HENRY J. AUSTIN™
HEALTH CENTER
The center for wellness

INSTITUTIONAL REVIEW BOARD (IRB) FINAL STUDY REPORT/ STUDY CLOSURE FORM

Do not terminate IRB approved research until all activities involving human subjects (including data analysis with individually identifiable or coded private information) have been discontinued.

STUDY TITLE	IRB PROTOCOL NUMBER	EXPIRATION DATE OF STUDY APPROVAL*

***IF THE IRB APPROVAL OF YOUR STUDY HAS EXPIRED,**
PLEASE COMPLETE THE *REQUEST FOR CLOSURE OF EXPIRED PROTOCOL* FORM WHICH IS APPENDED.

PRINCIPAL INVESTIGATOR (PI)
Full Name: Title(s): Highest earned degree
Phone: Fax: E-mail:
Mailing address:

ADDITIONAL CONTACT *(If* additional information about this application is needed, specify the contact person if other than the PI (e.g., study coordinator).	
Full Name:	E-mail: Fax: Phone:

1. SPONSOR INFORMATION

☐ Government/Foundation
Government agency/foundation name:

☐ Corporate/Industry
Company name:

☐ Internal/Institutional Funding:

☐ Other Sources
Specify:

2. STUDY STATUS (*Check all that apply):*

☐ Study was never initiated/no study participants were ever enrolled/study was never funded. *(IF YOU SELECT THIS OPTION, PLEASE SKIP TO SECTION 8 ONCE YOU PROVIDE AN EXPLANATION REGARDING WHY THIS STUDY WAS NOT INITIATED BELOW)*

If not yet initiated, please state reasons, then skip to section 8:

☐ Study has been discontinued, and there will be no further data collection (including long-term follow-up or re-contact) or analysis of identifiable/coded data.

☐ Sponsor is discontinuing the study.

☐ Principal Investigator and/or Co-investigator is/are leaving their current position.

☐ Study is completed; all enrollment, treatment, follow-up and data analysis are completed

☐ Jurisdiction transferred to another IRB, + a*nswer the four questions below; if any are not applicable, note "N/A"*

1.) To whom and why?

2.) Was prior IRB approval obtained?

☐ Yes

☐ No

3.) What precautions were taken to protect the interests of any subjects who were enrolled in the study at the time of transfer?

4.) Was the research data transfer process completed?

☐ Yes

☐ No

☐ Other, specify:

3. STUDY PROGRESS

- Summarize the results of the study, including any plans for scholarly/scientific presentations or publications:

- Summarize any IRB-approved amendments or changes made to the study since last IRB review (initial or continuing). If IRB approval was not obtained for changes, provide an explanation:

- Discuss whether any significant new findings or other information should be provided to past participants:

4. PARTICIPANT ENROLLMENT/CHARTS/RECORDS/SPECIMENS ANALYSIS INFORMATION

The number of participants is defined as the number of individuals who agreed to participate (i.e., those who provided consent or whose records were accessed, etc.) even if all did not complete the study.

a) The maximum number of participants approved by the IRB:

b) Total number of participants actually ***enrolled*** in the study:

c) Number of participants enrolled since last IRB review (initial or continuing):

d) If the total number of participants actually enrolled (b) is different from the maximum number of participants approved by the IRB (a), provide an explanation:

e) The number of individuals screened (those who signed consent, including screen failures):

f) The total number who actually completed the study:

g) The total number of ***dropped/withdrawn*** from the study:

- Due to adverse events:
- Other reasons:
- Total:

Hint: The total of f + g must = b

CHARTS AND SPECIMENS

a. Number of specimens and/or charts approved by the IRB (This number can be found on your approval notices):

b. Did you review medical records, patient charts, radiographs or other patient information for this study?

☐ Yes

☐ No

Number of charts reviewed to date:

c. Did you analyze specimens (e.g., archival tissue, blood, blood products, or body fluids) for this study?

☐ Yes

☐ No

Number of specimens analyzed to date:

Is this a multi-center study?

☐ Yes

☐ No

If yes, complete *HJAHC IRB Final Study Report/ Study Closure Form FOR MULTICENTER STUDIES Addendum*

DEMOGRAPHIC INFORMATION

Did you collect demographic information during the conduct of this study?

Yes ☐

No ☐

If yes, please complete the table below. Provide a demographic breakdown of participants enrolled to date (totals should equal Item 4b above). If this study involves a chart review or specimen analysis, and if this data was not collected as part of your study design, please skip to Section 6.

Adult	White/ Non-Hispanic	White/ Hispanic	Black/ Non-Hispanic	Black/ Hispanic	Asian/Pacific Islander	American Indian/Alaskan Native	Other or UNKOWN	Total
Male								
Female								
Total								

If you enrolled minor participants and you collected their demographic information during the conduct of this study, please complete the table below.

Children	White/ Non-Hispanic	White/ Hispanic	Black/ Non-Hispanic	Black/ Hispanic	Asian/Pacific Islander	American Indian/Alaskan Native	Other or Unknown	Total
Male								
Female								
Total								

5. PARTICIPANT COMPLAINTS & VOLUNTARY WITHDRAWALS

Did any participants make complaints about the research?

☐ No

☐ Yes

If Yes → List and describe each **complaint,** and any **actions taken** to resolve the complaint(s).

Did any participants voluntarily withdraw from the research? ***Do not include individuals whose participation was discontinued by the investigator or sponsor because of unanticipated problems, study completion, etc.***

☐ No

☐ Yes

If Yes → List and describe each **withdrawal** and any **actions taken** (e.g., changes to the research or consent process) in response to the withdrawal(s).

6a. Data Management/Record Retention

1. IRB Policy requires research record retention for a period of six years or more from the date of closure. Please confirm that your research data will be maintained for the required duration by initialing here:
2. Please provide the address of the location where you will store your research data.
3. Who is your data steward (this individual is responsible for data management, entry, statistical analysis, etc. and should be a member of study personnel)?
4. Do you have up-to-date software to assure integrity and security of your data (i.e., virus protection programs such as Norton Anti-Virus/McAfee)? Yes ☐ No ☐
5. Does your database software provide you with an audit trail? ☐ Yes ☐ No
6. Is your computer password protected? ☐ Yes ☐ No

6b. Protected Health Information (PHI)

1. Do you have PHI for this study? ☐ Yes ☐ No

2. How long will you keep the ***link*** (identifying code) to the PHI identifiers? *(Please state in month/year format, state "never", if not planned*)

3. Who will have access to the PHI identifiers collected for this research study?

4. <u>List individuals:</u> (Please provide the dates when each individual completed Human Subjects Protections Training)

NAME	DATE WHEN COMPLETED PROTECTING HUMAN RESEARCH PARTICIPANTS TRAINING

5. Please provide your plan to ensure that PHI will not be improperly disclosed:
6. Do you have encryption capabilities for transmission of PHI?
   ☐ Yes
   ☐ No

7. SAFETY MONITORING

1. Since the last IRB review (initial or continuing), did any unanticipated problems (adverse events and other unanticipated problems) involving risks to subjects or others occur in the study at a site(s) approved by IRB?

   ☐ No

   ☐ Yes

   If *Yes*, have you completed and submitted the *HJAHC IRB Unanticipated Problem or Adverse Event Form* for IRB review?

   ☐ No

   ☐ Yes

   If *No,* please complete *HJAHC IRB Unanticipated Problem or Adverse Event Form* along with this closure report for IRB review and determination.

2. Was the research subject to Data Safety Monitoring Board (DSMB) or other similar committee/group review?

   ☐ No

   ☐ Yes

   If *yes*, did you provide a copy of the final or most current report for IRB review and determination prior to this submission?

   ☐ Yes

   ☐ No

3. Did events occur in the study approved by a non-HJAHC IRB?

   ☐ No

   ☐ Yes

   If *yes*, have you completed and submitted the *HJAHC IRB Unanticipated Problem or Adverse Event Form*?

   ☐ Yes

   ☐ No

If you have not completed the required form, please complete *HJAHC IRB Unanticipated Problem or Adverse Event Form* along with this closure report for IRB review and determination.

4. ☐ No external events to report

8. Please add the Abstract of your completed study findings to this form.

9. 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;
- 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) even if I leave the University;
- 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 Final Study Report is accurate and complete.

Printed Name of Principle Investigator

Signature of Principle Investigator

Date

INSTITUTIONAL REVIEW BOARD (IRB) FINAL STUDY REPORT/ STUDY CLOSURE FORM

IRB REQUEST FOR CLOSURE OF EXPIRED PROTOCOL

When continuing review of a study protocol does not occur prior to the end of the approval period specified by the IRB, IRB approval expires automatically. Enrollment of new subjects/study related activities cannot occur after the expiration of IRB approval. In order for the IRB to determine whether they can approve your request for closure the following information is required.

Name of Principal Investigator:

IRB Protocol Number:

Title of Study/IRB Protocol:

1. Have you been previously suspended on this or any other study? *(If yes, please provide an explanation in your response to Question # 4)*

   ☐ No

   ☐ Yes

2. Were any subjects enrolled or did any research activities (including data analysis) occur after the expiration date?

   ☐ Yes

   ☐ No

3. Please state why a timely Request for Closure was not submitted prior to the expiration date.

4. What changes in procedure are being implemented to prevent delayed submissions from occurring in the future?

Please attach any previously unreported Adverse Events that occurred during the period ***after*** expiration. Please note that your study will not be closed until these reports have been reviewed and accepted by the IRB.

Submit this form along with the *HJAHC IRB Final Study Report/Study Closure Form*.

PI Printed Name

P.I. Signature: Date: