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| --- | --- |
| Institutional Review Board | New Protocol Submission Application  -Expedited- |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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: 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. | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 3: Site Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| The study will be performed at the following investigational/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. *NOTE: If the study is conducted off site, please attach a letter of permission.-* | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| **Section 4: 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 5: 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 6. 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 7. 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  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 8. 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. | | | | | | | | | | | | | | | | | | | | | | | | |
| List research methods that will be used. Include study design, statistical analysis methods, sample size, and power analysis- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| Describe plan for voluntary and involuntary withdrawal of participants from the study- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| Describe how all study personnel is adequately informed and trained about the protocol, including their research-related duties- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| **Section 9: 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 10: 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 11: 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 12: 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 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. | | | | | | | | | | | | | | | | | | | | | | | | | |
| Describe safeguards implemented to protect this vulnerable population- | | | | | | | | | | | | | | | | | | | 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 14: Privacy** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Explain how the confidentiality and security of study records will be maintained (check all that apply)- | | | | | | | | | | | | | | | | | | Paper-based records will be kept in a secure location only accessible to authorized staff  Computer-based files will be available only to authorized staff using access privileges and passwords  De-identified subject information  Limited data set  Other: Click or tap here to enter text.  Not applicable | | | | | | | | | | | | | | |
| Explain how the privacy of subjects will be maintained during study visits? | | | | | | | | | | | | | | | | | | N/A Chart review  Private room for health-related questions  Other: Click or tap here to enter text. | | | | | | | | | | | | | | |
| Will data identifying the human subjects be made available to anyone other than the PI, (e.g. study sponsor, NIH, DHHS)? | | | | | | | | | | | | | | | | | | Choose an item.  If yes, Explain- Click or tap here to enter text. | | | | | | | | | | | | | | |
| Will identifiers be maintained? | | | | | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
| If yes- | | | Who will have access to the identifiers? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Who will keep the link? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| How will research data be stored and ultimately disposed of to ensure confidentiality? | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Will information from the medical record of anyone other than the subject be collected (i.e. maternal data for neonate studies or infant data for a study involving the mother?)- | | | | | | | | | | | | | | | | | | Choose an item.  If yes, Explain- Click or tap here to enter text. | | | | | | | | | | | | | | |
| **Section 15- HIPAA** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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. | | | | | | | | | | | | | | |
| Are you requesting a Waiver or Alteration of Informed Consent[[6]](#footnote-6)? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| If yes- | | | | Describe why the research involves no more than minimal risk to subject- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Describe why the waiver or alteration will not adversely affect the rights and welfare of the subjects- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Describe why the research could not practicably be carried out without the waiver or alteration of informed consent- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Is the research team collecting identifiable private information and/or identifiable biospecimens?- | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
| If yes- | | | Explain why the research could not practicably be carried out without using such information or biospecimens in an identifiable format- | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Do you expect that additional pertinent information will become available during or after the research? - | | | | | | | | | | | | | | Choose an item. | | | | | | | | | | | | | | |
| If yes- | | | How will information be provided to participants? | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Are you requesting a Waiver of Documentation of Informed Consent[[7]](#footnote-7)? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| If yes,  check either A, B, or C and explain why the research meets the condition in the space provided. | | | | A. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. *(Permissible for non-FDA regulated research only.)* | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| B. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| C. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained. *(Permissible for non-FDA regulated research only.)* | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| Describe plans, if any, that you have for providing subjects with a written statement regarding the research- | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | |
| **Section 16- Informed Consent and Authorization** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Who is authorized to conduct informed consent discussions with subjects for this study? Check all that apply- | | | | | | | | | | | | | | | | | | Principal Investigator  Sub-investigator  Research Coordinators  Research Nurse  Research Assistant  Other: Click or tap here to enter text. | | | | | | | | | | | | | | |
| What education related to informed consent will be provided to the individuals above for the purposes of this study? Check all that apply- | | | | | | | | | | | | | | | | | | Job Orientation  Role Play  In-house Education  Education provided by Sponsor/CRO  Knowledge of Protocol  Other: Click or tap here to enter text. | | | | | | | | | | | | | | |
| Explain in detail when and where the human subject will be approached to obtain informed consent- | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | |
| Explain in detail how much time you will give the human subject to consider participation in the study- | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | |
| Explain how you will determine whether the human subject understands the information that was provided in the informed consent document- | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | |
| Explain the steps you will take to minimize coercion and undue influence- | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | |
| Explain how consent will be handled when a human subject’s decision-making capacity is in question- | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | |
| Do you plan to consent/enroll non-English speaking subjects? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | |
| If yes- | | | | What language? | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| Who will be responsible for obtaining translations? | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| Who will be obtaining informed consent for the subjects? | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| Are you requesting to enroll subjects utilizing legally authorized representatives? | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. |
| If yes- | | | | Which individuals will you allow to give consent (e.g., durable power of attorney for health care, spouse, legal guardian, etc.)? | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| How will you verify what constitutes a LAR? | | | | | | | | | | | | | | | Legal Counsel  Sponsor  CRO  Other: Click or tap here to enter text. | | | | | | | | | | | | | |
| Explain why it is not practicable to conduct the study without the use of LARs- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| **Section 17- Biological Specimens** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Will biological samples, such as blood, tissue, urine or specimens, be collected?- | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| If yes- | | | | Check all that apply- | | | | | | | | | | | Blood  Tissue  Urine  Specimen | | | | | | | | | | | | | | | | | |
| Explain the purpose for collecting these biological samples | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| Will sample(s) be destroyed after a specified one-time use? | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Will participant be informed of results of the sample testing? | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| If yes- | | | Are any biological samples to be collected for genetic or unspecified future? | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| If yes- | | | Check all that apply- | | | | | | | | | Blood  Tissue  Urine  Specimen | | | | | | | | | | | | | |
| Name and address of storage facility- | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| Purpose for collecting samples- | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| Will samples be destroyed after a specified one-time use? | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Will the participant be informed of the results of the sample testing? | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Will the donor be informed of any results obtained by their DNA? | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Will the sample be made anonymous to maintain confidentiality? | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Will the privacy and confidentiality of the subject be adequately protected? | | | | | | | | | | | | | | | | | | | | | Choose an item. | |
| Describe measures to minimize potential for psychological, social, and/or physical harm from participating in this aspect of the research? | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | |
| **Section 18- Compensation and Reimbursement** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Will compensation for study participation be provided? | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| If yes- | | | | Provide amount of compensation | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| Describe the payment schedule (i.e., amount for screening and completed visit, telephone contact, etc.) | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| Describe when the participant will receive their payments (i.e., after each visit, etc.)- | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| Will reimbursement for time and travel be provided? | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| If yes- | | | | Provide amount of reimbursement- | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| Describe the payment schedule- | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| Describe when the participant will receive their payments- | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| **Section 19- Costs to Participants** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Choose one- | | | | | | | There is no cost to the subject for their participation in the study.  The subject will not be responsible for any costs related to the research; however, the subject or their insurance company will still be responsible for the cost of their routine/standard medical care.  Taking part in this study may lead to additional costs to the subject or their insurance company. (\*If checked complete box below) | | | | | | | | | | | | | | | | | | | | | | | | | |
| |  |  | | --- | --- | | Additional Cost and/or Procedure | Estimated expense | | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | Click or tap here to enter text. | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Section 20- Alternative Treatment** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Is this a treatment study?- | | | | | | | | | | | | | | | | | | | | | | | | | | | | Choose an item. | | | | |
| If yes- | | | | Explain any alternative treatment(s)- | | | | | | | | | | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | |
| **Section 21- Benefits** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Choose one- | | | | | | | There is no specific benefit to the participant for taking part in this study.  There is possible benefit to the participant for taking part in this study (\*If checked list potential benefits to participants in box below).   |  | | --- | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Section 22- Risks and Discomforts** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Describe in detail the possible risks and discomforts to participants. Use supporting evidence from animal studies, if available- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| Describe how the risks to human participants are minimized, such as screening to ensure appropriate selection of subjects, identifying standard of care procedures, sound research design, safety monitoring and reporting, combining research procedures with clinical care, etc.- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |
| Describe the potential risk versus potential benefit to human participants. Justify the risk in terms of the potential scientific yield in relation to the anticipated benefits to the human participants- | | | | | | | | | | | | | | | Click or tap here to enter text. | | | | | | | | | | | | | | | | | |

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| Section 23: 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): | |

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| Section 24: 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): | |

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| Section 25: 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)
6. For 1. Anonymous Questionnaires and Surveys and 2. Secondary Data. 1. Anonymous Questionnaires and Surveys- Written consent may be waived if the subject is better protected without the existence of a signed document. This may be utilized in cases where the only link to the subject would be the signed consent form. Please note that signed informed consent is required, however, when (1) coding or demographics preclude anonymity, and (2) the collected information could be damaging to the subject. (2) Secondary Data- Written consent may be waived if an investigator receives secondary data about human subjects or biological samples from human subjects where no possible personal identifiers are transferred to the researcher. The source of the data, however, must be disclosed to the IRB in the protocol submission. [↑](#footnote-ref-6)
7. For some telephone or internet surveys, questionnaires, or when signing the consent document could have a negative consequence for the subject. Request this waiver to waive the requirement to obtain a signed consent document (cannot be used for FDA-regulated research); or give participants a signed copy of the document. The IRB will require the use of an Information Sheet to be given to the potential subject or an oral script to be read to the potential subject. With this waiver, you will not need to obtain the subject’s signature on a consent form. The script or information statement must be provided to the IRB at the time of original protocol submission for review and approval. The PI and/or research staff will document the participant’s consent, as well as the date, and the name of the person conducting the consent in the study files. [↑](#footnote-ref-7)