HENRY J. AUSTIN HEALTH CENTER
The center for wellness

PROTOCOL REQUEST FORM

This form is to be completed by any potential investigator who would like to conduct research at Henry J. Austin Health Center (HJAHC). An IRB meeting to review your request will be scheduled within 45 days of receipt of this form, and all required documents.

1. PRINCIPAL INVESTIGATOR (PI) INFORMATION		
Identifying Title of Protocol:		
PI Name:	PI Signature:	Date:
PI Affiliation (*Institution Name and Address):*	PI Phone Number and Email Address:	
Faculty Supervisor Name (*for student investigators, only*):	Faculty Supervisor Signature:	Date:
Faculty Department (*for student investigators, only*):	Faculty Supervisor Phone Number and Email Address:	

Has the PI completed an approved course on Protecting Human Research Participants?
☐ Yes ☐ No

- If yes, please include a copy of the certification with this protocol. (Note: expired certification will NOT be accepted.)
- If no, please STOP. All PIs must complete an approved course on Protecting Human Research Participants prior to submitting a Protocol Request Form.

2. INVESTIGATORS AND STUDY PERSONNEL INFORMATION		
Investigator Name:	Investigator Signature:	Date:
Investigator Affiliated Institution:	PI Phone Number and Email Address:	
Describe the Investigator's Role in the Study:		

☐ Check this box to indicate that the investigator has completed an approved course on Protecting Human Research Participants. Please include a copy of the certification with this protocol. (Note: expired certification will NOT be accepted.)

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3. FUNDING INFORMATION

Have you received funding for this study by an agency outside of HJAHC?
☐ Yes ☐ No
If yes, specify the agency or agencies:

Is this study being submitted for funding to an agency outside of HJAHC?
☐ Yes ☐ No
If yes, specify the agency or agencies:

4. BASIC STUDY INFORMATION

4.1 Purpose/Specific Aims
Clearly state the overall purpose of the study:

4.2 Objectives
Outline specifically what will be achieved by this study:

4.3 Hypotheses/Research Questions
Describe underlying reasons/motivations for this project specific to the topic and/or population being studied OR express any scientific hypotheses that are testable and that include measurable outcomes/endpoints that correspond directly to the objectives.

4.4 Research Significance
Provide the scholarly or scientific background rationale and significance of the research based on the existing literature and how it will add to existing knowledge [500 words or less].

4.5a Research Procedures
Describe, in order of occurrence, all research procedures being performed, when and where they will be performed, and by whom.

4.5b Data Points
Describe the data elements that will be collected across the duration of this study.

4.5c Study Duration
Specify the overall duration of the study. If enrolling human subject participants, specify the length of time each subject will participate.

4.5d Endpoints
Describe any primary and secondary study or safety endpoints.

Study Site Name:	Study Site Address:

What type of research are you planning to conduct?
☐ Basic Research ☐ Applied Research

Is your research regarding a training activity and/or education?
☐ Yes ☐ No
If yes, specify the type:
☐ Intuitional Training ☐ Graduate Training ☐ Continuing Education
☐ Undergraduate Training ☐ Post-Graduate Training ☐ Resource Development

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☐ Other, please specify:

Is your research regarding a clinical trial?
☐ Yes ☐ No
If yes, specify what is being studied:
☐ Drug(s)
☐ Device(s)
☐ Treatment Regimen(s)
☐ Other, please specify:

Will human subjects be enrolled in this study?
☐ Yes ☐ No
If yes, complete Section 5.

Will protected health information (PHI) be used in this study?
☐ Yes ☐ No
If yes, complete Section 6.

5. ENROLLMENT OF HUMAN SUBJECTS *(Skip this section if human subjects will NOT be enrolled into this study)*

Please explain, in detail, the process for obtaining informed consent from subjects for participation in this study.

Describe the characteristics of the target subject population.

Describe, in detail, how you determined the target number of subjects to be recruited for this study.

Describe, in detail, the justification for including vulnerable research subjects into this study.

Will subjects be expected to personally bear any costs in order to participate in this study?
☐ Yes ☐ No
If yes, please list all expenses the subjects are likely to incur by taking part in the research.

Will subjects be compensated or incentivized for participating in this study?
☐ Yes ☐ No
If yes, please explain what compensation and/or incentive will be provided and whether it will be prorated depending on what parts of the study the subjects complete. Include the types of payments to subjects and justification for the amounts. State the form the compensation/incentive will take (cash, tickets, coupons, etc.). Indicate how you will document that compensation was provided to subjects. The PI is responsible for maintaining a full account of all compensation disbursed to subjects.

Describe, in detail, the reasonably foreseeable risks of harm, discomforts, hazards, or inconveniences to subjects related solely to their participation in the research. Consider physical, psychological, genetic, social, legal, economic, and privacy/confidentiality risks of harm. Provide a description of any procedures you plan to use to minimize harm.

6. DATA MANAGEMENT PLAN *(Skip this section if PHI will NOT be enrolled into this study)*

Data analysis

Describe the data analysis plan. Include any statistical procedures and power analysis, if applicable to the research.

Data security

Describe the steps that will be taken to secure the data through all phases of the research—from the time of its collection, to its storage, use and study closure— such as staff training, transporting or transmitting data from the study site or 'field' to HJAHC, methods to restrict access, password protection, encryption, use of key codes to separate identifiers from the data, and state how and when identifiers will be deleted from the data. Identify who will be responsible for each of these tasks.

Data and Safety Monitoring

NOTE: This section is required when research poses greater than Minimal Risk of harm to subjects.

- *Data/Safety Monitoring Plan*: Detail your plans to periodically evaluate the data collected regarding harms and benefits to determine whether subjects remain safe. Specify what data will be reviewed—such as safety data, untoward events and efficacy data—how often it will be reviewed and by whom. Also explain how the safety information will be collected—such as case report forms, by study visits or remote contact with subjects.

- *Data/Safety Monitoring Board Details*: Detail also any plans to establish a data monitoring committee and regularly report committee findings to the IRB and sponsor, if applicable. Be sure to specify any conditions that trigger immediate suspension of the research.

Reporting Results

- **Individual Subjects' Results**: Describe whether study results—such as results of investigational diagnostic tests, genetic tests, or incidental findings—will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared with them. If results are clinically actionable, provide evidence of the appropriate lab certifications (e.g., CLIA) providing the results and the qualification(s) of the study staff who will return such results.

- **Aggregate Results**: Describe your plan to share aggregate research results with study subjects.

- **Professional Reporting**: Describe your plan to share the results of your research with the scientific community.

- **Clinical Trials Registration, Results Reporting and Consent Posting**: Indicate whether the research qualifies as a clinical trial that must comply with this federal requirement for public registration, results reporting and consent posting at its conclusion.

- **Secondary Use of Data**: Describe the details of any plans to share the data with other researchers (with or without identifiers) for secondary research. Be sure disclosure of such a plan is included in the consent document.

7. RESEARCH REPOSITORIES – SPECIMENS AND/OR DATA

If data or specimens collected in the course of this research will be stored for future research:

1. Specify the data elements and/or type(s) of specimens to be stored

2. Identify the HJAHC IRB-approved Research Repository and IRB Protocol Number where the data and/or specimens will be stored OR, if it is not a HJAHC IRB-approved Repository, state the name/address of the Repository and upload the other institution's IRB approval. Be sure the consent document discloses your plan to store data and/or specimens for future research.

8. APPROVALS/AUTHORIZATIONS

Describe any approvals that will be obtained prior to commencing the research. (e.g., Letters of Cooperation from the study site, including schools, non-HJAHC IRB approval, Institutional Authorization Agreements, Data Use Agreements, Material Transfer Agreements, funding agency agreements, Bio-Safety Approvals, Radiation Safety Approval, etc.).

NOTE: a copy of all approvals/authorizations must be received by the HJAHC IRB prior to commencing research

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9. BIBLIOGRAPHY

Statement of Researcher Responsibility

As a researcher you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulations imposed by the governing IRB over this research project. You must abide by the following principles when conducting your research within HJAHC:

1. Perform the project by qualified personnel according to the approved application.
2. Adhere to ethical codes and applicable policies and procedures of HJAHC, your affiliated institution (if outside of HJAHC), the sponsoring agency, relevant professional organizations, and cooperating institutions (if any).
3. Do not implement changes in the approved study or consent form without prior approval of HJAHC (except in a life-threatening emergency, if necessary to safeguard the well-being of human subjects).
4. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved consent form. Store informed consents and data in a secure place for a minimum of three (3) years.
5. Promptly report all undesirable and unintended, although not necessarily unexpected adverse reactions or events, that are the result of therapy or other intervention, within five (5) working days of occurrence. All fatal or life-threatening events or events requiring hospitalization must be reported to the Henry J. Austin Health Center in writing within 48 hours after discovery.
6. Retain required records for a minimum of three (3) years.
7. Make study results available to the HJAHC IRB upon request.

I, , agree to follow all requirements set forth by the HJAHC IRB. I agree **to provide HJAHC with** period summary reports as requested.

I understand that it is my responsibility to adhere to the approved protocol. I agree to notify the HJAHC IRB of any deviation from the approved protocol. I agree that I will not continue to conduct research after the expiration of approval of this protocol.

Printed Name of PI

Signature of PI Date

Note: By e-signing this form you agree to abide by HJAHC IRB policies and confirm your role as the principal investigator of the above-mentioned project.