Virginia Department of Health

Institutional Review Board

109 Governor Street, 7th Floor

P.O. Box 2448

Richmond, Virginia 23218-2448

VDHIRB@vdh.virginia.gov

 **REQUEST FOR EXEMPTION FROM IRB REVIEW**

**Part 1 – Administrative Information**

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| --- | --- |
| 1. Title of Study or Project: Click here to enter text. | ID No. (to be assigned by IRB staff) |
| 2. Name of Principal Investigator: Click here to enter text. Institution: Click here to enter text. | E-mail Address: Click here to enter text. |
| Address: Click here to enter text. | Telephone Number: Click here to enter text. |
| 3. Name of Department of Health Collaborator, if included in study and different from Principal Investigator: Click here to enter text. | E-mail Address: Click here to enter text. |
| Address: Click here to enter text. | Telephone Number: Click here to enter text. |
| 4. Name of Faculty Supervisor, if this is a student project and different from the Principal Investigator: Click here to enter text. | E-mail Address: Click here to enter text.  |
| Address: Click here to enter text. | Telephone Number: Click here to enter text. |
| 5. Funding Source: Click here to enter text. |  |

**Part 2 – Exemption Review Checklist**

While the VDH IRB has the ultimate responsibility for deciding if research qualifies for exemption, investigator(s) are asked to make an initial determination of the appropriate exemption category. Please select all the categories that apply from the list below.

The Federal Code [45 CFR 46.104] permits research activities in the following eight categories to be exempted. Please check the relevant exemption category/categories that apply to your research.

**The Federal Office of Human Research Protections has made Decision Charts available** [**here**](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html) **to help in determining whether a particular study falls within a particular Exemption Category.**

**Categories of Research Activities Exempt from Continuing Review**

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| --- | --- |
| **❑** | **d(1).** Research, conducted in established or commonly accepted educational settings, that specifically involves 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, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. **NOTE:** Research with minors is exemptible if the activities fall within this category. |
| **❑** | **d(2).** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:1. The information obtained 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
2. Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. 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 conducts a limited IRB review to make the determination required by §46.111(a)(7)

**NOTE:** Paragraphs (d)(2)(i) and (ii) only may apply to research subject to subpart D (minors) involving educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph (d)(2)(iii) of this section many not be applied to research subject to subpart D (minors). |
| **❑** | **d(3)(i)** Research involving benign behavioral intervention in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:1. The information obtained 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:
2. Any disclosure of the human subjects’ response outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or
3. 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 conducts a limited IRB review to make the determination required by §46.111(a)(7).

 (ii) For the purpose of this provision, 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.1. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
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| **❑** | **d(4).** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:1. The identifiable private information or identifiable biospecimens are publicly available;
2. 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.
3. The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501or for “public health activities and purposes” as described under 45 CFR 164.512(b); or
4. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if 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, 5 U.S.C 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq*.
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| **❑** | **d(5).** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedure for obtaining benefits or services under those programs, possible changes in or alternative to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.1. Each Federal department or agency conducting or supporting the research and demonstration 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. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
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| **❑** | **d(6).** Taste and food quality evaluation and consumer acceptance studies,1. If wholesome foods without additives are consumed, or

(ii)If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level  found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of  Agriculture. |
| **❑** | **d(7).** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8). |
| **❑** | **d(8).** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if the following criteria are met:1. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through(4), (a)(6), and (d).
2. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117.
3. An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section, and (iv). The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
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 **NOTE: The exemptions in the above sections do not apply to research subject to subpart C (prisoners), except for research aimed at involving a broader subject population that only incidentally includes prisoners. The above exemptions may be applied to research subject to subpart B (pregnant women, fetuses, neonates) if the conditions of the exemption are met.**

**Part 3 – Study Design, Methods and Procedures**

1. Type of Project/study: Please select ALL of the categories of work that apply to this proposed project.

❑ Active collection of data (not human biological materials or physiological data)

❑ Use of existing data (not human biological materials)

❑ Use of existing human biological materials

2. Please provide a lay summary of the study, including the purpose and the research questions and hypothesis to be tested. (attach a copy of the **complete** study protocol)

3. Please describe briefly how this study will contribute to existing knowledge in the field.

**Part 4 – Privacy and Confidentiality**

1. Will you or any member of your research team collect or have access to any of the personal identifiers listed below? Select all that apply.

❑ Subject’s name

❑ Date of birth

❑ Mailing or email address

❑ Phone or fax numbers

❑ Social Security number

❑ Medical records

❑ License, certificate or Vehicle ID

❑ Biometric identifiers

❑ Photos/images/audio recording

❑ Signatures, handwriting samples

❑ Any unique identifier not mentioned above

❑ No member of the research team will have access to any personal identifiers

2. Briefly describe the measures that will be used to protect the individual privacy of the research subjects.

3. How will the confidentiality of data be ensured? Check all the following precautions that will be used to maintain the confidentiality of identifiable information.

❑ Paper-based records will be kept in secure location and only accessed by authorized study personnel.

❑ Electronic records will be made available only to those personnel in the study through the use of access controls and encryption.

❑ Identifiers will be removed from study-related data (data is coded with a key stored in a separate secure location).

❑ For research involving web-based surveys, data is secured via passwords and encryption.

❑ Audio or video recordings of subjects will be transcribed and then destroyed to prevent audio or visual identification.

❑ Other precautions: ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Part 5 – Informed Consent Process**

Please indicate the informed consent process(es) and document(s) to be used in the study. Check all that apply. **Provide copies of documents, as applicable**.

❑ Not applicable (existing data or specimens)

❑ Informed consent - form ❑ Informed consent – oral script

❑ Assent (participants under 18) – form ❑ Assent – oral script

❑ Parental Permission – form ❑ Parental Permission – oral script

❑ Translated Consent/Assent – form(s), script(s)

**Part 6 – Signature**

**Principal Investigator**

You may submit an electronic copy of this application and required materials by clicking on the attestation box below and entering name and date. After clicking on the attestation box, please save a copy of the form before emailing the form and required materials to VDHIRB@vdh.virginia.gov

I certify that the information I provided in this application is correct and complete. I also certify that all research staff and I have completed the protection of human research subjects training ([www.citiprogram.org](http://www.citiprogram.org/)). I will not change any of the procedures, forms, or protocols used in this study without first seeking review and approval from the VDH Institutional Review Board.

\_\_\_\_ Attestation of Principal Investigator \_\_\_\_Attestation of Faculty Supervisor (if applicable)

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Signature of Principal Investigator Date

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Signature of Faculty Supervisor (if applicable) Date

(If the principal investigator is a student, the faculty supervisor must also sign)

**SUBMISSION CHECKLIST**

1. Completed and signed Request for Exemption from IRB Review Form

2. Complete Study Protocol including:

* + - Hypothesis
		- Methods and procedures
		- Subject selection/recruitment
		- Risks and benefits
		- Subject compensation – if applicable
		- Study Management/Personnel
		- Privacy Protection
		- Confidentiality and data storage
		- Data analysis and dissemination plans

3. Principal Investigator’s CV.

4. Copies of survey/interview instruments.

5. Copies of informed consent/assent forms, scripts, and recruitment material.

6. Evidence (letter or email) that the district health director and/or VDH Central office supervisor is aware/approves of the involvement of Virginia Health Department clients or the use of VDH data for the purposes of this study.

7. Application and Approval letter from any other IRB reviewing this proposal.

This form along with supporting documentation may be submitted electronically to vdhirb@vdh.virginia.gov or by mail to:

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