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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **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. | | | | | | | | | | | | | | | | | | | | |
| Is the IRB accredited? | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | |
| IRB Contact name- | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | |
| IRB Contact phone- | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | |
| IRB Contact email- | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | |
| **Section 3: Contact Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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. | | | | | | | | | | | | | | | | | | | | | | | | |
| 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. | | | | | | | | | | | | | | |
| Justify why the research location(s) is adequate for the conduct of your research- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Describe any facilities (the setting in which the research will take place) and justify that the facilities are adequate. | | | | | | | | | | | | | | | 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 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** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| What is the purpose, design, and rationale for the study? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| List all inclusion criteria- | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | |
| List all exclusion criteria- | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | |
| Justify any exclusionary criteria specific to gender, age, and racial or ethnic groups- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Does the study involve study-related tests, procedures, and interventions? | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
| If yes, List all study-related tests, procedures, and interventions and their corresponding visit schedule- | | | | | | | | | | |  |  |  | | --- | --- | --- | | Test, Intervention, or Procedure | Only Conducted for Research Purposes | Schedule / Visit | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | Click or tap here to enter text. | Choose an item. | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | |
| **Section 10: Study Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Type of Study (check all that apply)- | | | | | | | | | | | | | | Prospective | | | | | | | | | Double-blind | | | | | | Chart Review |
| Retrospective | | | | | | | | | Single Blind | | | | | | Database Search |
| Outpatient | | | | | | | | | Open-Label | | | | | | Cross-sectional |
| Inpatient | | | | | | | | | Placebo Control | | | | | | Questionnaire/Survey |
| Phase of study- | | | | | Phase I -  Phase II -  Phase III -  Phase IV -  Not Applicable | | | | | | | | | | | | | | | | | | | | | | | | |
| Is this study FDA Regulated? | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | |
| Source of Funding- | | | | | Choose an item. | | | | | | | | | | | | | | | | | | | | | | | | |
| Sponsor name and address- | | | | | | | | | | 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: Sub-Study** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is there a Sub-Study? | | | | | | **YES**- Complete the rest of the section  **NO**- Stop and Move to Section 13 | | | | | | | | | | | | | | | | | | | | | | | |
| Check all that apply- | | | | | | Optional | | | | | | | | | | | | | | | | | | | | Mandatory | | | |
| Pharmacogenetics | | | | | | | | | | | | | | | | | | | | Pharmacokinetics | | | |
| Biorepository | | | | | | | | | | | | | | | | | | | | Data Repository | | | |
| Identifiable | | | | | | | | | | | | | | | | | | | | De-Identifiable | | | |
| Single-coded | | | | | | | | | | | | | | | | | | | |  | | | |
| Other: Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | |
| Is it part of the main protocol? | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | | | | |
| **Section 14: 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. | | | | | | | | | | | | | | | | | | | | | | | |
| Describe plan for how subjects will be recruited- | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | |
| Recruitment Materials (check all that apply)- | | | | | Media Advertisements | | | | | | | | | | | | | | | | | | | | | Subject Programs | | | |
| Website Advertisements | | | | | | | | | | | | | | | | | | | | | Generic pre-screening informed consents | | | |
| Subject Letters | | | | | | | | | | | | | | | | | | | | | Not applicable | | | |
| Newsletters | | | | | | | | | | | | | | | | | | | | | Pre-screening scripts | | | |
| Telephone Scripts | | | | | | | | | | | | | | | | | | | | |  | | | |
| Other: Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Related Materials (check all that apply)- | | | | | Diaries | | | | | | | | | | | | | | | | | | | Not applicable | | | | | |
| Subject Questionnaires | | | | | | | | | | | | | | | | | | | Brochures | | | | | |
| Other: Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | |
| Referral fees- | | | | | I confirm that this site will not pay referral fees (finder’s fees) for referrals of research subjects without board approval. | | | | | | | | | | | | | | | | | | | | | | | | |
| **Section 15- Waivers** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Will your project involve the use of Protected Health Information (PHI)? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| Are you requesting a HIPAA Full[[2]](#footnote-2) or Partial[[3]](#footnote-3) Waiver of Authorization? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| If yes- | | | 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. | | | | | | | | | | | |

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)