**The Christ Hospital Exemption Application Request**

IRB Study Number: **E**-\_\_\_\_\_\_

**Study/Project Title**

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**Please use this form to submit a request for exempt determination for research involving human subjects.**

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) Identifiable private information. **Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs my include research activities. 45 CFR 46.012

For research regulated by the FDA:

**Human subject** means individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient. **Clinical investigation** means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies. 21 CFR 50.3

**Section 1: Study Personnel**

**Principal Investigator**

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| **Name and Credentials:**  **Department, Primary Role and Job Title:**  **Address:**  **Phone/Fax/Email:**  **Qualifications to do the research:** |

**Co-Investigator**

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| **Name and Credentials:**  **Department, Primary Role and Job Title:**  **Address:**  **Phone/Fax/Email:**  **Role in Study: (specific activities, including obtaining consent)** |

**Other Personnel**

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| **Name and Credentials:**  **Department, Primary Role and Job Title:**  **Address:**  **Phone/Fax/Email:**  **Role in Study: (specific activities, including obtaining consent)** |

**Section 2: Conflicts of Interest**

(The Christ Hospital IRB “Disclosure of Financial Interest” form, available by calling the IRB Office at 585-2742, must be completed by each investigator (PI and co-investigators) involved in the research project. The completed form(s) must be included with the protocol submission to the IRB.

Does the PI, co-investigator or research coordinator involved in this study (or in aggregate

with his/her spouse, dependents, or members of his/her household):

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| **Yes / No** |  |
| ⁮ ⁮ | Been an officer, director or employee of the sponsor of this research study? |
| ⁮ ⁮ | Held Ownership interest (equity or stock options) Related to the Research in excess of $5,000 when referenced to publicly traded prices (if the sponsor is a publicly traded company) or other measure of fair market value and when aggregated for the immediate family? |
| ⁮ ⁮ | Held Ownership interest (equity or stock options) Related to the Research whose value when aggregated for the immediate family represents 5% or more interest in any one single entity? |
| ⁮ ⁮ | Held Ownership interest (equity or stock options) Related to the Research of any value held in a non-publicly traded company? |
| ⁮ ⁮ | Had any proprietary interest Related to the Research? ( A proprietary interest is defined as property or other financial interest including, but not limited to, a patent, trademark, copyright or licensing agreement.) |
| ⁮ ⁮ | Received, or made any arrangement to receive, any significant payments of other sorts Related to the Research to support activities of the Investigator? (A significant payment of other sorts is defined as: **(i)** payments by the sponsor to support activities of the Investigator that have a monetary value of more than Five Thousand Dollars ($5,000) exclusive of the costs of conducting the research study, such as retainers for ongoing consultation or honoraria, during the course of the study and when aggregated for the immediate family) |
| ⁮ ⁮ | Agreed to or plan to accept recruitment bonuses for enrolling subjects into this research study? |
| ⁮ ⁮ | Entered into any financial arrangement Related to the Research whereby the value of compensation paid or of equity owned could be affected by the outcome of this study? (Compensation affected by the outcome of the study is defined as: **(i)** compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result; **(ii)** compensation in the form of an equity interest in the sponsor of the study; or **(iii)** compensation tied to sales of the product, such as royalty interest.) |

*(If the answer to any of the above questions is YES, include an explanation below of the disclosure for the IRB’s consideration to determine if a conflict exists.)*

**Section 3: Funding or Other Support**

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|  | **Name of Department, Agency or Sponsor** |
| **⁮ No Funding** |  |
| **⁮ Funded Internally** |  |
| **⁮ Program Project Grant** |  |
| **⁮ Federally Sponsored Project/DHHS** |  |
| **⁮ Industry-Sponsored Study** |  |

**Section 4: Screening Questions**

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| Will the research expose participants to discomfort or distress beyond that normally encountered in daily life? | Yes | No |
| Could disclosure of participants’ responses outside the research reasonably place participants at risk of criminal or civil liability or be damaging to participants’ financial standing, employability, or reputation? | Yes | No |
| Does any part of the research require deception or incomplete disclosure of information to participants? | Yes | No |
| Will prisoners (or their data and/or specimens) be participants in the research? | Yes | No |
| For research proposed under category 1, will the research be conducted outside of commonly accepted educational settings or deviate from normal educational practices? | Yes | No |
| For research proposed under category 2, will the research involve surveys or interview procedures with children? | Yes | No |
| For research proposed under category 2, will the research involve observations of the public behavior of children, during which an investigator participates in the activities being observed? | Yes | No |
| For research proposed under category 4, will any of the data, documents, records or biological specimens be collected or created after the date of this application for exemption? | Yes | No |
| For research proposed under category 4, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that participants could be identified directly or through identifiers linked to the participants? | Yes | No |
| For research proposed under categories 1-5, is the research subject to FDA regulations? | Yes | No |

***If you checked YES to any of the questions above, your research is NOT EXEMPT. Do not complete this application. Submit an IRB Study Application.***

**Section 5: Exempt Category**

Please check the categories of exemption for which you are applying. (A description of exemption categories are listed at the end of this form.)

Category 1□ 2□ 3□ 4□ 5□ 6□

**Section 6: Location of the Research**

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**Section 7: Summary of the Research**

Provide a brief description of the purpose of the study. Use lay language and avoid technical terms. Upon conclusion of the study, how will you share your results? ***(Attach a copy of the research protocol.)***

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Provide the estimated beginning and end dates of the projects.

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**Section 8: Participant Population**

Specify the age(s) of the individuals who may participate in the research:

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Specify the participant population(s) to be included (check all that apply)

□ Adults □ Children (< 18 years) □ Students □ Non-English speaking

□ Unknown (e.g., research using secondary data/specimens, non-targeted surveys, program protocols)

□ Other (Specify)

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Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking.

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Describe the characteristics of the population(s). \*\*\*(***If requesting exemption under category 4, fill out Section* *16 on page 5 before going forward)\*\*\****

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**Section 9: Recruitment Method:**

Describe how research participants will be identified? How will you contact them? **Attach a copy of any material you will use to recruit participants (e.g., advertisements, flyers, telephone scripts, verbal recruitment, cover letters, or follow-up reminders)**

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Describe the recruitment process, including the setting in which recruitment will take place. Explain how the process respects potential participants’ privacy.

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**Section 10: Participant Incentives**

Will you pay participants? □ Yes □ No

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

**Section 11: Informed Consent**

Indicate the consent process(es) and documents(s) to be used in the study. ***Provide copies of documents, as applicable***

□ Informed Consent – Form

□ Informed Consent – Verbal Script/Online/Unsigned

□ Not Applicable (existing data or specimens)

□ Other (Specify): May need to complete IRB Waiver of Informed Consent Form or Waiver of Documentation of Informed Consent Form (found on www.thechristhospital.com/irb)

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Describe the consent process. Explain when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity (e.g. waiting period, if any) to consider participation

□ N/A

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**Section 12: Research Methods and Activities**

Check all research activities that apply: **(Attach a copy of materials to be used)**

□ Audio, video, digital, or image recording □ Record review (may include PHI)

□ Existing data, not publicly available □ Existing data, publicly available

□ Specimen research (must be existing at time of application) □ Internet or email data collection

□ Surveys, questionnaires, or interviews(group) □ Observation of participants

□ Surveys, questionnaires, or interviews(one-on-one) □ Taste tasting

□ Oral history (does not include medical history) □ Focus Group

□ Other (specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Section 13: Privacy of Participants**

Describe the provisions to protect the privacy interests of the participants. *(Consider the circumstances and nature of information to be obtained, taking into account factors (e.g. age, gender, ethnicity, education level, etc.) that may influence participants’ expectations of privacy.*

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Does the research require access to personally identifiable private information? □ Yes □ No

If YES – describe the personally identifiable private information involved in the research. List the information source(s) (e.g., surveys, medical records, educational records, etc.)

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**Section 14: Confidentiality of Data**

Describe the security measures you will take to protect the confidentiality of the information obtained. Will participants be identifiable either by name or through demographic data? If yes, how will you protect the identity of the participants and their responses? Where will the data be stored and how will it be secured? Who will have access to the data? How will identifiers be maintained or destroyed after the study is completed?

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**Section 15: HIPAA Authorization**

Will individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements be accessed, used, or disclosed in the research study?

□ No

□ Yes – Check all that apply:

□ Full Waiver (entire research study) – Complete IRB Full HIPAA Authorization

□ Partial Waiver (recruitment purposes only) – Complete IRB Partial HIPAA form

**Section 16: Complete ONLY if using Exemption Category 4**

Provide a detailed description of the data or specimens and what information will be used

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What is the source of the data or specimens?

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Are the data or specimens publicly available without restriction or password? (that is, can the general public obtain the data or specimens? Data are not considered publicly available if access is limited to researchers) □ Yes □ No

*If yes, please contact the IRB staff for consultations. Your research may not meet the criteria for exemption*

If the data or specimens are not publicly available, how are you obtaining permission to access these or to use them for research purposes? (please attach a copy of the correspondence or agreement granting you permission)

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How will you receive the data or specimens (e.g., electronic files, access to hard copy records at record-holder’s institution, test tube)?

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How are the data or specimens identified when they are made available to you?

□ Direct Identifier (e.g., subject name, address, social security number)

a) will you record any direct identifiers that are available to you? □ \*Yes □ No

b) will you have access to the data from home or office? □ \*Yes □ N

□ Indirect Identifier (e.g. an assigned code that could be used by the investigator or the source providing the data or specimens to identify a subject, such as a pathology

tracking number or a tracking code used by the source).

1. Will you or a team member have access to the data set code key?

□ \*Yes □ No

*(If you will receive data with indirect identifiers only, please contact the IRB staff for consultation. Your research may not be exempt.)*

□ No Identifier (i.e., neither the researcher nor the source providing the data or

specimens can identify a subject based upon information provided with the data

or specimens). *If it will be impossible for anyone to identify subjects based upon*

*information provided with the data or specimens, you will not be conducting research*

*involving human subjects. Complete the “No Humans Designation Form”*

Will any data or specimens be collected from participants after the submission of this application? (Data or specimens are considered to “exist” if ALL the data or specimens to be used for the research have been collected prior to the submission of this application.)

□ **\***Yes □ No

**\*Your research does not qualify for exemption from IRB review under Exemption Category 4.**

**Section 17: Principal Investigator Responsibilities and Assurances**

**The principal investigator undertakes the primary responsibility for protecting the rights and welfare of research participants and must be familiar with the ethical principles of human subject protection requirements of federal regulations, Federal Wide Assurance, and IRB policy and procedures.**

**The principal investigator agrees to:**

1. I will review all protocol submissions in their entirety and be fully cognizant of, and in agreement with, all submitted statements.
2. I am familiar with clinical research regulations and during the conduct of the study I will comply with these regulations.
3. I have read the Belmont Report and understand the three ethical principles; respect for persons, beneficence, and justice. During the conduct of the study I will adhere to these principles.
4. I have adequate resources and facilities to carry out the proposed research projects.
5. I will conduct research in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
   * I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
   * I will request and obtain IRB approval of any proposed modifications to research protocol(s) or informed consent document(s) prior to implementing such modifications.
6. I will ensure that all co-investigators, and other personnel assisting in the conduct of research, have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (d) adverse event reporting requirements; (e) data and record-keeping requirements; and (f) the current IRB approval status of the research study.
7. I will not enroll any individual into a research study: (a) until such a time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of a research study has lapsed; (c) during any period wherein IRB approval of a research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of a research study or following sponsor/principal investigator termination of research study enrollment.
8. In situations in which consent will be obtained from a Legally Authorized Representative (LAR) rather than the subject, I understand the criterion per state or other law that these individuals must meet to consent on behalf of the subject to their participation in the procedures involved in the study.
9. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.
10. I will submit a research study in a timely manner for IRB approval (at least 21 days prior to the scheduled IRB meeting) and will provide progress reports within the established timeframe to avoid study expiration.
11. I will not enroll any individual into a research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).

* I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of the research procedures, and their rights as a research study volunteer.

12. I will ensure that research subjects are kept fully informed of any new information that may affect their

willingness to continue to participate in the research study.

13. I will maintain adequate, current and accurate records of research data, outcomes, and adverse events

to permit an ongoing assessment of the risk/benefit ratio of research study participation.

14. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing

human subject research including adverse event reporting, protocol deviations and violations, subject complaints and conflict of interest.

1. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
2. I will ensure that the conduct of this research study adheres to Good Clinical Practice guidelines.
3. I will ensure that all listed investigators have the appropriate credentials to conduct the portion of the study in which they are involved.
4. The privacy of research subjects and the confidentiality of the study data will be appropriately maintained at my site.
5. I understand that payments in exchange for referrals of potential participants (i.e., finder’s fees) are prohibited by The Christ Hospital.

20. In the event a hospitalized patient is to be asked to participate as a subject of my study, I will inform the patient’s attending physician. Prior to approaching the patient, I will obtain the attending physician’s approval of my requesting the patient’s participation.”

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| **Principal Investigator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**Section 18: Exempt Checklist**

Before submitting to the IRB, please make sure you have the following paperwork completed: All additional forms can be found at www.thechristhospital.com/irb

□ CITI Training Certificate

□ Exempt Study Application

□ Informed Consent, Waiver of Informed Consent or Waiver of Documentation of Informed

Consent

□ Financial Disclosure Form *\*(Everyone listed in the application needs to complete the COI*

*form)\**

□ HIPAA Full Waiver of Authorization, HIPAA Partial Waiver of Authorization, or Non -

Applicable

□ Research Protocol

□ Supporting documents (e.g. surveys, advertisements, flyers, etc.)

**Categories of Exempt Research Activities for Non-FDA Research**

For more information you can go to The Federal Code [45 CFR 46.101] at [www.hhs.gov](http://www.hhs.gov)

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| Category 1 | Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:   1. Research on regular and special education instructional strategies, OR 2. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.   NOTE: Survey and interview procedures with minors are exemptible if the activities fall within this category. |
| Category 2 | Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, UNLESS:   1. The information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; AND 2. Any disclosure of the human participants’ response outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, or reputation.   NOTE: Survey and interview techniques which include minors are not exempt. Observation of the public behavior of minors, if the researcher is not a participant, is exempt. |
| Category 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 Category 2,** if   1. The human participant 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. |
| Category 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 participants cannot be identified directly or through identifiers linked to the participants. |
| Category 5 | Research and demonstration projects which are conducted by or subject to the approval of appropriate Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:   1. Public benefit or service programs; or 2. Procedures for obtaining benefits or services under those programs; or 3. Possible changes in or alternatives to those programs or procedures; or 4. Possible changes in methods or levels of payment for benefits or services under those programs |
| Category 6 | Taste and food quality evaluation and consumer acceptance studies,   1. If 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 sage, or agricultural chemical or environmental contaminant 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. |