**GENERAL INFORMATION**

1. Research project title:
2. Type of submission: ***(Check one)*** Date of submission:

|  |  |  |
| --- | --- | --- |
| [ ]  | New research project |  |
| [ ]  | Re-submission of a previously rejected research project | If you checked Re-submission or Reopening, provide the previous HRRC application number:       |
| [ ]  | Re-opening of an expired research project |

***(Check one)***

|  |  |  |
| --- | --- | --- |
| [ ]  | Full Committee Review  |  |
| [ ]  | Expedited Review | If you checked Expedited or Exempt, complete and submit appropriate supplemental form to identify applicable category for an Expedited or Exempt review. [ ]  |
| [ ]  | Exempt |

1. Principal Investigator, Project Coordinator and Co-Investigator(s):

|  |  |  |
| --- | --- | --- |
| **Principal Investigator** |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

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| --- | --- | --- | --- |
| **Co-Investigator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

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| Note: Additional space is provided at the end of this application to identify all other Co-Investigators. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Project Coordinator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

Source(s) of funding support:

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name of funding source | Project ID # | Funding period(from month/year to month/year)  |
| Federal |       |       | FROM:       TO:       |
| Federal |       |       | FROM:       TO:       |
| State |       |       | FROM:       TO:       |
| State |       |       | FROM:       TO:       |
| Private |       |       | FROM:       TO:       |
| Private |       |       | FROM:       TO:       |

**DESCRIPTION OF THE RESEARCH PROJECT**

1. Brief description of the research:

Write an original, brief, non-technical description of the research project. ***Include in your description:***

|  |  |
| --- | --- |
| a) | Your research hypothesis(ses) and/or question(s) |
|  |       |
| b) | Purpose of the research project  |
|  |       |
| c) | The methodology |
|  |       |
| d) | From where/whom the data will be collected |
|  |       |
| e) | How the information collected from this research project will advance your research hypothesis(ses) and/or question(s) |
|  |       |

1. What specific role(s) will DARS and/or WWRC play is this research project?
2. What will the subjects do in the research project? ***Describe all steps that the subjects will follow.***
3. What instruments, surveys, interview questions or outlines, observation checklists, etc. will be used in this research project?

Note: A copy of all instruments, surveys, etc. must be included with this application. [ ]

1. If this research project uses existing data, please fully describe the data source(s) and contents of the data file(s)
2. Location(s) where research project will be conducted. ***Please be specific.***
3. Anticipated start and completion dates for collecting and analyzing data:

|  |  |  |
| --- | --- | --- |
|  | Start date (mm/dd/yr) | End date (mm/dd/yr) |
| Collecting data |       |       |
| Data analyses |       |       |

|  |  |
| --- | --- |
| 1. Describe what will be done with the data and resulting analysis.
 | 12a. Who will have access to this information?       |

1. What benefits can reasonably be expected from the research project? *(Benefits may be either to the subjects or to the knowledge base of the area.)*

**RECRUITMENT AND SELECTION OF SUBJECTS**

1. Subjects: *(If working with different groups, please list for each category.)*

|  |  |  |
| --- | --- | --- |
| Group A, please describe       | Group B, please describe       | Group C, please describe       |
| Annual number of subjects to be recruited |       | Annual number of subjects to be recruited |       | Annual number of subjects to be recruited |       |
| Sample size for archival data set |       | Sample size for archival data set |       | Sample size for archival data set |       |
| Ages |       | Ages |       | Ages |       |
| Gender |       | Gender |       | Gender |       |
| Race/Hispanic origin/ethnic background |       | Race/Hispanic origin/ethnic background |       | Race/Hispanic origin/ethnic background |       |

|  |  |  |
| --- | --- | --- |
|  | a) | What criteria will you use to select subjects? |
|  |  |       |
|  | b) | How will the subjects be contacted? |
|  |  |       |
|  | c) | State the relationship between Principal Investigator and/or Co-Investigator(s)and Subjects. |
|  |  |       |

1. Describe in detail how you will obtain consent and/or assent from subjects or parents. Please include all groups as listed in item 12 above.

Note: A copy of all Informed Consent/Assent Agreement(s) must be included with this application. [ ]

 Is a Waiver of Consent being requested?

1. How will you protect the confidentiality of subjects? ***(Check one)***

|  |  |  |
| --- | --- | --- |
| [ ]  | Data are archival (already collected) ***AND*** researcher will receive data stripped of identifying information. Identifying information includes name, postal address, telephone numbers, E-mail address, social security number, DARS case number, etc. | ***If an archival data set is being used***, please attach a list of all data elements that will be included in the data set OR provide the original instrument from which the data were obtained. |
| [ ]  | Data to be collected do not contain identifying information, or cannot be linked to identifying information by use of codes or by other means (data are anonymous). |
| [ ]  | Data to be collected contain identifying information or can be linked to identifying information by use of codes or by other means (data are confidential or confidentiality is not assured in the research project) ***AND*** the list linking codes to personal identifiers will be kept secure. |
| [ ]  | Other (please describe): |       |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Will ***pictures*** of subjects be taken or Will subjects be recorded on ***audio recording*** or ***video recording***? | [ ]  | No | [ ]  | Yes | ***If yes***, the Consent/Assent Form(s) must explain how these images and/or recordings will be used and what will be done with the images and/or recordings at the conclusion of the research project. [ ]    |

1. What are the possible physical, psychological, professional or personal risks and/or hazards for the subjects?
2. What will you do to protect subjects from these risks or hazards?
3. Research project background/literature review: Describe any previous studies related to your research project, including any adverse events.
4. Does the research project involve use of an investigational new device? If so, please describe.
5. Will subjects receive payment of any kind?
6. Will any drugs be used in this research project?
7. State the point at which the research project will be terminated if there are any hazards.
8. Qualifications of Investigators (Please add Co-investigators as needed):

|  |  |
| --- | --- |
| 1. Principal Investigator
 |       |
| 1. Co-Investigator
 |       |
| 1. Co-Investigator
 |       |
| 1. Co-Investigator
 |       |
| 1. Project Coordinator
 |       |

*Add additional research project personnel as applicable.*

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| **Co-Investigator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

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| --- | --- | --- | --- |
| **Co-Investigator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

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| --- | --- | --- | --- |
| **Co-Investigator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

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| --- | --- | --- | --- |
| **Co-Investigator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

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| --- | --- | --- | --- |
| **Co-Investigator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

|  |  |  |  |
| --- | --- | --- | --- |
| **Co-Investigator** |  |  |  |
| Name: |       | Title: |       |
| Organization: |       | Department: |       |
| Mailing address: |       |  |  |
| Telephone: |       | E-mail : |       |
| Completed Training in Human Subjects Protection*?* *(If yes, please attach a copy of the Certificate of Training.)* | [ ]  | No | [ ]  | Yes | Date of Training       |

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| **PRINCIPAL INVESTIGATOR STATEMENT OF COMPLIANCE:** |
| I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including sub/co-investigators, project coordinators, and myself have completed required training on human subjects protection. I agree to a continuing exchange of information with the DARS HRRC including the requirements to (i) obtain HRRC approval before making non-emergency changes/revisions to the project, (ii) provide progress reports to the DARS HRRC at their request (and at least annually), and (iii) report promptly to the DARS HRRC all unanticipated problems or serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the DARS HRRC). |
| **Signature of Investigator:** |  | **Date of Signature:** |       |

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| **Co-INVESTIGATOR STATEMENT OF COMPLIANCE:** |
| I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including sub/co-investigators, project coordinators, and myself have completed required training on human subjects protection. I agree to a continuing exchange of information with the DARS HRRC including the requirements to (i) obtain HRRC approval before making non-emergency changes/revisions to the project, (ii) provide progress reports to the DARS HRRC at their request (and at least annually), and (iii) report promptly to the DARS HRRC all unanticipated problems or serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the DARS HRRC). |
| **Signature of****Co-Investigator:** |  | **Date of Signature:** |       |

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| --- |
| **CO-INVESTIGATOR STATEMENT OF COMPLIANCE:** |
| I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including sub/co-investigators, project coordinators, and myself have completed required training on human subjects protection. I agree to a continuing exchange of information with the DARS HRRC including the requirements to (i) obtain HRRC approval before making non-emergency changes/revisions to the project, (ii) provide progress reports to the DARS HRRC at their request (and at least annually), and (iii) report promptly to the DARS HRRC all unanticipated problems or serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the DARS HRRC). |
| **Signature of****Co-Investigator:** |  | **Date of Signature:** |       |

|  |
| --- |
| **CO-INVESTIGATOR STATEMENT OF COMPLIANCE:** |
| I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including sub/co-investigators, project coordinators, and myself have completed required training on human subjects protection. I agree to a continuing exchange of information with the DARS HRRC including the requirements to (i) obtain HRRC approval before making non-emergency changes/revisions to the project, (ii) provide progress reports to the DARS HRRC at their request (and at least annually), and (iii) report promptly to the DARS HRRC all unanticipated problems or serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the DARS HRRC). |
| **Signature of****Co-Investigator:** |  | **Date of Signature:** |       |

|  |
| --- |
| **CO-INVESTIGATOR STATEMENT OF COMPLIANCE:** |
| I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including sub/co-investigators, project coordinators, and myself have completed required training on human subjects protection. I agree to a continuing exchange of information with the DARS HRRC including the requirements to (i) obtain HRRC approval before making non-emergency changes/revisions to the project, (ii) provide progress reports to the DARS HRRC at their request (and at least annually), and (iii) report promptly to the DARS HRRC all unanticipated problems or serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the DARS HRRC). |
| **Signature of****Co-Investigator:** |  | **Date of Signature:** |       |

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| **CO-INVESTIGATOR STATEMENT OF COMPLIANCE:** |
| I understand and accept responsibility for ensuring the safety and welfare of all human subjects who participate in the proposed research project. I certify that all key project personnel, including sub/co-investigators, project coordinators, and myself have completed required training on human subjects protection. I agree to a continuing exchange of information with the DARS HRRC including the requirements to (i) obtain HRRC approval before making non-emergency changes/revisions to the project, (ii) provide progress reports to the DARS HRRC at their request (and at least annually), and (iii) report promptly to the DARS HRRC all unanticipated problems or serious adverse events involving risk to human subjects (in accordance with required reporting timelines by the DARS HRRC). |
| **Signature of****Co-Investigator:** |  | **Date of Signature:** |       |

***The Signature of each Investigator’s Supervisor MUST be included with this application.***

|  |
| --- |
| **Principal Investigator’s Supervisor Statement of COMPLIANCE** |
|  |
| I certify that I have reviewed the research project referenced in this document. I believe that it is well designed and likely to yield new knowledge that will be useful to society. |
|  |
| **print name** |       |
| **degrees, title** |       |
| **Department and Organization:** |       |
| **Signature of Investigator’s Supervisor:** |  | **Date of Signature:**  |

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| --- |
| **Co- Investigator’s Supervisor Statement of COMPLIANCE** |
|  |
| I certify that I have reviewed the research project referenced in this document. I believe that it is well designed and likely to yield new knowledge that will be useful to society. |
|  |
| **print name** |       |
| **degrees, title** |       |
| **Department and Organization:** |       |
| **Signature of Investigator’s Supervisor:** |  | **Date of Signature:** |

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| **Co - Investigator’s Supervisor Statement of COMPLIANCE** |
|  |
| I certify that I have reviewed the research project referenced in this document. I believe that it is well designed and likely to yield new knowledge that will be useful to society. |
|  |
| **print name** |       |
| **degrees, title** |       |
| **Department and Organization:** |       |
| **Signature of Investigator’s Supervisor:** |  | **Date of Signature:** |

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| **Co- Investigator’s Supervisor Statement of COMPLIANCE** |
|  |
| I certify that I have reviewed the research project referenced in this document. I believe that it is well designed and likely to yield new knowledge that will be useful to society. |
|  |
| **print name** |       |
| **degrees, title** |       |
| **Department and Organization:** |       |
| **Signature of Investigator’s Supervisor:** |  | **Date of Signature:** |

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| **Co -Investigator’s Supervisor Statement of COMPLIANCE** |
|  |
| I certify that I have reviewed the research project referenced in this document. I believe that it is well designed and likely to yield new knowledge that will be useful to society. |
|  |
| **print name** |       |
| **degrees, title** |       |
| **Department and Organization:** |       |
| **Signature of Investigator’s Supervisor:** |  | **Date of Signature:** |

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| --- |
| **Investigator’s Supervisor Statement of COMPLIANCE** |
|  |
| I certify that I have reviewed the research project referenced in this document. I believe that it is well designed and likely to yield new knowledge that will be useful to society. |
|  |
| **print name** |       |
| **degrees, title** |       |
| **Department and Organization:** |       |
| **Signature of Investigator’s Supervisor:** |  | **Date of Signature:** |

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| --- |
| **Investigator’s Supervisor Statement of COMPLIANCE** |
|  |
| I certify that I have reviewed the research project referenced in this document. I believe that it is well designed and likely to yield new knowledge that will be useful to society. |
|  |
| **print name** |       |
| **degrees, title** |       |
| **Department and Organization:** |       |
| **Signature of Investigator’s Supervisor:** |  | **Date of Signature:** |

**Application Checklist:**

|  |  |  |
| --- | --- | --- |
| Attached |  | N/A |
| [ ]  | DARS HRRC Application Form A | [ ]  |
| [ ]  | Research Project Approval Letter from another IRB to include the full application as submitted to the approving IRB *(if applicable)* | [ ]  |
| [ ]  | Supplement 1: Principal Investigator’s Request for Exempt Review ***(Submit ONLY if your research project may qualify for exempt status.)*** | [ ]  |
| [ ]  | Supplement 2: Principal Investigator’s Request for Expedited Review ***(Submit ONLY if your research project may qualify for expedited status.)*** | [ ]  |
| [ ]  | Consent form(s) *(if applicable)* | [ ]  |
| [ ]  | Assent form(s) *(if applicable)* | [ ]  |
| [ ]  | All recruitment materials *(if applicable)* | [ ]  |
| [ ]  | Photograph, video and audio recording permission form *(if applicable)* | [ ]  |
| [ ]  | One (1) copy of the complete grant/research project as submitted to funding source *(if applicable)* | [ ]  |
| [ ]  | A Letter of Agreement to participate in the research project from any DARS division(s) that will be involved in the research *(if applicable)* | [ ]  |
| [ ]  | One (1) copy of each survey, interview questions, tests and/or other tools/instruments used for the research project | [ ]  |
| [ ]  | Investigator(s) Certificate(s) of Training in Human Research Protections ( If training completed) | [ ]  |
| [ ]  | Investigator’s Supervisor Statement of Compliance | [ ]  |
| [ ]  | If an archival data set is being used, a list of all fields that will be included in the data set OR the original instrument from which the data were obtained | [ ]  |
| [ ]  | Conflict of Interest Disclosure Statement *(and Supplement if applicable)* | [ ]  |
| [ ]  | Other materials specific to the proposed research project (e.g., documentation related to cooperative research projects, individual investigator agreement(s), etc. *(if applicable)* | [ ]  |

Electronic copies of the completed signed application and all supporting documents are required via email or some other electronic format, such as CD, to be sent to:

**Human Research Review Committee**

 **Policy and Legislative Services Division**

**Department for Aging and Rehabilitative Services**

**8004 Franklin Farms Drive**

**Richmond, VA 23229**

If you have questions about the protection of human subjects, please contact:

Catherine Harrison, Chair of the HRRC or DiVette M. Brisco, HRRC Administrator

(804) 662-9968 (804) 840-0250

Catherine.Harrison@DARS.virginia.gov Divette.Brisco@DARS.virginia.gov