IRB CONTINUING REVIEW APPLICATION

If you plan on closing your study, do not complete this form. Instead, please complete the HJAHC IRB Final Study Report/Study Closure Form.

1. STUDY IDENTIFYERS

STUDY TITLE	IRB PROTOCOL NUMBER	STUDY APPROVAL EXPIRATION DATE *

**If IRB approval of your study has expired, in addition to this form, please also provide the HJAHC IRB Expired Study Report Form.*

2. PRINCIPAL INVESTIGATOR (PI)

Please enter as last name, first name, MI, highest earned degree	
Title(s):	
Phone:	Fax:
Mailing address	E-Mail:
ADDITIONAL CONTACT If additional information is needed, specify the contact person other than the PI (e.g., study coordinator).	
Please enter as last name, first name, MI, highest earned degree	E-Mail:
Fax:	Phone:

3. STUDY PERSONNEL (Please list all current research personnel for this study)

Co-Investigators (Last name, first name, MI, highest earned degree)	Other Study Personnel (research coordinators, data managers, etc) (last name, first name, MI, highest earned degree)

Have there been any changes in study personnel not previously reported to the IRB?

- ☐ No
- ☐ Yes (To add study personnel please attach the Additional Study Personnel)

If yes, please describe here.

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4. STUDY DESCRIPTION

A. What is your research question (hypothesis)?

B. Describe research design.

C. What will the subjects be asked to do?

D. What will be done to subjects?

E. Describe risks to subjects:

F. Describe potential benefits to subjects or others, if any:

5. STUDY STATUS (check all that apply)

A. ☐ Active - Open to Enrollment
- ☐ No enrollment to date
- ☐ Participant enrollment has begun
- ☐ Specimen collection or chart review occurring

B. ☐ Active - Closed to Enrollment
- ☐ Treatment, and/or active follow-up continues
- ☐ Long-term follow-up of subjects as patients (e.g., following for survival)
- ☐ Data analysis only (data analysis being performed by or on behalf of investigators)

C. ☐ Study Closed Prior to Completion*
**Do not complete this form. Instead, please complete the Final Study Report/Study Closure Form.*

D. ☐ Study completed*. Enrollment, treatment, data collection, follow-up, and data analysis are complete.
**Do not complete this form. Instead, please complete the Final Study Report/ Study Closure Form.*

6. STUDY FUNDING/SPONSOR

A. Is the research funded at this time?
- ☐ Yes
- ☐ No

B. Has the sponsor/funding source changed since the last review?

☐ Yes

- If yes, please also attach the *Sponsor/Funding Information Form* (Appendix 3)

☐ No

7. DRUG AND DEVICE STUDIES

A. Since the last continuing review, has your study site been inspected by the FDA?
☐ No
☐ Yes
If yes, did the site receive Form 483 Inspectional Observations?
☐ No
☐ Yes

- If yes, please also attach a copy of Form 483, and your response to the FDA.

B. Is the PI the holder of the IND or IDE?
☐ No
☐ Yes

- If yes, please also provide a copy of the most recent IND/IDE annual report submitted to the FDA.

8. ENROLLMENT

A. Has enrollment been lower than anticipated?
☐ No
☐ Yes
If yes, explain the reasons for low enrollment and if relevant, what steps have been/will be taken to increase enrollment.

B. Cumulative summary of subjects enrolled to date. (*For studies involving record and/or specimen review only, skip and continue to part C "**Records and Specimens**".)*

1. Number of subjects accrued
2. Number currently active/on study. For example, subjects receiving study interventions/interactions or long-term follow-up.
3. Number completed, without events leading to early termination/withdrawal from study.
4. Number who voluntarily withdrew consent after enrolling. For example, subject met toxicity drop point or experienced a serious adverse event.
   If any, please explain.
5. Number terminated/withdrawn from study by the investigator due to adverse event(s)

   For example, non-compliance with the protocol, pregnancy, etc.
   If any, please describe.

6. Number terminated/withdrawn from study by the investigator due to other reasons
   For example, non-compliance with the protocol, pregnancy, etc.
   If any, please describe.
7. **N**umber lost to follow-up

   If any, please explain.

8. Number no longer participating for reasons other than those above.
   If any, please describe.
9. Total of items 2 through 7 (this should equal item 1)
10. Number of subjects approved ay HENRY J. AUSTIN HEALTH CENTER

C. Records and Specimens

1. Number of specimens and/or records approved by the IRB (This number can be found on your approval notices)
2. Did you review medical records, patient charts, radiographs or other patient information for this study?
   ☐ Yes
   ☐ No
3. Number of records reviewed to date
4. Did you analyze specimens (e.g. archival tissue, blood, blood products, or body fluids) for this study?
   ☐ No
   ☐ Yes

   If yes, number of specimens analyzed to date

9. PROGRESS REPORT: Please complete all sections in sufficient detail to assess current risk/benefit.

HENRY J. AUSTIN™
HEALTH CENTER
The center for wellness

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The primary purpose of continuing review is to re-assess the risk/benefit ratio at intervals appropriate to the degree of risk associated with the study procedures, and not less than once per year. At the time of continuing review, the IRB must ensure that the regulatory criteria for IRB approval at §45 CFR 46.111, and when applicable, at § 21 CFR 56.111, continue to be satisfied. Please answer the following questions so that both you and the IRB can determine whether any new information has emerged, either from the research itself or from other sources that could alter the IRB's previous determinations, particularly with respect to risk to subjects.

A. Unanticipated problems

1. Since the last IRB review, have any serious, unexpected adverse events occurred, that were considered related to participation in the research, not been previously reported to the IRB?

   ☐ No
   ☐ Yes

   If yes, please complete *HJAHC IRB Unanticipated Problem Adverse Event Report Form* appended below

2. Since the last IRB review, have any <u>other</u> unanticipated problems involving risks to subjects or others occurred, for example, medication or laboratory errors, loss or unintended disclosure of confidential information, investigator suspension or termination?

   ☐ No
   ☐ Yes

   If yes, please complete *HJAHC IRB Unanticipated Problem Adverse Event Report Form* appended below

B. Protocol deviations/violations

Since the last IRB review, have any protocol deviations/violations involving risks to subjects or others occurred that have not been previously reported to the IRB?

☐ No
☐ Yes

If yes, please complete *HJAHC IRB Protocol Deviations Form* appended below

C. Complaints about the research

Since the last IRB review, have any subjects or others complained about the research?

☐ No
☐ Yes

If yes, please provide a summary of the complaints and how they were resolved.

D. Progress report and interim findings

Provide a brief, general summary of the progress of the study.
Has there been an interim analysis or are there any interim findings to report?

☐ No
☐ Yes

If yes, please provide results of interim analysis or a summary of any findings to date.

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E.Data and safety monitoring

Is this a trial subject to oversight by a Data Safety and Monitoring Board (DSMB), Data Monitoring Committee (DMC), other similar body (e.g., coordinating or statistical center), or group whose responsibilities include review of adverse events and interim findings?

☐ No
☐ Yes

- If yes, please indicate type of monitoring plan below, and attach a copy of the most recent report or communication.

☐ DSMB/DMC/DSMC
☐ Monitor/monitoring group
☐ Coordinating or statistical center

F.Other information relevant to the research

Since the last IRB review, have there been major advances, changes in standards of care, drug approvals, device recall, new black box warning, or key publications in major peer-reviewed journals which would alter the risk/benefit assessment of this study?

☐ No
☐ Yes

If yes, please provide a summary of relevant information. Provide key references and interpretation/commentary.

G.Investigator's assessment of risks and benefits

1. Since the last IRB review, have the risks to subjects changed?

☐ No
☐ Yes

If yes, please provide a summary of the changes in the risks to subjects.

2. Since the last IRB review, has the magnitude of benefit, or likelihood of benefit, to subjects changed?

☐ No
☐ Yes

If yes, please provide a summary of the changes in the anticipated benefits.

3. Do the risks to subjects continue to be reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result from this study?

☐ Yes
☐ No

If no, please explain.

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10. PROPOSED MODIFICATIONS/AMENDMENTS/CHANGES TO THE STUDY

Are any changes to the research being proposed at this time?

☐ No
☐ Yes

If yes, please complete the *HJAHC IRB Modification Request Form* appended below, detailing proposed changes.

NOTE: The IRB must approve all changes to protocols and consent forms and other study documents (e.g., questionnaires, recruitment letters, advertisements, etc.) prior to implementation.

11. ATTACHMENTS

Please attach the following:

- ☐ Research Protocol: Current *dated* version of the protocol. Provide highlighted or strikeout copy of any changes proposed with this continuing review submission, if applicable.

☐ Investigator Financial & Other Personal Interests Disclosure Form: Include for *each* investigator and key personnel.

- ☐ Research Consent Forms: Copy of *most recent* IRB-approved consent forms with IRB-approval stamp
- ☐ Research Consent Forms: Consent forms for re-approval *without IRB-approval stamp.* If changes are proposed, include one copy with proposed changes highlighted, and one copy *without* proposed changes highlighted.
- ☐ For multi-center trials: Please attach any relevant multi-center reports

12. PRINCIPAL INVESTIGATOR'S ASSURANCES

I have followed all applicable policies and procedures of Henry J. Austin Health Center, and federal, state, and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

The research was performed as approved by the IRB under the direction of the Principal Investigator by appropriately trained and qualified personnel;

Unanticipated problems were promptly reported to the IRB, as well as any other information necessary for appropriate oversight of the research;

Research-related records (and source documents) will be maintained in a manner that documents the validity of the study and integrity of the data collected, while protecting the confidentiality of the data and privacy of participants;

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Study-related records will be retained and available for audit for a period of at least six years after the study has ended, or longer, according to sponsor or publication requirements;

IRB approval or exemption will be obtained before initiating any new research activities involving human subjects; and

All co-investigators, research staff, employees, and students assisting in the conduct of the research will be informed of their obligations in meeting the above commitments.

I verify that the information provided in this *HJAHC IRB Continuing Review Application* is accurate and complete.

Signature of Principal Investigator_____

Date

HENRY J AUSTIN HEALTH CENTER USE ONLY:

Research Project Continuing Review Approved ----------

Signature/Title

Research Project Continuing Review NOT Approved ----------

Signature/Title

Comments

Date