For Internal Use Only – Hatton assigned Hatton/IRB #:	

Non-Interventional & Non-Sponsored New Study Submission Form

Please indicate if the following statements apply to your research. You can use this submission form if ALL the following statements apply to your research:

☐	Your research is NOT sponsored by a pharmaceutical/device company, NOT supported by a Non-TriHealth hospital or institution, and is NOT supported by government funding.
☐	Your project solely involves survey, questionnaires, interviews, and/or review of existing database(s) or review of TriHealth medical records.
☐	Your project meets the regulatory definition of **Minimal Risk**. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

If you cannot check ALL the boxes above, please complete and submit the longer New Study Submission Form instead of this abbreviated Non-Interventional & Non-Sponsored New Study Submission Form.

1. Study Information

Study Title:	
Protocol Version/Date:	

2. Principal Investigator Information

Principal Investigator Name:	
TriHealth E-mail:	
Telephone Number:	
Department/Group:	

Name of Regulatory Support Staff Assisting Principal Investigator:	
TriHealth E-mail:	
Telephone Number:	

3. Site Information

Please indicate the TriHealth location(s) where the research will be conducted:

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

Please identify other TriHealth locations, if applicable:

4. Confidentiality

Please indicate if the following applies to your research:

Yes	No	
☐	☐	Paper records will be kept in a secure location, accessible only to authorized personnel involved in the study.
☐	☐	Computer records will be accessible only to authorized personnel involved in the study through access privileges and passwords.
☐	☐	All site staff members will protect the security and confidentiality of the information collected in this study.
☐	☐	Whenever feasible, identifiers will be removed from study-related information.
☐	☐	Electronic data obtained in this study will be stored only on encrypted devices.
☐	☐	Identifiable electronic health information obtained in this study will be stored in a manner compliant with the HIPAA Security Rule.

If you answered "No" to any of the above items, please explain:

Yes	No	Not Applicable	If the research involves electronic survey or electronic questionnaire, please confirm that you will utilize Key Survey (if PHI will be collected) or Checkbox (if no PHI will be collected).
☐	☐	☐	

If you answered "No" to the above item, please indicate the survey tool that you will use and confirm that your survey tool is approved by TriHealth Information Security for use in the research. (At this time, Survey Monkey is not approved by TriHealth Information Security for research use at TriHealth):

5. Privacy

Please indicate if the following applies to your research:

Yes	No	Researchers will collect private information from and/or about subjects only after measures are in place to prevent disclosure to or access to the information by others.
☐	☐	

If you answered "No" to the above item, please explain:

Yes	No	Not Applicable	If the research involves obtaining photographs or audio/video recording subjects, researchers will obtain informed consent before obtaining any photographs of participants or audio/video recording participants.
☐	☐	☐	

If you answered "No" to the above item, please explain:

6. Study Subjects

Subject Sample Size*:	

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.*

Subject Age Range:	

Please confirm that the study will not discriminate based on sex, ethnicity, and/or race. If only certain groups will be included, provide scientific and ethical rationale:

Yes	No	Not Applicable	
☐ (Protections in place for employees in study.)	☐ (No protections in place for employees in study.)	☐ (Employees and/or information from employees will NOT be included in study.)	**TriHealth employees may be included in the study AND protections are in place to protect TriHealth employees** (employee participation will NOT influence hiring, promotion, performance evaluation, or other employment benefits and, if applicable, any informed consent documents and other research-related communications with employee participants clearly indicates that participation will have no impact on employment benefits).

Please explain how subjects will be recruited and indicate if any recruitment materials will be used:

Yes	No	Not Applicable	
☐	☐	☐	ALL subject-facing materials (including, but not limited to, surveys, questionnaires, and recruitment materials) will be submitted

7. Informed Consent and/or Waivers

Please indicate if any of the following apply to your research:

Yes	No	
☐	☐	This is a **retrospective*** database review/medical chart review study that involves Waiver of Informed Consent. The Request for Waiver of Informed Consent Form will be included with my submission to the IRB.
☐	☐	This is a **retrospective*** database review/medical chart review study that involves Waiver of Authorization. The Request for Waiver of Authorization Form will be included with my submission to the IRB.

**The distinction between retrospective chart review and prospective chart review is important. This may influence whether obtaining informed consent from subjects is practicable. In truly retrospective research, it is often not practicable to find and contact all the targeted subjects to obtain informed consent (and only locating and consenting a part of the subject population may impact analysis and the scientific validity of the study). In prospective chart review research, there is typically an opportunity to engage potential subjects and obtain informed consent since they will be coming in "prospectively" for regular care visits.*

Please indicate if any of the following apply to your research:

Yes	No	
☐	☐	This is a **prospective** study that involves **Informed Consent and HIPAA Authorization**. The document(s) are included in this submission for IRB review.
		If your study involves an **Informed Consent Document**, please explain the process and logistics of obtaining informed consent from subjects and how **privacy of subjects** will be maintained during the process:

Yes	No	
☐	☐	This is a **prospective** survey/questionnaire study that involves an **Informed Consent Document Cover Letter/Sheet** and **Waiver of Documentation of Informed Consent**. The Informed Consent Document Cover Letter/Sheet and Waiver of Documentation Submission Form will be included with my submission to the IRB.
		If your study involves an **Informed Consent Document Cover Letter/Sheet** and **Waiver of Documentation of Informed Consent**, please explain the process and logistics of providing subjects the Informed Consent Document Cover Letter and how the **privacy of subjects** will be maintained during the process:

Yes	No	
☐	☐	This is a **survey/questionnaire or interview study** that involves **HIPAA Authorization**. The HIPAA Authorization will be included with my submission to the IRB.

Yes	No	
☐	☐	This is a **survey/questionnaire study** that involves **Waiver of HIPAA Authorization**. The Request for Waiver of Authorization Form will be included with my submission to the IRB.

8. Regulatory History

Please clarify the following:

Yes	No	
☐	☐	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?
☐	☐	Have you had a sponsor, CRO, or an IRB terminate, suspend, impose restrictions or sanctions on any of your other research projects?
☐	☐	Has the FDA or OHRP terminated any of your research projects?

If you answered "Yes" to any of the above items, please explain:

KEY STUDY PERSONNEL:

Please list and describe key personnel (Investigator, Sub-Investigator, Lead Study Coordinator, Research Specialist) who are responsible for the design, conduct, or reporting of this research study.

Name & Degree	Role (PI, Sub-I, etc.)	Research Task (see key below)	CITI Expiration Date	Employer

Research Task Key:

1. Obtain Informed Consent
2. Reviewing Medical History
3. Reviewing database or medical charts
4. Reviewing for Inclusion/Exclusion
5. Update/maintain IRB documents
6. Data Analysis
7. Administering research surveys and/or questionnaires
8. Other (explain in task column above)

PRINCIPAL INVESTIGATOR RESPONSIBILITY LIST:

The following are the minimum responsibilities. 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**. All original signed consent documents are to be retained by the PI for the period of time required by the federal regulations and TriHealth policies.

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**.

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**.

CERTIFICATION AND APPROVAL

I attest to the information contained in my Non-Interventional & Non-Sponsored New Study Submission Form and will abide by the requirements of TriHealth and the IRB, as per the above Responsibility List and any applicable Federal and State regulations. I have not been disbarred, suspended, or restricted by any federal or state agency. My Department leadership and/or TriHealth supervisor is aware of and supports my conduct of this study. I have resources from TriHealth, my Department, and/or the TriHealth Hatton Research Institute to complete my project, including data analysis and manuscript preparation.

Signature of Principal Investigator	Date

Please submit this form to **New_Study@trihealth.com**.
If you have questions about this form, please call **513-865-5248** or **513-862-5213**.