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 EXPEDITED/FULL REVIEW FOR RESEARCH INVOLVING HUMAN PARTICIPANTS**

**Part 1 – Administrative Information**

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| --- | --- |
| 1. Title of Study or Project: Click here to enter text. | ID No.  |
| 2. Name of Principal Investigator: Click here to enter text. Name of 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:  |
| 5. Funding Source: Click here to enter text. |  |

**Part 2 – Type of Review**

While the VDH IRB has the ultimate responsibility for deciding if research qualifies for a full or expedited review, investigators are asked to make an initial determination of the type of review.

❑ Full board Review – **the research involves greater than minimal risk to the subjects.**

❑ Expedited Review – **the research must involve no more than minimal risk to the subjects**. (For expedited review, please indicate the category or categories in which your research falls in the list below.)

**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 may be reviewed using Expedited Review Procedures.**

Categories of Research that May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

|  |  |
| --- | --- |
| ❑ | 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met:
2. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increase the risks or decrease the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
3. Research on medical devices for which 1) an investigational device exemption application is not required or 2) the medical device is cleared or approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
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| ❑ | 1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
2. From healthy, non-pregnant adults, who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml. in an eight week period and collection may not occur more than two time per week; or
3. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount may not exceed the lesser of 50 ml. or 3 ml. per kg. in an eight-week period, and collection may not occur more than two times per week.
 |
| ❑ | 1. Prospective collection of biological specimens for research purposes by non-invasive means.

Examples: 1. hair and nail clippings in a non-disfiguring manner;
2. deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction.
3. permanent teeth if routine patient care indicates need for extraction;
4. excreta and external secretions (including sweat);
5. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
6. placenta removed at delivery;
7. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
8. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
9. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
10. sputum collected after saline mist nebulization.
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| ❑ | 1. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: 1. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy;
2. weighing or testing sensory acuity;
3. magnetic resonance imaging;
4. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow and echocardiography;
5. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing when appropriate given the age, weight, and health of the individual.
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| ❑ | 1. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnoses).
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| ❑ | 1. Collection of data from voice, video, digital, or image recordings made for research purposes.
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| ❑ | 1. Research on individual or group characteristics, behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
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**Part 3 – Study Design, Methods and Procedures**

1. **Study Sample:** (Groups specifically targeted for study)

Age range of participants: \_\_\_\_\_\_\_\_\_\_\_ Projected number of participants \_\_\_\_\_\_

❑ Employees ❑ Students ❑ Children ❑ Pregnant women

❑ Fetuses/neonates ❑ Educationally/economically disadvantaged ❑ Incarcerated

❑ Children who are wards of the state ❑ Military personnel ❑ Incompetent persons

❑ Other – specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Recruitment Method:**

Describe how research participants will be recruited in the study. How will you identify potential participants? How will you contact them? **Attach a copy of any material you will use to recruit participants (e.g. advertisements, flyers, telephone scripts, cover letters, etc.)**

1. **Participant Incentives:**
2. Will you pay participants? ❑ Yes ❑ No

 Amount $\_\_\_\_\_\_\_\_\_ When will money be paid? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Will you give participants an incentive? ? ❑ Yes ❑ No If yes, please describe.

4. Please provide a brief 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)**

5. 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 (specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

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

2. 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.

❑ No data will be published or released in any form if a particular individual supplying the information or described in it is identifiable without the written permission of the subject(s) involved.

❑ The identifying information will be used only for statistical purposes in medical and health research.

❑ The identifying information will be used only for the study or project proposed and the purposes described in the study protocol. Use of the information for a research project other than the one described will not be undertaken unless a separate request is made to and approved by the Virginia Department of Health IRB.

❑ The identifying information will not be used as a basis for legal, administrative, or other actions which may directly affect those particular individuals as a result of their specific identification in this project.

❑ 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 Expedited/Full Review Request Form

2. Complete Study Protocol including:

* + - Hypothesis
		- Methods and procedures
		- Subject selection/recruitment
		- Risks and benefits
		- Subject compensation – if applicable
		- Study Management/Personnel
		- 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 (email/letter) that the district health director and/or VDH Central office supervisor is aware/approves of the study if it includes Virginia Health Department clients or data.

7. IRB 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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