and Development Committee – Louis Stokes DVA Medical Center

Form Directions: This form is protected (limited access to fill-in fields). Use the tab key or mouse to navigate the fill-in fields. Formatting is limited to text only (no bulleted lists, numbering, etc). In the event that you are unable to navigate through this document or would like to format it or add additional information, you may disable the protected feature by selecting “Tools” and “Unprotect Document.” Do not delete or modify items.

NOTE: THIS FORM MUST BE ACCOMPANIED BY EITHER AN INVESTIGATOR’S CHECKLIST FOR SRS ANNUAL REVIEW OF PROTOCOLS ORIGINALLY APPROVED BY EXPEDITED REVIEW or an INVESTIGATOR’S CHECKLIST FOR SRS ANNUAL REVIEW OF PROTOCOLS INVOLVING HAZARDOUS MATERIALS (both of which may be found [here](#)). Scanned versions of the Checklists for SRS Annual Review of Protocols with a PI’s signature are acceptable. Please email completed forms to: lscdvamcanrev@va.gov.

1. Principal Investigator Name: Investigator
2. Project Title: Title
3. Please list any changes to the Project Data Sheet here **(if there are no changes please enter N/A):** N/A
4. Is this a final report for this project?
 Yes **(If “Yes,” go to Item 4A)**
 No **(If “No,” go to Item 4B)**

(If “Yes,” to Item 4) 4A. Discuss the anticipated contributions of the proposed study in terms of products or outcomes; i.e., how the study results may be used in the VA healthcare system in a new abstract (less than 1 page). You may summarize progress since the last report by editing the abstract - do NOT return an unchanged abstract. **DO NOT INCLUDE TABLES, JUSTIFY THE MARGINS, UNDERLINE, OR USE SUBSCRIPTS, SUPERSSCRIPTS, OR SYMBOLS** in the abstract or submit copies of articles. As this is the FINAL report, summarize the results of your study and state in the Abstract that this is the Final Abstract. :

(If “No,” to Item 4) 4B. Please describe the progress made on this project in the past year **(There is a 200 word limit for responses. DO NOT INCLUDE TABLES, DO NOT UNDERLINE, USE SUBSCRIPTS, SUPERSSCRIPTS, OR SYMBOLS. DO NOT submit copies of articles.)**:
We have made the following progress on this project...

5. Has this project resulted in any journal articles that have been published or accepted for publication?
 Yes **(If “Yes,” go to Item 5A)**
 No **(If “No,” go to Item 6)**

(If “Yes,” to Item 5) 5A. List these publications:
Author. (year). Article Title. Journal Title. 0(0); 0 - 99999.

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6. Has this project resulted in any conference papers that have been presented or accepted?

- Yes (If “Yes,” go to Item 6A)
 No (If “No,” go to Item 7)

(If “Yes,” to Item 6) 6A. List these conference papers:
Author (year) Title. Conference.

7. Describe any impediments to the progress of this project and your recommended solutions: **(Note that any impediments to the progress of your project will be kept confidential.)**

8. Does this project involve the collection of any of the following information as it relates to individual, human, research participants?

	Yes	No
A. Names or initials	<input checked="" type="checkbox"/>	<input type="checkbox"/>
B. Geographic subdivisions smaller than a state	<input type="checkbox"/>	<input checked="" type="checkbox"/>
C. Any elements of dates except the year and all ages over 85	<input checked="" type="checkbox"/>	<input type="checkbox"/>
D. Telephone numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
E. Fax numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
F. E-mail addresses	<input type="checkbox"/>	<input checked="" type="checkbox"/>
G. Social Security Numbers (fragments or scrambled)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
H. Medical record numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
I. Health plan beneficiary numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
J. Account numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
K. Any certificate or license numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
L. Vehicle identifiers and license plate numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
M. Device identifiers and serial numbers	<input type="checkbox"/>	<input checked="" type="checkbox"/>
N. Websites	<input type="checkbox"/>	<input checked="" type="checkbox"/>
O. IP addresses	<input type="checkbox"/>	<input checked="" type="checkbox"/>
P. Biometric identifiers, including finger and voice prints	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Q. Full-face photographs and any comparable images	<input type="checkbox"/>	<input checked="" type="checkbox"/>
R. Any other unique identifying number, characteristic or code	<input type="checkbox"/>	<input checked="" type="checkbox"/>

(If “Yes” to Item 8R), describe these identifiers:

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If the answer to *any* of the information types listed in Items 8A through 8R is, “Yes” go to Item 9.

If the answer to *all* of the information types listed in Items 8A through 8R are, “No” this portion of the R&D Committee Annual Review is complete.

- | | Yes | No |
|---|-------------------------------------|-------------------------------------|
| 9. Are all hardcopies of the information described in Item 8 used and stored within the LSCDVAMC? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |
| 10. Are all electronic copies of the information described in Item 8 used and stored within the LSCDVAMC? | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 11. Are all of the electronic versions of the information described in Item 8 on network accessible media behind the VA Firewall? | <input checked="" type="checkbox"/> | <input type="checkbox"/> |

If the answer to *all* of the Items 9, 10, and 11 is, “Yes” this portion of the R&D Committee Annual review is complete.

If the answer to *any* of the Items 9, 10, and 11 is, “No”:

- Contact the LSCDVAMC Larry Campbell Information Security Officer (ISO – phone: 440 526-3030 x6625, email: larry.campbell@va.gov) to discuss your data storage and security plans
 - A “Memo to Remove Sensitive Research Information” signed by your Service Line Chief, LSCDVAMC Information Security Officer, Associate Chief of Staff for Research (Neal Peachey – phone: 216 791-3800 x4641, email neal.peachey@va.gov), and Medical Center Director available through the Research Office. You can find a blank copy of the, “Memo to Remove Sensitive Research Information” [here](#)
 - Respond to the following items:
12. Is the delivery or transmission and use of the information described in Item 8 of this document discussed in this study’s consent form(s)?
- Yes
- No (Please provide a justification for why the offsite delivery or transmission and use of this information is not described in this study’s consent form)

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13. Indicate the method of delivery or transmission that is being or will be used to send the information described in Item 8:

- Secured web site
- Encrypted email
- US Postal Service or other trackable courier services (not campus mail)
- Fax in a secured area
- Shared drive with password protection
- Personal delivery by authorized research personnel
- Private telephone conversation to authorized personnel
- Other: **(Describe)**

14. Access and Security

a. Who or what organizations have access to the information described in Item 8 once it has been transported or transmitted offsite?

Name, Degrees / Organization and Organizational Contact Name, Degrees (Use the <u>Enter</u> key in this column to insert additional names and information)	Phone Number	E-mail Address
John Smith, M.D., Ph.D. / Organization	(123) 555-4567	johnsmith@email.em ail

b. Please describe the measures you are taking to safeguard the information/information described in Item 8:

- Two locking barriers (cabinets, desks, doors, etc.)
- Computers and/or files will be password-protected
- Information will be kept in electronic format behind a firewall
- PDAs and removable media (such as CDs, diskettes, etc.) will kept in a secure location and be encrypted
- Other: **(Describe)**

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16. Information Retention and Destruction

- a. How long will the information described in Item 8 be stored / used outside of the LSCDVAMC?

10 years

- b. After the period in Item 8 has expired, what will the disposition of the sensitive information be **(A copy of all human subjects research records are to be retained within the LSCDVAMC indefinitely until Record Control Schedule 10-1 is modified to reflect facility retention/disposal authority. Subsequent to approval all human subject research records will be retained for at least five (5) years after the completion of the research with which they are associated or as otherwise stipulated by any sponsors. According to the HIPAA Privacy Rule, accounting for disclosures of protected health information is required for disclosures that occurred for six (6) years following the date of the request for the accounting. Therefore, the LSCDVAMC requires that all human subjects' research records be retained for at least six (6) years. Sponsors may have additional requirements.)**:

Returned to the LSCDVAMC

Destroyed **(Describe Method of Destruction if Applicable)**

Method of destruction:

Paper will be shredded

Delete files from or destroy diskettes and CDs

Permanent deletion of information described in Item 8 from computers and PDAs

Other: **(Describe)**