In addition to being used during Administrative Review, this document also serves as:

- **Part 1 of Legal Review of the Clinical Trial Agreements**.

This form must be completed **electronically**. **NO** handwritten applications will be accepted.

Administrative Review Meetings are held weekly. Submissions are due the Friday before the meeting **by 12:00 p.m.** Submissions received after this time will be not be added to the agenda until the next scheduled meeting.

You will be provided with a scheduled date and time for your study to be discussed via conference call with the Administrative Review Team.

At your scheduled time, please follow the conference call instructions listed below:

- All parties dial **513-878-1440 or 1-800-967-7145**
- An automated system will answer, and prompt the parties to enter their PIN code.
- The Conferee PIN code is **534852** followed by the # sign.
- If participants dial in prior to the Moderator they will go to "Music on Hold."
- Once the Moderator dials in, the music will cease and the conference call will begin.

If you experience any issues while using this line, call 1-866-908-2751 or 1-719-325-5794 for assistance. Our Client ID is 5164521. Our Online Password is d060v5.

Please provide a number where you can be reached the day of your scheduled conference call in the event a member of the Administrative Review Team needs to contact you.

Name: **Phone:**
E-mail:

If someone other than yourself will be participating on the call, please provide their name and a number where they can be reached, if necessary.

Name: **Phone:**
E-mail:

Please submit this application to Hatton_Admin_Review@trihealth.com.

For questions, please call Sandy Kiefer @ 862-2416.

Date of Submission:		**Study Number:**	
Protocol Title:			
Protocol Version/Version Date:			
Sponsor's Protocol #:			
Study Nickname:			
Name of Sponsor/funding source			
Principal Investigator (PI) full name:			
PI full address:			
PI Phone/e-mail			
PI employed by TriHealth:	***PI must be a TriHealth employee, hold a TriHealth leadership position, or be credentialed Medical Staff at the TriHealth-owned location*** ☐ Yes ☐ No **Department**		
Resident Study:	☐ Yes ☐ No		
PI designated contact for study:	**Name:** **email:**		
Supervisor:	**Name:** **email:**		
TriHealth site(s) for study: **Mark all the TriHealth sites where you will be performing your study**	☐ Bethesda North Hospital ☐ Good Samaritan Hospital ☐ TriHealth Physician Practice: please specify which one(s): ☐ Other (specify):		
Study Category: **(i.e. Academic – Internal Medicine, Cardiac – Sponsored, Oncology – Federally Funded)**	Select Category		

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ADMINISTRATIVE REVIEW SUBMISSION CHECKLIST

- ☐ ADMINISTRATIVE REVIEW APPLICATION
- ☐ PROTOCOL
- ☐ INFORMED CONSENT(S) or CHECK IF N/A ☐
- ☐ SPONSOR'S INFORMED CONSENT (if using TriHealth IRB only) or CHECK IF N/A ☐
- ☐ WAIVERS (Informed Consent, Documenation of Informed Consent or Waiver of Authorization or CHECK IF N/A ☐
- ☐ HIPAA(S) (Main, Data and Biospecimen, as applicable) or CHECK IF N/A ☐
- ☐ PATIENT INFORMATION (brochures, letters, questionnaires, diaries, etc. which will be seen by the patient – if applicable) or CHECK IF N/A ☐
- ☐ DATA COLLECTION FORMS or CHECK IF N/A ☐
- ☐ SCIENTIFIC REVIEW APPROVAL LETTER (if applicable) or CHECK IF N/A ☐
- ☐ FACILITY IMPACT FORM (if applicable) or CHECK IF N/A ☐
- ☐ PHARMACY CHECKLIST (if applicable) or CHECK IF N/A ☐
- ☐ BUDGET or CHECK IF N/A ☐
- ☐ FEDERAL FUNDING SHEET - CHI ONLY or CHECK IF N/A ☐
- ☐ CLINICAL TRIAL AGREEMENT or CHECK IF N/A ☐
- ☐ RESEARCH SUPPORT SERVICES AGREEMENT or CHECK IF N/A ☐
- ☐ DATA USE AGREEMENT or CHECK IF N/A ☐
- ☐ MATERIAL TRANSFER AGREEMENT or CHECK IF N/A ☐
- ☐ MCA/SOC (unsigned) or CHECK IF N/A ☐
- ☐ SIGNED IRB DEFERRAL AGREEMENT (If applicable) or CHECK IF N/A ☐
- ☐ CIRB OR CHIRB APPROVAL LETTER - CHI ONLY or CHECK IF N/A ☐
- ☐ CONFIRM CITI/CV/MEDICAL LICENSE ARE IN DATABASE

Provide a brief summary (less than 300 words) of your protocol.

Where if any will the data be reported?

Will the data be completely de-identified when reported: ☐ **Yes** ☐ **No**

If no, please explain:

How many subjects / charts do you wish to enroll / review:

Protocol Risk Assessment **TO BE COMPLETED BY THE PRINCIPAL INVESTIGATOR**

Definitions of Levels of Risk: There are four levels of protocol risk, number **one representing no more than minimal risk** (as defined in federal regulations), and numbers **two, three, and four representing greater than minimal risk**. Criteria for each and examples are given below. Various factors are taken into consideration when determining the level of risk and are described below. Additional factors may include potential for invasion of privacy/breach of confidentiality, the psychological impact of the protocol, social implications, or potential for conflicts of interest. Some studies may not clearly fit into one category and instead have elements of two or more categories. In that case, the highest risk category should be selected.

Based on the highest level of risk determined, the following legal review of the clinical trial agreement will take place:

Level 1 – Minimal Risk	No review by legal
Level 2 – Minor Increase over Minimal Risk	Review determined by Medical Director, Hatton Institute
Level 3 – Moderate Risk	Review determined by Medical Director, Hatton Institute
Level 4 – High Risk	Legal review required

Please check the appropriate boxes below which reflect your perceived risks for the protocol you have submitted:

Level 1 – Minimal Risk	
Definition: means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and where confidentiality is adequately protected. This category includes protocols that pose "no greater than minimal risk" according to federal regulations.	
Does protocol contain any of the following elements of risk?	**√ if Yes**
Study poses no more risk than expected in daily life (blood draw, physical exam, routine psychological testing).	☐
Non-interventional studies (e.g., observational studies of behavior or nutrition).	☐
Survey/Questionnaire studies of a non-sensitive nature.	☐
Other – please specify:	☐

Level 2 - Minor Increase over Minimal Risk	
Definition: Research involves a minor increase over minimal risk. There is medium to high probability of the occurrence of a low-severity event that is completely reversible (e.g., headache from lumbar puncture) or the likelihood of serious harm occurring is low (e.g., fatal anaphylaxis from allergy skin testing).	
Does protocol contain any of the following elements of risk?	**√ if Yes**
Studies of normal volunteers using well-described research procedures and/or single dose of experimental agent.	☐
Post-marketing study - Phase IV drug study or device (as defined by FDA) with minor safety concerns	☐
Interventions or invasive procedures present low risks, reasonably commensurate with those expected in medical or dental practice.	☐

Studies that involve sensitive information or a potential risk of breach of confidentiality	☐
Other – please specify:	☐
Level 3 – Moderate Risk	
Definition: Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severe event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects.	
Does protocol contain any of the following elements of risk?	**√ if Yes**
Protocol that has a secondary data repository	☐
Subjects treated with placebo for a recognized disease	☐
Substantial risk of a serious adverse event originating from the underlying condition of the enrolled subject	☐
Involves subjects with serious viral, autoimmune, and malignant illness in a treatment study	☐
Phase II clinical trial with available safety data in humans	☐
Minimal risk studies involving vulnerable populations (i.e., subjects with impaired capacity to give informed consent)	☐
Other – please specify:	☐
Level 4 – High Risk	
Definition: The study risk is greater than a moderate risk study due to increased probability for generating serious adverse events. There is a high probability of an event that is serious and prolonged or permanent occurring as a result of study participation or there is significant uncertainty about the nature or likelihood of adverse events.	
Does protocol contain any of the following elements of risk?	**√ if Yes**
Phase I trial or Phase II without available safety data in humans	☐
Trial presents a significant risk to the institution	☐
Trial involves an invasive procedure that poses significant risk to the patient – i.e., spinal fusion devices	☐
Protocol that has a secondary tissue repository	☐
Clinical trials of interventions to prevent or treat diseases that lead to death or irreversible morbidity	☐
Involves an intervention or invasive procedure with substantial risk or potential for severe toxicity	☐
An investigator initiated IND trial	☐
Implantation of a device with an IDE	☐
Involves the use of a new chemical or drug for which there is limited or no available safety data in humans	☐
A gene transfer study or research involving recombinant DNA molecules	☐
An investigator initiated Phase III clinical trial	☐
Other – please specify:	☐

_____ _____

Signature of Principal Investigator **Date**

Study Personnel

List all study personnel for a TriHealth site (PI, sub-investigators, local coordinators, data managers, etc.) by completing the table below. Provide their Name, Degree(s), Assigned study role, CITI Completion Date and Employer

Name/Degree(s)	Role/Role Code (see below)	Date CITI was completed (Date must be within the last three years)	Employer

Delegated Study Role Codes:

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. Other (please define):

Study Number:

Protocol Title:

The above referenced study has been approved to move forward to the following IRB :

☐ **TriHealth IRB** ☐ **Other:** Choose the approved IRB

The following agreements are required:

☐ **CTA (legal review required)** ☐ **Research Support Agreement**

☐ **Data Use Agreement** ☐ **Facility Use Agreement**

☐ **Material Transfer Agreement** ☐ **Other**_____

☐ **The above referenced study is on hold for the following contingencies:**

_____

_____

☐ **The above referenced study is not given administrative approval at this time.**

Comments:_____

_____

_____ _____

Signature of Ginger LaMar, RN, MSN, CCRC
TriHealth Research Director **Date**

_____ _____

Signature of J. Michael Smith, MD
Medical Director, Hatton Institute **Date**

_____ _____

Signature of Scott Woods, MD
Program Director, Family
Medicine Residency Program **Date**