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| **DCF LogoNEW** | DEPARTMENT of CHILDREN and FAMILIES *Making a Difference for Children, Families and Communities* | statecolorseal |

**DCF Institutional Review Board**

**Application for Consideration**

**DCF IRB Number:**

*For IRB use only*

**Utilize the “TAB” key to move between fill-in fields**

The Connecticut Department of Children and Families (DCF) Institutional Review Board (IRB) policies and procedures should be consulted prior to the development of any study involving human subjects, inclusive of any records and charts.

**Please be aware that applications submitted to the DCF IRB have been determined by the department to be disclosable under the Freedom of Information Act provisions, unless otherwise exempt.**

**The completed application submitted to the IRB must contain:**

This form filled out in full.

A sample of the consent form to be used. The consent must cover the specific risks and benefits to the individual subject. Consent forms should be available in languages and at the reading level appropriate to the study population. (See also: *Informed Consent Checklist*)

A copy of any questionnaires or other data collection instruments to be used in the study.

A copy of the grant application if the study is grant funded and a copy of the research design or proposal.

A copy of the approval if the study has been cleared by any other institution’s IRB. **NOTE:** The DCF IRB will not review any study until it has been cleared by all other applicable institution’s IRBs.

Any research at DCF sites must have initial approval from the chief administrator at that (those) site(s). The Riverview Hospital’s executive committee must approve research involving its patients. A letter from the applicable site(s)’ chief administrator or, in the case of Riverview Hospital, the executive committee indicating initial approval must accompany the application.

A current resume or C.V. of the principal investigator(s).

A copy of the Exempt Research or Expedited Review Checklist.

Assurance of completion of investigator training.

The above materials must be submitted electronically with one original, signed application sent to the DCF IRB. An initial discussion and review of your proposed study will occur in order to determine whether your proposed study is exempt from IRB review (e.g., will not deal with personally identifiable case data), or suitable for an expected review (e.g., does not directly involve DCF children), or requires a full Board review.

The IRB will make every effort to schedule full board reviews as promptly as possible, upon receipt of a complete application. This review will occur no later than sixty (60) days following the receipt of all materials. Every attempt will be made to review at the next Board meeting complete applications received ten (10) business days before that meeting, although this cannot be guaranteed.

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| SECTION I. GENERAL INFORMATION | | | | | | | |
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| **1.** | | | **Submission Date of This Application**: | | | | |
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| **2.** | | | **Study Title**: | | | | |
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| **3A.** | **Principal Investigator Information** | | | | | | |
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|  | First Name | | | | Last Name: | | |
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|  | Role In the project | | | | | | |
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| **3B.** | | | **Principal Investigator Information** | | | | |
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|  | Role In the project | | | | | | |
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| **4.** | | **Faculty Advisor Information (For Student Submitted Protocols)** | | | | | |
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|  | First Name | | | | Last Name: | | |
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|  | Job Title | | | | Academic Degree(s): | | |
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| **5. Project Sponsor and/or Funding Source** | |
| **Project Sponsor/funding Source** | **Funding Amount** |
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| **6. Conflict of Interest**  Does the Principal Investigator, Co-Investigator or other key personnel have a conflict of interest (financial or other conflict) in the results of this project? | Yes | No |
| If yes, please detail. Attach an additional sheet if necessary. *A significant conflict of interest may require disclosure to participants in the informed consent form. Final IRB approval cannot be granted until all potential conflict matters are settled.* |

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| **7. Exempt or Expedited Review (see definitions)** Please indicate whether you believe that your project is exempt from IRB review or qualifies for an expedited review? | Exempt: | Yes | No |
| *If you think that your submission is either exempt from IRB review or is suitable for an expedited review, an Exempt / Expedited Review Checklist must be included with this application.* | Expedited Review: | Yes | No |

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| **8. Non-DCF IRB Review**  Please indicate the other IRBs to which your project has been submitted and those bodies’ determination (e.g., approved, denied, exempt, etc.) *Evidence of review by other applicable IRB’s must be submitted with this application.* | |
| Name of Institutional Review Board | IRB’s Determination |
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| SECTION II. STUDY ABSTRACT Please provide a brief description of your project. This description should not be more than 50 words. |
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| **SECTION III. CHARACTERISTICS OF PARTICIPANT POPULATION AND RECRUITMENT PROCEDURES** **1. Study Subjects**  Please provide a general description of the proposed participant population and the anticipated number of participants. This should include information about the participants’ age, sex, ethnicity, race, language, and health status. Also, a rationale for the sample size must be included. |
| **2. Participant Selection**  Please detail the method for participant selection. Be sure to include any inclusion / exclusion criteria. In addition, if an advertisement, flyer, e-mail or phone invitation will be used in recruitment, please include the text and/or an attachment. |
| **3a. Special and Vulnerable Populations**  Please identify if the study will involve any of the following populations. *Check all that apply.*   1. Children/minors (person under age 18) 2. Prisoners 3. Institutionalized individuals 4. DCF employees 5. Pregnant women/fetuses 6. Cognitively impaired individuals 7. Terminally ill patients 8. Elderly/aged persons 9. Ethnic minorities 10. Economically disadvantaged persons 11. Individuals seeking emergency treatment |
| **3b. Special and Vulnerable population rationale**  Please provide a rationale for the participation of subjects from the special and/or vulnerable groups noted above. |

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| SECTION IV. PROJECT DESCRIPTION Please use lay-language, where feasible, in describing your project. Be sure to explain all technical terms and jargon. The description should be understandable to any person unfamiliar with the area of research. The project description must address all the following elements:   1. **Purpose of the study, including relevant background information:** 2. **Study site(s)/setting(s) and how the researcher(s) will interact with the participants:** 3. **Type of study, including the basic study design:** 4. **Research hypothesis or questions:** 5. **Objectives of the study:** 6. **Please describe how and who will conduct the research, including relevant methodology (design, procedures, questionnaires, etc.). Cultural competency considerations as informed by the targeted participants should be addressed:** 7. **Proposed method of analysis of the data:** 8. **Relevant literature citation:** 9. **Approximate duration of the project, including beginning and ending dates:** 10. **If participants will be paid or given other forms of compensation, please provide details including how compensation will be delivered and at what point in the project:** |

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| SECTION V. RISKS AND BENEFITS |
| **1. Risk to Subjects**  Please describe any potential risks to participants (e.g., physical, psychological, social, legal, other). Risk factors also include procedures that could involve threat, embarrassment or deception. Assess the probability, severity, potential duration and reversibility of any potential risk: |
| **2. Risk Abatement**  Describe procedures utilized to prevent or minimize potential risks. Include names of any clinicians, psychiatrists, physicians, professionals and/or services that will use used to prevent or minimize risks: |
| **3. Benefits to Subjects**  Please describe any potential benefits to be gained by the participants and/or that may accrue to society in general. |
| **4. Risk-Benefit Analysis**  Please state why the risks to participants are reasonable in relation to the anticipated benefits. |
| **5. Contingency Plans**  The Department of Children and Families is responsible for the care of children and youth in its custody. As such, DCF requires information about contingency plans for medical or psychiatric emergencies related to research studies. If your study directly involves children, especially using drug trial or clinical interviews, please indicate your plans. (If this is not applicable, please indicate.) |

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| SECTION VI. PRIVACY AND CONFIDENTIALITY | | | |
| **1. Confidentiality**  Please describe the extent to which the confidentiality of any information obtained from or about the participants will be maintained, including who will have access to the data. If identifiable subject data or responses will be made available to anyone other than the principal investigator and research team, please include a rationale. A description of the length of time in which participant data will be maintained and the means for disposal of that material should also be provided. | | | |
| **2. Protected Health Information**  Will this study require the use of disclose of protected health information from a covered entity as defined in the HIPAA Privacy Rule? If yes, please describe the authorization process. | | Yes | No |
| **3. Videotapes and Audio**  Please indicate whether videotaping and audio recording of study subjects will occur. If yes, please describe procedures for its storage and disposal. | Videotapes: | Yes | No |
| Audio: | Yes | No |
| **4. Study Dissemination**  Will the results of this study be publicly disseminated? If yes, please detail how and to who the study will be disseminated. If the study is not to be publicly disseminated, please set forth how the results of this study will be used. | | Yes | No |

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| SECTION VII. INFORMED CONSENT AND ASSENT |
| Please address the following consent and assent elements:   1. **Explain who will obtain informed consent and in what setting:** 2. **Will all participants have the capacity to consent? If no, explain:** 3. **Describe the assent process for children, if applicable:** 4. **Will all participants be fluent, including literacy, in English? If no, explain how informed consent will be obtained:** 5. **Describe how you will ensure that all subjects understand that participation is voluntary and they can withdraw at anytime without penalty:** 6. **Will any information be purposefully withheld from the participants? If yes, provide a script of what will be explained to the participants:** 7. **Include the informed consent documents as an attachment:** 8. **Include, as applicable, the assent documents as an attachment:** |

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| SECTION VIII. OTHER INFORMATION Please add any additional information that you believe would be helpful to the IRB in considering your project: |

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| SECTION IX. RESEARCHER RESPONSIBILITIES |  |
| The following are the minimum responsibilities of principal investigators. Please initial each item to indicate that you have carefully read and understand your responsibilities: |  |
| INITIAL |
| 1. Principal investigator(s) acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of the Assurance below |  |
| 2. Principal investigator(s) who are conducting research as part of an academic program will have documentation that the research has been approved by the academic institution’s IRB. |  |
| 3. Unless otherwise authorized, principal investigators are responsible for obtaining and documenting informed consent in accord with applicable federal regulations at 45CFR 46.116 and 46 CFR 46.117 |  |
| 4. Principal investigator(s) shall be responsible for promptly submitting any proposed changes concerning this study for approval by the DCF IRB. The Principal investigator(s) understands that proposed changes to the research protocol may not be initiated until DCF IRB has approved such modifications. (See: Protocol Revision and Amendment Form) |  |
| 5. Principal investigator(s) will report to the IRB any unexpected and serious events or other unanticipated problems involving risks to subjects or others (See: Adverse Event Report Form) |  |
| 6. Principal investigator(s) will submit a continuation to request an extension, if applicable, of research before DCF IRB’s approval expires. (See: IRB Continuing Review Form) |  |

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| SECTION X. INVESTIGATOR(S) ASSURANCE  **Assurances:**  The original, inked signature of the Principal Investigator(s) is required. Other investigators are also responsible for this assurance and are encouraged to sign. In addition, for student protocols that are being submitted, the **student’s faculty advisor must also sign below**. Neither stamps nor proxy signatures are accepted in this section.  Investigator Assurance:  I certify that the information supplied in this form, with attachments, is complete, accurate and correct, and that no other procedures will be used in this protocol. The research will be conducted according to the protocol approved by the IRB, applicable federal, state and local laws regarding the protection of human participants in research. I will ensure that all protocol changes will be prospectively reviewed by the IRB. I will request approval from the DCF IRB for changes to the study’s protocol and/or consent and assent forms, and will not implement proposed changes until I receive IRB approval. I will promptly report to the IRB all research related accidents, injuries, complaints, problems, and/ or breaches of confidentiality. In addition, any significant new findings that may affect the risks and benefits to the subjects and other participants will be reporting in writing to the subjects and the IRB. (Please see "Protocol Revision and Amendment Form" and "Reporting Adverse Events Form.")  Student’s Faculty Advisor Assurance:  This is to certify that I have reviewed this application and that I attest to the scientific merit of this study and the competency of the investigator(s). The investigators are knowledgeable about the regulations and policies governing research with human subjects. I agree to meet with the investigator(s) on a regular basis to monitor study progress and compliance with DCF IRB approval stipulations and policy for the conduct of ethical research. | | |
| Principal Investigator Date |  | Investigator Date |
|  |  |  |
| Investigator Date |  | Faculty Advisor (for student protocols) Date |

**Please submit your completed application to:**

DCF Institutional Review Board

c/o DCF Bureau of Continuous Quality Improvement • 505 Hudson Street • Hartford, CT 06106

Email: [dcf.irb@ct.gov](mailto:dcf.irb@ct.gov)

**INVESTIGATOR TRAINING ASSURANCE**

DCF IRB use only

Approved ❒ Not Approved ❒

Approval Period:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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IRB Designee Signature Date

I certify that as the Principal Investigator for the project titled:

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I have completed the following online National Institutes of Health Office of Extramural Research Training:

<https://phrp.nihtraining.com/users/login.php>

Alternately, I have completed the following Research Investigator Training application:

(Include the training’s title, URL and Certificate of Completion)

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My signature below is also an assurance that Co-Principals for this project and other staff assigned to this project have completed the aforementioned training and are familiar with their role and responsibilities as it pertains to research involving human subjects.

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Principal Investigator Date

## **EXEMPTED and EXPEDITED DEFINITION**

## Categories for Exempt Review

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies or (b) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

Educational research proposals may be exempt provided that all of the following conditions are met:

* 1. All of the research is conducted in a commonly accepted educational setting (e.g., private or public school).
  2. The research involves normal educational practices (e.g., comparison of instructional techniques).
  3. The study procedures do not entail a significant deviation in time or effort from those educational practices already existent in the study site.
  4. The study procedures do not involve an increase in the level of risk or discomfort beyond normal, routine educational practices.
  5. The study procedures do not involve sensitive topics (e.g., a survey that deals with socially questionable or highly personal issues, e.g., substance abuse).
  6. Provisions are made to ensure the existence of a non-coercive environment for all students, including those who choose not to participate.
  7. The school or other institution grants written approval for the research to be conducted.

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   1. information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects and
   2. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

**NOTES TO RESEARCHERS:**

If minors or prisoners are the proposed subjects in interview/survey research, the project cannot be filed as exempt and will require expedited or full Committee review.

Observational research involving sensitive aspects of subjects' behavior, or in settings where subjects have a reasonable expectation of privacy, is not exempt. Similarly, sensitive survey research is seldom considered exempt.

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior that is not exempt under paragraph # 2 (above) if:
   * + 1. the human subjects are elected or appointed public officials or candidates for public office, or
       2. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
2. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects.
3. Research and demonstration projects which are conducted by or subject to the approval of (federal) department or agency heads and which are designed to study, evaluate or otherwise examine:

* public benefit or service programs,
* procedures for obtaining benefits or services under those programs,
* possible changes in or alternatives to those programs or procedures or
* possible changes in methods or levels of payment for benefits or services under those programs.

**NOTE TO RESEARCHERS:** This category may also be applied to service/program evaluations of State, City or County programs providing: (a) the program being studied delivers public benefits or services; (b) there is specific statutory authority over the program; (c) there is no statutory requirement that the program evaluation plan be reviewed at full Committee; and (d) there is no significant intrusion or invasion of the privacy of the participant.

1. Taste and food quality evaluation and consumer acceptance studies, if:
   1. wholesome foods without additives are consumed or
   2. 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.

## **Categories for Expedited Review**

**Applicability:**

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
2. The categories in this list apply regardless of the age of subjects, except as noted.
3. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
4. The expedited review procedure may not be used for classified research involving human subjects.
5. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review utilized by the IRB (i.e., expedited or full committee review).
6. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

**Research Categories:**

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   1. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   2. from other adults and children,2 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 drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive 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 a need for extraction;
   3. permanent teeth if routine patient care indicates a need for extraction;
   4. excreta and external secretions (including sweat);
   5. uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase 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 prophylactic 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.
4. Collection of data through noninvasive 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 where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt (category 4) from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or 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. NOTE: Some research in this category may be exempt (category 2 or 3) from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
8. Continuing review of research previously approved by the convened IRB as follows:
   1. where
      * the research is permanently closed to the enrollment of new subjects;
      * all subjects have completed all research-related interventions; and
      * the research remains active only for long-term follow-up of subjects; or
   2. where no subjects have been enrolled and no additional risks have been identified; or
   3. where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Informed Consent Checklist - Basic and Additional Elements**

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|  | A statement that the study involves research |
|  | An explanation of the purposes of the research |
|  | The expected duration of the subject's participation |
|  | A description of the procedures to be followed |
|  | Identification of any procedures which are experimental |
|  | A description of any reasonably foreseeable risks or discomforts to the subject |
|  | A description of any benefits to the subject or to others which may reasonably be expected from the research |
|  | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |
|  | A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained- particularly as related to mandated reporting requirements |
|  | For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained |
|  | An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject |
|  | A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled |

**Additional elements, as appropriate:**

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|  | A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable |
|  | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent |
|  | Any additional costs to the subject that may result from participation in the research |
|  | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject |
|  | A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject |
|  | The approximate number of subjects involved in the study |

**EXEMPT RESEARCH CHECKLIST**

DCF IRB use only (IRB #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

Exempt ❒ Not Exempt ❒

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Designee Date

Principal Investigator:

Title of Project:

Research activities in which ONLY involvement of human subjects will be in one or more of the categories specified below are eligible for exemption certification. If the research study involves a vulnerable population, such as children, prisoners, pregnant women, refer to 46 CFR subparts B, C, and D for protections afforded these groups.

Check the appropriate categories that apply to your research project:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation. *Note: According to 45 CFR 46.401, if the subjects are children, this exemption applies only to research involving educational tests or observations of public behavior when the investigator(s) do not participate in the activities being observed.*

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under #2 (above) of this section if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such as manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) 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.

**EXPEDITED REVIEW CHECKLIST**

DCF IRB use only (IRB #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)

Exempt ❒ Not Exempt ❒

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

IRB Designee Date

Principal Investigator:

Title of Project:

Check off the item(s) below that qualifies this project for Expedited Review. If a study is submitted for Expedited Review and does not qualify as such, the application will be returned to you for correction and submission for Full Review.

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children2, 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 drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) air and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive 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: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. 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 diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.