

StDavid's HEALTHCARE

Institutional Review Board

EXEMPT RESEARCH DETERMINATION FORM

All research activities that meet the HHS or FDA definitions of “human research” must be conducted under the oversight of an IRB. However, the United States Code of Federal Regulations (CFR) that govern human subjects research defines several categories of research that are exempt from the regulations, including the requirement for IRB oversight. **While many investigators may believe their studies are Exempt from these regulations, the IRB should make the determination that a research project meets the criteria for Exemption.**

Research studies that are exempt from IRB review must meet the following criteria:

- (i) the research must pose no less than minimal risk to the research participants, AND
- (ii) the research must fall into at least one of the following six categories defined in the regulations (45 CFR 46.101b):
 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:
 - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, AND
 - b. 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.
 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 paragraph (b)(2) of this section, if:
 - a. the human subjects are elected or appointed public officials or candidates for public office; OR
 - b. 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 a 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:
 - a. Public benefit or service programs;
 - b. procedures for obtaining benefits or services under those programs;
 - c. possible changes in or alternatives to those programs or procedures; OR
 - d. possible changes in methods or levels of payment for benefits or services under those programs.

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6. Taste and food quality evaluation and consumer acceptance studies:
 - a. if wholesome foods without additives are consumed; OR
 - b. 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.

Please also note: although a research study may meet the criteria to be eligible for considering an exemption from the regulations, when St. David's HealthCare facilities or employees are engaged in the research, then the St. David's HealthCare IRB at its sole discretion retains final judgement as to whether IRB oversight will be required for the research study under consideration. St. David's HealthCare IRB reserves the right to disapprove any requests for exemption determinations to protect the rights and welfare of our patients and employees.

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DESCRIPTION OF RESEARCH PROJECT

INSTRUCTIONS FOR REQUESTING AN EXEMPT DETERMINATION

Prior to initiating your research, please complete the Description of Research Project below to provide the IRB with information necessary to consider whether the proposed research meets the criteria as exempt from IRB oversight.

Study Title	
Protocol Version #/ Date	

PRINCIPAL INVESTIGATOR INFORMATION

Name of Principal Investigator	
Email Address	
Phone Number	

Please list all locations where research activities will take place. Do not include locations that are used for diagnostic purposes only (i.e. imaging center, blood draw lab).

RESEARCH SITES

PRIMARY RESEARCH SITE

Name of Site			
Department			
Address			
City	State	Zip	
Is site outside of St. David's network?	<input type="checkbox"/> Yes- Provide rationale: If so, is the site located in a hospital or institution? <input type="checkbox"/> Yes <input type="checkbox"/> No (IRB waiver may be required) <input type="checkbox"/> No		
If site is outside of St. David's, will research coordinators conduct any part in a St. David's facility?	<input type="checkbox"/> Yes- Are all study coordinators credentialed by St. David's for conducting clinical research at St. David's facilities? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No		

ADDITIONAL RESEARCH SITE

Name of Site			
Department			
Address			
City	State	Zip	
Is site outside of St. David's network?	<input type="checkbox"/> Yes- Provide rationale: If so, is the site located in a hospital or institution? <input type="checkbox"/> Yes <input type="checkbox"/> No (IRB waiver may be required) <input type="checkbox"/> No		

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If site is outside of St. David's, will research coordinators conduct any part in a St. David's facility?	<input type="checkbox"/> Yes- Are all study coordinators credentialed by St. David's for conducting clinical research at St. David's facilities? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> No
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If there are additional locations where the study will take place, please copy the table above as many times as needed to provide this information for each location where research activities will be conducted.

BRIEF PROTOCOL DESCRIPTION

*** Please delete the italicized instructions below when providing your information.**

1. **Purpose**
Briefly describe the purpose, specific aims, or objectives of the study.
2. **Procedures**
Briefly describe the procedures used to obtain information from the individuals with whom you will interact or intervene for this activity, including communication or interpersonal contact with individuals and physical procedures, if any.
3. **Data and/or specimens**
Describe the data and/or specimens that you will gather about individuals, including names of datasets you will access and links to data sources.
4. **Data and/or Specimen Collection and Analysis**
Describe the data and/or specimens you will collect and how they will be analyzed.
5. **Data and/or Specimen Collection Method**
Describe how you will obtain the data or specimens. (Are you obtaining them from another researcher? Are you pulling data from directly from a medical record? Are you pulling leftover samples?)
6. **Identifiability of Data or Specimens**
Indicate whether the data or specimens you collect for this activity can be directly linked to individuals, (e.g., the dataset includes names), indirectly linked through a code (e.g., the dataset includes a code and you have the key to the code), or not linked at all to individuals (e.g., the dataset includes a code, but no one but the person giving you the data or specimens has the key to the code).

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CONFLICT OF INTEREST

The **PI must personally review and answer** the questions below before signing this form. Please carefully consider potential conflicts with the sponsor, test article, or manufacturer of the test article when providing responses. The responses must also consider any conflicts of interest of the Principal Investigator's spouse and immediate family members.

<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have or anticipate any financial arrangements with the study sponsor, whereby the compensation for conducting the study could be influenced by the outcome of the study?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you received or do you anticipate receiving significant payments (exclusive of the payment for services provided in connection with the study) from the study sponsor, such as research grants, compensation in the form of equipment, retainers for consulting services, speaking honoraria, travel reimbursement, or other compensation that will exceed \$10,000 (\$5,000 for PHS funded research) in aggregate ?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have any proprietary interest in the product tested in the study, including, but not limited to, property, patents, trademarks, copyrights, or licensing agreements?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have any significant equity interest in the study sponsor, such as ownership interest, stock options, or other financial interest that exceeds \$10,000 (\$5,000 for PHS funded research) in aggregate , or more than 5% ownership, in the sponsoring company or business entity?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Do you have any financial interest or scholarly or social commitment or relationship that would impair your ability to make fair and impartial judgements about an application?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Have you accepted payment arrangements from the sponsor such as financial incentives for early enrollment or high enrollment, such as a recruitment bonus incentive?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Are you an employee of the sponsor or do you have any executive relationship to the sponsor or the product or service being tested, regardless of compensation?
<input type="checkbox"/> Yes <input type="checkbox"/> No	Is there any other conflict of interest you would like to disclose? If so, explain: _____

If you answered yes to any of the questions above, please attach a detailed explanation of the conflict of interest and how this will be managed to ensure that the safety and well-being of subjects is not affected. (This could include disclosure of the COI in the consent form, having another non-conflicted person perform the consent process or collect data, or establishment of a more sufficient monitoring plan.)

By signing below, I agree to conduct this study according to the protocol and in compliance with local, state, and federal laws and St. David's policies. I have thoughtfully considered the potential risks and benefits of this research and agree that the risk/benefit ratio is acceptable and does not put an undue burden on potential research subjects.

I certify that I have reviewed the protocol (if applicable) and submission form and agree that all information in this document is true and accurate.

Name of Principal Investigator

Signature of Principal Investigator

Date

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DOCUMENTATION OF IRB REVIEW

Human Research Determination

Research activity meets the following definitions of Human Research (check all that apply):

- FDA-regulated Human Research
- DHHS-regulated Human Research

Research activity does not meet the criteria to be considered Human Research, as defined in 45 CFR 46 and 21 CFR 56.

Comments: _____

Exempt Determination

Research activity is exempt from IRB oversight.

Category: _____

Research activity is *not* exempt from IRB oversight.

By signing below, I certify that the review of the research activities above was conducted according to the relevant Federal regulations. I also certify that I do not have a conflict of interest related to the investigator or protocol as described in SDH IRB SOPs.

Printed Name

Signature

Date

Title