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| Title of Research Project: |
| Click here to enter text. |

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| IRB Submission Number (Obtain from the VDSS IRB): | Submission Date |
| Click here to enter text. | Click or tap to enter a date. |

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| Principal Investigator (PI) Information: Please provide information about the person legally responsible for the conduct of the research. | |
| PI Name: Click here to enter text. | |
| PI University/Organization: Click here to enter text. | |
| PI Mailing Address: (Street, City, State, Zip)  Click here to enter text. | |
| PI Telephone Number (incl. area code):  Click here to enter text. | PI E-mail:  Click here to enter text. |

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| Other Contact Information: Please provide information about the Co-PI or Study Coordinator | |
| Role:  Co-PI  Study Coordinator Other: (specify) Click or tap here to enter text. | |
| Other Contact Name: Click here to enter text. | |
| Other Contact University/Organization: Click here to enter text. | |
| Other Contact mailing address: (Street, City, State, Zip)  Click here to enter text. | |
| Other Contact Telephone Number (incl. area code):  Click here to enter text. | Other Contact E-mail:  Click here to enter text. |

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| Funding Source: |
| Federal. If federal, which agency? Click here to enter text. |
| State. If state, which agency? Click here to enter text. |
| Other: (specify) Click here to enter text. |

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| Study Sponsor: |
| Click here to enter text. |

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| Who completed this form? | | | |
| PI  Co-PI | Project Coordinator | Other (specify below) | |
| Name of Person Completing this form (if “Other” is checked): Click here to enter text.  University/Organization: Click here to enter text.  E-mail: Click here to enter text.  Phone number: Click here to enter text. | | | |
| Description of Research Project (300 words or less) | | | |
| Click here to enter text. | | | |

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| Section Is an activity Human Subjects Research covered under 45 CFR Part 46? (CHART 01) | | | |
| 1. | Is the activity a **systematic investigation** **designed** to develop or contribute to **generalizable knowledge**? | Yes↓ | No |
| 2. | 1. Does the activity fit any of the criteria below for excluded research at [45 CFR 46.102(l)(1)-(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.102)?  * Scholarly and journalistic activities * Public health surveillance activities * Collection and analysis of information, bio-specimens, or records by or for a criminal justice agency or for criminal justice/investigative purposes * Authorized operational activities in support of intelligence, homeland security, defense, or other national security purposes   If “Yes” ⮊ Activity is NOT research and does not require an IRB review. | Yes | No↓ |
| 3. | Does the research involve a living individual about whom an investigator conducting research: (check all that apply)  Obtains information or bio-specimens through intervention or interaction with the individual and uses, studies, or analyzes the information or bio-specimens?  Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable bio-specimens? | Yes\* | No |
| \* If Q.3 = Yes ⮊ Activity is considered human subjects research. Answer Q. 4 and then go to Chart 02 to determine if the research is eligible for exemption.  If Q.3 = No ⮊ The study is NOT considered human subjects research and does not require IRB review. | | | |
| 4. | Is the research involving human subjects conducted or supported by the U.S. Department of Health and Human Services (USDHHS)?  *Even if human subjects research is not conducted or supported by HHS, the VDSS IRB still requires that the investigator follow regulatory procedures under 45 CFR Part 46.* | Yes | No |

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| Is the research involving Human Subjects eligible for exemption under 45 CFR 46.104(d)?  (CHART 02) | | | |
| 5. | Has HHS prohibited exemption of the human subjects research? (Most research involving prisoners, some research involving children.) | Yes | No\* |
| 6. | Will the only involvement of human subjects be in one or more of the following categories? Check any that apply.  Research conducted in **established or commonly accepted educational settings**, involving normal education practices (**Chart 03**)  Research only including interactions involving **educational tests**, **survey procedures**, **interview procedures**, or **observation of public behavior** (**Chart 04**)  Research involving **benign behavioral interventions** and collection of information from adults with their agreement (**Chart 05**)  **Secondary research** use of identifiable private information or identifiable biospecimens (**Charts 06 & 10**)  Research studying, evaluating, or examining **public benefit or service programs** (**Chart 07**)  Research involving **taste and food quality evaluation** or **consumer acceptance** studies (**Chart 08**)  **Storage or maintenance** of **identifiable private information** or identifiable biospecimens for secondary research use (**Chart 09**) | Yes\* | No |
| \* If Q.5 =No and Q.6 = Yes ⮊ The research may be eligible for an exemption under [45 CFR 46.104(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104).  If Q.5=Yes ⮊ The research is NOT eligible for exemption and requires an IRB review. Complete the *Request for Initial Review Form* (available on the [VDSS IRB web page](https://www.dss.virginia.gov/about/irb.cgi)). | | | |

The research may be eligible for exemption from VDSS IRB review under federal regulations [45 CFR 46.104(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104). However, the research must be declared exempt by the VDSS IRB (not the PI) based on responses on this IRB submission form.

For the activities listed above that apply, go to the specified category tables starting on the next page. Indicate if the statements are true (Yes) or not (No). For categories that do not apply, check “NA” (Not Applicable). You may use the [Decision Charts (2018 Requirements)](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c2) on the Office for Human Research Protections (OHRP) web site as a guide.

*If the research involves subjects from certain populations, regulations under subparts* [*B*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html) *(pregnant women),* [*C*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-c/index.html) *(prisoners), or* [*D*](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html) *(children) may apply.*

Research may involve activities exempt under more than one category. For research with multiple types of activities, if there are both exempt and nonexempt activities, the entire project is NOT exempt and must undergo an IRB review.

**Exempt Research Categories**

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| CATEGORY 1 (45 CFR 46.104(d)(1)): For Educational Settings (refer to Chart 03) | | N/A |
| 1. The research will only be conducted in established or commonly accepted educational settings (e.g., schools, colleges). | Yes | No |
| 1. The research will involve only normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. *This includes most research on regular and special education instructional strategies, instructional techniques, curricula, or classroom management methods.* | Yes | No |

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| CATEGORY 2 (45 CFR 46.104(d)(2)): For Educational Tests, Surveys, Interviews or Observation of Public Behavior (refer to Chart 04) | | N/A |
| 1. The research will involve only the use of the following interactions: (check all that apply)   Educational tests (cognitive, diagnostic, aptitude, achievement)  Survey procedures  Interview procedures  Observation of public behavior (incl. visual and auditory recordings)  If “Yes”, attach a copy of the Consent Form or description of consent process. | Yes | No |
| *Answer #4 only if the research will involve children as participants. If children will NOT participate, check N/A and continue with #5.*   N/A   1. The procedures will be limited to the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the investigator will NOT participate in the activities being observed. | Yes | No |
| 1. The above-mentioned research meets at least one of the following criteria: (Check all that apply)   The information obtained will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects;[[1]](#footnote-1) or  Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or  The information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be ascertained, directly or through identifiers linked to the subjects, and  An IRB conducted a limited review and determined that there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data.[[2]](#footnote-2) | Yes | No |

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| CATEGORY 3 (45 CFR 46.104(d)(3)): For Benign Behavioral Interventions in conjunction with the collection of information from an adult subject (Refer to Chart 05) | | N/A |
| 1. Research involves benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording.   *Benign behavioral interventions are “brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.”* | Yes | No |
| 1. The human subjects will prospectively agree to the intervention and information collection.   -- or --  The subjects will authorize the deception through prospective agreement to be unaware of or misled regarding the nature or purposes of the research.  If “Yes”, attach a copy of the Consent Form or description of consent process.  If “No”, submit the *Request for Waiver of Informed Consent* form.  *Exemption 45 CFR 46.104(d)(3) does not apply if the research involves deceiving subjects regarding the nature or purposes of the research unless the subject authorizes the deception through prospective agreement to be unaware of or misled regarding the nature or purposes of the research.* | Yes | No |
| 1. The above-mentioned research meets at least one of the following criteria: (Check all that apply)   The information obtained will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects (see footnote #1 on page 5); or  Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation; or  The information obtained is recorded by the investigator in such a manner that the identity of the human subjects CAN readily be ascertained, directly or through identifiers linked to the subjects, and  An IRB conducted a limited review and determined that there are adequate provisions to protect the privacy of subjects and maintain confidentiality of data (see footnote #2 on page 5)*.* | Yes | No\* |

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| CATEGORY 4 (45 CFR 46.104(d)(4)): For Secondary Research for which consent is not required (Refer to Chart 06) | | N/A |
| 1. The research involves secondary uses of identifiable private information or identifiable biospecimens. | Yes | No |
| 1. The identifiable private information or identifiable biospecimens are publicly available. | Yes | No |
| 1. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects. (See footnote #1 on page 5.) | Yes | No |
| 1. The research involves only information collection and analysis involving the investigator's use of identifiable health information for the purposes of “health care operations” or “research” or for “public health activities and purposes”. | Yes | No |
| 1. The research is conducted or supported by, or on behalf of, a Federal (or State) department or agency using government-generated or government-collected information obtained for nonresearch activities, and the research generates identifiable private information that is or will be maintained on information technology subject to and in compliance with section 208(b) of the E-Government Act of 2002, and all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995. | Yes | No |

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| CATEGORY 5 (45 CFR 46.104(d)(5)): For Public Benefits and Service Program Research & Demonstration Projects (Refer to Chart 07) | | N/A |
| 1. This is a research or demonstration project conducted or supported by a Federal (or State) department or agency and designed to study, evaluate, improve, or otherwise examine public benefit or service programs.   If “Yes”, enter the program name: Click here to enter text.  Check the type of evaluation being conducted.  Procedures for obtaining benefits or services under those programs  Possible changes in or alternatives to those programs or procedures  Possible changes in methods or levels of payment for benefits or services | Yes | No |
| 1. Projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. | Yes | No |
| 1. There is a statutory requirement for IRB review of research on this benefit or service program. If “Yes”, cite the authority: Click here to enter text. | Yes | No |

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| CATEGORY 6 (45 CFR 46.104(d)(6)): For Taste and Food Quality and Consumer Acceptance Studies (Refer to Chart 08) | | N/A |
| 1. The research involves only a taste and food quality evaluation or a food consumer acceptance study in which:  * Wholesome foods without additives will be consumed, or * Food consumed that contains an ingredient at or below the level and for a use found to be safe, or an agricultural chemical or environmental contaminant at or below the level found to be safe by the Food and Drug Administration, Environmental Protection Agency, or the USDA’s Food Safety and Inspection Service. | Yes | No |

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| CATEGORY 7 (45 CFR 46.104(d)(7)): Storage for Secondary Research Requiring Broad Consent (Refer to Chart 09) | | N/A |
| 1. Research involves the storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use. | Yes | No |
| 1. An IRB conducted a limited review (see footnote #2 on page 5) and made the determination that: (Must meet all criteria)   Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained; and  Broad consent is appropriately documented or waiver of documentation is appropriate; and  If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data. | Yes | No |

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| CATEGORY 8 (45 CFR 46.104(d)(8)): Secondary Research Requiring Broad Consent (Refer to Chart 10) | | N/A |
| 1. Research involves use of identifiable private information or identifiable biospecimens for secondary research use. | Yes | No |
| 1. The above-mentioned research meets all of the following criteria: (check all that apply)   Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained; and  Broad consent is appropriately documented or waiver of documentation is appropriate; and  An IRB conducted a limited IRB review and determined that the research is within the scope of the broad consent; and  The researcher will not include returning individual research results to subjects in the research plan. | Yes | No |

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| PI Acknowledgement |
| I confirm that this project does not involve research on an FDA regulated product such as a drug or device. The VDSS IRB does not provide exemption determinations for investigations of products regulated by the FDA except for taste and food quality evaluation and/or consumer acceptance studies (Category 6 above).  I confirm this is not an FDA regulated project. |
| Please confirm that the data generated in this research will not be submitted to The Food and Drug Administration (FDA) for marketing approval and is not intended to be later submitted to, or held for inspection by the FDA as part of an application for a research or marketing permit.  I confirm that we will not submit any research data to the FDA for marketing approval. |
| Please confirm that you do not intend to include prisoners in this research. If prisoners will be included, the research is not exempt under federal regulations [45 CFR 46.104(b)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104).  I confirm that this research will not intentionally include prisoners. |
| By submitting this form, I am confirming that I am the Principal Investigator (PI). The information within this form is accurate and complete with the PI’s full awareness of the information submitted.  I confirm that I am the Principal Investigator and the information submitted is accurate and complete. |

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| PI SignatureClick or tap here to enter text. | DateClick or tap to enter a date. |

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| **Required Attachments** |

Please submit the following additional documentation with your application

1. Final study protocol, incl. research-related materials (e.g., survey questionnaire, interview questions, educational test/curriculum, administrative data elements requested)
2. Consent form or description of consent procedures
   * If none, complete and submit a Request for Waiver of Informed Consent form
   * If secondary research requires Broad Consent, submit a copy of the Consent form
3. PI’s curriculum vita (CV) or NIH biographical sketch; documentation of IRB training (e.g., certificates of completion)
4. A copy of the complete grant or contract
5. Documentation of previous review(s) by other IRB(s) with approval letter(s), if applicable
6. Other supporting documents as noted for exemption category

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| **VDSS IRB Contact Information** |

Please e-mail electronic copies of this form, along with copies of the project protocol and other supporting documents, to **irb@dss.virginia.gov**

**Questions?** Contact the VDSS IRB ([irb@dss.virginia.gov](mailto:irb@dss.virginia.gov))

1. A code (e.g., client or subject ID) that links the information to the subject is considered an identifier; thus, the research may not qualify for this exemption. [↑](#footnote-ref-1)
2. A limited IRB review as required by [***45CFR46.111(a)(7)***](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111)makes the determination that there are adequate subject privacy and data confidentiality safeguards. [↑](#footnote-ref-2)