|  |  |
| --- | --- |
| Institutional Review Board | New Protocol Submission Application  -Reliance Agreement- |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Section 1: Protocol Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| IRB # | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | |
| Protocol Title | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Sponsor | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Sponsor Protocol # | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | |
| Protocol Version/Date | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | |
| Expected Duration of Research | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | |
| **Section 2: Reviewing IRB Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of reviewing IRB- | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| FWA# | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| **Section 3: Contact Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Site Principal Investigator (PI) | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | |
| PI Phone Number | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| PI Email | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Sub-Investigators | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Other Key Research Personnel (include role in study) | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| Regulatory Contact (RC) Name | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | |
| RC Phone number | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | |
| RC Email | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| **Section 4: Site Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| The study will be performed at the following research location(s)- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| **Section 5: Departmental Clearance** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Which area of TCCHN will the research mainly take place? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | |
| Is this a drug study? | | | | | Choose an item. | | | | | | | | | | If yes, does sponsor provide study drug? | | | | | | | | | | Choose an item. | |
| Will you be utilizing the TCH pharmacy for storage and/or dispensing of the study drug(s)? | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | |
| **Section 6: Education and Credentials** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Have all key research personnel completed their mandatory CITI modules within the last 3 years? | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| Do all investigators maintain active TCH credentials and privileges? | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | |
| **Section 7. Conflict of Interest** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Have any key research personnel disclosed any potential COI by checking YES on their individual Disclosure of Financial Interest forms? | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | |
| If yes, list a detailed description of said conflict from their individual Disclosure of Financial Interest form- | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | |
| **Section 8. Qualifications of Site Principal Investigator (PI)** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Has the PI or any of the Sub-Investigator(s) been audited by the FDA or the Office for Human Research Protections (OHRP) in the past 5 years? | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Has the PI or any of the Sub-Investigator(s) had a sponsor, CRO, or an IRB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol? | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Has the PI or any of the Sub-Investigator(s) had the FDA or OHRP terminate a study? | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| If yes answered to any of the above, submit a detailed description- | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| How many years has the PI been involved in the conduct of research? | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| What is the current number of research studies supervised by the PI?- | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| How many sub-investigators with clinical trials experience are assisting the PI? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| How many research staff members with clinical trials experience are assisting the PI? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| Specialty of the PI | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| **Section 9: Study Description** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Provide a description of the study- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| Are there any research procedures that will not be performed as described in the protocol? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | |
| If Yes- | Please describe how this institution will deviate from the protocol: | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | |
| **Section 10: Funding Information** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Source of Funding- | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | |
| Sponsor name and address, if applicable- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | |
| **Section 11: Drug Studies** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is this a drug trial? | | | | | **YES**- Complete the rest of the section  **NO**- Stop and Move to Section 11 | | | | | | | | | | | | | | | | | | | | | |
| Drug Name- | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Drug Strength- | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Drug Route- | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Drug Manufacturer- | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Type of Drug Trial- | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | |
|  | | | | | \*If Placebo checked, provide rationale for use of placebo- | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | |
| If an investigational New Drug or Investigational Use of Marketed Drug, has an IND been applied for? | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| If Yes- | Who holds the IND- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | |
| Provide the IND#- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | |
| If Phase I or II study, provide the date of IND submission to FDA- | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | |
| If No- | If an IND has not been applied for, confirm that this study is exempt from IND regulations and satisfies all criteria of 21 CFR312.2- | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | |
| Where will the drug be stored? | | | | | | | | | | | | | | Choose an item. | | | | | \*For Other, explain- | | | | | | Click or tap here to enter text. | |
| How will the drug be dispensed? | | | | | | | | | | | | | | Choose an item. | | | | | \*For Other, explain- | | | | | | Click or tap here to enter text. | |
| How will the drug be stored? | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | |
| How will you control the use? | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | |
| Explain methods used to determine dosing, expected maximum dosage, and duration of exposure to the drug. Include measurements taken to monitor effects and minimize risks to human participants | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| Will the cost of the drug be billed to participants? | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | |
| **Section 12: Device Studies** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is this a device trial? | | | | | **YES**- Complete the rest of the section  **NO**- Stop and Move to Section 12 | | | | | | | | | | | | | | | | | | | | | |
| Device Name- | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Manufacturer- | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | |
| Does the device have an IDE# | | | | | | | | | | | | | | Choose an item. | | | | | If yes, provide IDE#- *(must submit FDA approval letter)* | | | | | | Click or tap here to enter text. | |
| Risk Classification- | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | |
| Provide rationale for risk classification- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | |
| Where will the device be stored? | | | | | | | | | | | Choose an item. | | | | | | | \*For Other, explain- | | | | | | | | Click or tap here to enter text. |
| How will the device be stored? | | | | | | | | | | | Choose an item. | | | | | | | \*For Other, explain- | | | | | | | | Click or tap here to enter text. |
| How will you control the use? | | | | | | | | | | | Choose an item. | | | | | | | \*For Other, explain- | | | | | | | | Click or tap here to enter text. |
| Is this an HUD/HDE device? | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | |
| Will the cost of the device be billed to participants? | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | |
| **Section 13: Study Recruitment** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| What is the protocol sample size[[1]](#footnote-1)? | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Is this a multi-center trial? | | | | | Choose an item. | | | | | | | | | | If yes, how many subjects will be enrolled at TCH? | | | | | | | | | | Click or tap here to enter text. | |
| Indicate an age range to be included in the study? | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | |
| Will you target and/or include a vulnerable population? | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | |
| If yes- | | Check all that apply- | | | | Children | | | | | | | | | | | | | | | | | Economically Disadvantaged | | | |
| Physically Impaired | | | | | | | | | | | | | | | | | Mentally Disabled/Cognitively Impaired | | | |
| Educationally Disadvantaged | | | | | | | | | | | | | | | | | Non-English Speaking | | | |
| Employees | | | | | | | | | | | | | | | | | Pregnant Women | | | |
| Nursing Home Residents | | | | | | | | | | | | | | | | |  | | | |
| Other: Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | |
| **Section 15- Waivers** | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Will your project involve the use of Protected Health Information (PHI)? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| Will the reviewing IRB or TCH serve as the Privacy Board? | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| If TCH- | | | Are you requesting a HIPAA Full[[2]](#footnote-2) or Partial[[3]](#footnote-3) Waiver of Authorization? | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| Which Waiver of Authorization are you requesting? | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| List all PHI for which you are seeking an authorization (check all that apply)- | | | | | | | | | | | | | | Names  Street Address, city, precinct, zip code  Dates directly related to an individual, including birth date, admission date, discharge date, date of death  Telephone phone numbers, fax numbers, email addresses  Social Security Numbers  Medical Record Numbers  Health Plan Beneficiary Numbers  Account Numbers  Certificate/license numbers  Vehicle identifiers and serial numbers, including license plate numbers  Device identifiers and serial numbers  Web Universal Resource Locators (URLs)  Biometric Identifiers, including finger on voice prints  Full Face Photographic images or any comparable images  Any other unique identifying number, characteristic, or code | | | | | | | | | |
| Explain why this PHI is the minimum necessary[[4]](#footnote-4) to accomplish the research objectives- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |
| What is the plan to protect subjects from improper use/disclosure of their identifiers? | | | | | | | | | | | | | | Confidentiality agreements with study staff  Policies and procedures relating to privacy and confidentiality  Initial and continuing staff education on the HIPAA Privacy Rule and/or subject privacy & confidentiality  Other: Click or tap here to enter text. | | | | | | | | | |
| When and how will identifiers of subjects be destroyed[[5]](#footnote-5)? | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |
| What steps have been taken to ensure that PHI will not be used reused or disclosed to any other person or entity? Choose one or more from the following- | | | | | | | | | | | | | | Limited access to individuals who need to know the information. Explain how this is accomplished: Click or tap here to enter text. | | | | | | | | | |
| Electronic safeguards (e.g. password protection) where only study staff has access to electronic study information. Describe these safeguards: Click or tap here to enter text. | | | | | | | | | |
| Physical safeguards (e.g. locked cabinets) where only study staff has access to areas with study information. Describe the safeguards in place: Click or tap here to enter text. | | | | | | | | | |
| Other: Click or tap here to enter text. | | | | | | | | | |
|  | | | Explain why it is not practicable to conduct the study without access and use of PHI- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |
| Explain why it is not practicable to conduct the study without a waiver of authorization- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |
| Describe your plan to safeguard the PHI- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |
| Describe your plan to protect the PHI from improper use and disclosure- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |
| How will you destroy PHI of individuals who do not authorize use and disclosure of their PHI? | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |
| Describe the expiration of the waiver authorization, such as expiration date or end of the research study- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | |

|  |  |
| --- | --- |
| Section 24: PRINCIPAL INVESTIGATOR ASSURANCE AND RESPONSIBILITIES | |
| A Principal Investigator (PI) is the primary individual responsible for the preparation, conduct, and administration of research study in compliance with applicable laws and regulations and institutional policy governing the conduct of research. The PI 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.  **As principal investigator, you must agree to:**   1. Review protocol submissions in their entirety and be fully cognizant of, and in agreement with, all submitted statements. 2. Be familiar with clinical research regulations and during the conduct of the study comply with these regulations. 3. Read the Belmont Report and understand the three ethical principles; respect for persons, beneficence, and justice, and adhere to these principles during the conduct of the study in adherence to these principles. 4. Have adequate resources and facilities are available to carry out the proposed research projects. 5. Identify and disclose financial interests according to organizational policies and regulatory requirements and, with the Organization, manage, minimize, or eliminate financial conflicts of interest. 6. 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. 7. Notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject. 8. Request and obtain IRB approval of any proposed modifications to research protocol(s) or informed consent document(s) prior to implementing such modifications. 9. 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. 10. 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. 11. In situations in which consent will be obtained from a Legally Authorized Representative (LAR) rather than the subject, 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. 12. Respond promptly to all requests for information or materials solicited by the IRB or IRB Office. 13. Submit continuing reviews (for applicable research) for IRB review and approval within the established timeframe listed on the study approval letter to avoid study expiration. 14. Recruit participants in a fair and equitable manner. 15. Agree not to enroll any individual into a research study until such time his/her written informed consent is obtained, or, if applicable, the written informed consent of his/her authorized representative, except in instances that the IRB has granted a waiver of the requirement to obtain written informed consent. 16. 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. 17. 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. 18. 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. 19. Be cognizant of, and 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. 20. 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. 21. Ensure that the conduct of this research study adheres to Good Clinical Practice guidelines. 22. Ensure that all listed investigators have the appropriate credentials to conduct the portion of the study in which they are involved. 23. Ensure that the privacy of research subjects and the confidentiality of the study data will be appropriately maintained at the study site. 24. Understand that payments in exchange for referrals of potential participants (i.e., finder’s fees) are prohibited by The Christ Hospital. 25. Inform and obtain approval of the attending physician prior to approaching and seeking enrollment of a hospitalized patient.   By signing below, I attest that I have reviewed the submission and confirm to the above terms. | |
| Principal Investigator Signature: | Date: |
| Principal Investigator Name (Printed): | |

|  |  |
| --- | --- |
| Section 25: DEPARTMENT ASSURANCE | |
| Your department has been designated as the principal area in which the conduct of this research study will take place. For institutional oversight and protection of human subjects involved in research within TCHHN, it is necessary for your review of the submission and confirmation that the research is scientifically and scholarly sound and that competencies and resources within your department are adequate before this research can commence. | |
| **As department head, you must agree that:**  1. the principal investigator is competent to conduct this research and protect participants.  2. the principal investigator has:  a. the resources needed to protect research participants and adequately pursue and complete the  project,  b. access to a population that will allow recruitment of the required number of participants within  the proposed recruitment period,  c. sufficient time to conduct and complete the research within the agreed research period,  d. adequate numbers of qualified staff for the foreseen duration of the research,  e. a process to ensure that all persons assisting with the research are adequately informed about  the protocol and their research-related duties and functions, and  f. access to provide medical or psychologic resources that participants might require as a  consequence of their participation in the research.  3. the research has scientific merit and:  a. uses procedures consistent with sound research design and which do not unnecessarily expose  participants to risk,  b. is designed to answer the proposed question, and  c. the knowledge reasonable expected to result from the research has importance.  By signing below, I attest that I have reviewed the submission and confirm to the above terms. I find that the research is scientifically and scholarly sound and that competencies and resources are adequate. | |
| Department Head Signature: | Date: |
| Department Head Name (Printed): | |

|  |  |  |
| --- | --- | --- |
| Section 26: PHARMACY REVIEW (for drug studies) | | |
| Your department has been designated as the principal area in which the conduct of a research study will take place. For institutional oversight and protection of human subjects involved in research within TCHHN, it is necessary for your review of the submission and confirmation that competencies and resources within your department are adequate before this research can commence.  By signing below, I attest that I have reviewed the submission and confirm that competencies and resources are adequate within my department. | | |
| Pharmacy Director Signature: | | Date: |
| Pharmacy Director Name (Printed): | Justin Gamble, PharmD | |

1. For sponsored studies this is the number of subjects involved across all research sites; for TCH PI-initiated studies, this number should include attrition for withdraws, screen fails, etc. For survey/questionnaire studies, this number should include the total number of surveys/questionnaires being sent electronically to potential patients. For retrospective chart reviews, this number should be the total number of charts to be reviewed. Please note: The protocol sample size must be explained in the protocol. [↑](#footnote-ref-1)
2. For Retrospective Chart Abstraction Research Studies [↑](#footnote-ref-2)
3. For Purposes of Patient Recruitment into Research Studies. The HIPAA Privacy Rule establishes the conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes, without specific patient authorization. In order to recruit individuals into research studies using PHI from The Christ Hospital, and contact the patient to seek informed consent and authorization for use and disclosure of PHI, the principal researcher must obtain partial waiver to Individual Authorization from the IRB. [↑](#footnote-ref-3)
4. Under federal regulations, investigators may obtain only the minimum necessary PHI to achieve the goals of the research. [↑](#footnote-ref-4)
5. Identifiers must be destroyed at the earliest opportunity. [↑](#footnote-ref-5)