Staff Modification Request Form

(for submission to TriHealth IRB at irb_hrpp@trihealth.com)

Use this form to add or remove Principal Investigator, Sub-Investigator, Lead Study Coordinator / Lead Research Specialist, and any study team member(s) who answer "yes" to question(s) on the Researcher Conflict of Interest Form.

1. PROTOCOL AND STUDY TEAM (INDICATE "NOT APPLICABLE" ON ANY ITEMS THAT DO NOT APPLY TO YOUR PROJECT)

a. IRB / Hatton #:

b. Protocol #:

c. Protocol Version/Date:

d. Protocol / Project Title:

e. Current Principal Investigator:

f. Current Lead Study Coordinator / Lead Research Specialist:

g. Current Sub-Investigator(s) (list all):

h. Sponsor:

i. Age Range of Subjects:

2. RESEARCH SITE LOCATION(S)

a. Indicate site location(s) approved by the TriHealth IRB:

- ☐ Bethesda North Hospital
- ☐ Good Samaritan Hospital
- ☐ TriHealth Physician Practice Locations
- ☐ TriHealth Heart Institute Locations

b. Specify any other site location(s) approved by the TriHealth IRB:

3. STUDY STATUS (INDICATE "NOT APPLICABLE" ON ANY ITEMS THAT DO NOT APPLY TO YOUR PROJECT)

a. Indicate the status of subject enrollment:

- ☐ Enrollment open
- ☐ Enrollment has not started
- ☐ Enrollment on hold
- ☐ Enrollment closed

b. If enrollment has not yet started, explain why:

c. If enrollment is closed, indicate the date that it closed:

d. Indicate the status of study:

- ☐ Subjects are actively participating in study procedures
- ☐ Subjects are in long term follow-up and not actively participating in study interventions or procedures
- ☐ Patient charts / information under review
- ☐ Database sets are under review
- ☐ Study is in data analysis or manuscript review phase
- ☐ No subjects have been enrolled yet

e. If enrollment is open and no subjects have been enrolled yet, explain why:

4. REMOVING STUDY STAFF (SKIP THIS SECTION IF NOT APPLICABLE)

a. Name the study staff member(s) being removed AND identify role in study:

b. Explain why study staff member(s) are being removed:

5. ADDING NEW PRINCIPAL INVESTIGATOR (SKIP THIS SECTION IF NOT APPLICABLE)

a. Name AND employer:

b. CURRENT CV, CITI, and any applicable license and/or training included in Hatton Credentials Database (or attached)

☐ Yes

c. Submission includes Annual Researcher Conflict of Interest Questionnaire:

☐ Yes

d. Submission includes signed "Principal Investigator Responsibility List"

☐ Yes

e. Submission includes written confirmation of support for the Principal Investigator change from Institutional Leadership / Department Leadership

☐ Yes

6. ADDING SUB-INVESTIGATOR, LEAD COORDINATOR/RESARCH SPECIALIST, AND/OR TEAM MEMBER(S) WHO INDICATE "YES" ON RESEARCHER CONFLICT OF INTEREST QUESTIONNAIRE (SKIP THIS SECTION IF NOT APPLICABLE)

Staff Addition #1: (skip this section if not applicable)

a. Name, role, AND employer:

b. CURRENT CV, CITI, and any applicable license and/or training included in Hatton Credentials Database (or attached):

☐ Yes

c. Submission includes Annual Researcher Conflict of Interest Questionnaire:

☐ Yes

d. Study tasks:

☐ Obtain consent
☐ Review medical history
☐ Perform physical exams
☐ Inclusion / exclusion
☐ Drug dispensing
☐ Drug accountability
☐ AE assessment
☐ Regulatory
☐ Data analysis
☐ Recruitment

e. Explain any other tasks that will be performed:

Staff Addition #2: (skip this section if not applicable)

a. Name, role, AND employer:

b. CURRENT CV, CITI, and any applicable license and/or training included in Hatton Credentials Database (or attached):

☐ Yes

c. Submission includes Annual Researcher Conflict of Interest Questionnaire:

☐ Yes

d. Study tasks:

☐ Obtain consent
☐ Perform physical exams
☐ Drug dispensing
☐ AE assessment
☐ Data analysis
☐ Review medical history
☐ Inclusion / exclusion
☐ Drug accountability
☐ Regulatory
☐ Recruitment

e. Explain any other tasks that will be performed:

Staff Addition #3: (skip this section if not applicable)

a. Name, role, AND employer:

b. CURRENT CV, CITI, and any applicable license and/or training included in Hatton Credentials Database (or attached):

☐ Yes

c. Submission includes Annual Researcher Conflict of Interest Questionnaire:

☐ Yes

d. Study tasks:

☐ Obtain consent
☐ Perform physical exams
☐ Drug dispensing
☐ AE assessment
☐ Data analysis
☐ Review medical history
☐ Inclusion / exclusion
☐ Drug accountability
☐ Regulatory
☐ Recruitment

e. Explain any other tasks that will be performed:

7. STUDY DOCUMENTS (INDICATE "NOT APPLICABLE" ON ANY ITEMS THAT DO NOT APPLY TO YOUR PROJECT)

a. Indicate if staff change requires a modification to the protocol (revised protocol must be submitted to the IRB for review and approval prior to implementation):

- ☐ Yes
- ☐ No
- ☐ Not applicable (for example, project represents the clinical use of HUD without protocol)

b. Indicate if staff change requires a modification to the informed consent document and/ or HIPAA authorization (revised document(s) must be submitted to the IRB for review and approval prior to use):

- ☐ Yes
- ☐ No
- ☐ Not applicable (for example, IRB approved waivers of informed consent and authorization)

c. If a revised informed consent document and/or HIPAA is required, indicate who will sign the revised document(s) (check any that apply):

- ☐ New enrollees
- ☐ Current subjects
- ☐ Subjects no longer in study
- ☐ Not applicable (revised document(s) not required)

d. If applicable, explain if Subjects Letters or other documents will be developed to inform subjects of staff change (document(s) must be submitted to the IRB for review and approval prior to use):

NOTE: Revised protocol, informed consent document, and/or other documents can be submitted to the IRB with this form if the revisions to the document(s) are limited to changes regarding the staff modification. If other changes to the document(s) are made, the investigator must also submit the Modification Submission Form to further explain the rationale for the additional changes to the document(s).

Revisions to protocol, informed consent document, and/or other documents must be submitted to the IRB in tracked changes / red-lined form so that the IRB can clearly distinguish all changes to the document(s). Revised protocols must also include updated version date/number.

8. CERTIFICATION

I attest that I will not implement the staff changes stated above until the TriHealth IRB has granted approval of this request. I confirm that I will abide by the requirements of TriHealth and TriHealth IRB, as per Researcher Responsibilities, Federal and State Regulations, and any sponsor agreements.

DATED Signature of Current Principal Investigator: