New Study Submission Form

(for Hatton Regulatory Document Review for Compliance (DRC), Hatton Administrative Review, and IRB Review)

1. Protocol Information

Hatton/IRB # (assigned by Hatton):

Title (this must match on all documents):

Sponsor:

Sponsor Protocol Number:

Protocol Version/Version Date:

Who developed the protocol?

- ☐ Principal Investigator
- ☐ Industry Sponsor
- ☐ Non-Industry Sponsor (i.e., other institution or sponsor, foundation, NIH, DOD, etc.)
- ☐ Both PI and sponsor
- ☐ If both, who initiated the protocol

Has this protocol been previously submitted on behalf of another TriHealth PI?

- ○ Yes
- ○ No

2. Contact Information

A1. Principal Investigator:

A2. Phone / E-mail:

B1. Regulatory Contact for this submission:

B2. Phone / E-mail:

C1. PI Designee for Administrative Review Call, if PI not available:

C2. Phone / E-mail:

3. Type of IRB Review requested:

- ☐ Full Board
- ☐ Expedited
- ☐ Exempt

Check here if you are requesting to rely on Outside IRB Review and Oversight ☐

Check here if you are requesting reliance through SMART IRB ☐

4. Site Information

The study will be performed at the following site(s):
(check all that apply)

- ☐ Good Samaritan Hospital (375 Dixmyth Ave., Cincinnati, OH 45220)
- ☐ Bethesda North Hospital (10500 Montgomery Rd., Cincinnati, OH 45242)
- ☐ TriHealth Physician Practices (please specify locations below):

- ☐ Other locations(s) (please specify below):

What are the attitudes of the community towards research at this site?

- ○ Positive
- ○ Negative

If negative, please explain:

Which of the following resources are available at your site in the event a subject requires emergency care?
(check all that apply)

- ☐ N/A Chart Review
- ☐ AED
- ☐ Crash Cart
- ☐ Other - please specify

5. Privacy

Explain how the confidentiality and security of study records will be maintained:
(check all that apply)

- ☐ Paper based files
- ☐ De-identified subject information
- ☐ Limited data set approved by TriHealth Legal
- ☐ Other

Explain how the privacy of subjects will be maintained during study visits:
(check all that apply)

- ☐ N/A Chart Review
- ☐ Private room for health-related discussions
- ☐ Other

Will information from the medical record of anyone other than the subject be collected (i.e., maternal data for pediatric or neonatal studies or infant data for a study involving the mother)?

- ○ Yes
- ○ No

If yes, please provide explanation:

6. Study Information

Type of study: **(check all that apply)**

- ☐ Prospective
- ☐ Retrospective
- ☐ Cross-sectional
- ☐ Inpatient
- ☐ Outpatient
- ☐ Active Control
- ☐ Placebo Control
- ☐ Double-blind
- ☐ Single Blind
- ☐ Open Label
- ☐ Chart Review
- ☐ Database Search
- ☐ Questionnaire/Survey

Study is classified as:

○ Phase I ○ Phase II ○ Phase III ○ Phase IV ○ N/A

Source of Funding:

- ☐ Sponsor (Drug or Medical Device Company)
- ☐ US Government (NIH, NCI, etc.)
- ☐ MERF
- ☐ Bethesda Foundation
- ☐ Ortho Fund
- ☐ Other

Is this study being conducted under a Federal Wide Assurance (FWA)?

- ○ Yes
- ○ No

If yes, and other than TriHealth FWA #00003114, please provide the FWA number:

7. Drug Trial?

- ○ Yes
- ○ No

If yes, complete the questions below:

Check type of drug trial:

- ☐ Investigational New Drug(s) — Provide Drug(s) name(s):
- ☐ Marketed Drug(s) — Provide Drug(s) name(s):
- ☐ Investigational Use of Marketed Drug(s) — Provide Drug(s) name(s)

☐ Placebo, provide rational for the use of placebo below:

Are any of the above listed drugs a controlled substance?

- ◯ Yes
- ◯ No

If yes, what controlled substance class:

☐ I ☐ II ☐ III ☐ IV ☐ V

Provide generic name of controlled substance:

If Investigational New Drug(s) or Investigational Use of Marketed Drug(s), has an IND been applied for?

- ◯ Yes
- ◯ No

Who holds the IND?

Provide IND#:

If Phase I or II study, please provide the date of the IND Submission to FDA

If an IND has not been applied for, confirm that this study is exempt from IND regulations and satisfies all criteria of 21CFR312.2.

- ◯ Yes
- ◯ No

Please Note: The site is not permitted to obtain informed consent for this study until 31 days after the IND has been submitted or released by FDA and any questions by FDA have been answered (if applicable).

Does this study include an off-label use of a FDA approved drug?

- ◯ Yes
- ◯ No

8. Device Trial?

- ◯ Yes
- ◯ No

If yes, complete the questions below:

- ☐ Significant Risk as described in 21 CFR 812.3(m), please provide FDA Approval Letter for IDE
- ☐ Non-Significant Risk does not meet definition of significant risk as described in 21 CFR 812.3(m), please provide a letter or e-mail from the Investigator or Sponsor explaining why the test article is a non-significant risk device
- ☐ Exempt from IDE requirements per 21 CFR 812.2(c), provide letter explaining why it is exempt

If Significant Risk, please indicate below the name of the IDE holder, device name and IDE#:

Is the device an HUD/HDE device? If yes, complete the **HUD/HDE checklist**.

- ◯ Yes
- ◯ No

9. Is there a Sub-Study? If yes, complete questions below. If you have more than one sub-study, complete the Sub-Study Form.

◯ Yes
◯ No

If yes,

☐ Pharmacogenetics ☐ Pharmacokinetics ☐ Biorepository ☐ Data Repository
☐ Other

If yes,

☐ Optional ☐ Mandatory

If yes,

☐ Identifiable ☐ De-identifiable ☐ Single-coded

Is sub-study part of the main protocol? If no, provide a copy of the sub-study protocol, supplement or addendum.

◯ Yes
◯ No

10. Data Safety

Does this study involve a Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC)?

◯ Yes
◯ No

By checking yes, it confirms you will submit a copy of the Data Monitoring Report when it comes available.

11. Study Recruitment

What is the protocol sample size*?

If study is being done at non-Trihealth and TriHealth sites, how many subjects will be involved at TriHealth?

The protocol sample size represents the number of subjects a study must involve for researchers to find meaningful results. For **sponsored studies this is the number of subjects involved across all research sites; for **TriHealth 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. Any changes to the protocol sample size during the course of a study must be submitted to the IRB for review and approval prior to implementation. Also note, 45 CFR 46.116 indicates that the total number of subjects involved in a study must be specified in the informed consent document.*

Indicate **Age Range** of subjects to be included in this study:

From what groups will the subjects be recruited? (check all that apply)

Biological Sex :

☐ Male ☐ Female

Race:

☐ White
☐ Black or African American
☐ American Indian or Alaska native
☐ Asian or Pacific Islander

Ethnicity:

- ☐ Hispanic or Latino Origin
- ☐ Not of Hispanic or Latino Origin

Will your study **TARGET AND/OR INCLUDE** a vulnerable population? **(check all that apply)**

- ☐ None
- ☐ Children
- ☐ Educationally Disadvantaged
- ☐ Physically Impaired
- ☐ Non-English Speaking Subjects
- ☐ Prisoners
- ☐ Life-Threatening Condition / Serious Debilitating Illness
- ☐ Mentally Disabled / Cognitively Impaired
- ☐ Economically Disadvantaged
- ☐ Employees
- ☐ Nursing Home Residents
- ☐ Pregnant Women

Please describe the safeguards that will be implemented to protect vulnerable subjects:

Please describe plan for how subjects will be recruited:

Recruitment materials: **(check all that apply)**

- ☐ Media Advertisements
- ☐ Website Advertisements
- ☐ Subject Letters
- ☐ Newsletters
- ☐ Telephone - screen scripts
- ☐ Pre-screening scripts
- ☐ Subject Programs
- ☐ Generic pre-screening informed consents
- ☐ Other

Study Related Materials: **(check all that apply)**

☐ Diaries ☐ Subject Instructions ☐ Questionnaires ☐ Brochures
☐ Other

Other: **(check all that apply)**

☐ Gifts ☐ Translated Documents

Referral fees (finder's fee) to physicians/healthcare providers for referrals of research subjects:

☐ I confirm that this site will not pay referral fees (finder's fees) for referrals of research subjects without board approval.

12. Waivers

Are you asking for a waiver? If yes, select requested waiver and complete the appropriate form(s).

☐ Waiver or Alteration of Informed Consent
☐ Waiver of Documentation of Informed Consent
☐ Waiver or Alteration of Authorization
☐ Partial Waiver of Authorization for Recruitment Purposes

13. Informed Consent and Authorization

Who is authorized to conduct informed consent discussions with subjects for this study?

☐ N/A Chart Review
☐ PI
☐ Sub-I
☐ Research Coordinators
☐ Research Nurse
☐ Research Assistant
☐ Other

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

Will compensation for study participation be provided?

○ Yes
○ No

If yes, who will receive compensation for participation? **(check all that apply)**

☐ Adult subjects ☐ Minor subjects
☐ Parents/Guardians of Minor Subjects ☐ Caregivers
☐ Other

Provide the amount of compensation and describe the payment schedule (i.e., amount of money for screening visit, completed visit, telephone contact, etc.) and when the subject will receive their payments (i.e., after each visit, etc.):

Do you plan to consent/enroll non-English speaking subjects?

- ○ Yes
- ○ No

If yes, who be responsible for obtaining translations?

- ☐ Sponsor/CRO
- ☐ IRB approved, certified translator

If yes, what language?

If yes, who will be obtaining informed consent for the subjects?

- ☐ Staff Member
- ☐ Professional Translator

Do you plan to enroll subjects through a legally authorized representative (LAR)?

- ○ Yes
- ○ No

If yes, which individuals will you allow to give consent (e.g., durable power of attorney for health care, spouse, legal guardian, etc.)?

How will you verify what constitutes a LAR?

- ☐ Legal Counsel
- ☐ Sponsor
- ☐ CRO
- ☐ Other

Is the Investigator/Sponsor or Hospital planning to collect and store identifiable or coded data for future research?

- ○ Yes
- ○ No

Is the Investigator/Sponsor or Hospital planning to collect and store identifiable or coded biospecimen (blood, urine, tissue, etc.) samples for future research?

- ○ Yes
- ○ No

Does the study involve genetic testing?

- ○ Yes
- ○ No

If yes, complete the **Genomic Sub-Study Checklist**

14. Regulatory Information

Have you or any of the Sub-Investigators been audited by the FDA or the Office for Human Research Protections (OHRP) in the past 5 years?

- ◯ Yes
- ◯ No

If yes, please provide the name of the Agency, the name of the investigator and the date of the audit:

Have you or any of the Sub-Investigators:

Had a sponsor, CRO, or an IRB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol?

- ◯ Yes
- ◯ No

Had the FDA or OHRP terminate a study?

- ◯ Yes
- ◯ NO

If yes to any of the above, please provide a written explanation and copies of relevant documents.

15. Clarifications or notes to the Board:

KEY STUDY PERSONNEL
(NEW STUDY SUBMISSION)

Please list key personnel below (Investigator, Sub-Investigator, Lead Study Coordinator, Research Specialist) who are responsible for the design, conduct or reporting of this research study. Attach the following documents unless they are already on file in Hatton for each person: CV, CITI Completion Certificate, and Medical License. Contact Kelly Blackwell at Kelly_Blackwell@trihealth.com if you need to confirm documents are in database. Use the ***Key Study Personnel for New Study Submission Form*** if you need to add additional personnel.

Name & Degree	Role (PI, Sub-I, etc.)	Tasks (see key below)	CITI Expiration Date	Other Training (optional) GCP, FDA Info sheets or the Belmont Report; HSR Seminar web-based training; HSR Training by Sponsor/CRO	Employer

1. Obtain Informed Consent
2. Reviewing Medical History
3. Perform Physical Exams
4. Reviewing for Inclusion/Exclusion
5. Drug Dispensing
6. Drug Accountability
7. Ongoing AE Assessment
8. Update/Maintain IRB docs
9. Data Analysis
10. Other -

PRINCIPAL INVESTIGATOR RESPONSIBILITY LIST
(NEW STUDY SUBMISSION)

The following are the minimum responsibilities of the Principal Investigator. Please carefully read and understand your responsibilities.

1. Principal Investigator acknowledges and accepts his/her responsibility for **protecting the rights and welfare of human subjects** and for **complying with all applicable regulations**.

2. Principal Investigator who intends to involve human research subjects will be **responsible for obtaining IRB review and approval PRIOR to the initiation of research**.

3. Unless otherwise authorized by the IRB, **Principal Investigator is responsible for obtaining and documenting informed consent and authorization** in accord with applicable institutional and federal regulations.

4. Principal Investigator is responsible for **providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent**, unless the IRB has specifically waived this requirement, or the study is determined by IRB to be exempt. All original signed consent documents are to be retained by the PI for the period of time required by the federal regulations or as outlined in the contract with the sponsor.

5. Principal Investigator shall be **responsible for promptly reporting proposed changes in previously approved human subject research activities to the IRB**. The **proposed changes may not be initiated without IRB review and approval, except** where necessary to **eliminate apparent immediate hazards** to the subjects.

6. Principal Investigator will **report to the IRB all Unanticipated Problems Involving Risks to Human Subjects or Others (Unanticipated Problems) that occur within 5 business days**. All Unanticipated Problems that **involve death must be reported within 24 hours**.

7. Principal Investigator will submit a **progress report at least eight weeks prior to the date at which the IRB has determined continuing review is required for full board review**. If the progress report is not received by the due date, it cannot be guaranteed that a study will be reviewed before the study's approval lapses. If a study is not reviewed prior to the expiration date, new enrollment is suspended and you may not continue with the study for previously enrolled subjects except as approved by the IRB.

8. Principal Investigator will **report all noncompliance issues that have an adverse effect on the safety or welfare of the subject(s), and/or the data collected and/or are related to breach of confidentiality within 10 business days of discovery**.

9. Principal Investigator will **disclose any new conflicts of interest that arise during the course of the study** as outlined in the TriHealth Conflict of Interest in Clinical Research Policy.

10. Principal Investigator will **maintain a list of appropriately qualified persons to whom significant clinical trial related duties have been delegated** and will **seek approval from the IRB for any change in Sub-Investigator, Lead Study Coordinator and/or Research Specialist**.

CERTIFICATIONS AND APPROVALS

I attest to the information contained in my New Study Submission and will abide by the requirements of TriHealth and the IRB, as per the above Researcher's Responsibilities, Federal and State regulations, and if applicable, any agreements with the sponsor in the conduct of the protocol. I have not been disbarred, suspended or restricted by any federal or state agency.

_____ _____

Signature of Principal Investigator **Date**