The Christ Hospital

IRB Study Application for Full Board Review

IRB Study Number:

Protocol Number:

**Protocol Title**

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**SECTION 1: STUDY PERSONNEL**

**Contact Person for this study:**

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| **Name:**  **Phone:**  **Email:**  **Role in Study:** |

**Principal Investigator**

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| **Name:**  **Department:**  **Address:**  **Phone/Fax/Email:**  **Qualifications to do the research:**  **Do you maintain active TCH Credentials and Privileges?**  **Yes -  No** |

**Sub-Investigator**

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| **Name:**  **Department:**  **Address:**  **Phone/Fax/Email:**  **Role in Study: (specific activities, including obtaining consent)**  **Do you maintain active TCH Credentials and Privileges?**  **Yes -  No** |

**Sub-Investigator**

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| **Name:**  **Department:**  **Address:**  **Phone/Fax/Email:**  **Role in Study: (specific activities, including obtaining consent)**  **Do you maintain active TCH Credentials and Privileges?**  **Yes -  No** |

**Sub-Investigator**

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| **Name:**  **Department:**  **Address:**  **Phone/Fax/Email:**  **Role in Study: (specific activities, including obtaining consent)**  **Do you maintain active TCH Credentials and Privileges?**  **Yes -  No** |

**Other Personnel**

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

**Other Personnel**

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

**SECTION 2: CONFLICTS OF INTEREST**

Does the research study have a Sponsor?  Yes -  No

Has ANY PI, sub-investigator or research staff involved in this study (or in aggregate with his/her spouse,

dependents, or members of his/her household):

|  |  |
| --- | --- |
| **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.) |

Note: 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**

**Type of funding?**

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

**SECTION 4: HUMAN RESEARCH PROTECTION**

**1. Describe how you will ensure that all study personnel is adequately informed and trained about the protocol and their research-related duties.**

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**2. Describe any facilities (the setting in which the research is going to take place) and justify that the facilities are adequate. (NOTE: If the study is conducted off site, please attach a letter of permission.)**

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**SECTION 5: STUDY DESCRIPTION**

**Use lay-language…avoid acronyms or technical jargon.**

**1. What is the purpose, design and rationale of your study?**

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**2. Identify inclusion and exclusion criteria for the study:**

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| **Inclusion criteria:** |

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| **Exclusion criteria:** |

**3. List all primary related tests, procedures and interventions from screening to closeout, which the human subjects must undergo in the research.**

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| **Test-Intervention-Procedure** | **Only conducted for research purposes** |  |
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**4. What research methods will you use? Give a brief non-technical explanation. Include study design, statistical analysis methods, sample size, and power analysis.**

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**5. Describe your plan for voluntary and involuntary withdrawal of human subjects in the study?**

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**SECTION 6: BENEFITS**

**1. What direct benefits do you expect the human subjects you enroll to get from this study? If there is no direct benefit to the subjects, simply state that there will be no benefit to the human subjects enrolled.**

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**2. As the investigator, what is your analysis of the potential risk versus potential benefit to participating in this study? Justify the risk in terms of the potential scientific yield in relation to the anticipated benefits to the human subjects.**

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**SECTION 7: RISKS**

**1. Describe in detail, with supporting evidence from animal studies if available, the possible effects, discomforts and risks. The risks and harms must be disclosed in the consent form.** *Note:**If subject is of child-bearing potential and is or may become pregnant, address whether or not the investigational drug, treatment or procedure may involve unforeseeable risks to the subject (or to the embryo or fetus). Include method of pregnancy test (TCH IRB requires serum pregnancy test) and indicate that the contraceptive options will be discussed and approved by the investigator. If applicable, also include reference to risk regarding sperm production or alteration.*

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**2. Describe how the risks to human subjects are minimized (e.g. screening to ensure appropriate selection of subjects, identifying standards of care procedures, sound research design, safety monitoring, and reporting).**

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**3. For drug studies, provide a brief explanation of methods used to determine dosing, expected maximum dosage, and duration of exposure to the drug. This should include measurements taken to monitor test articles’ effects and minimize the risks to human subjects.**

**N/A**

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**SECTION 8: BIOLOGICAL SPECIMENS (BLOOD, TISSUE, URINE, SPECIMEN)**

**1. Are biological (blood, tissue, urine, specimen) samples collected?**

**No, skip this section and go to Section 9**

**Yes**

**2. List biological (blood, tissue, urine, specimen) samples to be collected:**

1.       2.       3.

4.

**3. Are any biological samples to be collected for genetic or unspecified use?**

**No, skip #4**

**Yes – explain in box below**

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**4. List biological samples to be collected for genetic or unspecified use:**

1.       2.       3.

4.

|  |  |
| --- | --- |
| Does the research involve genetic testing? | Yes  No  N/A |
| Will samples be made anonymous to maintain confidentiality? | Yes  No  N/A |
| Will samples be destroyed after a specified one time use? | Yes  No  N/A |
| Will the privacy and confidentiality of the subject be adequately protected? | Yes  No  N/A |
| Will the donor be informed of any and all results obtained by his/her DNA? | Yes  No  N/A |
| Will the donor be informed of the results of the sample testing? | Yes  No  N/A |
| Have measures been taken to minimize the potential for psychological, social, and/or physical harm from participating in this aspect of the research? | Yes  No  N/A |

**3. How are the biological specimens stored and by whom?**

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**SECTION 9: HUMAN SUBJECT PARTICIPANT INFORMATION**

**1. How many human subjects do you expect to enroll at TCH and other sites?**

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**2. Please describe the study population(s), if you are targeting a specific ethnic group and age ranges of human subjects to be enrolled?**

**N/A**

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**3. Justify any exclusionary criteria specific to gender, age, and racial or ethnic groups.**

**N/A**

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**4. Are any of the vulnerable populations below going to be enrolled in this study (i.e. target population)?**

**N/A**

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| --- | --- |
| Individuals with diminished mental/physical capacity | Pregnant women |
| Fetuses | Economically/educationally disadvantaged persons |

**5. If vulnerable populations will be enrolled, please provide a description of the special considerations/steps/safeguards that will be taken to ensure that the vulnerable populations will be adequately protected (i.e. utilizing an interpreter, LAR, etc.).**

**N/A**

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**6. What is your justification for using the vulnerable population?**

**N/A**

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**SECTION 10: INFORMED CONSENT**

**1. Check all that apply**

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| --- | --- |
| **Adults** | **Parental** |
| Informed Consent | Parental Informed Consent |
| Waiver of Documentation of Informed Consent |  |
| Waiver of the Process of Informed Consent |  |

**If any of the above are checked, attach appropriate informed consents or waiver forms.**

**SECTION 11: OBTAINING INFORMED CONSENT**

**1. Explain in detail when and where the human subject/LAR will be approached to obtain informed consent (e.g. clinic waiting room, private room, by mail, etc.). List who will be obtaining consent (principal investigator, sub-investigator, study nurse, etc.).**

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**2. Explain why informed consent will not be obtained.**

**N/A**

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**3. Explain in detail how much time you will give the human subject to consider participation in the study.**

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**4. Explain the steps you will take to minimize coercion and undue influence.**

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**5. Will you obtain consent from each prospective human subject or the human subject’s LAR?**

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**6. Explain how consent will be handled when a human subject’s decision-making capacity is in question. Include the assessment tool (which needs to be approved by the IRB prior to initiation of study) and description of how you will assess people to determine their decision making capacity and then plan consent, appropriate assent, and LAR consent based on the assessment process.**

**N/A**

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**7. Explain how you will determine whether the human subject/ LAR understands the information that was provided in the informed consent document.**

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**SECTION 12: HIPAA**

**If you are collecting PHI (see below for PHI), HIPAA authorizations or waivers may be appropriate.**

**1. Check PHI you are collecting, check all that apply.**

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| --- | --- | --- | --- |
| Not known at this time | Names/Initials | Phone numbers, Fax numbers, Electronic Mail Addresses | Social Security numbers |
| Medical Record Numbers | Geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code | Elements of dates (except year) for dates related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) | Health plan beneficiary numbers; Account numbers; Certificate/license numbers |
| Device identifiers and serial numbers |  |  |  |

**2. Does your study require HIPAA authorizations or Waivers?**

**N/A (skip this section and go to Section 13)**

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| Full Waiver of Authorization  Usually used for retrospective chart abstraction. (attach form) | Partial Waiver of Authorization  Used for recruiting, screening and enrolling. (attach form) |

**SECTION 13: PROJECT INFORMATION**

**1. Will subjects be recruited or data collected at an external site(s)?  No**  **Yes** (Fill out section below)

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| List each site and include a letter or email giving you permission.  Name of external site:  Address of external site:  If more than one site, list below: | Does this site have an IRB?  No  Yes, they have an IRB and I have applied, or I am in the process of applying for approval.  Yes, they have an IRB but are willing to accept  The Christ Hospital’s IRB approval.  Name and phone number of IRB: |

**2. Is this a multicenter study?**

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| **No**  **Yes**  **Are you the lead investigator?**  **No: (skip the remainder of these questions and go to section 14)**  **Yes**  **If you answered Yes to being a lead investigator of a multicenter study; explain how you plan to coordinate and manage information, (such as: Unanticipated problems involving risks to participants or others, interim results, protocol modifications)**  **Explanation:**  **(If you need assistance call the IRB Office)** |

**SECTION 14: OVERSIGHT AND MONITORING**

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| **The IRB requires a data and safety monitoring plan (DSMP) for all studies greater than minimal risk.**   * **For externally-sponsored studies, the DSMP is normally incorporated into the protocol.** * **For an investigator-sponsored study greater than minimal risk, the principal investigator is responsible for creating and implementing a data and safety monitoring plan (DSMP).** * **A DSMP is not required for minimal risk protocol** * **The IRB will review the proposed level of risk and data safety and monitoring plan and will accept or amend the DSMP.** |

**1. Provide a plan for data safety monitoring. Indicate if there is a safety monitoring plan in the protocol, how the data will be monitored, how often, and how reports will be routed to the investigator and the IRB. If there is no DSMB, explain why there isn’t one.**

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**2. Indicate, if applicable, whether medical or psychological resources will be made available to participants after their completion of the study, if the research produces consequences in which these services are required.**

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**3. How are serious adverse events defined by the study protocol and what are the reporting requirements as dictated by the protocol?**

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**SECTION 15: PRIVACY, CONFIDENTIALITY, AND PROTECTION OF THE DATA**

**1. Describe procedures used to protect the privacy of human subjects: (This is about the subject’s privacy…not about the data.)**

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**2. How will paper documents that contain private information be stored to ensure confidentiality?**

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**3. How will the confidentiality of electronic documents that contain private information be ensured?**

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**4. Will data identifying the human subjects be made available to anyone other than the PI, (e.g. study sponsor, NIH, DHHS)?**

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| **No  Yes**    **If yes, explain:** |

**5. Will identifiers be maintained?**

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| **No  Yes**    **If yes, explain:** |

**6. Who will have access to the identifiers and who will keep the link?**

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**7. Describe how you plan on protecting the confidentiality of data.**

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**8. Explain how the data will be collected, analyzed, coded, transmitted to others, and kept secure.**

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**9. How will research data be stored and ultimately disposed of to ensure confidentiality?**

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| **Please list address:** |

**SECTION 16: HUMAN SUBJECT RECRUITMENT INFORMATION**

**1. Indicate which, if any, recruiting methods you will use. Please note that ALL planned recruitment activities/materials must be reviewed and approved by the IRB prior to engaging in any recruitment activities. Check all that apply:**

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| --- | --- | --- | --- | --- |
| **No advertisements will be used** | **E-mail** | **Poster** | **Mailings** | **Other: (list)** |

**2. How will human subjects be identified and recruited (e.g. chart review, referral from treating MD, responses to ad). *Note: You must include all recruitment, announcements, and invites with your IRB application.***

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**3. Describe your screening procedures, including how qualifying lab values will be obtained. If you are collecting PHI prior to enrollment (e.g. telephone screening, chart reviewing) you will need to request a HIPAA partial waiver. See Section 12.**

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**4. Subject compensation: Check all that apply.**

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| **No compensation** |  |
| **Cash** | **Amount and distribution:** |
| **Gift cards** | **Amount and distribution:** |
| **Other: explain** | **Amount and distribution:** |

**SECTION 17: INVESTIGATIONAL DRUGS OR DEVICES**

**This section must be completed if you are engaged in a study involving an FDA-regulated project. Pursuant to FDA guidance, unless a waiver of an Investigational New Drug (IND) or Investigational Device Exemption (IDE) is granted by the FDA, an IND/IDE is required.**

**1. Is this an FDA-regulated study?  Yes  No, skip to Section 18**

**2. Please check all that apply**

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| --- | --- |
| **Drug**  **Drug Name and Manufacturer:**  **IND #**  **-or-**  **Does not require IND:**  **Explain why:** | **Device**  **Device Model and Manufacturer:**  **IDE #**  **-or-**  **Does not require IDE because it involves a non-significant risk (NSR) device.** |

**3. Describe your inventory controls for storage, monitoring, and dispensing of study drugs or devices.**

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| **How will you store the drug or device:** |
| **How will you control the drug or device:** |
| **Describe how you will dispense the drug or device (include any other staff that has this responsibility):** |

**4. If the investigator holds the IND or IDE, what is your plan for holding the IND or IDE?**

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**5. What are the non-research alternatives to the research interventions or treatments?**

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**6. Will device be billed to human subject or their insurance?**

**Yes**

**No**

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| **Explain:** |

**SECTION 18: 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 19: SUB-SPECIALTY HEAD/DEPARTMENT CHAIR ASSURANCES:**

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| ***Note: Sub-Specialty Head must review and sign this document. If the Principal Investigator is the Sub-Specialty Head, the Department Chair must review and sign instead.***  **By signing below, I attest that I reviewed the above application and find the research is scientifically and scholarly sound and that competencies and resources are adequate.**  **The responsibilities of the Sub-Specialty Head/Department Chair are to:**   * **Confirm the competency of the researcher(s) to conduct this research and protect participants** * **Confirm that the researcher(s) has:**   + 1. **The resources needed to protect research participants and adequately pursue and complete the project**     2. **Access to a population that will allow recruitment of the required number of participants within the proposed recruitment period.**     3. **Sufficient time to conduct and complete the research within the agreed research period.**     4. **Adequate numbers of qualified staff for the foreseen duration of the research**     5. **Adequate facilities for the foreseen duration of the research**     6. **A process to ensure that all persons assisting with the research are adequately informed about the protocol and their research-related duties and functions**     7. **Availability of medical or psychological resources that participants might require as a consequence of the research.** * **Confirm that the research has scientific merit**   + 1. **The research uses procedures consistent with sound research design and**   **Which do not unnecessarily expose participants to risk**   * + 1. **The research is designed to answer the proposed question**     2. **The knowledge reasonably expected to result from the research has importance.**   **Department Name:**        **Sub-Specialty Head Name:**        **E-Mail Address:**    **Phone Number:**    **Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |